
CMS Manual System

Pub. 100-07 State Operations

Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 177

Date: January 26, 2018

SUBJECT: Revisions to State Operations Manual (SOM) Appendix G, Guidance for Surveyors: Rural Health Clinics

I. SUMMARY OF CHANGES: Appendix G has been comprehensively revised to add a survey process component; to re-organize the presentation of the regulatory text and associated guidance into separate sections each having a unique “tag” number; and to improve the clarity and precision of the interpretive guidance and survey procedures.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 26, 2018
IMPLEMENTATION DATE: January 26, 2018

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix G/Table of Contents
N	Appendix G/Part I Rural Health Center Survey Protocol
R	Appendix G/Part II Regulations and Interpretive Guidelines
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0001 §491.3 Certification Procedures
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0002 Standard-Level Tag §491.3 Certification Procedures
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0003 Standard-Level Tag §491.3 Certification Procedures
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0010 §491.4 Compliance with Federal, State and local laws
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0011 Standard-level Tag §491.4 Compliance with Federal, State and local laws
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0012 §491.4(a) Licensure of clinic
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0013 §491.4(b) Licensure, certification or registration of personnel

R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0020 §491.5 Location of clinic
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0021 §491.5(a)(1) An RHC is located in a rural area that is designated as a shortage area, §491.5(c) Criteria for designation of rural areas, §491.5(d) Criteria for designation of shortage area
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0022 §491.5(a)(3)(i) – (ii) ... the RHC...may be permanent or mobile units
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0023 §491.5(a)(3)(iii) Permanent unit in more than one location
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R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0061 §491.7(a)(1) & §491.7(b)(3) Basic requirements
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0062 §491.7(a)(2) & §491.7(b)(1)-(2)
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0080 §491.8 Staffing and Staff Responsibilities
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0081 §491.8(a)(1)-(2) Staffing, Physician
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R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0086 §491.8(a)(6) Staffing
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0100 §491.8(b)(1) & (3) Physician responsibilities

R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0101 §491.8(b)(3) & (c)(1)(ii)
R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0102 §491.8(c)(2)
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R	Appendix G/Part II Regulations and Interpretive Guidelines/J-0162 §491.10(d)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2015 operating budgets.

IV. ATTACHMENTS:

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X	Manual Instruction
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State Operations Manual

Appendix G - Guidance *for* Surveyors: Rural Health Clinics (RHCs)

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Part I

Rural Health Clinic Survey Protocol

Introduction

The Rural Health Clinic (RHC) statutory provisions are set forth in Section 1861(aa) of the Social Security Act (the “Act”). Specifically, Section 1861(aa)(2)(K) of the Act requires Medicare participating RHCs to meet other requirements as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services at the RHC. In accordance with 42 CFR §405.2402, RHCs are required to be certified as in compliance with the Medicare Conditions for Certification (CfC) at 42 CFR Part 491, Subpart A in order to enroll in the Medicare program. Further, as required at 42 CFR §405.2403(a), as part of the agreement between the Medicare program and an RHC, the RHC agrees to maintain its compliance with the RHC CfCs. The goal of an RHC survey is to determine if the RHC is in compliance with the CfCs.

Determination of a facility’s compliance with the RHC CfCs is accomplished through:

- an off-site review of the facility’s location by the CMS Regional Office (RO), to determine whether the facility meets the location criteria at §491.5; and*
- an on-site survey using observations, interviews, and document/record reviews to assess compliance with the rest of the CfCs.*

In the case of initial applicants for RHC certification, to facilitate an efficient survey and certification process, CMS requires the applicant to complete and submit to the State Survey Agency (SA) Form CMS-29, Verification of Clinic Data – Rural Health Clinic Program, as part of its application for certification. Facilities provide basic information related to their location and staffing on this document. To make efficient use of survey resources, SAs make a /preliminary assessment of the information contained on the Form CMS-29 prior to conducting a survey, to avoid conducting a survey of an ineligible location. However, since only the CMS RO may make a determination whether the RHC applicant has satisfied all Federal requirements, including the location and staffing requirements, the SA must not notify the applicant of the results of the SA’s preliminary assessment of the Form CMS-29. (See State Operations Manual (SOM) Section 2242A)

The on-site survey process focuses on an RHC’s delivery of patient care, including its organizational functions and processes for the provision of care. The RHC on-site survey is the means used to assess compliance with Federal health, safety and quality standards that will assure that patients receive safe, quality care and services.

Regulatory and Policy References

- *General RHC definitions, Medicare participation requirements, RHC Medicare agreement, and provisions for termination of the RHC Medicare agreement are located at 42 CFR Part 405, Subpart X.*
- *The CfCs for RHCs are located at 42 CFR Part 491, Subpart A.*
- *General survey and certification requirements and survey authority are located at 42 CFR Part 488, Subpart A.*
- *Should an individual or entity/RHC refuse to allow immediate access upon reasonable request to either a SA or CMS surveyor, the Department of Health and Human Services, Office of Inspector General (OIG) may exclude the RHC from participation in all Federal healthcare programs in accordance with 42 CFR 1001.1301. If a surveyor intends to make a request for immediate access with the threat of possible exclusion for non-compliance, the SA must first contact the CMS RO, which must then contact the OIG Administrative and Civil Remedies Branch at 202-619-1306.*
- *The CMS SOM, Publication 100-07, provides CMS policy regarding survey and certification activities.*

All RHC surveys are unannounced. Do not provide existing RHCs or RHC applicants with advance notice of the survey.

Tasks in the Survey Protocol

The tasks included in a survey protocol for an RHC are:

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|---------------|---|
| <i>Task 1</i> | <i>Off-Site Survey Preparation</i> |
| <i>Task 2</i> | <i>Entrance Activities</i> |
| <i>Task 3</i> | <i>Information Gathering/Investigation</i> |
| <i>Task 4</i> | <i>Preliminary Decision-Making and Analysis of Findings</i> |
| <i>Task 5</i> | <i>Exit Conference</i> |
| <i>Task 6</i> | <i>Post-Survey Activities</i> |

Task 1 – Off-Site Preparation

General Objectives

The objectives of this task are to make a preliminary assessment of whether the RHC applicant meets the basic location and staffing requirements and, if it does, to determine the size and composition of the survey team and analyze information about the RHC applicant in order to identify areas of potential focus during the survey. See SOM Section 2242 for detailed information about making the preliminary assessment of compliance with the location requirements, as well as S&C 13-30, May 10, 2013 and S&C 15-09, November 14, 2014 for

information on the process the ROs are to use when making determinations concerning RHC location compliance.

In the case of a recertification of an RHC, the objective of this task is to determine the size and composition of the survey team and analyze information about the RHC in order to identify areas of potential focus during the survey.

*Review of other information about the RHC allows the SA (or RO for Federal teams) to develop a preliminary survey plan. Refer to the below section, **Assembling Background Information**, for more details.*

A full or standard survey will be conducted if the purpose of the survey is for initial certification, recertification, or as part of the annual CMS representative sample validation survey program for deemed status providers and suppliers.

Surveys in response to a complaint or multiple complaints, or as a revisit to determine if a previously cited problem has been corrected, focus on the CfC(s) related to the complaint or on the CfC(s) for which deficiencies were previously identified. This does not preclude the scope of a complaint or revisit survey being expanded, if surveyors observe deficient practices related to other CfCs while on site. In the case of a deemed status RHC, the SA may only conduct a complaint survey when authorized to do so by the RO. (See Chapter 5 of the SOM, Sections 5075, 5100.1 and 5200.1)

Types of Surveys

Standard (or Full) surveys: *Initial certification, recertification and representative sample validation requires assessment of the RHC's compliance with all CfCs.*

- *Initial surveys are conducted when a facility first seeks to participate in the Medicare program as an RHC and does not choose to seek deemed status based on accreditation by a CMS-approved Medicare RHC accreditation program.*
- *Recertification surveys are required for non-deemed status RHCs to reconfirm, at periodic intervals, the RHC's ongoing compliance with the CfCs.*
- *Representative sample validation surveys are conducted to support CMS's oversight of national accrediting organizations (AOs) whose Medicare accreditation programs have been recognized by CMS as suitable for deeming facilities as meeting the applicable Medicare CfCs or CoPs. CMS selects the facilities for this type of validation survey, and the SA must complete its survey no later than 60 days after the AO's survey. Although the primary purpose of the survey is to validate the AO's oversight, if substantial noncompliance is found by the SA and the RO concurs, the RO initiates appropriate enforcement actions. SAs may only survey a deemed status RHC when authorized to do so by the CMS RO.*

Complaint or On-site Revisit Surveys: *Generally, these types of survey are more narrowly focused than a full standard survey.*

- *A complaint is an allegation of noncompliance with Medicare health and safety standards. The purpose of a complaint survey is to determine the validity of the allegation and assess the current compliance of the RHC with those CfCs that are relevant to the substance of the allegation that triggered the survey. Surveyors assess compliance with all of the requirements of the condition(s) being investigated related to the complaint, just as they would on a full survey. It is not sufficient simply to review the clinical record of the patient that triggered the complaint.*
- *The purpose of the on-site revisit survey is to determine the RHC's current compliance with the CfC(s) for which the RHC was cited for condition-level noncompliance on a prior related standard or complaint survey. The SA must receive an acceptable Plan of Correction (PoC) from the RHC before it conducts a revisit survey.*

Generally, complaints received by the SA or CMS concern specific cases or incidents that occurred in the past. However, CMS evaluates RHCs only for their current compliance or noncompliance at the time of the survey. Nevertheless, if an investigation of a complaint about a past event indicates there was a violation of one or more of the CfC requirements, and there is no evidence that the RHC subsequently implemented effective corrective action prior to the complaint survey, then the findings concerning the violation are documented on the Form CMS-2567, Statement of Deficiencies and PoC as evidence of current noncompliance. On the other hand, if an investigation shows that a past violation occurred, but the RHC subsequently implemented effective corrective action and the survey reveals no current noncompliant practices, then the RHC is in current compliance and is not cited for a deficiency based on the past noncompliance.

Survey Team Size and Composition

The SA (or the CMS RO for Federal teams) decides the composition and size of the team. In general, a standard, i.e., full, RHC survey includes one health standards surveyor who is on-site for one day, but individual circumstances may call for a larger team, or a shorter or longer period of time on-site. The following factors are considered when determining survey team size and the scheduled length of the survey:

- *Size of the RHC, based on its number of patient exam rooms, hours of operation, and/or available information about its average monthly volume of patients;*
- *Whether the RHC has an historical pattern of serious deficiencies or complaints;*
- *Whether new surveyors are to accompany the surveyor as part of their training.*

For a complaint or on-site revisit survey, only one surveyor will usually be needed and should be chosen based on their knowledge of the CfC(s) that will be reviewed during the survey.

RHC surveyors must have the necessary training and experience to conduct a survey. Completion of the Principles of Documentation Training Course is required. In addition, completion of the Basic RHC Surveyor training course is required for all RHC health standards surveyors, unless such training has not been offered by CMS in the previous two years. The RHC surveyor, or at least one member of a survey team, should be a registered nurse with hospital or RHC survey experience who has the expertise needed to determine if the facility is in compliance with the CfCs. New surveyors may accompany existing surveyor(s) prior to completing the required training but not as a team member.

Single Surveyor or Team Coordinator

An RHC survey may be conducted by one surveyor. The SA (or the RO for Federal teams) designates a Team Coordinator when the survey team consists of more than one surveyor. The surveyor, or Team Coordinator when applicable, is responsible for assuring that all survey preparation and survey activities are completed within the specified time frames and in a manner consistent with this protocol. Responsibilities of the surveyor, or Team Coordinator when applicable, include:

- Acting as spokesperson to the RHC;*
- Conducting the entrance and exit conferences,*
- Providing other on-going feedback, as appropriate, to RHC leadership on the status of the survey;*
- When there is more than one surveyor, assigning team members specific survey tasks;*
- Facilitating time management during the survey;*
- Encouraging ongoing communication among team members, when applicable;*
- Evaluating team progress in completing the survey and coordinating team meetings, when applicable;*
- Preparing the Form CMS-2567, Statement of Deficiencies and PoC, as well as all other reports/documentation required by CMS. If there is a survey team, coordinating the preparation of the documentation.*

Assembling Background Information

Surveyors must prepare for the on-site survey offsite, in order to make efficient use of the time onsite at the RHC. The type of background material to be gathered from the SA's files and/or the CMS database prior to the on-site survey includes:

- *Basic characteristics of the RHC, including the facility's ownership, hours of operation, size, and types of services offered. The most recent Form CMS-29 Verification of Clinic Data - Rural Health Clinic Program shows the RHC's location, basic staffing information and type of control. Other sources of information may include the SA's licensure file;*
- *Any additional information publicly available about the RHC, e.g., from its Website, media reports, etc.;*
- *Any available information on the physical layout of the RHC;*
- *For existing RHCs, determine whether a mid-level Staffing Waiver has been issued and is still in effect;*
- *For existing RHCs, determine whether the clinic has applied to offer Visiting Nurse Services (VNS) and has been found by the CMS RO to be eligible to offer VNS;*
- *Survey history and results of previous Federal and State surveys. In the case of a complaint survey, information on whether there were similar complaints investigated in the past;*
- *Directions to the RHC*

If the survey involves more than one surveyor, the Team Coordinator will arrange an offsite preparation meeting. During the meeting, or independently in the case of a single surveyor, the survey preparation should include consideration of:

- *Any significant information identified from the background information assembled;*
- *Whether there are CfCs requiring particular attention;*
 - *In the case of a complaint survey, the SA – or, in the case of a deemed status RHC, the RO - identifies in advance of the onsite investigation which CfCs will be surveyed for compliance;*
 - *In the case of an on-site revisit survey, surveyors will focus on the RHC's current compliance with those CfCs where deficiencies were cited on the most recent related Form CMS-2567. Surveyors also review the RHC's PoC and will look for evidence while onsite that the plan was implemented. (However, surveyors may not assume that implementation of the plan always means that the RHC is in substantial compliance with the CfC. It is possible that a PoC may be implemented, but is not sufficient to bring the RHC into compliance.);*
- *Preliminary team member assignments;*
- *Any questions the team has about how they will evaluate the CfCs;*

- *Date, location, and time team members will meet to enter the facility;*
- *When daily team meetings will take place, if needed; and*
- *The anticipated date and time of the Exit Conference.*

Note: Conduct RHC surveys during the RHC's normal business hours. All surveys are unannounced. Do not provide RHC applicants or existing RHCs with advance notice of the survey.

Resources:

The following resources are useful to bring on surveys:

- *Appendix G – Guidance for Surveyors: Rural Health Clinics;*
- *Appendix Q - Immediate Jeopardy;*
- *Copy of the regulations at 42 CFR §§ 405.2402 – 2404, concerning the RHC basic requirements, Medicare agreement and termination;*
- *Several copies of the regulatory language located at 42 CFR § 489.53 regarding the basis for terminating a provider/supplier agreement which applies to RHCs; and*
- *Several copies of the regulatory language at 42 CFR 1001.1301 regarding the consequences of failure to permit the survey team access to the facility;*

Task 2 – Entrance Activities

General Objectives

The objectives of this task are to explain the survey process to the RHC staff and obtain the information needed to conduct the survey.

General Procedures

Arrival

For surveys requiring more than one surveyor, the entire survey team should enter the RHC together. Upon arrival, the surveyor(s) must present identification. If the RHC denies entrance to the facility or otherwise tries to limit required survey activities, explain that this may be grounds for terminating the RHC's participation in Medicare. (See 42 CFR §1001.1301.)

If the surveyor(s) encounter any problems onsite, they should feel free to contact the SA manager or the RO for guidance. For instance, if RHC staff will not let a surveyor into the facility even after they're informed of the possible sanctions that can be imposed for restricting access to their facility, a call to the SA or RO would be appropriate.

The surveyor, or Team Coordinator when more than one surveyor is assigned, announces to the RHC's Administrator, or whoever is in charge, that a survey is being conducted. If the Administrator (or person in charge) is not onsite or readily available, the surveyor or Team Coordinator asks that the Administrator be notified that a Federal survey is being conducted. Do not delay the survey because the Administrator is not available.

Entrance Conference

The entrance conference sets the tone for the entire survey. The surveyor(s) must be prepared and courteous, and make requests, not demands. The entrance conference should be informative, concise, and brief.

During the entrance conference, the surveyor or Team Coordinator:

- Explains the purpose and scope of the survey (initial certification or recertification; representative sample validation; complaint investigation; revisit);*
- Briefly describes the survey process;*
- Introduces themselves and/or the survey team members, including any additional surveyors who may join the team at a later time, and discusses in general what the surveyors will do and the various documents they may request;*
- Clarifies that all areas of the RHC may be surveyed, but emphasizes that the survey will not interfere with the provision of patient care and will take all standard precautions to avoid any infection control breaches; patients will be asked by the surveyors if they object to being observed while examination or treatment is being provided;*
- If the RHC provides VNS, ask for a list of visits scheduled during the survey period. If visits are scheduled, explain that at least one visit will be observed;*
- Explains that all interviews will be conducted privately with patients, staff, or visitors, unless requested otherwise by the interviewee;*
- Discusses how the facility will provide the surveyor(s) in a timely manner access to a copy machine as well as access to clinical and other records, and other information as needed;*

- *Obtains the names, locations, and telephone numbers of key RHC staff and their responsibilities;*
- *Discusses the appropriate time, location, and possible attendees of any meetings to be held during the survey; and*
- *Proposes a preliminary date and time for the Exit conference.*

During the entrance conference, the single surveyor or Team Coordinator arranges with the RHC's Administrator, or available administrative supervisory staff in his/her absence, to obtain the following:

- *A list of all patients scheduled for that day. The list should include, at a minimum, the date, each patient's name, purpose of office visit, and the physician/mid-level furnishing the office visit. The surveyor or Team Coordinator indicates that a surveyor will be following the progression of at least one patient, selected by the surveyor from the list, through the office visit, so it is essential that information on the patients be provided as soon as possible, including the expected time between registration and being seen by medical staff.*
- *A list of:*
 - *All office visits from the past six months. In the case of a complaint survey concerning an office visit that took place further in the past, be sure to request a list that includes the month of the complaint case;*
 - *All cases in the past year, if any, where the patient was transferred from the RHC to another health care facility for emergency services;*

The list should include, at a minimum, the date, each patient's name, purpose of office visit, and the physician/mid-level furnishing the office visit. The surveyor or Team Coordinator explains to the RHC that, in order to complete the survey within the allotted time, it is important the surveyor(s) is given this information as soon as possible. The RHC should begin compiling this list as soon as the entrance conference concludes. Generally an RHC should be able to provide this information within an hour of the request.

- *A location (e.g., conference room, an office not in use) where the surveyor(s) may meet privately during the survey, and also conduct patient record reviews, interviews, etc.;*
- *Access to a copy machine;*
- *A list including the names of the Medical Director, active Medical Staff, Allied Health professionals, and all other staff providing patient care;*
- *A copy of the facility's organizational chart;*

- *Specific written policies and procedures, upon request from the surveyor;*
- *Selected RHC personnel records identified by the surveyor;*
- *Written documentation related to the RHC's program evaluation or QAPI for ongoing self-assessment of quality;*
- *A list of services provided through agreement or arrangements; and*
- *A copy of the facility's floor plan.*

For recertification or representative sample validation surveys, arrange an interview with the administrative staff member who will be providing information to complete the Form CMS-29 Verification of Clinic Data for Rural Health Clinic Program. SA may not require a certified RHC to submit an updated Form CMS-29 in advance of recertification. However, in the case of relocation of an RHC, the RHC must submit an updated Form CMS-29 to the SA at the same time it submits an updated Form CMS-855A to the Medicare Administrative Contractor (MAC.)

Task 3 – Information Gathering/Investigation

General Objective

The objective of this task is to determine the RHC's compliance with the CfCs through observations, interviews, and document review.

During the Survey

- *Surveyors should always maintain a professional and calm demeanor;*
- *The SA and surveyors have discretion whether to allow, or to refuse to allow, facility personnel to accompany the surveyor(s) during a survey. However, maintaining open and ongoing dialogue with the facility staff throughout the survey process generally enhances the efficiency and effectiveness of the survey. Surveyors should make a decision whether to allow facility personnel to accompany them based on the circumstances at the time of the survey.*
- *Surveyors need to respect patient privacy at all times during the survey.*
- *Surveyors are not permitted to conduct clinical examinations or provide clinical services to any of the RHC's patients. Surveyors may direct the attention of the RHC staff to address an immediate and significant concern affecting a patient's care.*

- *The surveyor should be aware of all significant issues or significant adverse events, particularly those that a surveyor believes may constitute an immediate jeopardy. Immediate jeopardy is defined as a situation in which the RHC's noncompliance with one or more CfCs has caused, or is likely to cause, serious injury, harm, impairment or death to a patient. If the surveyor believes, and, when applicable, the Team Coordinator agrees, that there is an immediate jeopardy situation, the guidance in Appendix Q of the SOM is followed.*
- *Informal discussions with facility staff may be held while the survey is ongoing in order to inform them of preliminary survey findings. This affords facility staff the opportunity to present additional information or to offer explanations concerning identified issues.*
- *When more than one surveyor is on-site, the survey team should meet at least once daily in order to assess the status of the survey, progress on completion of assigned tasks, and areas of concern, as well as to identify areas for additional investigation. If areas of concern are identified in the discussion, the team should coordinate efforts to obtain additional information. Additional team meetings can be called at any time during the survey to discuss crucial problems or issues.*
- *Surveyors should maintain their role as representatives of a regulatory agency. Although non-consultative information may be provided upon request to the RHC, the surveyor is not a consultant and may not provide technical advice or consulting services to the RHC.*

Observations

Observations provide direct knowledge of the RHC's practices, which the surveyor(s) must compare to the regulatory requirements in order to determine whether the RHC is in compliance. The interpretive guidelines for each of the CfCs provide detailed guidance as to what the regulations require, as well as tips for surveyor activities to determine compliance.

Patient Care Observation

The surveyor, or Team Coordinator when applicable, should make it a priority at the beginning of the survey to select one or two patients scheduled to receive patient care services during the survey to observe. In addition to observing onsite patient care, if an existing RHC which has been identified by CMS RO as eligible to provide VNS has a scheduled VNS visit(s), the surveyor will also observe patient care services provided during the VNS visit. AOs may contact the appropriate CMS RO to ascertain whether or not an existing RHC has been approved to provide VNS. It is preferable to observe a patient on the first day of the survey, if a two day survey is scheduled, in order to get a more accurate picture of the RHC's routine practices. The number of patients selected will depend on the size of the RHC, as well as the size of the survey team and/or the scheduled length of the survey.

The surveyor(s) should observe various types of patient care services to look for evidence of compliance related to the various CfCs, e.g., physical plant and environment, provision of services and patient health records.

RHC Tour

The tour of the RHC may be accomplished while RHC staff is assembling the information requested during the entrance conference. The purpose of the tour is to get an overview of the whole RHC and to begin making findings about its compliance with the CfCs governing an RHC's physical plant and environment, 42 CFR § 491.6. The amount of time spent on the tour will depend on the size of the RHC. For revisit surveys, a tour is generally not necessary, although observations in various parts of the RHC related to the areas of prior noncompliance will be required.

Observation Methods

Observations provide direct knowledge of the RHC's practices, which the surveyor must compare to the regulatory requirements in order to determine whether the RHC is in compliance with the requirements. The interpretive guidelines for each of the CfCs provide detailed guidance as to what the regulations require, as well as tips for surveyor activities to determine compliance.

In general, when making observations, surveyors should assess general conditions such as:

- Building structure and layout, general appearance and cleanliness, smells;*
- Staff-patient interactions, both clinical and non-clinical: for example, at what point are patients allowed into the facility? What happens to patients from the time they arrive to the time they leave? Is care provided by appropriate, qualified staff?*
- Other staff activities: for example, how is clinical staff supervised? How are clinical records protected? Are infection control precautions observed?*

A surveyor must take detailed notes of all observations, identifying the applicable regulatory standard(s). One set of observations might support findings related to multiple standards. Surveyors may find it convenient to use interpretive guidance "tag" numbers as a shortcut for identifying the applicable standards, but must always recall that tags are just a filing/sorting device, and that the regulatory authority is always based on the specific regulatory language.

Surveyors must attempt to obtain further verification of the factual accuracy of their observations from the patient, family, facility staff, or other team member(s), or by another mechanism. For example, when finding an outdated medication, surveyors can ask a member of the RHC's professional staff to verify the drug's expiration date.

Surveyors must introduce themselves to the patient and/or the patient's representative prior to seeking permission to observe the delivery of care to that patient. The privacy and dignity of the patient must always be respected, along with the patient's right to refuse to allow the surveyor to observe his/her care. However, an RHC does not have the right to prohibit/refuse any and all case observation by surveyors.

For each observation, the surveyor should document:

- *The date and time of the observation(s);*
- *Location within the RHC;*
- *Patient and staff identifiers; a key containing identifiable information for patients must be kept on an identifier list separate from that of the staff identifiers. Do not use names, medical record numbers, Social Security numbers, or billing record numbers to identify patients, or names or positions for staff members;*
- *Individuals present during the observation;*
- *Activity/area being observed (e.g., observation of injection practices for adherence to accepted standards of infection control, observation of handling of samples for required laboratory services, etc.).*

Document Review

RHCs maintain a variety of documents that provide evidence of their compliance/non-compliance with the regulations. Review of documents is a key component of the survey, but it is important to note that it must always be supplemented by surveyor observations and interviews. For example, it is not an efficient or effective use of surveyor time to request a copy of all RHC policies and procedures for review; instead, it is preferable to make selective requests for such documents when observations or interviews suggest noncompliance in an area, in order to determine whether the problems stem from inappropriate policies and procedures, or failure to follow appropriate policies and procedures.

While it is importance to verify specific policies and procedures are in place as required by 491.7 and 491.9, it is never sufficient to determine compliance by just verifying that an RHC has an appropriate written policy and procedure in place. Surveyors must use a variety of means, including review of other documents, such as medical records, personnel files, maintenance records, etc., to confirm that the RHC actually follows its policies and procedures in its daily operations. Documents reviewed may be written or electronic, or a mixture of both, and may include the following:

- *Clinical records (see discussion below);*
- *Personnel files to determine if staff members meet educational and training requirements, and are licensed or credentialed, if required. The RHC must comply with all Medicare requirements and State law governing scope of practice, as well as follow its own written policies for clinical staff responsibilities;*
- *Policy and procedure manuals or portions thereof. When reviewing policy and procedure manuals, verify with the RHC's leadership that they are current;*

- *Contracts or written agreements for services provided through agreements or arrangements. Review to verify these are current.*

Copies of Documents

Surveyors must be able to make copies of all documents needed to support deficiency findings, whether by photocopying paper records or printing out pertinent portions of electronic health records (EHR). In the case of paper documents, the surveyor needs access to a photocopier in the RHC in order to make photocopies. Generally surveyors must not rely upon RHC staff to make photocopies for them. However, if the RHC insists that one of its staff members must operate the copier, then a surveyor must observe the copying process, in order to assure that changes or omissions do not occur. If requested by the RHC, the surveyor must make the facility a copy of all items the surveyor photocopies. All copies need to be dated and timed by the surveyor as to when photocopied, and identified, such as “RHC Patient Care Polices Requirements” – 10-25-09, or “Patient Record #1 - 10-25-09.”

In the case of an RHC with an EHR system, CMS recommends that RHC surveyors not seek direct access to the EHR system, but instead have an RHC staff member operate the system to pull up any record information the surveyor requires, and to print out materials as requested by the surveyor. All copies need to be dated and timed by the surveyor as to when printed, and identified, such as “RHC Patient Care Polices Requirements” – 10-25-09, or “Patient Record #1 - 10-25-09.”

Clinical Record Review

Active Patient Record Sample Size and Selection

After the RHC provides a log or some other record of active medical records from the previous 60-90 days, the team/surveyor will select a sample of medical records to review.

Clinical Record Sampling for Standard (Full) Surveys

It is generally preferred that the clinical record sample consist of records for RHC patients seen by a physician or non-physician RHC practitioner within the previous 90 days. At a minimum, the sample should be at least 20 records for an RHC with a monthly case volume exceeding 50. For lower volume RHCs at least 10 records should be selected. The sample size may be expanded as needed in order to determine compliance with the RHC CfCs, at the surveyor or Team Coordinator’s discretion. For initial surveys, the surveyor or Team Coordinator determines if there are enough medical records for surveyors to determine whether the RHC can demonstrate compliance with all of the CfCs.

The sample must include Medicare beneficiaries as well as other patients. Any emergency transfers to hospitals or Critical Access Hospitals (CAHs) should also be included.

Sampling for Complaint Surveys

*CMS always assesses an RHC for its current compliance with the CfCs. For a complaint investigation, it is expected that the CfC(s) related to the complaint are evaluated in the same manner as they would be during a full or standard survey. Thus, it is **not** sufficient to look only at the clinical record for the complaint case in conducting a complaint survey.*

The SA - or the RO, in the case of a deemed status RHC - will determine in advance of the survey which CfCs the surveyor(s) will be evaluating in relation to the complaint. Selection of the CfCs will be determined based on the nature of the allegation(s) explicitly stated or implied by the complaint – i.e., an allegation of transmission of an infectious disease will require review of the Physical Plant and Environment CfC, and probably also of the Program Evaluation CfC.

It will be necessary to review multiple clinical records, including the record of any patient identified in the complaint, and the selection of the sample to review will in part be dependent on the complaint allegations. Depending on the CfCs to be surveyed for a complaint, as well as the date of service for any patient identified in the complaint, it may also be necessary to review older records.

A revisit survey may or may not require review of recent or older records, depending on the specific standards and conditions being re-evaluated.

Once the clinical records are available, the surveyor(s) can begin reviewing each record for evidence of compliance/noncompliance.

Give each clinical record observed/reviewed in the sample a unique identifier. A key containing identifiable information for patients must be kept on a separate identifier list. Do not use names, clinical record numbers, Social Security numbers, or billing record numbers to identify the patients or names or positions for staff. In reviewing the record, surveyors should confirm it contains items required by various CfCs, including but not limited to:

- 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 the instructions to the patient;*
- Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;*
- All practitioner's orders, reports of treatment and medications and other pertinent information necessary to monitor the patient's care;*
- Signatures of the physician and other health care professional.*
- Legible entries that are completed, dated, timed, and authenticated promptly in written or electronic form by the person responsible for ordering, providing or evaluating the service.*

Interviews

Interviews provide another method to collect information, and to verify and validate information obtained through observations, record review and review of other documents. Informal interviews are conducted throughout the duration of the survey. The information obtained from interviews may be used to determine what additional observations, interviews, and record reviews are necessary. When conducting interviews:

- *Prepare detailed notes of each interview conducted. Document the interview date, time, and location, the full name and title of the person interviewed, and key points made and topics discussed. To the extent possible, document quotes from the interviewee.*
- *Interviews with facility staff should be brief and to the point.*
- *Interviews should be used to determine whether staff is aware of and understand what they need to do for the RHC to comply with regulatory requirements, as well as the RHC's formal policies and procedures. It is not necessary for staff to be able to cite specific Medicare regulations, but they should be able to describe what they do in a way that lets surveyors determine compliance with the regulations.*
- *Be sure to interview staff having responsibilities related to each of the CfCs being surveyed.*
- *Use open-ended questions whenever possible to elicit staff knowledge rather than questions that lead the staff member to certain responses. For example, to determine if a staff member is aware of non-medical emergency procedures, and his/her role in such events, simply ask, "If you smelled smoke, what would you do?" Do not ask, "Does this RHC have policies and procedures to address non-medical emergencies?" Likewise, ask appropriate clinical staff, "Can you describe how a life-threatening/medical emergency is handled? Do not ask, "Does this RHC provide medical emergency procedures?"*
- *Surveyors must always introduce themselves and ask patients or their representatives for permission before they interview them. Surveyors must be sensitive when selecting patients for interview; for example, if a patient appears to be experiencing significant pain or anxiety, an interview request should not be made. The privacy, dignity and well-being of the patient must always be respected, along with the patient's right to refuse to allow the surveyor to conduct an interview.*
- *Patient interview questions should focus on factual matters about which the patient is likely to have information. For example, ask "Did you notice whether the nurse or physician washed their hands or used a cleaning gel before providing care to you today?"*

- *Problems or concerns identified during a patient or family interview must be addressed in the staff interviews to gather additional information and to potentially validate the patient's perception.*
- *Validate as much of the information collected via interviews as possible, e.g., by asking the same question of several staff or patients, or by integrating interview responses with related surveyor observations or record review findings.*
- *If necessary, telephone interviews may be conducted but in-person interviews are preferred.*

Task 4 – Preliminary Decision Making and Analysis of Findings

General Objectives

The general objectives of this task are to integrate findings, and to review and analyze all information collected from observations, interviews, and record reviews. The surveyor's preliminary decision-making and analysis of findings assist in preparing the exit conference report.

Preparation

Prior to beginning this task, the surveyor must review his/her notes related to observations and interviews, as well as the documents he/she has photocopied (or printed out if the RHC uses an electronic health record system). The surveyor must be confident that he/she has everything needed to support his/her presentation of findings to the team, when applicable, and to his/her SA manager when preparing a formal survey report.

Discussion Meeting

A discussion meeting takes place when more than one surveyor participates in the onsite survey. A survey team should use this time to share their individual findings. The team must reach a consensus on all findings of noncompliance. Decisions about deficiencies must be team decisions with each member having input. During this meeting, the survey team will begin evaluating the formation/evidence found during the survey.

Information Evaluation

The surveyor(s) must evaluate the evidence and make decisions regarding compliance with each requirement. For initial, recertification, and validation surveys (if applicable), the surveyor should review the evidence gathered, proceeding sequentially through the regulatory requirements for each CfC to determine if the requirements are met. For complaint surveys, the surveyor should review the evidence related to each CfC selected for the investigation. All evidence that supports each finding of noncompliance must be documented. Any additional documentation or evidence needed to support identified noncompliance must be gathered prior to exiting the facility.

All noted noncompliance must be cited as a deficiency, even when corrected onsite during the survey.

*When a noncompliant practice is determined to have taken place prior to the survey, this would be considered evidence of current non-compliance, **unless** there is documentation that the RHC identified the problem prior to the survey and implemented effective corrective action. In evaluating whether the RHC is currently in compliance, the surveyor(s) must consider:*

- *what corrective action the facility implemented and when it did this;*
- *whether the corrective action was sufficient to address the underlying causes of the deficiency;*
- *whether the corrective action was evaluated for its effectiveness to sustain long-term compliance; and*
- *whether there are any other findings from the survey indicating current non-compliance.*

If the deficient practice was identified and corrected by the RHC prior to the survey and there is no other evidence of current non-compliance, this would be a case of past noncompliance and surveyors must not cite current noncompliance.

In the case of a revisit survey, the surveyor's task is to determine current compliance with the regulatory requirements that were cited as deficiencies during the previous survey. The surveyor should conduct observations, document reviews and interviews to assess current compliance with the CfC(s) addressed by the PoC.

Integrating Findings

The surveyor(s) integrates the findings derived from document review, observations, and interviews that pertain to each CfC surveyed, in order to make a determination of whether there is evidence of compliance/non-compliance.

Determining the Citation Level of Deficiencies

Citing noncompliance at the appropriate level, i.e., standard or condition-level, is critical to the integrity of the survey process.

The regulations at 42 CFR § 488.26(b) state in part, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition." When noncompliance with a particular standard within the Conditions for Certification is noted, the determination of whether the lack of compliance is at the Standard or Condition level depends upon the nature of the noncompliance – i.e., how

serious is the deficiency in terms of its potential or actual harm to patients - and the extent of noncompliance – e.g., how many different regulatory requirements within a CfC are being cited for noncompliance, or how widespread was a given noncompliant practice, etc. One instance of noncompliance with a standard that poses a serious threat to patient health and safety is sufficient to find condition-level noncompliance. Likewise, when an RHC has multiple standard-level deficiencies in a CfC, the extent of the non-compliance could be sufficient to find condition-level noncompliance.

Determinations of citation level for complaint surveys follow the same process that is applied to full surveys; the only difference is that the complaint survey itself is generally limited to the CfCs implicated in the complaint.

Gathering Additional Information

If additional information is required in order to determine facility compliance or noncompliance, the surveyor determines the best way to gather such information. If the survey was conducted by a survey team, the Team Coordinator makes the determination of whether additional information is required.

Task 5 - Exit Conference

General Objective

The general objective of this task is to informally communicate preliminary survey team findings and provide an opportunity for the exchange of information with the RHC's administrator, designee or other invited staff. The Exit Conference is both a courtesy to the RHC and a way to expedite the clinic's planning ahead of the formal receipt of the survey findings in the Form CMS-2567, Statement of Deficiencies. Additionally, an Exit Conference is not always guaranteed, as is noted in section 2724 of the SOM.

Prior to the Exit Conference

- The surveyor is responsible for organizing his/her presentation for and facilitating the exit conference.*
- If the surveyor feels he/she may encounter a problem during the exit conference, he/she should contact the SA manager in advance to discuss the potential problems and appropriate methods to handle them.*

If the survey is conducted by a survey team, the Team Coordinator would be responsible for the above tasks.

Discontinuation of an Exit Conference

CMS' general policy is to conduct an exit conference at the conclusion of all types of surveys as a courtesy to the provider/supplier and to promote timely remediation of quality of care for

safety problems. However, there are some comparatively rare situations that justify refusal to conduct or continue an exit conference. For example:

- If the RHC is represented by an attorney (all participants in the exit conference, both surveyor(s) and RHC staff, must identify themselves prior to beginning the exit conference), surveyors may refuse to conduct the conference if the attorney attempts to turn it into an evidentiary hearing; or*
- If the RHC staff/administration create an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference, the surveyor(s) may refuse to conduct or continue the conference. Under such circumstances, it is suggested that the surveyor stop the exit conference and call the SA for further direction. If a survey team is onsite, the Team Coordinator should take the above actions.*

Recording the Exit Conference

If the facility wishes to audio tape the conference, it must provide two tapes and tape recorders, recording the meeting simultaneously. The surveyor or Team Coordinator should select one of the tapes at the conclusion of the exit conference to take back to the SA. Videotaping is also permitted, if: 1) the surveyor/team agrees to this, and 2) a copy is provided the surveyor/team at the conclusion of the conference. The surveyor or survey team is under no obligation to consent to videotaping and is not required to offer a reason if it refuses to permit videotaping.

General Principles

The following general principles apply when conducting an exit conference:

- The RHC management determines which RHC staff will attend the exit conference.*
- The identity of individual patients or staff members must not be revealed by surveyors when discussing the survey results. Identity includes not just the name of an individual patient or staff member, but also includes any reference or characterization by which identity may be deduced.*
- Because of the information-gathering activities the surveyor or survey team has already engaged in, in most instances members of the RHC's staff should generally be aware prior to the exit conference of the areas, if any, where the survey team has concerns. Accordingly, there should be few cases where the RHC has not already had the opportunity prior to the exit conference to present additional information that might be relevant to the survey findings. The exit conference is not the correct setting for further information-gathering activities.*

Exit Conference Sequence of Events

Introductory Remarks:

- *Thank everyone for their cooperation during the survey.*
- *Reintroduce all surveyors who participated in the survey, even if they are no longer in the facility.*
- *Briefly reiterate what was the reason for the survey (i.e., initial, recertification, representative sample validation, or complaint).*
- *Explain how the exit conference will be conducted and any ground rules, such as,*
 - *the exit conference is an informal meeting for surveyors to summarize their preliminary findings;*
 - *brief comments on the findings may be made by the RHC, but the surveyor/team will not engage in a debate; or*
 - *whether comments will be permitted in the middle of a surveyor’s presentation or only after the presentation has concluded;*

Presentation of Findings

- *The findings or information conveyed at the Exit Conference are preliminary in nature and are subject to change pursuant to the State and CMS supervisory review processes.*
- *Do not refer to any specific ASPEN tag numbers when describing deficiency findings as the tags numbers often identify the Condition or Standard-level classification for most non-long term care (LTC) deficiencies. Additionally, such specific details should wait supervisory review. This has been CMS’ long-standing policy, and will continue for non-LTC providers and suppliers. In the process of completing the Form CMS-2567 after exiting the RHC, the SA will establish which tags/regulatory text to cite for each finding. It would be premature to make such statements during the exit conference.*
- *Present the findings of noncompliance, explaining why the findings indicate noncompliance with the regulatory requirement. If the RHC asks for the pertinent regulatory reference, provide the citation for the applicable CfC.*
- *Do not make any general characterizations about the survey results (e.g., “Overall the facility is very good.” or “In general the facility is in compliance with Medicare requirements.”) Stick to presenting the specific factual findings.*
- *Do not make any statements about whether the findings represent condition-level or standard-level deficiencies. Avoid statements such as, “the condition was not met” or “the standard was not met.” It is better to state “the requirement related to XXX is not met.”*

- *If an immediate jeopardy situation was identified during the review process that had not previously been discussed with the RHC's management, explain the significance and need for immediate removal of the IJ. Follow instructions in Appendix Q*
- *Do not rank findings. Treat CfC requirements as equally as possible.*
- *Ensure each deficiency finding is discussed at the exit conference.*

Closure

- *Explain the State and/or RO will send the official survey findings presented in writing to the RHC via the Form CMS-2567, Statement of Deficiencies and PoC, which will be prepared and mailed to the RHC within 10 working days. The Form CMS-2567 documents for each regulatory requirement surveyed either that no deficiencies were found, or the specific deficiencies found. There will also be a letter communicating whether or not CMS will be taking enforcement action as a result of the survey's findings.*
- *If there are deficiencies and the RHC:*
 - *Does not have deemed status, advise the RHC that it will be required to submit a PoC for any deficiencies cited. Inform the RHC that a written PoC must be submitted to the survey agency within 10 calendar days following receipt of the written statement of deficiencies, i.e., the Form CMS-2567.*
 - *Has deemed status, advise the RHC that it will be required to submit a PoC (also due within 10 calendar days of receipt of the Form CMS-2567) only if the statement of deficiencies indicates that there was condition-level noncompliance. The deemed status RHC may voluntarily submit a PoC even when there is only standard-level noncompliance, but the SA will not evaluate the PoC for its acceptability.*
- *When a PoC is required, the RHC's PoC and timeframes for implementation of corrective actions are incorporated into the Form CMS-2567 by the RHC and returned to the SA. Explain that the Form CMS-2567 is the document disclosed to the public about the facility's deficiencies and what is being done to remedy those deficiencies (Form CMS-2567 with PoC). Pursuant to 42 CFR 488.325, the Form CMS-2567 and an associated PoC can be made public 90 calendar days following completion of the survey and receipt by CMS of the SA's survey report, or whenever the PoC has also been received by the SA/RO, whichever comes first.*
- *Explain that, if a PoC is required, the RHC will have the following three options for each cited deficiency:*
 - *Accept the deficiencies stated on Form CMS-2567 and submit a PoC;*

- Record objections to the cited deficiencies on Form CMS-2567 **and** submit a PoC; or
- Record objections to cited deficiencies on Form CMS-2567, without submitting a PoC, but with written arguments and documented evidence that the deficiency findings are invalid.
 - CMS will consider objections and accompanying documentation that attempt to refute the **factual** accuracy of the survey findings, but will not consider objections to CMS's judgment of the level, extent, scope or severity of a deficiency. CMS reviews additional documentation submitted by an RHC making an objection and, if the added evidence convincingly demonstrates the deficiency finding was factually inaccurate, will make a determination about removing the deficiency citation. In this instance, the SA will be asked to revise the CMS-2567.
 - If CMS disagrees with the RHC's objections, the RHC must submit an acceptable PoC. Failure to submit an acceptable PoC or failure to correct a deficiency may result in termination of the RHC's supplier agreement in accordance with 42 CFR §§ 488.28(a) and 405.2404(b). See Section 2728 of the SOM for more detailed information on PoC requirements and timelines.

Explain that an acceptable PoC must contain the following:

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will correct, and/or improve the processes that led to, the deficiency cited;
- The procedure for implementing the corrective actions;
- A completion date for correction of each deficiency cited;
- Monitoring and tracking procedures to ensure the PoC is effective in bringing the RHC into compliance, and that the RHC remains in compliance with the regulatory requirements;
- the title of the person responsible for implementing the acceptable PoC; and
- The administrator's signature and the date signed on page 1 of the Form CMS-2567;

Indicate that any required PoC will be reviewed by the SA, or in some cases, the RO, to determine whether it is acceptable. If a PoC is determined not to be acceptable, it will be returned to the RHC for revision.

State that in some cases, the SA will make an unannounced revisit survey to determine whether the RHC has come into compliance.

If the exit conference was audio- or videotaped, obtain a copy of the tape before exiting the facility.

All survey team members should leave the facility together immediately following the exit conference. If the facility staff provides further information for review, the surveyor, or team coordinator if applicable, determines the best way to review the additional information. It is usually prudent for at least two individuals to remain if all of the team members do not leave at the same time.

Task 6 – Post Survey Activities

General Objective

The general objective of this task is to complete the survey and certification requirements in accordance with the regulations found at 42 CFR Part 488.

General Procedures

Each SA and RO must follow the instructions in the SOM including:

- Timelines for completing each step of the process;*
- Responsibilities for completing the Form CMS-2567, Statement of Deficiencies following the “Principles of Documentation;”*
- Notification to the RHC regarding survey results, unless the RHC is a deemed status RHC, in which case the RO must review and concur with the Form CMS-2567;*
- Additional survey activities based on the survey results (e.g., revisit, forwarding documents to the RO for further action/direction, such as concurrence with findings for deemed RHCs, authorization of a full survey for deemed RHCs with condition-level deficiencies);*
- Compilation of documents for the supplier’s file;*

NOTE: An RHC has deemed status only if CMS has certified it based on accreditation by a CMS-approved Medicare RHC accreditation program. Surveys of deemed status RHCs are only conducted if approved by the CMS RO.

Survey Package

If a survey team conducted the on-site survey, the Team Coordinator will assign responsibilities for completion of the various elements of the survey package.

Statement of Deficiencies Report & Plan of Correction

The Statement of Deficiencies Report and Plan of Correction (Form CMS-2567) is the official document that communicates the determination of compliance or noncompliance with Federal requirements. Also, it is the form that the RHC will use to submit a plan to achieve compliance. Form CMS-2567 is an official record and is available to the public on request.

There must be an indication on Form CMS-2567 whether any deficiency constitutes immediate jeopardy to a patient's health and safety.

Each deficiency statement must be written in terms specific enough to allow a reasonably knowledgeable person to understand what regulatory requirements were not met. The consequence for incorrectly or unclearly documenting deficiencies can be the inability of CMS to take needed enforcement action.

Surveyors must refrain from making clinical judgments. Instead, they must focus on the RHC regulatory requirements and how they were or were not met by the RHC.

After the surveyor(s) complete Form CMS-2567 in ASPEN, it must be submitted to a supervisor for review. If, after reviewing the form, the supervisor approves it, surveyors begin working on the remainder of the survey package. If the supervisor does not approve the form, then the surveyor must make any requested changes.

Other Survey Package Documentation

Complete the following documentation in hard copy. For complaint investigations, attach these materials to the corresponding complaint in the Aspen Complaint Tracking System (ACTS):

- *Description of sample selection;*
- *Summary listing of sample cases;*
- *Summary of interviews;*
- *Complaint investigation narrative;*
- *Form CMS-29 – Verification of Clinic Data – Rural Health Clinic Program; and*
- *Form CMS-670, Survey Team Composition and Workload Report*

Part II

Regulations and Interpretive Guidelines

J-0001

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.3 Certification procedures

A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405. The Secretary will notify the State Medicaid agency whenever he has certified or denied certification under Medicare for a prospective rural health clinic in that State. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.

Interpretive Guidelines § 491.3

Sections 405.2401 – 405.2404 establish the procedures for certifying a clinic as an RHC and recertifying existing RHCs, including issuing a Medicare agreement, and the conditions under which an RHC’s participation in the Medicare program may be terminated. Section 405.2401(b) requires compliance with the Conditions for Certification (CfC) in 42 CFR Part 491 in order for an RHC to be certified.

Survey Procedures § 491.3

In general, there are no survey procedures specific to this Condition, with the exception of the provisions covered in the two standard-level tags below concerning provision of physician or visiting nurse services (VNS) outside the RHC.

With respect to the other requirements of Part 405, Subpart S, State Survey Agencies (SA) assess compliance with the remaining CfCs and make recommendations to the CMS Regional Office (RO). The RO determines whether to issue an initial RHC Medicare agreement or to terminate an existing RHC Medicare agreement, consistent with the requirements of 42 CFR Part 405 and as outlined in Chapter 2 of the State Operations Manual (SOM), sections 2240 - 2249.

J-0002

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

Standard-Level Tag

§ 491.3 Certification procedures

A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405....

§ 405.2412 Physicians' services.

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.

Interpretive Guidelines § 491.3 & § 405.2412

RHCs are permitted to provide their physician services outside the premises of the RHC, (i.e., a patient's home, a Part A SNF or at the scene of an accident, so long as there is a written agreement between the RHC and the physician. Note:

- Services provided inside a mobile RHC unit are considered to be provided inside the RHC; and*
- A physician who provides RHC services is also free to provide physician services that are not RHC services outside the RHC; in this case the physician bills for those services separately rather than being reimbursed for them by the RHC.*

The agreement between the RHC and a physician must 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.

Survey Procedures § 491.3 & § 405.2412

- 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.*

J-0003

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

Standard-Level Tag

§ 491.3 Certification procedures

A rural health clinic will be certified for participation in Medicare in accordance with subpart X of 42 CFR part 405 . . .

§ 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 or 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 residence" 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 serviced 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.

Interpretive Guidelines § 491.3 & § 405.2416 - §2417

RHCs are permitted to offer visiting nurse services (VNS) in patients' homes if they are located in an area with a shortage of home health agencies. To provide VNS, the RHC must apply to the SA, which performs an assessment in accordance with Section 2246 of the SOM. Based on this assessment the SA makes a recommendation to the CMS RO, and the RO makes the determination whether the RHC will be permitted to offer VNS.

If an RHC provides VNS, the SA must confirm that the services are being provided:

- *by a registered nurse (RN) or a licensed practical nurse who is employed by or receives compensation from the RHC for providing such services;*
- *in accordance with a written plan of treatment which is:*
 - *established and signed by a supervising RHC physician, nurse practitioner, physician assistant, or certified nurse midwife;*
 - *reviewed and signed at least every 60 days by the supervising RHC physician; and*
 - *identifies the nursing and personal care services that are to be provided to the individual.*

The VNS must be provided in the patient's home and must be documented in the RHC's clinical records, in accordance with the requirements at § 491.10.

Survey Procedures § 491.3 & § 405.2416 - §2417

- *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.*

J-0010

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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.

Interpretative Guidelines § 491.4

The RHC must ensure that it meets all applicable Federal, State and local law and regulations. Depending on the manner and degree of noncompliance with the standards contained in this Condition, condition-level noncompliance may be present and must be cited.

J-0011

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

Standard-level Tag

§ 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.

Interpretative Guidelines § 491.4

Other Federal Requirements

*Neither CMS, nor State surveyors conducting surveys on its behalf, has the authority to interpret and enforce the laws and regulations of other Federal agencies. Further, surveyors are not expected to be knowledgeable about the requirements of other Federal agencies. However, a surveyor who suspects an RHC may not be in compliance with other Federal requirements may refer the matter to the appropriate agency having jurisdiction. If CMS is notified of or becomes aware of another Federal agency's **final** enforcement action, citations under this regulation*

would be appropriate, but **only** if the other agency's **final** enforcement action remains in effect and the violation of the other agency's regulations has not been corrected.

Survey Procedure § 491.4

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.)

J-0012

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.4(a) Licensure of clinic ...

The clinic . . . is licensed pursuant to applicable State and local law.

Interpretative Guidelines: § 491.4(a)

State licensure requirements generally exist for healthcare facilities. States may vary in their licensure requirements for entities that meet the Medicare definition of an RHC. Some States may not require licensure of these facilities at all, or may permit them to be licensed as part of another entity. In States where a separate facility license is required for a facility seeking to participate or already participating in Medicare as an RHC, the RHC must have a current license that has not expired or been suspended or revoked. The RHC must also be in compliance with all the State licensure requirements.

Neither CMS nor State surveyors conducting surveys on its behalf have the authority to interpret or enforce State licensure or other state laws. Failure of the RHC to meet State licensure law may be cited during the Federal survey only if the State has made a determination of noncompliance and has also taken a **final** enforcement action as a result. (Citation of licensure deficiencies on a State survey may represent an initial step rather than a final action or determination by the State licensure authority.) Additionally, the Federal survey of the RHC focuses on current compliance or non-compliance, not past noncompliance. Thus, for example, evidence that an RHC had received a State licensure citation in the previous year would not be grounds for citing the RHC for noncompliance with State licensure law, unless the State licensure authority has taken a **final** action and indicates the RHC is noncompliant at the time of the survey.

If as a result of a State citation of an RHC for deficiencies in its compliance with licensure requirements, the RHC has ceased operations and no longer furnishes services, it would be considered to have voluntarily terminated its Medicare agreement as of the last date on which it provided services to Medicare beneficiaries in accordance with § 405.2404(a)(3), which is cross-referenced in § 491.3 of the RHC CfCs). The SA must advise the RO of the RHC's cessation of business, and the RO will process a voluntary termination.

If at the time of the survey the RHC's State license has been revoked or suspended, then the RHC is not in compliance with this condition and must be cited for a condition-level deficiency.

Furthermore, survey of the rest of the CfCs cannot be completed, since the RHC is not providing medical services to patients. The SA must advise the RO of such revocation or suspension, and the RO will proceed with action to terminate the RHC's Medicare agreement in accordance with standard termination procedures.

If the surveyor identifies a situation that suggests the RHC may not be in compliance with State or local licensure laws, the information may be referred to the State licensure authority for follow-up.

Survey Procedures § 491.4(a)

- 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.*

J-0013

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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.

Interpretative Guidelines § 491.4(b)

The laws requiring licensure vary from State to State. Examples of healthcare professionals that a state may require to be licensed could include: MD/DOs, dentists, physician assistants, nurse practitioners and nurses. Examples of personnel that a state might require to be certified or registered could include dietitians, technicians who administer diagnostic imaging procedures, pharmacy technicians, laboratory technicians, etc.

All RHC staff members that are required to be licensed, certified or registered by the State where the RHC is located must possess a current license, certification or registration, as applicable. It is the RHC's responsibility to ensure that all clinic personnel hold an appropriate and current license, certification or registration. There are considerable variations in the States' health care professional laws and regulations governing scope of practice acts relative to the extent to which physicians may delegate responsibilities to physician assistants, nurse practitioners and certified nurse-midwives. If a State requires a nurse practitioner or physician assistant to have all of

their orders co-signed by a physician or establishes other requirements for supervision, the RHC must ensure that its staff complies. In all cases, patient care must be provided by practitioners practicing within their permitted scope of practice under State law.

Survey Procedure § 491.4(b)

- *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.*

J-0020

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.5 Location of clinic.

Interpretative Guidelines § 491.5

Depending on the manner and degree of noncompliance with the standards of this condition, condition-level noncompliance may be cited.

J-0021

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.5(a) Basic requirements.

(1) An RHC is located in a rural area that is designated as a shortage area.

§ 491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

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

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

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

§ 491.5(c) Criteria for designation of rural areas.

(1) Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau.

(2) Excluded from the rural area classification are:

(i) Central cities of 50,000 inhabitants or more;

(ii) Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined populations of 50,000 and constitute, for general economic and social purposes, single communities;

(iii) Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban.

(3) Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural.

§ 491.5(d) Criteria for designation of shortage areas.

(1) The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are:

(i) The ratio of primary care physicians practicing within the area to the resident population;

(ii) The infant mortality rate;

(iii) The percent of the population 65 years of age or older; and

(iv) The percent of the population with a family income below the poverty level.

(2) The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are:

(i) The area served is a rational area for the delivery of primary medical care services;

(ii) The ratio of primary care physicians practicing within the area to the resident population; and

(iii) The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area.

Interpretative Guidelines § 491.5(a)(1), § 491.5(c) & § 491.5(d)

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:

- *The US Census Bureau as to whether a location is in a rural area; and*
- *The Health Services and Resources Administration (HRSA) as to whether a location is in a designated shortage area.*

*See Sections 2240 - 2242 of the SOM for more information about how the RO makes determinations as to whether an RHC meets the location requirements. The SAs may conduct preliminary assessments of the eligibility of an initial applicant for certification as an RHC, in order to avoid conducting a survey of a potentially ineligible applicant. If the SA suspects an applicant's location is not eligible, it advises the RO promptly, so that the RO can make a determination. Should this situation occur, the SA should **not** conduct a survey of the applicant unless the RO advises that it has found the applicant's location to meet the location requirements.*

Survey Procedure § 491.5(a)(1), § 491.5(c) & § 491.5(d)

- *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.*

J-0022

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[Basic requirements]

§ 491.5(a)(3) . . . the RHC . . . may be permanent or mobile units.

- (i) ***Permanent unit. The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic . . . are housed in permanent structure.***
- (ii) ***Mobile unit. The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic . . . are housed in a mobile structure, which has fixed, scheduled location(s).***

Interpretative Guidelines § 491.5(a)(3)(i)-(ii)

An RHC may be housed in:

- *a fixed, permanent structure;*
- *a mobile unit; or*
- *a permanent structure which also provides RHC services in one or more mobile units.*

In all cases, each structure or unit must contain within it all the objects, equipment, and supplies required by the RHC for the clinical services that it furnishes.

Mobile Unit

An RHC that consists only of a mobile unit must comply with all of the CfCs in that unit, including the location requirements. All mobile units, regardless of whether they are the entire RHC or a part of an RHC that also has a permanent structure, must have a fixed set of locations in which the unit is scheduled to be providing services at specified dates and times, and each unit must adhere to this schedule. For new applicants, the mobile locations in which services are provided must meet the rural and shortage area requirements at the time of survey. For existing RHCs, if services are being provided at locations other than its original locations, the new locations must meet the rural and shortage area requirements at the time of survey. This does not mean that the RHC is not able to periodically change the schedule for its mobile services. Instead, it means that the mobile unit must operate at locations that meet the location requirements and those locations and times are documented by the RHC and made available to the public in advance of scheduled operations, so that patients can know when and where services will be available to them. The schedule of times and locations must be posted on the mobile unit but must also be publicized by other means that patients could consult in advance, e.g., on a website, in local libraries or stores, etc.

Survey Procedures § 491.5(a)(3)(i)-(ii)

- *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.*

J-0023

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[Basic requirements]

§ 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 . . .***

Interpretive Guidelines § 491.5(a)(3)(iii)

A Medicare-certified RHC is not permitted to have more than one permanent unit, i.e., it may not operate out of permanent structures in more than one location. Location is identified as the physical address where medical services are provided. If an organization owns several facilities operating out of permanent units at different locations; that it seeks to enroll in Medicare in order to provide RHC services in each facility, it must enroll each permanent unit separately, and each must independently and fully comply with the RHC CfCs. If one RHC occupies several suites within the same building, sharing the same address, it is considered to have only one permanent unit. It is also possible for separate RHCs to occupy different suites in the same building; when this occurs, each RHC must independently meet the RHC CfCs, and cannot co-mingle their services.

Survey Procedures § 491.5(a)(3)(iii)

- 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.*

J-0024

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.5(b) Exceptions.

(1) CMS does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area.

(2) A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July 1, 1977, it 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.

(3) Determinations on these exceptions will be made by the Secretary upon application by the facility.

Interpretative Guidelines § 491.5(b)(1) - § 491.5(b)(3)

Loss of Location Eligibility

A provider or supplier is expected to be in substantial compliance with its applicable conditions at all times. This applies to conditions which establish facility location requirements as well. But 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).

CMS makes a presumption that every RHC seeks continued certification for participation in Medicare, including by application of this exception when necessary, unless the RHC has notified CMS of a voluntary termination of its RHC agreement. As a result, there is no special procedure for the RHC to file a request for exception to the location requirements and there is no new determination by the CMS RO concerning a certified RHC's ongoing compliance with the location requirements when the SA conducts a full RHC survey, regardless of whether the survey is conducted for periodic recertification of the RHC, as a representative sample validation survey, or for any other purpose. Although the grandfathering provision means that CMS does not terminate a certified RHC's Medicare agreement due to its location no longer meeting the rural or shortage area location requirements, CMS does continue to collect RHC location data. SAs conducting full surveys must still collect this and other data specified on the Form CMS-29, Verification of Clinic Data – Rural Health Clinic Program. The information collected is updated in the Automated Survey Process Environment (ASPEN) which may be aggregated and used for future policy analysis.

If an existing RHC relocates, the grandfathering provision does not apply and the RHC must meet both the rural and shortage area location requirements at the new location. As with initial RHC location determinations, the CMS RO is responsible for making the actual determination of compliance with the location requirements. Determinations are made only after the relocation has occurred, and the CMS-855A has been submitted by the RHC to the appropriate Medicare Administrative Contractor, and the Form CMS -29 has been submitted by the RHC to the SA. Although an onsite survey is not required, the CMS RO has the discretion to require a survey in individual cases to verify that services are being provided at the new location identified in the submitted documentation.

Facilities Operating on July 1, 1977

This provision applies to initial applicants for RHC certification and therefore is not likely to have any practical application at this time. The SA should consult with the CMS RO if it believes it has encountered a situation where this provision would apply.

J-0040

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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.

J-0041

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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.

Interpretative Guidelines § 491.6(a)

The RHC must ensure that the physical plant of its permanent and/or mobile unit is constructed, arranged in terms of its layout, and maintained in a manner to ensure patient access and safety of its patients and personnel. The clinic's layout and fixtures must not present 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. The physical plant also must be designed and constructed in accordance with applicable State and local building, fire, and safety codes, but surveyors conducting RHC surveys on behalf of CMS do not assess compliance with such State and local code requirements.

Further, the clinic must have enough space, for the fixtures, equipment and supplies required, in order for it to provide those RHC services which must be furnished directly, i.e., provided within the RHC rather than under arrangement. The clinic must also comply with applicable Federal, State and local laws and regulations and accepted standards of practice for primary care services when determining how much space it requires for its direct services.

Survey Procedures § 491.6(a)

- *Observe whether the clinic's physical plant is well constructed and arranged, and does not present barriers to patient access or 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.*

J-0042

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.6(b) Maintenance:

The clinic . . . has a preventive maintenance program to ensure that:

(1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;

Interpretative Guidelines § 491.6(b)(1)

The RHC must have a preventive maintenance program which ensures all essential mechanical, electrical and patient-care equipment is maintained so that it operates safely. Essential mechanical, electrical and patient care equipment includes things such as heating, ventilation and air conditioning systems, electrical systems, plumbing systems, telephone systems, elevators, and any biomedical equipment the clinic uses. Biomedical equipment means devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the clinic, e.g., blood pressure monitors, re-usable diagnostic scopes, EKG machines, scales, laboratory equipment, etc.

All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades.

All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using qualified clinic personnel, contracted services, or through a combination of clinic personnel and contracted services. For example, clinics that rent space in buildings with other occupants generally would have a contractual agreement with the landlord for maintenance of essential building systems. Clinics may also contract for maintenance of their biomedical equipment. In all cases, clinics must follow or ensure that their contractors follow equipment manufacturers' recommended maintenance activities and schedules. Clinics must document their preventive maintenance activities. This documentation must be incorporated into the RHC's program evaluation plan.

Survey Procedures § 491.6(b)(1)

- 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*

J-0043

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[The clinic . . . has a preventive maintenance program to ensure that:]

§ 491.6(b)(2) Drugs and biologicals are appropriately stored; and

Interpretative Guidelines § 491.6(b)(2)

*The RHC must ensure the appropriate storage of drugs and biologicals which are used in the clinic. Drugs and biologicals must be stored and maintained in accordance with the manufacturer's instructions for temperature and other environmental conditions as well as expiration dates, etc. They may not be stored in areas that are readily accessible to unauthorized individuals/personnel. The clinic's policies and procedures must identify which types of clinic staff are authorized access to drugs and biologicals. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional, they are considered secure. If medications are kept in cabinets located in areas where patients, visitors or other unauthorized personnel have ready access when clinic personnel are **not** also present, the cabinets must be locked.*

Survey Procedures § 491.6(b)(2)

- *Verify drugs are stored according to manufacturer instructions.*
- *Verify that drugs are not accessible to unauthorized individuals/personnel.*

J-0044

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[The clinic . . . has a preventive maintenance program to ensure that:]

§ 491.6(b)(3) The premises are clean and orderly.

Interpretative Guidelines § 491.6(b)(3)

The RHC must provide and maintain a clean and orderly environment. All areas of the clinic must be clean. These areas include, but are not limited to, the waiting area(s), exam room(s), staff lunch room(s), rest room(s), and office space. The clinic must appropriately monitor housekeeping, maintenance (including repair, renovation, and construction activities), and other activities to ensure a functional and clean environment. Policies and procedures for an orderly and clean environment must address the following:

- *Measures taken to maintain a clean and orderly environment during internal or external construction/renovation;*
- *Measures to prevent the spread of infectious diseases. At a minimum the following must be addressed:*
 - *Hand hygiene for staff having direct patient contact;*
 - *Safe injection practices;*
 - *Single-use devices, and, when applicable, high-level disinfection and sterilization;*
 - *Safe use of point-of-care devices;*
 - *Routine cleaning of environmental surfaces, carpeting, and furniture;*
- *Disposal of waste, including medical waste;*
- *Food sanitation, if employee food storage and eating areas are provided; and*

- *Pest control.*

Survey Procedures § 491.6(b)(3)

- *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.*
- *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 room(s), office space, rest rooms, floors, horizontal surfaces, patient equipment, mechanical rooms, central supply, and storage areas, etc.*

J-0060

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.7 Organizational structure.

Depending on the manner and degree of noncompliance identified for standards within this condition, there may be condition-level noncompliance.

J-0061

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§.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.

§ 491.2 Definitions. *As used in this subpart, unless the context indicates otherwise:*

Physician means the following:

(1) As it pertains to the supervision, collaboration, and oversight requirements in sections 1861(aa)(2)(B) and (aa)(3) of the Act, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and

(2) Within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor (see section 1861(r) of the Act for specific limitations).

Interpretative Guideline §§ 491.7(a)(1) & 491.7(b)(3)

The clinic must be under the medical direction of a physician who is responsible for the quality and appropriateness of health care services furnished in the RHC. In light of the definition of a physician at § 491.2 and due to the supervisory and oversight responsibilities involved in providing medical direction, only an MD or DO may serve as the RHC's medical director. The MD or DO must hold a current license that is issued or recognized by the State in which the RHC is located. The nature of medical director's duties are specified at § 491.8(b). By contrast, the language of § 491.7(a)(1) is focused on the requirement for the RHC to have an individual who is explicitly charged with being the clinic's medical director. There must be documentation available in the RHC identifying the name, address, and phone number of the clinic's medical director.

Any change in the physician responsible for the clinic's medical direction requires immediate notification to the appropriate SA. When identifying a new physician responsible for medical direction, the RHC provides the SA with the name, address, and phone number of the new medical director and evidence that the physician is licensed to practice in the State in which the RHC is located. Such change in medical director does not require resurvey or recertification, if the change can otherwise be adequately verified.

*There is no waiver available should the physician functioning as the medical director leave a clinic that is already certified as an RHC. However, CMS affords currently certified RHCs a reasonable time to come back into compliance with the physician medical director requirement if the RHC can provide documentation that it initiated good faith efforts **prior to the survey** to obtain the regular services of a physician medical director, as well as arrangements it has made for immediate temporary physician services to perform required physician responsibilities in accordance with § 491.8(b). This flexibility is not available to an applicant for initial RHC certification.*

In this situation, the already-certified RHC must still be cited for violating § 491.7(a)(1), but there is discretion with respect to the length of time the RHC is allowed to implement a plan of correction. Since the RHC regulations permit the RHC physician medical director to carry out many of his/her responsibilities via telecommunications and to provide telemedicine services, generally an RHC should be able to secure the required physician services within a reasonable period of time. The SA must make a recommendation to the CMS RO on whether to provide an RHC an extended period of time to implement a PoC. The RHC must inform the SA of all actions taken to recruit a replacement and expected outcome.

NOTE: To ensure continuity of care, it is permissible to use a locum tenens (i.e., temporary) MD/DO as the medical director of the RHC, providing that same MD/DO is contractually bound to provide services to the clinic for a minimum of six months.

The clinic must also have a health care staff that meets the requirements of § 491.8. This portion of this standard is evaluated under § 491.8, but deficiencies cited under that provision may also be cited under § 491.7(a)(1)

Survey Procedures §§ 491.7(a)(1) & 491.7(b)(3)

- 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.

J-0062

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 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 . . .

Interpretative Guidelines § 491.7(a)(2) & § 491.7(b)(1)-(2)

The clinic must establish in writing the manner in which it is organized, including the person who is principally responsible for the day-to-day operations, the lines of authority between that individual and the owner(s) and between that individual and other staff of the RHC. The RHC

must identify in writing all types of staff positions, their place in the organizational arrangement, and their functions and responsibilities. There must be a written record of the name and address of the person who is principally responsible for the day-to-day operations of the clinic and this information must be furnished to surveyors upon request.

With respect to the requirement for disclosure of the clinic's owners, the latest disclosure should be contained in the latest copy of the Form CMS-855A, Medicare Enrollment for Institutional Providers, which the clinic is required to file in order to enroll in the Medicare program and required to update if its information changes. The MAC provides the CMS RO and SA copies of updates to the Form CMS- 855A information it receives. Review of this information disclosure is handled primarily by the MAC. It is the responsibility of the RHC to file an updated Form CMS 855A with the MAC if there are changes to the information it previously submitted.

The Form CMS-29, Verification of Clinic Data – Rural Health Clinic Program, which is used to collect clinic ownership information and clinic personnel data, is also completed. See Chapter 2 of the SOM, section 2200 for detailed instructions on completing the CMS-29.

The clinic must have written policies and procedures addressing both administrative and clinical activities. Requirements for patient care policies are specified at §491.9(b) and are not evaluated under § 491.7(a)(2). Administrative policies and procedures would address topics such as personnel, fiscal, purchasing, and building and equipment maintenance, as well as any other topics the clinic's management finds pertinent.

Survey Procedures § 491.7(a)(2) & § 491.7(b)(1)-(2)

- 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.*

J-0080

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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.

J-0081

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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, an employee of the clinic . . ., or under agreement with the clinic . . . to carry out the responsibilities required under this section.

§491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

Physician means the following:

(1) As it pertains to the supervision, collaboration, and oversight requirements in sections 1861(aa)(2)(B) and (aa)(3) of the Act, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and

(2) Within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor (see section 1861(r) of the Act for specific limitations).

Interpretative Guidelines § 491.8(a)(1) & (2)

An RHC must, at a minimum, have a health care staff that includes one or more physicians; if the clinic has only one physician, that physician must be either an MD or a DO in order to perform the responsibilities of the clinic's medical director. The physician must hold a current license issued or recognized by the State in which the RHC is located.

The physician(s) may be the clinic's owner (who may also be an employee of the clinic at the same time), an employee of the clinic, or providing services to the clinic under a contractual arrangement. CMS interprets an "employee" to be an individual to whom the clinic issues an IRS Form W2, Tax and Wage Statement (See 79 FR 25462, May 2, 2014). If the physician is not responsible for medical supervision nor the medical direction of the clinic, contractual arrangements may either be directly between the clinic and an individual physician, or between the clinic and a third-party entity that supplies the clinic with physician services, such as a locum tenens agency.

In all cases the RHC must have sufficient practitioners, both physician and non-physician, to furnish the volume of RHC services it provides to its patients, consistent with accepted standards of practice.

Survey Procedures § 491.8(a)(1) & (2)

- *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.*

J-0082

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 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 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.

§491.2 Definitions. *As used in this subpart, unless the context indicates otherwise: . . .*

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

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or

(2) Has satisfactorily completed a formal 1 academic year educational program that:

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart . . .

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or

(2) Has satisfactorily completed a program for preparing physician's assistants that:

(i) Was at least 1 academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

Interpretative Guidelines § 491.8(a)(1) & (3)

In addition to having a physician on staff, the RHC's health care staff must also include one or more nurse practitioner(s) (NP) or physician assistant(s) (PA), as defined at § 491.2. The RHC's NP and/or PA must meet the Medicare definition of an NP or PA and be licensed in accordance with the law of the State in which the RHC is located and practicing within their permitted State scope of practice.

At least one NP or PA must be an employee of the RHC (note that a clinic's owner may also be an employee; this is at the owner's discretion). CMS interprets an "employee" to mean an individual to whom the clinic issues an IRS Form W-2, Wage and Tax Statement. (See 79 FR 25462, May 2, 2014) However, once the clinic has employed at least one NP or PA, the other practitioners may furnish services under contract to the clinic instead of being employees. These other NPs or PAs may contract directly with the clinic or may have an arrangement with a third party that contracts with the clinic to furnish the practitioner's services.

In all cases the RHC must have sufficient practitioners, both physician and non-physician, to furnish the volume of RHC services it provides to its patients, consistent with accepted standards of practice.

- As provided by § 1861(aa)(7) of the Act, and implemented in Section 2248 of the SOM, an existing RHC may request a waiver of the requirement to employ a NP or PA. The mid-level staffing waiver is applicable to Medicare-participating RHCs only. Initial applicants to***

*participate in Medicare as an RHC are **not** eligible for staffing waivers. CMS grants a currently certified RHC a one-year waiver of the requirement to employ a NP or PA if:*

- The RHC submits the written request for a waiver to the appropriate SA;*
- The RHC demonstrates that it has been unable, despite reasonable efforts, to hire a NP or PA in the previous 90-day period; and*
- The RHC's request is submitted six months or more after the date of the expiration of any previous such waiver for the RHC.*

The SA is responsible for reviewing the evidence the RHC provides regarding its efforts to hire an NP or PA in the previous 90 days and recommending approval or disapproval of the requested waiver to the RO. The SA must complete its review and recommendation within 30 calendar days of receiving the written waiver request from the RHC.

The waiver is deemed to have been granted, unless the waiver request is denied by the RO within 60 calendar days after the date the SA received the RHC's waiver request. In cases where the waiver request is deemed to have been approved, the effective date of the 1-year waiver is the 61st day after the date the request was received by the SA.

See Section 2248 for more details on the waiver process and the expectations for RHCs and SAs

Survey Procedures § 491.8(a)(1) & (3)

- 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.*

J-0083

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[\$ 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 . . .

Interpretative Guidelines § 491.8(a)(3)

The clinic is not required to have a nurse-midwife, clinical social worker or clinical psychologist on staff. If it does have any of these on staff, they must be licensed as required by State law of

the State in which the clinic is located, and must be practicing within their permitted scope of practice.

A nurse midwife, clinical social worker or clinical psychologist who is on the clinic's staff may be the clinic's owner (who may also be an employee at the same time), an employee of the clinic, or providing services to the clinic under a contractual agreement. These types of practitioners may contract directly with the clinic or may have an arrangement with a third party that contracts with the clinic to furnish the practitioner's services.

Survey Procedures § 491.8(a)(3)

- *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.*

J-0084

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 491.8(a) Staffing.]

(4) The staff may also include ancillary personnel who are supervised by the professional staff.

Interpretative Guidelines § 491.8(a)(4)

The clinic's staff may include personnel who are not practitioners but who provide clinical services, for example, registered nurses, licensed practical nurses, laboratory technicians, etc. In all cases personnel must hold current State licenses when required. All such personnel must be supervised at all times by a practitioner, either a physician or a non-physician practitioner, on the RHC's professional healthcare staff. Supervisory responsibilities may be shared among practitioners. For example, an NP on the RHC's staff may be the official supervisor who conducts regular performance reviews, but when that NP is not on duty, the RHC's physician or another NP or other non-physician practitioner may provide supervision.

Survey Process § 491.8(a)(4)

- *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.*

J-0085

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 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. . . .

Interpretative Guidelines § 491.8(a)(5) & (6)

The clinic must be sufficiently staffed to provide the services offered by the RHC. Specifically, this means that the clinic has sufficient staff practicing within their permitted scope of practice to provide RHC services to the clinic's patients at all hours that the clinic is open and operating. Consistent with § 491.9(c), the RHC services the clinic furnishes are diagnostic and therapeutic services and supplies similar to those furnished in a physician office, including, but not limited to, performing history and physical examinations, assessment of health status, and treatment for a variety of medical conditions. The clinic must also furnish specified laboratory services and first responder-type emergency services to individuals in the clinic experiencing a medical emergency. The clinic must have sufficient staff members who are qualified to furnish these services to the volume of patients the RHC sees. Even when staffing meets the minimum requirement in terms of practitioner time at the RHC, the staffing may be insufficient for the volume of services the RHC provides.

The clinic may only be open and furnishing RHC services if there is a physician, NP, PA, certified nurse midwife, clinical social worker, or clinical psychologist on site and available to furnish services. Although the physician medical director may perform many, not all, of his/her responsibilities remotely via telecommuications, this does not mean the clinic can be open and furnishing services without any practitioner on-site. With the exception of services the clinic's medical director or other MDs or DOs may provide by telemedicine, the clinic may only furnish those services that are within the scope of practice of the practitioners who are on site at the time the services are offered. The loss of a PA or NP staff member may require the RHC to request a temporary staffing waiver via its SA. It may also require a temporary adjustment of the clinic's operating hours or services and an adjustment in visits by the physician(s) providing medical direction. It is the responsibility of the clinic to promptly advise the SA of any changes in staffing which would affect its certification status.

(NOTE: See the guidance for § 491.8(a)(3) and Section 2248 for more details on the waiver process and the expectations for RHCs and SAs.)

RHCs may allow beneficiary entry to the waiting room or other non-patient care areas to handle billing inquiries or to get out of the weather when the mid-level practitioner as defined in §493.2, clinical social worker, clinical psychologist or physician staff member is not present to provide health care services. However, the clinic is not considered to be in operation as an RHC during

this period. No health care services may be provided until a mid-level practitioner, clinical social worker, clinical psychologist or physician staff member is present onsite. There should be a reasonable timeframe between administrative transactions conducted on the premises outside the hours of operation of the RHC and the commencement of RHC operations with the healthcare professional's arrival. Any RHC that choose to exercise this flexibility should post the hours of administrative services only versus the hours of RHC operations. Signage should clearly delineate times the healthcare professional staff member is present onsite. If State law does not allow access to the RHC premises when the clinic is not in operation as an RHC, the facility must adhere to such laws.

Survey Procedures § 491.8(a)(5)& (6)

- *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.*

J-0086

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 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.

Interpretative Guidelines § 491.8(a)(6)

A NP, PA or certified nurse-midwife (CNM) must be available to furnish patient care services at least 50 percent of the operating hours during which RHC services are offered, even when a physician is also present in the clinic. All time that a NP, PA or certified nurse-midwife (CNM) is present in the clinic during the clinic's operating hours, even if not actually providing RHC services to patients, may be counted toward the 50 percent requirement. In addition, when RHC services are furnished to clinic patients outside of the clinic (e.g. in the patient's home, in a SNF, or in another residential facility), the time spent providing RHC services outside the clinic (excluding travel time) may be counted towards the 50 percent requirement.

For any portion of the RHC's schedule when neither a NP, PA, CNM, CSW nor a CP is available on-site, a physician must be available on-site to provide needed services in order for the RHC to be open and operating. With the exception of services the clinic's medical director or other MDs or DOs may provide via telemedicine, the clinic may only furnish those services that are within the scope of practice of the practitioner(s) who are on site at the time the services are offered".

The following are some examples of how determinations regarding the 50 percent requirement may be made:

A clinic offers RHC services from 10 a.m. to 5 p.m. Tuesday through Friday, for a total of 28 hours per week. A physician, NP, PA, CNM, clinical social worker, or clinical psychologist must be available to furnish patient care services, within their permitted scope of practice, during all 28 service hours. In addition, a NP, PA, or CNM must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence for at least 14 hours (50 percent of the 28 service hours) for the RHC to furnish patient care services.

Note: If the NP, PA or CNM are not providing RHC services on-site, the physician must be available on-site.

In some cases, the clinic's weekly schedule may not be a reasonable period of time on which to base these determinations, and consideration of a biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when the clinic's schedule offering RHC services is very limited. An example would be a clinic where RHC services are offered every other Tuesday from 10 a.m. to 4 p.m., and one Friday a month from 10 a.m. to 4 p.m., for a total of 18 hours per month. Of these 18 hours, a NP, PA, or CNM must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 50 percent of that time (9 hours) for the RHC to furnish patient care services. This requirement would be met if a NP, PA, or CNM was on-site on one Tuesday for 3 hours and on the Friday for 6 hours, or through some other schedule that results in their availability 9 hours/month.

*As provided by § 1861(aa)(7)(A) of the Act, and implemented in Section 2248 of the SOM, RHCs may request a waiver of the requirement that a NP, PA or CNM be available to furnish patient care services at least 50 percent of the time the RHC operates. The waiver is applicable to Medicare-participating RHCs only. Initial applicants requesting to participate in Medicare as an RHC are **not** eligible for mid-level staffing waivers. CMS grants a currently certified RHC a one-year waiver of the NP/PA/CNM staffing requirement if:*

- The RHC submits to the SA a written request for a waiver;*
- The RHC demonstrates that it has been unable, despite reasonable efforts, to arrange to have either a NP, PA, or CNM on duty at least 50 percent of the time the RHC operates in the previous 90-day period.*
- The RHC's request is submitted 6 months or more after the date of the expiration of any previous such waiver for the RHC.*

The SA is responsible for reviewing the evidence the RHC provides regarding its efforts to hire a NP, PA or CNM in the previous 90 calendar days and recommending approval or disapproval of the requested waiver to the RO. The SA must complete its review and recommendation within 30 calendar days of receiving the written waiver request from the RHC.

The waiver is deemed to have been granted, unless the waiver request is denied by the RO within 60 calendar days after the date the SA received the RHC's waiver request. In cases where the waiver request is deemed to have been approved, the effective date of the 1-year waiver is the 61st day after the date the request was received by the SA.

See Section 2248 for more details on the waiver process and the expectations for RHCs and SAs

Survey Procedures § 491.8(a)(6)

- Determine what the clinic's total hours of operation are, starting with its weekly schedule. Review hours listed on signs, 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 schedules 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.*

J-0100

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§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.*

Interpretative Guidelines § 491.8(b)(1) & (3)

In accordance with § 491.8(b), the MD or DO physician who serves as the RHC's medical director in accordance with § 491.7(a)(1) is responsible for the overall medical direction of the clinic's clinical activities. He or she also provides clinical consultation to and supervises the other physician(s) as well as the non-physician practitioners on the RHC's health care staff. This requirement for "supervision" does not limit the ability of non-physician practitioners to practice in accordance with their State scope of practice. For example, if State law permits an

NP to practice independently when providing diagnosis and treatment, including writing orders and prescriptions, the NP would be permitted to do so in the RHC as well. However, the NP, like any other member of the clinic's staff of health care practitioners, would be under the overall medical supervision of the clinic's medical director, who is responsible for the quality of care in the clinic.

In addition to medical direction as described above, the physician must provide assessment, diagnosis, and treatment of patients, and provide medical orders for patients in need of diagnostic tests and/or therapeutic treatments.

If the clinic has more than one physician on its staff, the other physician(s) may also provide medical services, medical orders, and consultation, but only one physician, who must be an MD or DO, can serve as the clinic's medical director and provide overall direction to its clinical activities.

NOTE: *To ensure continuity of care, it is permissible to use a locum tenens (i.e., temporary) MD/DO as the medical director of the RHC, providing that same MD/DO is contractually bound to provide services to the clinic for a minimum of six months.*

A physician is not required to be on-site in order to perform all of these duties, unless there are times during the RHC's operating hours when no other physician, NP, CNM, PA, clinical social worker or clinical psychologist is present in the RHC. With the development of technology that facilitates telemedicine, a physician has the flexibility to use a variety of ways and timeframes to provide medical direction, consultation, supervision, clinical record review, including being on-site at the facility to provide medical care services to patients. The regulation allows for use of team-based care while still requiring the physician to be on-site, as appropriate based on the needs of the clinic, to ensure the delivery of quality care. A State or the RHC itself is not precluded from establishing requirements for physician on-site presence that are more stringent, but these requirements are not enforced through the Federal Medicare certification process.

Survey Procedures § 491.8(b)(1) & (3)

- *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?*

J-0101

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 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.

Interpretative Guidelines § 491.8(b)(3) & (c)(1)(ii)

A physician must review periodically the RHC's patient clinical records. In States where State law requires a collaborating physician to review medical records, co-sign medical records, or both for outpatients whose care is managed by a non-physician practitioner, an RHC physician must review and sign all such records. If there is more than one physician on the RHC's staff, it is permissible for staff physicians other than/in addition to the medical director to review and co-sign the records.

The RHC's NP(s) and/or PA(s) must participate in the physician's review of the clinical records. Participation may be face-to-face or via telecommunications. If there is more than one NP or PA in the clinic, the NP or PA would participate only in the review of records of those patients for which the NP or PA provided care.

Where co-signature is not required, the regulation still requires periodic physician review of the clinical records of patients cared for by non-physician practitioners. If the RHC has more than one physician on its staff, it is permissible for physicians other than/in addition to the medical director to conduct the periodic review of clinical records, so that this task might be divided or shared among the physicians.

If the RHC has more than one physician, its policies and procedures must specify who is authorized (i.e. whether it is the medical director alone, or may include other staff physicians) to review and, if required under State law, co-sign clinical records of patients cared for by a non-physician practitioner.

The regulation does not specify a particular timeframe to satisfy the requirement for "periodic" review of clinical records, but the RHC must specify a maximum interval between record reviews in its policies and procedures. The RHC is expected to take into account the volume and types of services it offers in developing its policy. For example, an RHC that has office hours only one day per week would likely establish a different requirement for record review than an RHC that is open 6 days per week/ 10 hours per day. Further, there is no regulatory requirement for the review of records to be performed on site and in person. Thus, if the RHC has electronic clinical records that can be accessed and digitally signed remotely by the physician, this method of review is acceptable. Therefore, RHCs with and without the capability for electronic record review and signature might also develop different policies for the maximum interval between reviews.

Survey Procedures § 491.8(b)(3) & (c)(1)(ii)

- *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 has 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 cared for by non-physician practitioners are periodically reviewed.*
- *Is there documentation supporting that the required reviews have occurred?*

J – 0102

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.8(c)(2) 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.***

Interpretative Guidelines § 491.8(c)(2)

The NP or PA must perform the following functions if they are not being performed by a physician:

- *Providing health care services in accordance with the RHC's written policies. However, non-physician practitioners must also operate within their State-permitted scope of practice and may not provide clinic services that require a broader scope of practice;*
- *Arranging for or referring patients to services which cannot be provided at the RHC; and*
- *Ensuring that adequate patient health records are maintained. If a patient is referred for additional treatment elsewhere, the NP or PA must ensure that the records are transferred.*

Survey Procedures § 491.8(c)(2)

- *Ask the RHC's owner, or person in charge of operations for the RHC's policies governing which services may be provided by an NP or PA, whether there are any RHC services that are outside the scope of practice of an NP or PA.*
- *Interview NPs and/or PAs about the services they provide. If the RHC provides services that are outside their scope of practice, ask what they do if a patient requires such services when no MD or DO is available.*
- *Verify how new practitioners are made aware of the clinic's patient care policies.*
- *Ask to review medical records of patients who have been referred to health care services outside of the clinic. Confirm that an MD, DO, NP, or PA arranged for the referral. Is there evidence that appropriate portions of the patient's RHC record were transferred?*
- *Review patient care records for patients being treated by and NP or PA. Do the NP or PA make entries into the record documenting the care they provide? Were the patient's health records appropriately maintained, and were those records transferred with the referred patient?*

J-0120

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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.

J-0121

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.9(a) Basic requirements:

(1) All services offered by the clinic . . . are furnished in accordance with applicable Federal, State, and local laws; and

Interpretative Guidelines § 491.9(a)(1)

The regulation at § 491.4 also requires compliance with applicable Federal, State and local laws. Accordingly, the guidance and survey procedures for that regulation also apply to § 491.9(a)(1).

J-0122

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 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

§ 491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

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

Interpretative Guidelines § 491.9(a)(2) & (c)(1)

An RHC is required to be primarily engaged in providing outpatient or ambulatory health care services. In accordance with §§ 405.2411 - 2416, RHC services include the services of physicians, NPs, PAs, certified nurse midwives, clinical psychologists and clinical social workers, along with the services and supplies that are incident to these practitioners' services. In accordance with § 491.9(c)(1), the services of these practitioners are those commonly furnished in a physician's office or at the entry point into the health care delivery system. These services include taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs and family planning. Further, some RHCs may provide VNS if a request is submitted to the SA and approved by the CMS RO.

RHCs are not prohibited from furnishing other services, for example, ambulatory surgical procedures or diagnostic imaging services. However, they may not be primarily engaged in providing such specialized services. In the context of an RHC, "primarily engaged" is determined by considering the total hours of an RHC's operation, and whether a majority, i.e., more than 50 percent, of those hours involve provision of RHC services.

An example of a clinic schedule that combines RHC with other services would be a clinic that provides RHC services 9 a.m. to 4 p.m. Monday through Friday, and also offers diagnostic imaging services Tuesday and Friday afternoons from 1 p.m. to 4 p.m. The RHC is furnishing 35 hours of standard RHC services and 6 hours of imaging services, for a total of 41 hours of service. In this example, the RHC provides RHC services 85 percent of the time; therefore, it is "primarily engaged" in providing RHC services.

For clinics with a limited schedule, it may be more appropriate to consider the monthly total operating schedule verses the weekly schedule.

Survey Procedures § 491.9(a)(2) & (c)(1)

- 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.*

J-0123

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[\$ 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 annually by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic . . .

Interpretative Guidelines § 491.8(b)(2) & (c)(1)(i), § 491.9(b)(1), (2) & (4)

The clinic must have written policies governing the clinical services provided. At least one RHC physician and one RHC PA or NP must participate in the development of the clinic's written policies and providing advice to the RHC's management on appropriate clinical policies. In addition, there must be at least one physician, NP, or PA who is not on the RHC's staff who participates in the development of the clinical policies. The clinic must identify in writing the names of all individuals involved in developing clinical policies. The clinical practitioners who participate in the policy development provide advice to the RHC's leadership. The RHC's leadership is not required to accept this advice, but if it exercises its authority to reject or modify the patient care policy advice of the practitioners it must be able to ensure that any changes it makes are clinically appropriate and supportable.

The clinic's patient care policies must be reviewed at least annually or more frequently when appropriate, by a group that also contains at least one RHC physician, one RHC NP or PA, and one outside healthcare practitioner.

Survey Procedures § 491.8(b)(2) & (c)(1)(i), § 491.9(b)(1), (2) & (4)

- Review meeting minutes or other documentation to verify that the required types of practitioners actually participated at least annually 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?*

J-0124

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 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 . . .

Interpretative Guidelines § 491.9(b)(3)(i) & (ii)

The written RHC patient care policies must include:

Description of Services

The written policies must provide a description of the services the RHC furnishes, whether directly using RHC staff or through an agreement or arrangement. The services furnished by the clinic must be described in sufficient detail to permit understanding of the scope of all services furnished in the RHC, and the scope/type of agreement or arrangement they are furnished through if applicable. An example of services under arrangement might be provision by a contractor of additional laboratory services beyond those required to be performed by RHC staff. Such statements as the following may sufficiently describe services: Taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs, family planning. Statements such as “complete management of common acute and chronic health problems” standing alone, would not sufficiently describe services.

Guidelines for Medical Management

The clinic’s written guidelines for the medical management of health problems include a description of the scope of medical care that may be furnished by a PA, NP, or CNM, including the extent and nature of required supervision. The guidelines would also include standard protocols for diagnosis and treatment of common conditions or for provision of preventive care. Acceptable guidelines may follow various formats. Some guidelines are collections of general protocols, arranged by presenting symptoms; some are statements of medical directives arranged by the various systems of the body (such as disorders of the gastrointestinal system); some are standing orders covering major categories such as health maintenance, chronic health problems, common acute self-limiting health problems, and medical emergencies. The manner in which these guidelines describe the criteria for diagnosing and treating health conditions may also vary. Some guidelines will incorporate clinical assessment systems that include branching logic. Others may be in a more narrative format with major sections covering specific medical conditions in which such topics as the following are discussed: The definition of the condition; its etiology; its clinical features; recommended laboratory studies; differential diagnosis, treatment procedures, complications, consultation/referral required; and follow-up. Guidelines also may be based on guidelines of nationally recognized professional organizations, which are referenced and reproduced, such as the immunization guidelines developed by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. However, the guidelines must include information on actions non-physician practitioners in the RHC are permitted to take, as well as circumstances warranting referral.

Even though approaches to describing guidelines may vary, acceptable guidelines for the medical management of health problems must:

- Be comprehensive enough to cover most health issues covered in a primary and preventive care setting;*
- Describe the actions a NP, PA or CNM may initiate or implement, consistent with State scope of practice requirements; and*

- Describe the circumstances that require consultation with the RHC's MD or DO, as well as external referral.

Guidelines may be in electronic or paper format, but should be readily accessible to RHC practitioners, all of whom must be familiar with them.

Survey Procedures § 491.9(b)(3)(i) & (ii)

- 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?

J-0125

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 491.9(b) Patient care policies.]

(3) The policies include:

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

Interpretive Guidelines § 491.9(b)(3)(iii)

The RHC's written patient care policies must address storage, handling, and administration of drugs and biologicals within the RHC. The policies must be in accordance with accepted professional principles of pharmacy and medication administration practices. Accepted professional principles include compliance with applicable Federal and State law and adherence to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations, including, but not limited to: U.S. Pharmacopeia (USP) (www.usp.org); the American Society of Health-System Pharmacists (<http://www.ashp.org/>); the Institute for Safe Medication Practices (<http://www.ismp.org/default.asp>); the National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org); the Institute for Healthcare Improvement (<http://www.ihl.org/ihl>); and the Infusion Nurses Society (<http://www.insl.org>).

Note re: US Pharmacopeia/National Formulary (USP/NF)

According to the Federal Food, Drug and Cosmetic Act (FCDA), the official compendia of the United States for excipients, drug substances, and drug products is the USP/NF. It is published every year in November by the United States Pharmacopeial Convention (<http://www.usp.org/>) and includes two supplements published in February and June.

The USP is a not-for-profit, non-governmental organization that since 1820 has established quality standards for, among other things, drug substances, drug products and compounded preparations. Congress established a role for USP standards in the adulteration provision of the 1906 Food and Drug Act. That role was expanded in the modern Food, Drug and Cosmetic Act (FDCA) beginning in 1938, with a role for USP compendial standards for naming and identity; strength, quality, and purity; and packaging and labeling, in both the adulteration and misbranding provisions of FDCA. (See, for example, § 501(b) of the FDCA regarding compendial standards for strength, quality and purity, § 502(g) for compendial standards for packaging and labeling). Under the FDCA, a drug with a name recognized in the USP/NF must comply with compendial identity standards, or be deemed adulterated, or misbranded, or both. To avoid being deemed adulterated, such drugs must also comply with compendial standards for strength, quality, and purity, unless labelled to show all respects in which the drug differs.

The RHC's policies must address the following:

Storage of drugs and biologicals

Consistent with accepted professional principles, RHC's must demonstrate appropriate storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

Proper environmental conditions

Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for storage of drugs, the RHC is expected to follow the labelled conditions. Absent the manufacturer's labelled conditions, USP indicates that storage of drugs and biologicals be done according to USP/NF, or the food chemicals codex (FCC) monograph requirements. RHC's must exercise caution in administering any drug or biological that is not labelled to indicate proper storage conditions or that may have been stored under inadequate conditions.

Security

The RHC must have policies and procedures that are consistent with State and Federal law to address how drugs and biologicals are stored and secured, including who is authorized access to the drug storage area. Drugs and biologicals must be stored in a secure manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not

allowed without the supervision or presence of a health care professional, they are generally considered secure. Areas restricted to authorized personnel only would generally be considered “secure areas.”

RHCs are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff members are actively providing care to patients or preparing to receive patients, i.e. setting up for injections, would generally be considered a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked, in accordance with state and Federal law.

If the RHC uses cart(s) containing drugs or biologicals, whenever the cart is in use and unlocked, someone with authorized access to the drugs and biologicals in the cart must be within close eyesight of and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with State and Federal law and RHC policy is authorized access to the drugs and biologicals in the cart. That individual must monitor the cart and be aware of other people’s activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

Record keeping for the receipt and disposition of all scheduled drugs.

The U.S. Department of Justice Drug Enforcement Administration (DEA) classifies drugs that are controlled in accordance with the Controlled Substances Act into five “schedules,” ranging from Schedule I substances, which have a high potential for abuse and no currently accepted medical use in treatment, to Schedule V substances, which have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

The RHC is required to accurately track the receipt and disposition of all scheduled drugs used in the RHC. Components of a record system for scheduled drugs would include:

- Locked storage of scheduled drugs when not in use;*
- Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs;*
- Tracking 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, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.*
- Prompt reconciliation of any discrepancies in count. The RHC is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.*

Handling drugs and biologicals.

“Handling” includes reconstituting or mixing medications in accordance with directions contained in approved labeling provided by the drug’s manufacturer.

Compounding

“Handling” also includes compounding or admixing of sterile intravenous preparations or of other drugs, either on- or off-site, using either facility staff or a contracted pharmacy service.

Generally, RHCs are not settings that use compounded sterile preparations (CSPs) nor are CSPs typically furnished as part of the RHC’s services. However, some RHCs may provide additional services beyond RHC services and these might include use of CSPs. If an RHC uses CSPs, it is responsible to ensure that compounding is performed consistent with accepted professional principles. These principles must be equivalent to, or more stringent than, those described in the compounding-related chapters in the USP/NF, which are recognized as authoritative standards regarding minimum standards of safe practice applicable to both sterile and non-sterile compounding.

The definition of compounding as that term is used in the USP is found in USP Chapter <795> (USP <795>):

“The preparation, mixing, assembling, altering, packaging and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

- Preparation of drug dosage forms for both human and animal patients*
- Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns*
- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients*
- Preparation of drugs or devices for the purposes of, or as incident to, research (clinical or academic), teaching or chemical analysis*
- Preparation of drugs and devices for prescriber’s office use where permitted by federal and state law”*

Compounded medications, whether non-sterile or sterile, may be subject to physical and chemical contamination and unintended variations in strength. Microbial contamination and bacterial endotoxins are particularly hazardous with respect to compounded medications that are intended to be sterile.

Generally even if an RHC uses CSPs, it would not be likely to have its own pharmacy that could meet the USP/NF requirements for preparation of CSPs; it is more likely that an RHC

that uses CSPs would be acquiring them from an external source. The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The DQSA created a new section 503B in the FDCA under which a compounder may elect to become an “outsourcing facility.” The law defines an “outsourcing facility” as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA. Facilities that elect to register as outsourcing facilities:

- *Must comply with the FDA’s Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA’s publishes the most current versions of its draft and final regulations and guidance related to compounding on its website: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>;*
- *Will be inspected by FDA according to a risk-based schedule; and*
- *Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.*

In a January 2014 letter to purchasers of compounded medications (available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm>), the Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that, “[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling.”

FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether other FDA actions were taken based on the last inspection, at: <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm>

Note that these registered outsourcing facilities are also popularly referred to as “503B pharmacies.”

Use of Compounding Pharmacies

If an RHC uses compounded medications and obtains them from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the RHC must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations. For example, does the contract with the vendor include provisions:

- *Ensuring that the RHC has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements, and can the CAH document that it obtains and reviews such data?*
- *Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?*

Note that these types of compounding pharmacies are also popularly referred to as “503A pharmacies” and generally are subject to oversight only by their State pharmacy board.

Expiration & Beyond Use Dates

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer’s approved labeling.

A drug or biological is also outdated after its “beyond-use date” (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available.

Basic safe practices for medication administration within the RHC

The RHC’s patient care policies must reflect accepted standards of practice that require the following information be confirmed prior to each administration of medication that takes place in the RHC (such as administration of vaccines or medications via injection):

- *Right patient: ensuring the patient’s identity. Acceptable patient identifiers include, but are not limited to: the patient’s full name; an identification number assigned by the RHC; or date of birth. Identifiers must be confirmed by patient identification card, patient statement (when possible), or other means outlined in the RHC’s policy. The patient’s identification must be confirmed to be in agreement with the medication administration record and medication*

labeling prior to medication administration to ensure that the medication is being given to the correct patient.

- *Right medication: the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;*
- *Right dose: the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);*
- *Right route: the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc. - is the appropriate one for that particular medication and patient; and*
- *Right time: the appropriate time, to ensure adherence to the prescribed frequency and time of administration.*

Note: the “5 rights” focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. Errors may occur in other components of the process, even when there is strict adherence to the “5 rights” of medication administration, for example when there has been a prescribing or a dispensing error.

RHCs are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly.

Survey Procedures § 491.9(b)(3)(iii)

- *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 or unusable medications, 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?*

- *Observe medication administration to verify whether staff members confirm the “5 rights” of medication administration, i.e., the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the RHC’s policies and procedures?*

J-0135

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 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.*

Interpretative Guidelines § 491.9(a)(3) & (c)(2)

Basic laboratory services must be provided in the RHC by RHC staff in order to facilitate the immediate diagnosis and treatment of the patient. To the extent permitted under State and local law, the 6 basic laboratory services listed in § 491(c)(2) are considered the minimum laboratory services the RHC must have available within the clinic, provided by RHC staff. If any of these laboratory services cannot be provided at the RHC due to a State or local law prohibition, that laboratory service is not required for Medicare certification. These laboratory services must be 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. However, compliance with CLIA requirements is not assessed by surveyors conducting RHC surveys. Surveyors should, however, ask to see the RHC’s CLIA certificate.

RHCs may also provide additional laboratory services, either on-site or through an off-site arrangement, but if it does so, these optional services must also comply with the CLIA requirements. For example, an RHC may have an arrangement with some other provider of clinical laboratory services. However, such arrangements are not permitted to substitute for the requirement to actually provide the 6 basic laboratory services within the RHC, by RHC staff.

Survey Procedures § 491.9(a)(3) & (c)(2)

- *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.*

J-0136

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 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

Interpretative Guidelines § 491.9(c)(3)

The RHC ensures staff is available to appropriately handle medical emergencies at all times the clinic operates. The clinic maintains the types and quantity of drugs and biologicals typically used by first responders in accordance with accepted standards of practice. The RHC's patient care policies are expected to address which drugs and biologicals it maintains for emergencies and in what quantities. The regulation lists examples of such drugs and biologicals, and the RHC must maintain a supply of drugs and biologicals adequate to handle the volume and type of emergencies it typically encounters, in each of the following categories:

- *Analgesics;*
- *Local Anesthetics;*
- *Antibiotics;*
- *Anticonvulsants; and*
- *Antidotes, emetics, serums & toxoids.*

It is appropriate for a RHC to store a small volume of a particular drug/biological, if it generally handles only a small volume/type of a specific emergency. For example, if a RHC is located and region of the country that generally does not encounter snake bites and the RHC itself has not

encountered such an emergency, it would be acceptable if the clinic maintain a smaller volume of an antidote.

Survey Procedures § 491.9(c)(3)

- *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 the specified drugs and biologicals are on hand in the quantities specified per RHC policy and have not expired?*

J-0140

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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.

Interpretative Guidelines § 491.9(d)

The clinic has referral agreements with at least one Medicare/Medicaid-participating:

- *Hospital or CAH, for inpatient acute care;*
- *Physician;*
- *Diagnostic testing facility (which could be a hospital or CAH or a freestanding diagnostic testing facility) for ambulatory diagnostic tests not furnished in the RHC; and*
- *Clinical laboratory, for laboratory services not furnished in the RHC.*

The referral arrangements do not have to be in writing, but if they are not there must be evidence that RHC patients referred for additional services are being accepted and treated by the provider/supplier they are referred to.

Survey Procedures § 491.9(d)

- *Determine whether the RHC has referral 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.*

J-0150

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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.

J-0151

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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 documented, readily accessible, and systematically organized*

Interpretative Guidelines § 491.10(a)(1)-(2)

The RHC must maintain a complete, comprehensive and accurate clinical record (also referred to as a medical record) for each RHC patient. The RHC must use the information contained in each clinical record in order to ensure the delivery of appropriate care to each RHC patient.

The RHC must have a designated member of its professional staff (which may be an administrative professional rather than a clinical professional) who is responsible for the RHC's clinical record system. That individual is responsible for developing and implementing, with

approval of the RHC's professional staff and leadership, written clinical record policies and procedures.

A RHC that has an electronic health record (EHR) system may be part of a larger EHR system or may participate in a systematic exchange of patient health care information to promote good patient care. In either instance, only the appropriate RHC staff may have access to the medical records of RHC patients. The RHC's written clinical records policies and procedures reflect that it is part of a larger system or exchange, when applicable. Further, even when the RHC participates in a larger EHR system, the clinical records for all RHC visits must still meet the requirements of the RHC Patient Health Records Condition and must be readily retrievable and distinguishable from other information in the shared EHR system.

The RHC must also comply with the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules at 45 CFR Parts 160 and 164 when sharing clinical record information that is Protected Health Information. However, CMS does not interpret or assess compliance with HIPAA requirements, and thus surveyors also are not authorized to assess HIPAA compliance. If surveyors suspect a serious breach of HIPAA, they should refer their concerns to the regional U.S. Department of Health & Human Services Office of Civil Rights.

Complete and accurate

All clinical records entries must be legible, i.e., able to be read clearly and unambiguously. Any entries or information contained in the clinical record that are not legible may be misread or misinterpreted and may lead to medical errors or other adverse patient events.

The clinical record must also be complete, i.e., it must contain for each patient at least the information required at § 491.10(a)(3). Implicit in the requirement for the record to be complete is an expectation that all entries of required information are made into the clinical record promptly, so that it is available to subsequent caregivers. The clinical record must be complete.

The RHC must ensure that all clinical records are accurately written. All clinical records must contain the correct information for the correct patient. The identity of the patient must be clear through use of identifiers such as name, date of birth, etc. The RHC may have a system in place that assigns a unique patient identifier to each patient, such as a medical record number or financial identification number. If the RHC has such a system in place, its clinical records policies and procedures must address the manner in which the unique identifiers are generated and assigned to each individual patient. The RHC must also take steps to ensure the accurate identity of the patients if using unique identifiers.

Entries in the clinical record may be made only by individuals authorized by the RHC in accordance with its written policies and procedures to do so, and must be dated, timed, and authenticated by the individual making the entry. When authenticating the entry, the author indicates by his/her signature/authentication that the entry is accurate. Entries made on behalf of a practitioner by authorized individuals must also be promptly dated, timed, and authenticated by the practitioner. A clinic policy stating that a practitioner must disapprove an entry within a

specific time period or the entry is by “default” authenticated is **not** acceptable; the practitioner must affirmatively authenticate each entry.

The RHC must have in place a method to identify the author of each entry and to ensure that entries are not made by any individual using another individual’s identity. For example, if the RHC uses an EHR system that requires individuals to use passwords or card keys to access the system, individuals may not share their passwords or card keys with other individuals. Likewise, if the RHC uses a paper clinical record system and authorizes the use of rubber stamps for signatures, the individual whose signature the stamp represents must **not** allow any other individual to use it.

Readily accessible

The clinical record must be readily accessible to RHC staff. The RHC must have a clinical record system that allows clinical staff timely access when needed to all open records, i.e., records of all RHC patients who, per clinical record policy, are considered to still be active RHC patients. The clinical records policies and procedures must also address how long closed clinical records will be readily accessible to staff (This is distinguishable from the 6 year retention of closed records requirement at §491.10(c)).

The RHC’s clinical record system must be systematically organized to facilitate completion, storage, and retrieval of records in a manner that supports timely provision of evaluation or treatment services to RHC patients.

Survey Procedures §491.10(a)(1)-(2)

- 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 arrangements 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 an 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?*

J-0152

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

[§ 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.

Interpretative Guidelines §491.10(a)(3)(i) - (iv)

The clinical record for each RHC patient must contain at least the following information:

Identification and Social Data

The clinical record must contain information that allows the identity of the patient to be clear through the use of patient identifiers such as name, date of birth, etc.

“Social data” may include the patient’s address, work information, insurance information, names of family members, designated representative (if any), etc.

Informed Consent

The RHC must have written patient care policies that address the circumstances when the patient’s informed consent to diagnosis or treatment is required, and under what emergency circumstances the informed consent requirement may be waived.

The clinical record must include a record of the patient’s (or that of the patient’s representative, determined in accordance with State law) informed consent in all cases where the RHC’s policies require informed consent. If there is applicable Federal or State law requiring informed consent, the RHC must comply with those requirements, but compliance is not assessed as part of the survey of the RHC’s compliance with the CfCs.

The clinical record must provide evidence the informed consent was properly executed. A properly executed informed consent form should reflect the patient consent process. Except as specified for emergency situations in the RHC’s informed consent policies, all clinical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent. An informed consent form, in order to be properly executed, must be consistent with RHC’s policies as well as applicable State and Federal law or regulation. A properly executed informed consent form contains the following minimum elements:

- Name of the specific procedure(s), or other type of diagnosis or treatment for which consent is being given;*
- Name of the responsible practitioner who is performing the procedure(s) or administering the medical treatment;*
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient’s*

representative (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity). RHCs are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits, and alternatives will be discussed with the patient.

- *Signature of the patient or the patient's representative; and*
- *Date and time the informed consent is signed by the patient or the patient's legal representative. If the RHC uses an EHR system, signature may be electronic. However, there must be documentation of how the patient's or representative's electronic signature is verified within the EHR system and may not be altered. Likewise, there must be documentation that makes clear what the patient or representative consented to and how alteration is prevented.*

If there is applicable State law governing the content of the informed consent form, then the RHC's form must comply with those requirements.

Pertinent Medical History

The purpose of a medical history is to determine whether there is anything in the patient's overall condition that would affect the patient's diagnosis or planned course of treatment, such as a prior occurrence of similar symptoms, a medication allergy, or a new or existing co-morbid condition that requires additional interventions to reduce adverse health risks to the patient.

Only qualified personnel as determined by RHC policy may enter the medical history into the clinical record, but in all cases, the medical history must be reviewed and authenticated promptly by a practitioner. The RHC must have written policies and procedures specifying when a new or updated medical history is required.

Assessment of the Health Status and Health Care Needs of the Patient

The clinical record must include assessment by a practitioner of the current health status and health care needs of the patient at the time of each RHC visit.

Brief Summary of the Episode, Disposition, and Instructions to the Patient

There must be a brief summary of the reason for the RHC visit and the patient's disposition, including any follow-up instructions provided to the patient. Only qualified personnel as determined by RHC policy may enter the summary into the clinical record, but in all cases the summary must be authenticated promptly by a RHC practitioner.

Reports of Physical Examinations

Physical examinations performed on the patient are typically conducted at the time the pertinent medical history is being collected, but may also be conducted at other times. The physical examination must be completed by a practitioner and documented and authenticated in the clinical record by a practitioner in accordance with State law and RHC policy.

Diagnostic and Laboratory Test Results

All results of diagnostic and laboratory tests that are performed by the RHC directly or under arrangement must be included in the patient's clinical record. Any interpretations of tests by a practitioner must be authenticated by the practitioner.

Consultative Findings

All findings of a practitioner who provides consultation at the request of a RHC practitioner on a RHC patient, and who reports those findings to the RHC practitioner, must be included in the patient's clinical record.

Other Required Content

The clinical record must also contain:

- Practitioner's orders, dated, timed, and signed, for all tests, medications, treatments, and any other matters requiring an order from a practitioner;*
- Nursing notes, properly authenticated, for all patients reflecting all nursing care provided;*
- Documentation of all treatments furnished (including any complications that occurred) by the practitioner furnishing the care;*
- Documentation of all medications administered (including adverse drug reactions) by the person administering the medication;*
- Documentation of the patient's response to all treatments furnished; and*
- Evidence of other pertinent information required to monitor the patient's progress, such as vital signs.*

Survey Procedures § 491.10(a)(3)(i) – (iv)

- 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?*

J-0153

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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.***

Interpretative Guidelines § 491.10(b)

The RHC must have sufficient safeguards to ensure that access to all information regarding patients is limited to authorized individuals only. Whether in paper or electronic format, clinical records must be protected from loss or unintended destruction, and must be protected from access by unauthorized individuals or unauthorized used by authorized individuals. However, the nature of the safeguards the RHC uses will vary depending on the medium in which records are created and stored. For example, closed paper records might be locked in a secure area that

is protected from environmental hazards, such as fire, floods, humidity, etc., while open paper records might be kept in an area where access is limited to authorized personnel. On the other hand, safeguards for EHR systems might be focused on back-up electrical power, arrangements for backing up information at a remote server, and limiting access through use of passwords, card readers, etc.

The RHC's clinical record policies and procedures must address who may use clinical records, how they may use them, who may "remove" clinical records (i.e., physically removing paper records or films, or deleting records from an EHR system), and under which conditions information in a clinical record may be released, and to whom.

Prior to releasing information from their clinical record, the RHC must obtain the written consent of the patient who is the subject of the record (or his/her representative), unless the release is required by law. Note that uses and disclosures of protected health information (PHI) which are, in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR parts 160 and 164, Subparts A and E), made without the patient's prior authorization are considered to also be permissible under the RHC CfCs and do not require the written authorization specified in § 491.10(b)(3). Note that CMS and State surveyors conducting surveys on behalf of CMS are not authorized to assess compliance with the HIPAA Privacy Rule, which is interpreted and enforced by the U.S. Department of Health and Human Services Office of Civil Rights (OCR). If surveyors and their managers have concerns about disclosures that the RHC makes without the written consent of the patient (or the patient's representative), they should refer such concerns to the Regional OCR office.

Survey Procedures §491.10(b)

- *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 or 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.*

J-0154

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.10(c) Retention of records.

The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

Interpretative Guidelines §491.10(c)

Clinical records are retained in their original form or legally reproduced form in hard copy, microfilm, or computer memory banks. The RHC must be able to promptly retrieve the complete medical record of every individual evaluated or treated at the RHC 6 years after the latest entry made into the patient's record. Therefore, clinical records must be maintained within the RHC.

Although RHCs are expected to comply with other Federal or State law requirements calling for longer retention periods, compliance with these other requirements is not assessed as part of the Federal RHC survey.

Survey Procedures §491.10(c)

Determine that records are retained for at least 6 years from the date of the last entry.

J-0160

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 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.

J-0161

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§491.11(a) The clinic . . . carries out, or arranges for, an annual 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.

Interpretative Guidelines §491.11(a)-(c)

The RHC is required to conduct an evaluation of its total clinical program, at least annually. This evaluation may be done by RHC staff or through arrangement with other appropriate professionals. The RHC must have documentation of who conducts the review or portions of the review, and what their qualifications are to do so.

The evaluation must include, at a minimum, the number of patients served and the volume of services provided. The evaluation should be able to determine whether the RHC provides appropriate types and volume of services based upon the needs of its patient population. It should also be able to evaluate whether RHC patient policies were followed and whether or not changes to the policies or to procedures are warranted. The evaluation does not have to be done all at once or by the same individuals. However, if the evaluation is not performed all at once, no more than one year may elapse between evaluating the same components.

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.

The evaluation must also include a review of a representative sample of both active and closed clinical records of RHC patients. The sample must also include at least 5 percent of the RHC's current patients or 50 records, whichever is less. The purpose of the review is to determine whether utilization of the RHC's services was appropriate, i.e., whether practitioners adhere to accepted standards of practice and adhere to the RHC's guidelines for medical management when diagnosing or treating patients. The review also must evaluate whether all personnel providing direct patient care adhere to the RHC's patient care policies. The evaluation of practitioners must be conducted by an MD or DO; if there is only one MD or DO practicing in the RHC, it is expected that the RHC will arrange for an outside MD/DO to review the selected sample of records of RHC patients cared for by the RHC's MD/DO. The evaluation of whether the RHC's patient care policies were followed may be conducted by an MD/DO, a non-physician practitioner, an RN, or other personnel who meet the RHC's qualifications criteria.

The evaluation findings must be documented in a summary report, and must include recommendations, if any, for corrective actions to address problems identified in the evaluation. If a RHC has developed a QAPI program and that program meets/exceeds the regulatory requirements for a Program Evaluation, the QAPI program would be acceptable.

Survey Procedures § 491.11(a)-(c)

- *Does the RHC have documentation that its clinical program is reviewed at least annually?*

- *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?*

J-0162

(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)

§ 491.11(d) *The clinic . . . staff considers the findings of the evaluation and takes corrective action if necessary.*

Interpretative Guidelines § 491.11(d)

The RHC's leadership must consider the evaluation findings and recommendations for change, if any. It must take corrective actions as necessary, such as changes in policies or, with respect to clinical personnel, provision of additional training, changes in level of supervision, or even limiting or terminating clinical privileges. The RHC must document where and when the evaluation findings and recommendations were considered, and by whom they were considered. It must also document what corrective actions, if any, were taken and by whom they were recommended. 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, it must document the rationale for its decision.

Survey Procedures § 491.11(d)

- *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?*