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RURAL HEALTH CLINIC

PREPARING FOR THE RHC CERTIFICATION INSPECTION

February 5, 2019



Healthcare Business Specialists

Specializing in RHC reimbursement

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Preparing for the RHC Certification Inspection

Powerpoint Presentation



Preparing for the RHC
Certification Inspection
January 31, 2019
www.ruralhealthclinic.com



HBS
Healthcare Business Specialists

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RURAL HEALTH CLINIC INFORMATION RESOURCES

We also would like to inform you of our educational resources including our Facebook Group, website, webinars, YouTube channel and seminars on RHCs. We highly recommend joining our Facebook Group as we use this to notify the 570 members about our free webinars and educational offerings by other consultants or the NARHC.

- Facebook Group (<https://www.facebook.com/groups/1503414633296362/>)
- Our website which is <http://www.ruralhealthclinic.com/>
- Youtube: https://www.youtube.com/channel/UCXW4pkwNzDXVTMFrFwMy2_A
- Certification Resources: <http://www.ruralhealthclinic.com/certification-materials>
- Emergency Preparedness for RHCs: <http://www.ruralhealthclinic.com/emergency-preparedness>
- RHC Billing: <http://www.ruralhealthclinic.com/rhc-billing/>

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RHC Information Exchange Group on Facebook


Join this group to post or ask questions regarding RHCs. Anyone is welcome to post about meetings, seminars, or things of interest to RHCs

<https://www.facebook.com/groups/1503414633296362/>

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RHC Information Exchange Group on Facebook




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The Process to Become a Rural Health Clinic.



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Timeline to Become a Rural Health Clinic

Estimated Timeline for the RHC conversion process (1-page PDF)

Process	Length of time.
1. 855A – Submitted 1/30/2019	60 Days
2. Preparation for State Inspection	30 to 60 days
3. State Inspection	30 to 90 Days
4. CCN and Rate Setting	30 to 180 Days
5. Medicaid Application and Rate Setting	60 to 180 Days

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THE PROCESS TO BECOME A RURAL HEALTH CLINIC

The process to become a rural health clinic is long and will involve pulling together certain documents for various governmental entities which will review the submissions and approve them as we go along. The usual process takes between 6 months to a year to complete all five steps listed below.

1. Preparation and submission of the 855As, State application, and deeming authority applications.
2. Preparation for State Inspection including preparing RHC and Emergency Preparedness Policy and Procedure manuals
3. Passing the RHC survey or responding to deficiencies in the survey.
4. Emergency Preparedness Training and Testing.
5. Obtaining provider numbers for Medicare and Medicaid as well as rate setting.

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FORMS FROM HBS TO HELP THROUGH THE CERTIFICATION PROCESS

Healthcare Business Specialists works with physician practices to convert them into rural health clinics. Here are some of the documents and questionnaires we use to get information from our clients.

- [Complete this 855A Questionnaire and email it to Dani Gilbert, CPA to prepare the 855A. The Medicare Administrative fee is \\$586 in 2019.](#)
- [Complete this RHC Policy and Procedure Manual Questionnaire and email it to Dani Gilbert, CPA to prepare the RHC Policy and Procedure Manual.](#)
- [If you are in Kentucky we recommend you join the Kentucky Primary Care Association for Medicaid Credentialing. This link will provide more information.](#)

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Preparation for the RHC Inspection

1. Prepare RHC Policy and Procedure Manual as well as Emergency Preparedness P and P Manual, OSHA Manual, and HIPAA Manual.
2. Train personnel in RHC Policies, Emergency Preparedness, OSHA, and HIPAA. Document training and approve policies.
3. Start Acting like a Rural Health Clinic. Implement required Forms and processes including Medical Director Review of Charts.
4. Prepare an Evidence Binder for the Inspector. Copy Records that will be requested by the Inspector for them to review.
5. Conduct a Mock Inspection and Prepare an Annual Evaluation
6. Perform and document two Emergency Preparedness Drills.

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Resources for RHCs



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RHC SURVEY PREPARATION STEPS AND RESOURCES

As you prepare for the RHC inspection here are some resources to help you comply with the nine conditions of participation to become a rural health clinic. It is important to start acting as if you are a rural health clinic before the inspection. We have provided some resources for you to review and start working on before the Mock Inspection occurs. The Mock Inspection is designed to be educational and instructional and will elaborate on the processes and procedures that the State Inspectors, AAAASF, and The Compliance Team will expect to be in place by the time of the Certification inspection. Please click on the links below to view the documents:

- [Assignments for Clinic Personnel Including Forms to implement](#)
- [RHC Certification, Mock Inspection, and Evidence Binder Summary Information](#)
- [Agenda for RHC Mock Inspections \(2-page PDF\)](#)
- [RHC Mock Inspection Form, Evidence Binder, and Resources for the initial inspection \(32-page PDF\)](#)

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PREPARING FOR THE RHC STATE INSPECTION WEBINAR AND MATERIALS

On December 13, 2018 Healthcare Business Specialists presented a webinar on preparing for the state/AAAASF/TCT inspections to become a rural health clinic and re-inspections conducted by the state, AAAASF, and TCT. Here is the recording of the webinar and the PDF of the presentation:

- [Webinar Recording on RHC State Inspections](#)
- [Powerpoint Presentation \(PDF\)](#)
- [Powerpoint Presentation by Kate Hill on RHC Certification](#)
- [Powerpoint Presentation by Elsie Crawford on RHC Certification](#)


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Other Survey Documents

- [RHC Survey Steps based upon Interpretative Guidelines \(21-page PDF\)](#)
- [Emergency Preparedness Required Activity Checklist \(1-page PDF\)](#)
- [Infection Control Checklist for ASCs used by RHC Inspectors \(17-page PDF\)](#)

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CMS 30 Survey Form – Last updated March 1, 1978


Changes over the last 40 years
NP/PA is now 50% not 60% - OBRA 89
Lab tests are now 6 instead of 9 – mid-90s
Medical Director not on site every two weeks – 7/1/2014
Guidance from the deeming organizations on emergency meds.
RHCs can now pay using 1099 for some NPs/Pas – 7/11/2014
Updated Version. Not official: http://www.healthandwelfare.idaho.gov/Portals/0/Health/Rural%20Health/survey-report-tool.pdf

Problem: Surveyors still cite this report.

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CHANGES TO SURVEY DUE TO THE INTERPRETATIVE GUIDELINES

The NARHC met with CMS to get certain things changed and succeeded on these

- 1-Physician responsibility to review all records
- 2-Clinical policies must be developed by one physician, NP, or PA outside the RHC
- 3-Rural Health Clinics must stock costly drugs and biologicals such as snake antidote that are typically thrown out (still need an antidote)

CMS would not agree to change the following

- 4-Survey team must include a registered nurse
- 5-Surveyors must witness a visit
- 6-Medical Director must practice in the RHC (1 visit per year minimum)

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What is your Mindset

Think about child proofing your home when you have small children.

Think about the safety of patients and Employees.

Think about privacy and HIPAA.



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Who Conducts RHC Certification Inspections

1. The State
2. AAAASF
3. The Compliance Team (See Presentation)

https://www.healthy.arkansas.gov/images/uploads/pdf/AR_RHC_Survey_4.13.2018_.pdf

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Objective of the RHC Certification Inspection

To determine if the RHC is in substantial compliance with the 9 conditions of participation for RHC participation or the standards of the deeming authority. See AAAASF's below.

[https://www.aaaasf.org/docs/default-source/accreditation/standards/standards-manual-and-checklist-v2-2-\(rhc\).pdf?sfvrsn=24](https://www.aaaasf.org/docs/default-source/accreditation/standards/standards-manual-and-checklist-v2-2-(rhc).pdf?sfvrsn=24)

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There are Nine Conditions of Participation

<https://www.law.cornell.edu/cfr/text/42/part-491/subpart-A>

- 1.491.4 Comply with Fed, State, & Loc Laws
- 2.491.5 Must meet location requirements
- 3.491.6 Physical Plant and Environment
- 4.491.7 Organizational Structure
- 5.491.8 Staffing and Staff Responsibilities
- 6.491.9 Provision of Services
- 7.491.10 Patient Health Records
- 8.491.11 Program Evaluation
- 9.491.12 Emergency Preparedness

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Preparing for the Inspection

Number	Step
11.	Prepare a Rural Health Clinic Policy and Procedure Manual addressing the plan to show compliance with 9 conditions of participation. The hospital policy manual does not work. HIPAA, OSHA, COLA, ETC.
12.	Prepare a State Inspector's file with copies of licenses, drills (conduct them), CPR, protocols, employee listing, schedules, etc - see listing provided by the state. Evidence Binder

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Annual Evaluation/Mock Inspection

Number	Step
13.	If the clinic is over one year old prepare an annual evaluation. If the clinic is less than one year old, conduct a Mock Inspection of the clinic ensuring the clinic is doing what is in the Policy and procedure Manual.
14.	Most Deeming authorities will review 20 charts. They will look for MSP, Consent to Treat, HIPAA Privacy forms, etc. Everything must be within one year. MSP is done every visit.

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State Inspection

Number	Step
15.	The State will complete the inspection and in most cases there will be no deficiencies. If there are, respond within 10 days and correct any issues. Stop billing to Medicare and Medicaid once you pass the inspection.

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Tennessee RHC Survey Evidence Binder


Please provide the following information to the RHC within the beginning of the RHC survey. Please enter a date of last update in the "Updated" column.

Item	Updated	Subcategory	Notes
1. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.1
2. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.2
3. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.3
4. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.4
5. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.5
6. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.6
7. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.7
8. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.8
9. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.9
10. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.10
11. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.11
12. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.12
13. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.13
14. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.14
15. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.15
16. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.16
17. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.17
18. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.18
19. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.19
20. Copy of all licenses from OSHPD for all staff	Yes	1.1	1.1.20

The clinic will have an Evidence Binder and give that to the surveyor.

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Have an Evidence Binder that is up to date at all times. (a file with copies for the inspector)

The Inspector will hand you a list of what they want to see in most cases. The list will typically have the same things listed:

- A. Physician/NP/PA/CNM/Nurses licenses
- B. Schedules for NPs/PA/CNMs (50%)
- C. Preventive maintenance logs and plans
- D. ALS or CPR updated certificates
- E. Chart Reviews by the Medical Director
- F. Emergency, Fire, and Medical Drills
- G. Fire Department inspection, Invoices for PM.....

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Licensed Providers and Staff

Licensed Staff Member	State of Origin License # (or Certificate #)	Expiration Date	Self Certification # (or equivalent)	Expiration Date	ALS/First Aid/ CPR/First Aid/ Certified Patient Care Personnel	Verification & copies of professional license, registration and/or certification if applicable

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OSHA requirements for healthcare

OSHA Compliance Assistance Quick Start
https://www.osha.gov/dxap/compliance_assistance/quickstarts/health_care/quickstart.html

Healthstream is the source that a lot of healthcare providers use for OSHA annual training
<https://www.healthstream.com/solutions/learning/compliance/compliance-learning>

Most States provide free OSHA training. Here is the link for Alabama
https://alabamastate.us.edu/safety-consultation/consultations_viet.php

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Free Medication Storage Training



CDC Safe Injection Practices
Training Videos on You Tube

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Place Hints Throughout The Clinic



LIDOCAINE AND XYLOCAINE are single use vials and should be discarded after each use.

STANDARD PRECAUTIONS

REMEMBER
Hand hygiene 2 times
before and after each visit
and after each procedure
and after the visit. Use hand sanitizer.

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The RHC Inspection

INSPECTION

PASSED
 FAIL



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The Surveyor is the key to the inspection.



The Receptionist will often determine Which Surveyor you get. Train Them!

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Have a plan for when the Inspector comes to your clinic

1. Provide the receptionist with instructions
2. Do not keep them waiting in the lobby
3. Give them a desk to work at that is quiet and away from activity.
4. Give them the P and P manual and RHC Evidence Binder.
5. Inform the staff that the inspection is underway.
6. Call your Consultant.



Call Your Consultant

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The Surveyor will give you a document something like this.

XXXXXX RHC - Medicare Inspection Checklist

1. Organization that was Suggesting Referral
 - Name of Contact Person(s) - Date and for Satisfaction with/through out of the organization.
2. Consultant Referral - Referral source and qualifications
3. Document Review - All Part 401 - Compliance with Federal, State, and Local Service Administrative Management
4. Plan of Care and Physician Involvement
5. Personnel of Services
6. Document Review - Current Services
7. Document Review - Patient Health Records
8. Physical Environment
9. Staffing and Staff Responsibilities
10. Quality Improvement
11. Program Evaluation
12. Survey Findings - The surveyor will document the survey findings and complete the survey forms.
13. Exit Interview - The surveyor will interview the surveyor as an exit interview will be completed. Administrative and staff will be aware of areas of deficiency and suggestions for improvement.
14. Patient Last Policy and Procedures
 - Homebased Auditing/Reporting
 - Adherence / Compliance Measures
 - Annual Review of all policies and procedures (update as necessary)

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Day of Survey Agenda

- On-site Meeting with Key Leadership
- Review of RHC policies
- Tour the entire Facility
- Observe Medication Storage
- Observe Infection Prevention Practices
- Interview Staff and Providers
- Patient Health Record review
- Personnel Files
- Exit interview


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Surveyor's Approach

- Expect Surveyor to to...
 - Review Documents and Records
 - Observe Processes
 - Interview Staff w/ Open-ended Questions to Reveal Underlying Issues
 - Discuss/Teach Best Practices when Non-Compliance is Discovered


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Surveyor/Staff Interaction Tips

- Staff should be familiar with routine policies/procedures and be able to describe the "how" and "why" of a process
- If unable to answer completely, it is acceptable to say "I would consult policy"
- When a surveyor is observing, staff should just do what they normally do

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Surveyor/Staff Interaction Tips

- Understanding the rationale for why they do what they do helps staff anchor information in their memory
- Placing written/visual reminders in the environment will help staff during day to day operations and when they interact with a surveyor

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Facility Tour



Clean and Maintained

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Facility Tour



Fire Safety Process per State Regulations
(note accreditation standards that may exceed CFR)

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Facility Tour



- Local Licenses or Certificates
- State Postings
- Federal Postings
- Dangerous Drug Certificates
- Provider Licenses

State and Federal Posters are required to be in Visible Places

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Facility Tour



Equipment Maintenance Best Practices

- All equipment resides on an Inventory List
- Policy determines need for inspection vs Preventive Maintenance
- PM based on Manufacturer's IFUs
- Process in place for tracking due dates for PM
- Evidence of initial inspection BEFORE use in patient care
- Annual Bio-Med inspection is evident with stickers or report
- Equipment not in use is labeled as such and stored away

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Medication Storage



ER Med Box/Cart is stocked according to a list and ready to meet the needs of the population.

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Medication Storage

Vaccination Storage Best Practices

- Temperature monitoring should alert staff to a temperature variance in the past 48 hours
- Clinic should have a process to be notified when the power goes off at the clinic (power grid call list, alarm with alerts, etc.)
- Bottled water stored in the doors, labeled not food
- No medications stored in the doors
- Expired medications MUST be identified
- No food or lab supplies stored in the med fridge or freezer

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Check for Expired Medications



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CHANGES TO THE ANNUAL EVALUATION SNAKE VENOM ANTIDOTE



Snake Venom Antiserum

- Contains 100 antitoxin units
- Most common type of venom
- For intramuscular use



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2018 Top Deficiencies
Multi-use Dose Vials stored in Patient Areas
MDVs Stored And Used In Immediate Treatment Areas

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2018 Top Deficiencies
Controlled Substances Not Adequately Secured / Not Reconciled

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Drugs Not Stored In Original Containers

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Proper Set-up

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Infection Prevention Best Practices

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Review of Laboratory Services

Laboratory Compliance

- 6 Required tests must be able to be performed in the Clinic
 - Urine Analysis
 - Hemoglobin/Hematocrit
 - Blood Glucose Testing
 - Urine Pregnancy Test
 - Occult Fecal Blood Test
 - Primary Culturing
- Clinic follows all Manufacturer's IFU for equipment and supplies
- Staff should have training/verification of competency (BEST PRACTICE)

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PHYSICAL PLANT AND ENVIRONMENT
491.6 Physical plant and environment. (J20)
(a) **Construction.** The clinic or center is constructed, arranged, and maintained to **insure access to and safety of patients**, and provides adequate space for the provision of direct services
(b) **Maintenance.** The clinic or center has a **preventive maintenance program** to ensure that: (J20-J21)

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Preventive Maintenance Regulations
(1) All essential mechanical, electrical and **patient-care equipment is maintained** in safe operating condition; (J22)
(2) **Drugs and biologicals** are appropriately stored; (J23) and
(3) The premises are **clean and orderly.** (J24)

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Preventive Maintenance
ANNUAL preventive maintenance log/documentation, calibration, etc.
Policies on annual check, how to handle new items, broken items, disposal of items
Cleaning/Disinfecting policies/logs/Contract
Spore check reports/Radiation reports
Policies for drugs/biologicals
Storage, disposal, handling, power outage

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Some things they will looking for
Training documentation
Fire, tornado, inclement weather, emergency evacuation, biohazard, Safety, etc. AED
Floor plan of clinic/identify routes of escape
MSDS sheets (do not copy for inspectors)
Policy for sanitation/cleaning of instruments that are not disposable.
Evidence of current BLS certificates

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What to look for in the walkthrough
Refrigerators labeled.
Food Only
Meds Only
Labs Only
DO NOT UNPLUG signs for refrigerators.
Notice on how to handle medications during power outage.
Nothing in the door of the refrigerator.
**Copy of policy available regarding handling medications during power outage. Also recommend to place copy of policy of front of medication refrigerator

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Emergency Procedures Regulations
(c) **Emergency procedures.** The clinic or center assures the safety of patients in case of non-medical emergencies by: (J25)
(1) **Training staff** in handling emergencies; (J26)
(2) Placing **exit signs** in appropriate locations; and (J27)
(3) Taking other appropriate measures that are consistent with the particular **conditions of the area** in which the clinic or center is located. (J28)

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First Response to Emergency

(3) *Emergency.* The clinic or center 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. (J62)

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Six Required Lab Tests

(2) *Laboratory.* These requirements apply to RHCs but not to FQHCs. 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: (J61)

- (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.⁶²

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Medical Records – Copy these items as well

Various Medical Records Policies/Forms used

- Contents of information within the chart
- Person responsible for Medical Record
- Confidentiality of record
- Protection of record
- Use and Removal of record
- Release of information
- Storage of record/Retention
- Minimum necessary Use
- Complaints
- Fax and email (forms)

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Provision of Services

- Policy stating all services rendered within the clinic, list all labs offered, and list name of outside lab.
- Policy for handling emergencies, maintaining emergency medications, handling Schedule II medications (if needed).
- Agreements with outside labs, hospitals, etc. for services not rendered within the clinic setting.
- Have a copy of the CLIA certificate and Waste Management agreement.

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Agreements - Regulations

(d) *Services provided through agreements or arrangements.* (1) The clinic or center 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; (J63-J65)
- (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.

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Agreements and Licenses

Policy stating all services rendered within the clinic, list all labs offered, and list name of outside lab.

Policy for handling emergencies, maintaining emergency medications, handling Schedule II medications (if needed).

Agreements with outside labs, hospitals, etc. for services not rendered within the clinic setting.

Have a copy of the CLIA certificate and Waste Management agreement.

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**Look for the following
Medical Director functions**

Documentation to evidence participation in policy review.
Documentation to evidence chart review and fulfillment of oversight requirements.
Copies of completed/signed collaboration agreements, waivers, contracts, guidelines of practice limitations.
Referral and tracking policies/ forms/logs, etc
Policy on assuring provider is licensed, approved (credentialing--this is not insurance)

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Review Update and Approve (RUA)

APPROVED

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Are Policies Updated and Signed

- Signatures on policies—with policy manual
 - Minimum, Medical Director, Non Physician providers and Community Member.
- Be sure chart contains required evidence of patient care
 - Also, consent to treat and informed consent.

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More Required Items in the P & P

Ownership Page
Current Organizational Chart
Be sure it reflects and includes the position of Medical Director
Job Descriptions for ALL positions reflected in the Organizational chart.
Current license/certifications for providers and required staff.
If the physician is unavailable, there should be a written plan for remote consultation and transfer of patients who require further evaluation and treatment.
Posted clinic hours/provider hours

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More Forms for the P and P manual

Policy for Samples (if needed) and template of sample distribution log.
Sample template of refrigerator temp log.
Evidence of proficiency testing (Lab controls)
Equipment manuals
Control logs

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RHC Forms to use from Idaho

Description	Link
Bureau of Rural Health & Primary Care (See 2012 Presentations)	http://www.healthandwelfare.idaho.gov/Health/RuralHealthandPrimaryCare/RuralHealthClinic/BHPC/Certification/Tabid/408/Default.aspx
Medical Record Review Form	http://www.healthandwelfare.idaho.gov/Portals/0/Health/Rural%20Health/PatientRecordQualityChecklist.pdf
CDC Temperature Logs	http://www.healthandwelfare.idaho.gov/Portals/0/Health/Rural%20Health/CDCTempLog.pdf
Equipment Maintenance Logs	http://www.healthandwelfare.idaho.gov/Portals/0/Health/Rural%20Health/Equipment%20Name.pdf
Sample Medication Log	http://www.healthandwelfare.idaho.gov/Portals/0/Health/Rural%20Health/SampleMedicationsLog.pdf

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The New Emergency Preparedness Plans Must be implemented by 11/15/2017

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The Emergency Preparedness Action Plan

1. Read the Regulations, Resources, Templates & watch MLM Videos.
2. Document any and all activities that are spent on EP. (phone calls)
3. Select an Emergency Preparedness Champion to lead the process and an Executive Team of three or more to implement EP.
4. Reach out to the local, CERT, county, state EP officials or coalitions and piggyback off their efforts. Be involved with any drills or tabletops.
5. Conduct the all hazards risk assessment or use the one obtained in 4. if appropriate.
6. Prepare your Emergency Plan to address the most common hazards.
7. Prepare your Emergency Policy and Procedures implementing EP.
8. Prepare your Communication Plan including how to contact people.

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The Emergency Preparedness Action Plan (2)

9. Train everyone in the RHC about the EP Plan. Test and document.
10. Train volunteers (spouses or immediate family in smaller RHCs) on HIPAA, OSHA, and the Emergency Plan.
11. Participate in a community-wide drill or a facility-drill if one is not available. Write up any lessons learned from the drill.
12. Participate in another community-wide drill or facility-drill or conduct a table-top exercise instead. (Recommended)
13. Review, Update and authorize changes to the EP, EPP, and CP yearly.
14. Repeat the following year. Document. Document. Document.

<http://www.ruralhealthclinic.com/emergency-preparedness>

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Most Commonly Cited Deficiencies

Citation	Standard	CMS CFR	Standard Text	Common Findings
63	900.010.020	491.1060.030	The clinic maintains a record for each patient covering health care services, identification and record data.	Lack of: <ul style="list-style-type: none"> Consent Advance Directives Response to Adverse Blindness/Deafness Medical History
55	800.010.020	491.603(2)	The clinic keeps the drugs and biologicals appropriately stored.	<ul style="list-style-type: none"> No date or units when opened Unlocked (w/Keys) Expired Refrigerator uncalibrated
30	900.010.111	491.903(3)	The clinic provides medical emergency protocols 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, antipyretics (local), antibiotics, non-steroidal anti-inflammatory drugs, sedatives, and resuscitation supplies.	<ul style="list-style-type: none"> EMS Agreements Office First Aid Recent Checklists Not as extensive list

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Most Commonly Cited Deficiencies cont.

Citation	Standard	CMS CFR	Standard Text	Common Findings
42	800.010.015	491.603(1)	The clinic has a preventive maintenance program to ensure that all essential mechanical, electrical and patient-care equipment is maintained in safe operating condition.	<ul style="list-style-type: none"> Many procedures for the Schedule-Maint for Clinic Equipment from storage must be checked General Appraisals (or "Time LINC")
31	800.010.065	491.604	The clinic is constructed, arranged, and equipped to assure access to and safety of patients, and provides adequate space for the provision of direct services.	<ul style="list-style-type: none"> Open/unlocked storage of clothing and other hazardous agents Trap Networks Stamps Electrical safety/plug covers
28	900.010.080	491.903(3)(a)	The clinic's policies include rules for the storage, handling, and administration of drugs and biologicals.	<ul style="list-style-type: none"> Using Hospital Policy Signage/Dispensing Inventory Labeling Expired

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Most Commonly Cited Deficiencies cont.

Citation	Standard	CMS CFR	Standard Text	Common Findings
28	900.010.080	491.903(2)(a)	The clinic provides basic laboratory services which implements the provision of section 353 of the Public Health Service Act wherein the RHC provides basic laboratory services essential to the accurate diagnosis and treatment of the patient, including Hemoglobin or hematocrit.	<ul style="list-style-type: none"> Lack of Quality Control Logs
21	900.010.015	491.903(2)	The clinic's 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, and at least one member that is not a member of the clinic staff.	<ul style="list-style-type: none"> Non-clinic member NP/PA involvement Timely Review (documented) Policy setting after accreditation
19	1100.010.040	491.110(3)(2)	The clinic conducts an evaluation to determine whether the established policies were followed.	<ul style="list-style-type: none"> OK for new clinics not to have a program evaluation, but must have a plan
19	1100.010.020	491.110(2)	The clinic conducts an evaluation, including a representative sample of both active and closed clinical records.	<ul style="list-style-type: none"> Minutes do not Reflect Evaluation No Specifications or Open/Close

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Questions, Comments, Thank You



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Preparing for the RHC Certification Inspection

Resources from Healthcare Business Specialists

502 Shadow Parkway, Suite 214, Chattanooga, Tennessee 37421
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www.ruralhealthclinic.com



RHC CERTIFICATION AND CONVERSION

THE PROCESS TO BECOME A RURAL HEALTH CLINIC

The process to become a rural health clinic is long and will involve pulling together certain documents for various governmental entities which will review the submissions and approve them as we go along. The usual process takes between 6 months to a year to complete all five steps listed below.

1. Preparation and submission of the 855As, State application, and deeming authority applications.
2. Preparation for State Inspection including preparing RHC and Emergency Preparedness Policy and Procedure manuals
3. Emergency Preparedness Training and Testing
4. Passing the RHC survey or responding to deficiencies in the survey.
5. Obtaining provider numbers for Medicare and Medicaid as well as rate setting.

RURAL HEALTH CLINIC INFORMATION RESOURCES

We also would like to inform you of our educational resources including our Facebook Group, website, webinars, YouTube channel and seminars on RHCs. We highly recommend joining our Facebook Group as we use this to notify the 550 members about our free webinars and educational offerings by other consultants or the NARHC.

- Facebook Group (<https://www.facebook.com/groups/1503414633296362/>)
- Our website which is <http://www.ruralhealthclinic.com/>
- Youtube: https://www.youtube.com/channel/UCXW4pkwNzDXVTMFrFwMy2_A
- Certification Resources: <http://www.ruralhealthclinic.com/certification-materials>
- Emergency Preparedness for RHCs: <http://www.ruralhealthclinic.com/emergency-preparedness>
- RHC Billing: <http://www.ruralhealthclinic.com/rhc-billing/>



PREPARING FOR THE RHC STATE INSPECTION WEBINAR AND MATERIALS

On December 13, 2018 Healthcare Business Specialists presented a webinar on preparing for the state/AAAASF/TCT inspections to become a rural health clinic and re-inspections conducted by the state, AAAASF, and TCT. Here is the recording of the webinar and the PDF of the presentation:

- [Webinar Recording on RHC State Inspections](#)
- [Powerpoint Presentation \(PDF\)](#)

RHC SURVEY PREPARATION STEPS AND RESOURCES

As you prepare for the RHC inspection here are some resources to help you comply with the nine conditions of participation to become a rural health clinic. It is important to start acting as if you are a rural health clinic before the inspection. We have provided some resources for you to review and start working on before the Mock Inspection occurs. The Mock Inspection is designed to be educational and instructional and will elaborate on the processes and procedures that the State Inspectors, AAAASF, and The Compliance Team will expect to be in place by the time of the Certification inspection. Please click on the links below to view the documents:

- [Agenda for RHC Mock Inspections \(2-page PDF\)](#)
- [RHC Mock Inspection Form, Evidence Binder, and Resources for the initial inspection \(32-page PDF\)](#)
- [Estimated Timeline for the RHC conversion process \(1-page PDF\)](#)
- [RHC Survey Steps based upon Interpretative Guidelines \(21-page PDF\)](#)
- [Emergency Preparedness Required Activity Checklist \(1-page PDF\)](#)
- [Infection Control Checklist for ASCs used by RHC Inspectors \(17-page PDF\)](#)



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Steps to Prepare for the RHC Inspection

- 1. Prepare RHC Policy and Procedure Manual as well as Emergency Preparedness P and P Manual, OSHA Manual, and HIPAA Manual.**
2. Train personnel in RHC Policies, Emergency Preparedness, OSHA, and HIPAA. Document training and approve policies.
3. Start Acting like a Rural Health Clinic. Implement required Forms and processes including Medical Director Review of Charts.
4. Prepare an Evidence Binder for the Inspector. Copy Records that will be requested by the Inspector for them to review.
5. Conduct a Mock Inspection and Prepare an Annual Evaluation
6. Perform and document two Emergency Preparedness Drills.



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Preparing for the RHC Certification Inspection

RHC Evidence Binder

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www.ruralhealthclinic.com



RHC EVIDENCE BINDER

RHC Evidence Binder

- The practice should maintain current documents to prove evidence of compliance at all times. As part of the initial and any follow-up survey, the surveyor will request various documents as evidence of compliance for all regulations. It is recommended that all documents be housed in one central location or binder. For the purpose of this course, this will be referenced as the “RHC Evidence Binder”. Having this binder will make the survey process go smoothly while also helping to avoid delays or possible citations if information cannot be located. It is also recommended that this manual be reviewed quarterly to update any new or outdated information.
- This should be a separate binder that is not part of your policy and procedure manual.

Tips To Help You Be Successful

- Organize the binder in the way that works best for you.
- Schedule calendar reminders to review the data quarterly for updates.
- Identify key staff and educate them on what is in the binder and where it is located. A surveyor could come at any time unannounced. The survey will take place regardless if the manager is there or not. Staff should be educated and feel confident that they can assist the surveyor with the requested documentation.
- Keep only the most current documents in the binder and archive old documents to separate files if needed.



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RHC Evidence Binder

- **The evidence binder should include:**
 - ✓ Copy of current HPSA
 - ✓ Copy of CMS initial/final tie-in notice
 - ✓ Copy of last survey document (if available)
 - ✓ ANNUAL preventive maintenance log/documentation, calibration, etc.
 - ✓ Roster of all current staff, (including providers) That includes hire date, job titles, FTE status and any hospital privileges
 - ✓ Evidence of yearly staff training (ex. hazardous waste, infection control, etc.)
 - ✓ All providers and clinical staff BLS certification
 - ✓ For Providers and licensed staff (when applicable) – copies of all licenses, DEA's, CV's, resumes and applications
 - ✓ Cleaning/Disinfecting logs/Contract
 - ✓ Spore check reports/Radiation reports if applicable

- Below is additional documentation and or evidence of compliance that the surveyor will request. This can also be placed in your evidence binder but it is recommended that you create a separate binder for easy reference.
 - Sample Medication logs – recommended placing in or near the sample medication storage area.
 - SDS (Safety Data Sheets) book – recommended placing near the eye wash station.
 - Lab manual – this should house all your lab policies and control logs and placed in the lab area.



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Evidence Binder List - RHC

HPSA Data
Copies of Providers: CV, State License, DEA and BLS
Copies of all staff job descriptions (including Medical Director)
Copy of Floor Plan
Yearly Electrical inspection by Bio-Medical Dept. report
Fire and Tornado evacuation etc. copy of site specific policy training log
Copy of Current ORG Chart hospital and practice
Roster of All Current Staff , providers, clinical and clerical with job titles, FTE, hospital privileges
Quarterly Chart Reviews
Housekeeping logs
Current Advisory meeting presentation/agenda/minutes
All Providers and Clinical Staff BLS certifications on file
Evidence of yearly staff training. (ex. Hazardous waste, inf. Control..)
Current Copy of DEQ
Current Copy of CLIA in binder as well as lab area

Separate Binders/Logs Needed
Sample Medication Logs
Medications biological and sterile supplies checked monthly for expiration dates
Lab supplies and reagents monthly inventory
Current MSDS list available for review
Patient's rooms checked monthly Log
Copies of the quarterly provider-app chart reviews, signed by both Physician and APP



RHC Survey Evidence Binder

Please provide the following information to the RHC Surveyor at the beginning of the RHC survey. Please make a copy of everything provided to the Surveyor for your records.

Number	Surveyor Requested Item	Reference	Status
1	Form CMS-29	A	Dani to provide
2	Copy of approval from CMS-RO for Visiting Nurse Services	N/A	No Visiting Nurses
3	Hours of operation	B	
4.	Name and address of owner	C	
5.	Copy of organizational chart	D	
6.	List of all patients scheduled for today, office visits for the past 6 months and any emergency transfers in past year	E	
7.	List of all staff with title and date of hire	F	
8.	Staffing for 2 weeks of operation (include all disciplines)	G	
9.	Program Evaluation	H	
10.	Copy of confidentiality policy	I	
11.	Copy of polices for maintaining medical records	J	
12.	Copy of policies for emergency procedures	K	
13.	Copy of patient care policies	L	
14.	Copy of Physician(s),PA(s), and/or NP(s) license(s)	M	
15.	Protocols for PA and/or NP to follow per physician	N	
16.	Procedures that PA and/or NP are allowed to perform	O	
17.	Copy of CLIA Certificate	P	
18.	Copy of preventive maintenance records for medical equipment	Q	
19.	List of all services provided through agreement or arrangement	R	
20.	Copy of facility floor plan	S	



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Items to look for in Rural Health Clinics (AAAASF)

AAAASF/RHC Medicare Inspection Checklist

1. Organization Tour with Supporting Policies:
 - a. Safety of General Environment: There will be familiarization walkthrough tour of the organization
 - b. Document Review: Personnel records and Qualifications
 - c. Document Review and Postings : Compliance with Federal, State, and Local laws and Administrative Management
 - d. Plan of Care and Physician Involvement
 - e. Provision of Services
 - f. Document Review: Contracted Services
 - g. Document Review: Patient Health Records
 - h. Physical Environment
 - i. Staffing and Staff Responsibilities
 - j. Disaster Preparedness
 - k. Program Evaluation
 - l. Survey Findings: The surveyor will document the survey findings and complete the survey forms.
 - m. Exit Interview: The surveyor will review the survey process in an exit interview with the organization administrator and key staff with discussion of areas of deficiency and suggestions for improvement.
2. Patient Care Policy and Procedures
 - a. Governing Authority/Ownership
 - b. Advisory Committee Minutes
 - i. Annual review of all policies and procedures (updated as necessary)



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- c. Governing Authority Minutes
 - i. Medical Director appointment
 - d. Policies and Procedures
 - e. Administration Management: contingency plan
 - f. Environment
 - i. Inspection and maintenance of equipment
3. Clinical Staff
- a. Licensed
 - b. Reappraisals review and evidence that these are occurring regularly (not more than two years).
4. Medications
- a. Check expiration date
 - b. Policy on how medication are stored & handled.
5. Personnel Record Review
(Use attached personnel record review form)
6. Clinical Records Review
(Use attached record review form)



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1. Clinic Walkthrough Tour – The inspector will observe the following:
 - a. Clinic is handicapped accessible.
 - b. Exit doors and signage are located in the appropriate places.
 - c. Fire extinguishers are inspected on a monthly basis.
 - d. Floor plans are posted throughout the clinic.
 - e. Sharps are secured throughout the clinic.
 - f. Nothing is stored under exam room sinks.
 - g. Closed trash containers are utilized in patient care areas.
 - h. Clinic has an OSHA Spill Kit and Eye Wash faucet.
 - i. Adult and pediatric scaled are balanced/calibrated annually.
 - j. Patient care equipment is calibrated per manufacturer's guidelines.
 - k. Clinic has a process for tracking preventive maintenance due dates.
 - l. All medications are stored in locked cabinets/drawers.
 - m. Medications, biological, and sterile supplies are inventoried monthly for expiration date.
 - n. Multi-injectable vials, ointments, and solutions are dated when opened and discarded in accordance with clinic policy.
 - o. Expired medications, biologicals, and sterile supplies are discarded in accordance with clinic policy.
 - p. Refrigerator and freezer temperatures are recorded daily.
 - q. Sample medications are logged out when dispensed to include: Date, Patient Name, Medication, Lot #, Expiration Date, Amount Dispensed, and NDC #
 - r. Controlled substances are inventoried on a weekly basis



Exhibit B

Hours of Operation

The hours of operation for the RHC are from 8:00 to 5:00 Monday through Friday.



Exhibit C Ownership

RHC is owned by _____

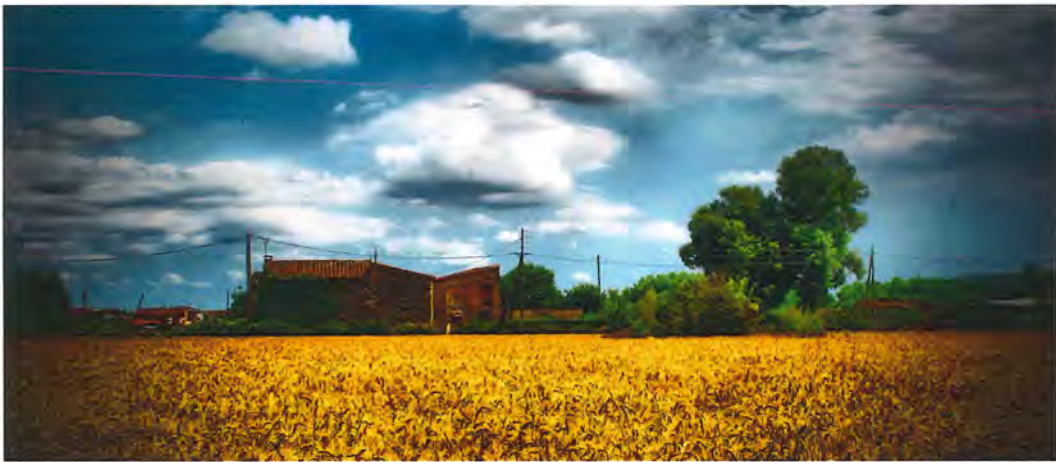


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Preparing for the RHC Certification Inspection

RHC ToDo List by Position with Sample Forms

RURAL HEALTH CLINIC RHC CERTIFICATION SPRING, 2019



Thank you for engaging Healthcare Business Specialists to help you convert your clinic into a rural health clinic. We have prepared this document as a listing of steps required to be completed before the survey. We will help you with the RHC Emergency Preparedness Policy and Procedure Manuals by drafting up these manuals for your review. There are a number of processes that need to be started before the survey in order to pass the inspection with as few deficiencies as possible. Please review the following report and assign the duties to the staff of the RHC as indicated by the image on each page of the forms.

Healthcare Business Specialists

Specializing in RHC reimbursement

502 Shadow Parkway Suite 214 Chattanooga, TN 37421

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Telephone: (423) 243-6185

RHC CERTIFICATION TO DO LIST

PLEASE INDICATE WHEN COMPLETED WITH A CHECKMARK



MEDICAL DIRECTOR DUTIES

<input type="checkbox"/>	Review and sign and date the Policy and Procedure Manual and Annual Evaluation
<input type="checkbox"/>	Review 15 charts for each NP/PA using a special form or at least list 10 charts you reviewed and sign and date the form along with the NP/PA.
<input type="checkbox"/>	Sign and Review Collaborative agreement with NP/PA
<input type="checkbox"/>	Review and sign the Emergency Preparedness Manual, participate in drills.
<input type="checkbox"/>	Determine which Emergency drugs will be in the Emergency Kit.



NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS

<input type="checkbox"/>	Review and sign and date the Policy and Procedure Manual and Annual Evaluation
<input type="checkbox"/>	Sign and Review Collaborative agreement with NP/PA
<input type="checkbox"/>	Review and sign the Emergency Preparedness Manual, participate in drills.
<input type="checkbox"/>	Keep a schedule of Nurse practitioners for review by the surveyors (50% rule)
<input type="checkbox"/>	Determine which Emergency drugs will be in the Emergency Kit.



NURSING AND MEDICAL ASSISTANTS

<input type="checkbox"/>	See Nursing Checklists for Monthly duties
<input type="checkbox"/>	Clean up areas. Remove clutter. Remove anything with an expired expiration date.
<input type="checkbox"/>	Undergo OSHA Training, Airborne pathogens, Emergency Preparedness.
<input type="checkbox"/>	Perform six required lab tests and document controls.
<input type="checkbox"/>	Remove any hazards from patient rooms. See walk through summary sheet.



OFFICE MANAGER AND ADMINISTRATION

<input type="checkbox"/>	Prepare Evidence Binder for State Inspection
<input type="checkbox"/>	Work with HBS to get RHC, OSHA, Lab, HIPAA, and EP Policy and Procedure Manuals
<input type="checkbox"/>	Arrange for Emergency Preparedness to be completed (work with HBS)
<input type="checkbox"/>	Arrange for preventive maintenance of patient equipment
<input type="checkbox"/>	Credential providers and all licensed personnel, update CPR, BLS, etc.



ANNUAL PROJECTS AND REQUIREMENTS

<input type="checkbox"/>	Conduct the Annual Evaluation/Program Evaluation (HBS)
<input type="checkbox"/>	Review, update and approve Emergency Preparedness (See One Page Checklist)
<input type="checkbox"/>	Arrange for preparation of Medicare Cost Report (HBS)
<input type="checkbox"/>	Review, Update, and Approve changes to the RHC Policy and Procedure Manual.
<input type="checkbox"/>	Conduct Preventive maintenance on all equipment.

Source: <https://www.ohsu.edu/xd/outreach/oregon-rural-health/clinics/rhc-ta-resources/upload/CMS-30.pdf>



Evaluation of Clinic Medical Records

Each quarter the Medical Director should review at least 15 charts which should include active and closed charts. A report should be submitted with the annual evaluation process that indicates that at least 50 charts per annum were reviewed. Here is some of the criteria to use during the evaluation of the clinic medical records.

Criteria Used in Evaluation of Clinic Records

1. Vital Signs measured and recorded
2. Problem list is completed
3. Allergies or lack thereof clearly noted
4. Chief complaint
5. History of illness completed
6. P.E. correlates with complaint
7. Results of diagnostic testing documented
8. Results of procedures documented
9. Medication list is complete
10. Treatment plan is documented
11. All entries signed and dated
12. Informed consent signed
13. Physician signature present
14. Patient education Provided



The Medical Director should review 50 charts per year and present the findings to the Annual Evaluation/Program Evaluation Committee. We recommend the Medical Director review 15 charts (14 active, 1 closed) each quarter and document using the following form or something similar.

PHYSICIAN SUPERVISION LOG

	CHART NUMBER	DATE OF SERVICE	TREATMENT ACCEPTABLE	RECOMMENDATION
1			Y N Y W/RECOM	
2			Y N Y W/RECOM	
3			Y N Y W/RECOM	
4			Y N Y W/RECOM	
5			Y N Y W/RECOM	
6			Y N Y W/RECOM	
7			Y N Y W/RECOM	
8			Y N Y W/RECOM	
9			Y N Y W/RECOM	
10			Y N Y W/RECOM	
11			Y N Y W/RECOM	
12			Y N Y W/RECOM	
13			Y N Y W/RECOM	
14			Y N Y W/RECOM	
15			Y N Y W/RECOM	

PHYSICIAN SIGNATURE _____
 CRNP SIGNATURE _____
 DATE OF REVIEW _____



Some clinics use this form to document the quarterly Evaluation of medical records. Any form that is similar should be acceptable to the surveyor.

**PATIENT RECORD QUALITY MANAGEMENT
CHECK LIST**

		DATE:		PROVIDER:								
		FACILITY:			OTHER:							
PATIENT NAME	DATE OF VISIT	SOCIAL INFO	CURRENT RX?	ALLERGIES NOTED?	IMMUNS REC?	P.E./OBJ FINDINGS	DX IMP	DX TESTS	RX	PT INST GIVEN	ED GIVEN	F/U VISIT
TOTAL AVERAGE GRADE Check=standard met 0= standard not met N/A= not applicable												
COMMENTS: (OVERALL GRADE _____ %)												

Reviewer Sig _____ Reviewed by Provider _____

*After review, this form is to be forwarded to the clinic manager for review and retention



Emergency Procedure and Emergency Kit Policy for Rural Health Clinic

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.

In the event of an emergency, 911 will be called immediately and Basic Life Support will be administered until the Ambulance arrives. All clinical staff will be BLS certified. An AED will be available in the clinic if needed.

The Medical Director of the RHC reviewed the required medication categories as suggested in the RHC regulations to respond to medical emergencies and based upon the clinic's proximity to emergency services, clinical competency of the providers and staff, and local conditions and expected emergency situations the clinic does have in an emergency kit with the following medications available to treat minor emergencies:

1. analgesics,
2. anesthetics (local),
3. antibiotics,
4. anticonvulsants,
5. antidotes
6. emetics,
7. serums
8. toxoids.

This policy has been reviewed by the Medical Director and signed effective with the signature date:

Signature

Date



Provider Schedules. Keep a schedule for Nurse Practitioners/Pas for two months before the expected inspection date. The clinic must have a nurse practitioner or Physician Assistant for 50% of the time the clinic is open and the clinic must be providing at least 51% of the visits in primary care

DATE TIME MUST INCLUDE:

- Clinic start time
- Clinic close time

NUMBER OF CLINIC PERSONNEL:

Current Monthly Case Load for Covered Services: _____
Date of Last Medicare Patient: _____

Facility ID: _____ Month: _____ Hours of Availability

Sun	Mon	Tues	Wed	Thu	Fri	Sat

Clinic Director/Administrator must be present on all available dates listed above. If your availability changes, be sure to contact our office immediately. A cancellation fee may be incurred if surveyors have made travel arrangements and failure to notify AAAASF of such changes is not done prior to the cost assessed.



Patient Safety Compliance Checklist
To be completed by – Medical Assistant
Year: _____

Month	Expired Drug Samples	Sample Doors Locked	Emergency Drugs	Patient Exam Rooms	Locked Vaccine Room	Multiuse Vials Dated
January						
February						
March						
April						
May						
June						
July						
August						
September						
October						
November						
December						

Instructions

1. The Medical Assistants will review all drug samples, injectibles, medical supplies and biologicals on the last day of the month. By the last day of the month the Medical Assistant will inspect all samples, vaccines, emergency drugs, patient exam room supplies and dispose of any outdated supplies or medications that expire during the upcoming month. (ie. All drugs with a February expiration date will be discarded by January 31)

2. All doors of the Sample Room and VFC Room will remain locked at all times.

3. All opened multiuse vials will be dated and initialed and discarded within 28 days of opening.

4. Please clean the supply cabinets, and remove all clutter from the clinic. The clinic should be completely dust free as well at the end of the month.

Please initial in each of the boxes that you completed the task for the appropriate month.

5. The Nurse Practitioner will oversee this process on a quarterly basis to ensure it has been completed:

1st Quarter

2nd Quarter

3rd Quarter

4th Quarter



Use the following form to conduct random walk throughs of the clinic to determine if the RHC is staying in compliance with RHC conditions of participation.

Date of review:

Reviewed by :

Exam Rooms and Procedure Rooms	Medication/nurse area
1. room logs being utilized?	31. signage on fridge - do not unplug. meds only..etc.
2. expired meds/supplies?	32. power outage procedure on door of fridges
3. plug protectors?	33. anything stored in doors of fridges?
4. closed trash containers?	34. schedule II drugs are double locked and logged separately?
5. holes or spots in walls that need repair?	35. allergy meds monitored separately for expiration?
6. locks on cabinets as necessary?	36. oxygen tanks secured
7. anything under sinks?	37. oxygen tanks labeled in use and empty? Cannula ready?
8. vials ointments and solutions dated appropriately?	38. emergency drug box easily accessible?
9. any single use items opened and not discarded?	39. sample meds logged?
10. cleaning products secured?	40. eye wash station checked and logged?
11. drawers and cabinets neatly organized?	41. spill kit?
12. sharps containers mounted and dated appropriately?	42. any safety concerns?
13. splash guards present?	43. any autoclave process concerns?
	waiting room and hallways
	44. holes or spots in walls that need repair?
	45. plug protectors?
	46. clean?
	47. Any safety concerns?
	48. lock on cleaning supply closet
	49. exit signs can be clearly seen and lights functioning?
	50. Secondary doors are locked?
	51. fire extinguishers are being checked monthly?
	52. hallways are clean and unobstructed?
	Check in area
	53. HIPAA review/PHI
	54. area neat and organized?
	Signage and parking lot
	55. hours of operation posted are correct?
	signage review
	any safety concerns?
	Miscellaneous
	APP hours meeting the 50% rule



Here are the regulations and steps to comply with OSHA requirements for healthcare:

https://www.osha.gov/dcsp/compliance_assistance/quickstarts/health_care/index.html#step1

Healthstream is the source that a lot of healthcare providers use for OSHA annual training.

<https://www.healthstream.com/solution/learning-compliance/compliance-learning>

You may want the University of Alabama to come out. They have a free program that you can use.

https://alabamasafestate.ua.edu/safety-consultation/consultation_visit.php



AED Defibrillator Checklist

Fiscal Year: _____

The AED should undergo monthly checks by a responsible person. Different models of defibrillator may require different checks, however the principles are the same.

Here's our recommended monthly check list for an AED:

1. Visual check of device – check for any obvious damage or missing parts
2. Battery check – different models have different methods of warning about low battery.
3. Check defibrillator pads are sealed and in-date
4. Check spare defibrillator pads are sealed and in-date
5. Check accessory equipment is present: towel, razor, CPR face shield, scissors, gloves, paperwork
6. Check integrity and security of defibrillator cabinet

Month	Visual Check	Battery Check	Pads Sealed	Spare Pads	Accessories	Security
January						
February						
March						
April						
May						
June						
July						
August						
September						
October						
November						
December						



RHC Policy and Procedure
Expired Drugs Disposal
Year: _____

Once a month drug sample rooms will be examined for expired drugs and any expired drugs will be disposed of in accordance with State law for that drug.

Month	Expired Samples Disposed	Performed by:	Comments
January			
February			
March			
April			
May			
June			
July			
August			
September			
October			
November			
December			



RHC Policy and Procedure
Emergency Drugs Expired Drugs Disposal
Year: _____

Once a month the crash cart will be examined for expired drugs and any expired drugs will be disposed of in accordance with State law for that drug.

Month	Expired Crash Cart Drugs Disposed	Performed by:	Comments
January			
February			
March			
April			
May			
June			
July			
August			
September			
October			
November			
December			



Clinical Manager – Controlled Substances should be inventoried and reconciled daily. Use a forms similar to the following.

Controlled Substance Usage Log

Inspector: _____ License No _____ Exp. Date _____
Company: _____ Address _____

Date	Drug	Form/Strength	Amount (Units)			Balance (Units)	Location
			Received	Used	Transferred		

www.FreePrintableMedicalForms.com



Daily – Record the Temperatures of Refrigerators (twice daily if VFC)

Temperature Log for Refrigerator and Freezer — Fahrenheit Month/Year: _____ Days 1–15

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an "X" in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month's completed form for 3 years, unless state or local jurisdictions require a longer time period.

- temperature range. Follow these steps:
1. Store the vaccine under proper conditions as quickly as possible.
 2. Temporarily mark exposed vaccine "do not use" until you have verified whether or not the vaccine may be used.
 3. Call the immunization program at your state or local health department and/or the vaccine manufacturer to determine whether the vaccine is still usable: _____
 4. Document the action taken on the reverse side of this log.

If the recorded temperature is in the shaded zone: This represents an unacceptable

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15			
Staff Initials																																
Room Temp.																																
Exact Time																																
°F Temp	am		pm		am		pm		am		pm		am		pm		am		pm		am		pm		am		pm		am		pm	
>49°	Take immediate corrective action if temperature is in shaded section*																															
48°																																
47°																																
46°																																
45°																																
44°																																
43°																																
42°																																
41°																																
40°																																
39°																																
38°																																
37°																																
36°																																
35°																																
34°	Take immediate corrective action if temperature is in shaded section*																															
33°																																
<32°																																
>8°	Take immediate corrective action if temperature is in shaded section*																															
7°																																
6°																																
5°																																
4°																																
<3°																																

*Some frozen vaccines must not be stored colder than -58°F. Check the Prescribing Information on the vaccine manufacturer's website for specific storage temperature instructions.

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

Technical assist. provided by the Center for Disease Control and Prevention, August 2011. www.immunize.org/catg.d/p3039f.pdf • ham #P3039F (8/11)

Distributed by the Immunization Action Coalition • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org • admin@immunize.org

Source for forms: <http://www.immunize.org/catg.d/p3037f.pdf>



Record samples provided to patients in case of a drug recall. Record patient name, medication, lot number, etc.

SAMPLE MEDICATION LOG

DATE	PATIENT NAME	MEDICATION	LOT NO.	DOSE	# of SAMPLES GIVEN	EXP. DATE	SIGNATURE



Contract with a Biomedical Company to calibrate all medical/patient equipment annually and keep a log of this activity.

Equipment Name	Location	Standard	Condition	Action



Monthly ensure that maintenance on the building is in good order and document.

MONTHLY MAINTENANCE

Year _____

MONTH	SMOKE ALARMS	MEDICAL & LAB EQUIP	AIR HANDLING	PEST EXTERMIN	LIGHTING	SIGNAGE	REVIEWED BY
January							
February							
March							
April							
May							
June							
July							
August							
September							
October							
November							
December							

INSTRUCTIONS: The individual performing the maintenance should place his/her initial in the appropriate area.
The office manager is to initial the last column to indicate he/she has reviewed the maintenance activity.



Daily and between each patient ensure the cleanliness and engage in infection control activities and log compliance.

CUSTODIAL SERVICES

Month: _____

Location: _____

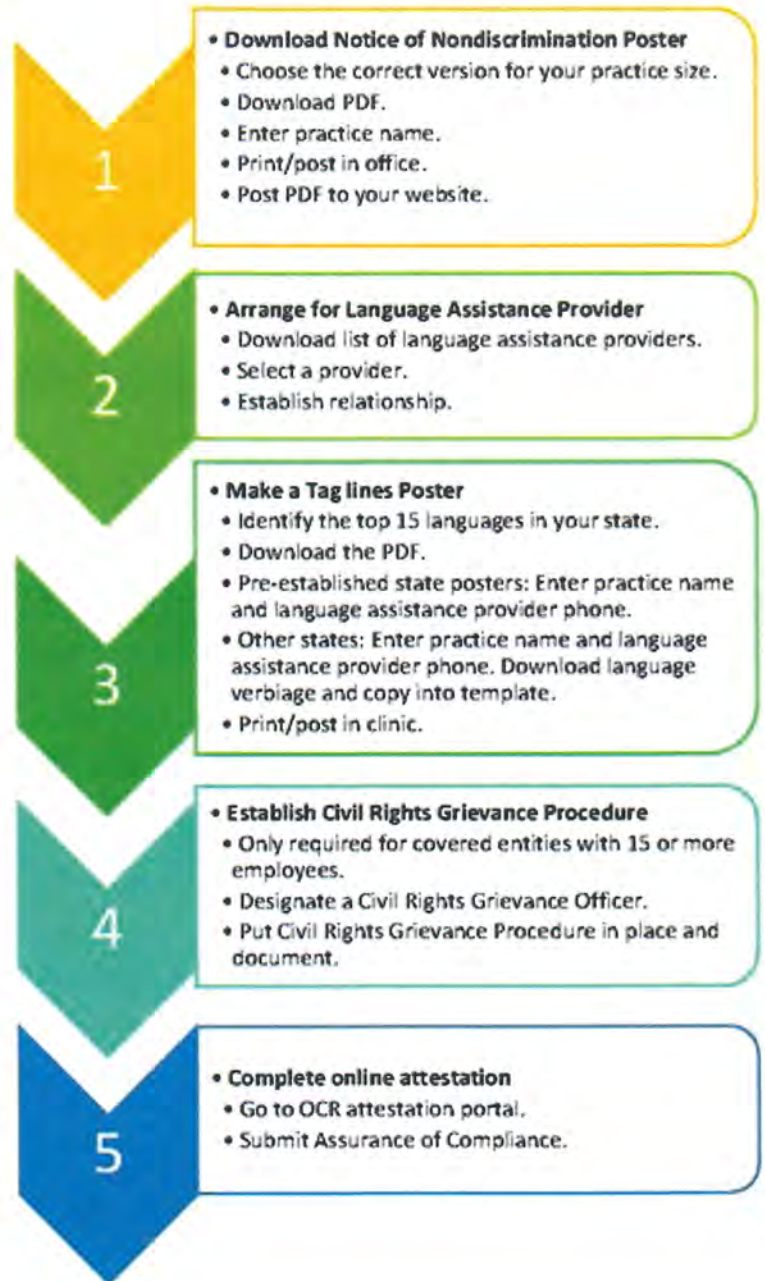
Day	Disinfect Bathroom	Mop All Bathrooms	Mop Lab	Vacuum	Empty Trash	Dust	Clean Glass
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
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12							
13							
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29							
30							
31							



ACA SECTION 1557 - ARE YOU IN COMPLIANCE?

Any practice that receives government funding (ie. Medicare Parts A, C & D [NOT B], Medicaid, Meaningful Use, etc.), you are **REQUIRED** to post information to be in compliance with Section 1557 of the Affordable Care Act (ACA) by Sunday, Oct. 16. All practices - regardless of practice size - are required to post the non-discrimination poster and the taglines poster, at minimum. Please read below for additional specifications regarding practices with 15 or more employees.

Section 1557 of the ACA contains an anti-discrimination provision. You may not discriminate in healthcare delivery based on a patient's race, color, national origin, sex, age or disability. You cannot delay or deny effective language assistant services to patient with limited English proficiency (LEP). These provisions apply to all patients in the US, legally or illegally. If your practice accepts payment from any HHS program or activity or an entity that HHS funds or you accept any Marketplace plans, this applies to YOU. Medicare Parts A, C & D (not Part B), Medicaid, Meaningful Use, etc) Patients can sue for NON-COMPLIANCE of this ruling. For complete 1557 Compliance resources go to <http://www.aonow.org/?page=1557>





Make sure you have this for all Employees

Health Care Professionals Hepatitis B Declination Statement

Hepatitis B Declination Statement*

The following statement of declination of hepatitis B vaccination must be signed by an employee who chooses **not to accept** the vaccine. The statement can only be signed by the employee following appropriate training regarding hepatitis B, hepatitis B vaccination, the efficacy, safety, method of administration, and benefits of vaccination, and that the vaccine and vaccination are provided free of charge to the employee. The statement is not a waiver; employees can request and receive the hepatitis B vaccination at a later date if they remain occupationally at risk for hepatitis B.

on Statement

and that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of a hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge. I decline hepatitis B vaccination at this time. I understand that by declining this vaccine I continue to be at risk for hepatitis B, a serious disease. If, in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge.

Signature: _____ Date: _____

*Taken from: *Bloodborne Pathogens and Acute Care Facilities*. OSHA Publication 3128, (1992).



Makes sure Consent to Treat Forms are all signed within one year. The Inspectors will review 20 charts to ensure compliance.

Name of RHC

General Consent for Care and Treatment Consent

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical or diagnostic procedure to be used so that you may make the decision whether or not to undergo any suggested treatment or procedure after knowing the risks and hazards involved. At this point in your care, no specific treatment plan has been recommended. This consent form is simply an effort to obtain your permission to perform the evaluation necessary to identify the appropriate treatment and/or procedure for any identified condition(s).

This consent provides us with your permission to perform reasonable and necessary medical examinations, testing and treatment. By signing below, you are indicating that (1) you intend that this consent is continuing in nature even after a specific diagnosis has been made and treatment recommended; and (2) you consent to treatment at this office or any other satellite office under common ownership. The consent will remain fully effective until it is revoked in writing. You have the right at any time to discontinue services.

You have the right to discuss the treatment plan with your physician about the purpose, potential risks and benefits of any test ordered for you. If you have any concerns regarding any test or treatment recommend by your health care provider, we encourage you to ask questions.

I voluntarily request a physician, and/or mid-level provider (Nurse Practitioner, Physician Assistant, or Clinical Nurse Specialist), and other health care providers or the designees as deemed necessary, to perform reasonable and necessary medical examination, testing and treatment for the condition which has brought me to seek care at this practice. I understand that if additional testing, invasive or interventional procedures are recommended, I will be asked to read and sign additional consent forms prior to the test(s) or procedure(s).

I certify that I have read and fully understand the above statements and consent fully and voluntarily to its contents.

Signature of Patient or Personal Representative

Date

Printed Name of Patient or Personal Representative

Relationship to Patient



Emergency Preparedness

The **Centers for Medicare & Medicaid Services (CMS)** requires **Rural Health Clinics** to be in compliance with **all components** of the Emergency Preparedness final rule: **42 CFR Part 491.12**. These components **include but are not limited to** the following:

Risk assessment and emergency planning: An “all-hazards” risk assessment was performed, and essential components of this assessment have been integrated into the emergency preparedness plan and planning.

1. _____ Date the most recent “all hazards” assessment was performed or updated.

2. _____ Date the most recent review (revision, if applicable) of the emergency plan.

Policies and Procedures: The facility has developed Policies and Procedures to promote and support the successful outcome of the emergency plan.

3. _____ Date the most recent review (revision, if applicable) of the Emergency Policies and Procedures.

Communication Plan: The facility has developed and maintains a comprehensive emergency preparedness communication plan. The communication plan is fully coordinated within the facility, with state and local emergency management agencies, and with other healthcare providers as necessary.

4. _____ Date the most recent review (revision, if applicable) of the Communication Plan.

Training and Testing: The facility developed and maintains a training and testing program for emergency preparedness. The program includes initial training of staff and involves personnel as well as refresher courses, drills and exercises. The program includes methods to identify areas of the plan that need improvement and the processes and procedures to enact those improvements. *Dates within this section may only be used once and must be within the previous 12 calendar months. To be considered compliant, providers must submit two test dates or one test date along with a date the facility emergency plan was activated.*

5. _____ and _____ Dates of the most recent tests.

6. _____ Date of the most recent training of staff on Emergency Preparedness

Contact with Local EMA Official regarding of Emergency Preparedness: The facility is knowledgeable of how to contact the local EMA Director and has consulted with them regarding the content of their emergency preparedness plans.

7. _____ Date of the most recent contact with local EMA Director.

For Resources to complete the Emergency Preparedness Process contact Mark Lynn at marklynnrhc@gmail.com or go to <http://www.ruralhealthclinic.com/emergency-preparedness>.



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Preparing for the RHC Certification Inspection

RHC Mock Inspection Report



RURAL HEALTH CLINIC

NAME OF RHC

RHC MOCK INSPECTION REPORT



502 SHADOW PARKWAY, SUITE 214
CHATTANOOGA, TENNESSEE 37421
TELEPHONE: (423)243-6185
MARKLYNNRHC@GMAIL.COM



INTRODUCTION

On Date of Inspection, Mark R. Lynn, CPA (inactive) conducted a mock inspection for compliance with RHC regulations and preparedness for the licensure survey from AAAASF and as an integral part of the program evaluation required by the RHC Conditions of Participation.

We conducted a mock inspection of the rural health clinic, reviewed the RHC policy and procedure manual, and discussed preventive services with the clinic care coordinator. The results of the mock inspection are color-coded in the following 20-page checklist. Please take special notice of those items in Yellow and Red. Those items are currently out of compliance with RHC regulations and require some attention to pass the RHC inspection.

COLOR STATUS DESCRIPTION
NO COLOR – STATUS IS GOOD. ITEM HAS BEEN CORRECTED OR IS READY FOR SURVEY.
YELLOW – THE ITEM REQUIRES ATTENTION TO PASS THE SURVEY WITHOUT DEFICIENCIES: HOWEVER, IT WILL NOT RISE TO THE LEVEL OF A CONDITION LEVEL DEFICIENCY.
RED – THE ITEM REQUIRES ATTENTION TO PASS THE SURVEY WITHOUT DEFICIENCIES AND WILL RISE TO THE LEVEL OF A CONDITION LEVEL DEFICIENCY. ITEM SHOULD BE REVIEWED CLOSELY.

We have formed a Facebook group to share information and ask questions regarding RHCs. This site will include links to documents and current (daily) updates regarding RHCs, Medicare, billing, and other important topics to RHC providers and personnel. **The Office Manager should join this group to keep apprised on changes to the RHC program, educational webinars, and seminars. Here is the link:**

RHC Information Exchange Group on Facebook
<https://www.facebook.com/groups/1503414633296362/>

"A place to share and find information on RHCs."



Executive Summary

Clinic Name: NAME OF RHC
Rural Health Clinic Survey – Mock Inspection Form
Date: Date of Inspection

This Executive Summary is prepared to list the additional items to be completed to be prepared for the RHC Inspection. Additionally, refer to the two page report called RHC Certification – Compliance and Inspection report.

Number	Recommendations or Items to Implement	Responsibility	Status
1	Print SDS Sheets. See OSHA Manual we have provided and several sheets of paper in the front of the manual.		
2	The RHC should have an OSHA approved eye wash station and that station should be checked weekly.		
3	Call the Biomedical company (Renew) and have all medical equipment calibrated.		
4	Section 1557 Compliance. Go to the following website http://www.aoanow.org/?page=1557 and follow the instructions.		
5	Emergency Kit. Have Review what is needed in the emergency kit and obtain a tackle box of minimal drugs to respond to an emergency.		
6	Prepare copies of documents asked for by the RHC Inspector. Have one copy for the inspector and one copy for the clinic. Place in Expandable Folders		
7	See Mock Inspection Report for items in Yellow. Please do the items in yellow and complete the Evidence Binder as indicated in Number 6 above.		



Compliance with Federal, State and Local Laws

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level One
 Date: **Date of Inspection**

J3: Compliance with Federal, State and Local Laws. The RHC and its staff are following applicable federal, state and local laws. The clinic is license pursuant to applicable state and local laws and regulations.

GENERAL				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J3	The RHC and its staff are following applicable Federal, State, and local laws. 491.4			
	Hours or operation are posted on the outside of the clinic. 491.4 (a)			
J5	All clinical staff have current BLS certificates on file 491.4 (b)			
J5	Personnel files include employee application, resume, current license, certificates, employment forms, performance appraisal, and I-9 forms.			
J62.3	If patients are allowed into the clinic prior to a provider being on the premises, all current BLS certificates are on file for clerical staff.			



Location of Clinic

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level Two
 Date: **Date of Inspection**

J8: The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic are housed in a permanent structure. If clinic services are regularly furnished at permanent unites in more than one location, each unit will be independently considered for certification as a rural health clinic.

J9: The objects, equipment, and the supplies necessary for the provision of the services furnished directly by the clinic are housed in a mobile structure, which has a fixed scheduled location.

J10: The facility meets location eligibility in a rural health shortage area through either of the following exceptions:

- 1) The area in which it is located subsequently fails to meet the definition of 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 in on July 1, 1977, it was operating in a rural area that is determined by the Secretary (based on the ratio of primary care physicians to general population) to have an insufficient supply of physicians to meet the needs of the area served.

LOCATION OF CLINIC				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J13	The facility meets rural area requirements under one of the following criteria:			
J14	1) Rural areas not delineated as urbanized areas in the last census conducted by the Census Bureau.			
J15	2) Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural.			
J16	The facility meets the shortage area requirements under one of the following criteria.			
J17	1) Clinic location is in current HPSA.			
	2) Determination of shortage of primary medical care.			
	3) Clinic is in a MUA that has been updated with the last 4 years.			
	4) The Governor has designated an area as eligible.			



Physical, Plant, and Environment Hallways

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level Three
 Date: **Date of Inspection**

J20: 491.6 (a) Physical Plant and Environment – Construction. The clinic is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

HALLWAYS				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J20.1	Clinic is handicapped accessible. See Handicapped Codes for more info.			
J20.2	Exit doors and signage are in the appropriate places.			
J20.3	Clinic does not have any exposed building materials. (i.e., insulation, holes in walls, etc.)			
J20.4	Fire extinguishers are inspected monthly and annually by an outside fire professional company or personnel with appropriate training.			
J20.5	Emergency exit routes are free of barriers.			
J20.6	Exit signs are appropriately placed.			
J20.7	Exit door(s) prevent unauthorized access from the outside but allows emergency exit from within.			
J20.8	Secondary doors are locked at all times.			
J20.9	Shatter proof light bulbs are used for all exposed lights.			
J20.10	Overhead ceiling lights are free of bugs and debris.			
J20.15	Floor plans were posted throughout the clinic.			
J24.3	Flooring is free from hazards.			
J24.4	Patient restrooms are free of staffs' personal hygiene products.			
J24.5	The clinic is free of clutter.			
J24.6	Hallway exits are free of obstructions.			



Physical, Plant, and Environment Patient Rooms

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level Three
 Date: **Date of Inspection**

J20: 491.6 (a) Physical Plant and Environment – Construction. The clinic is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

PATIENT ROOMS				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J20.12	Plug protectors were present in outlets.			
J20.13	Sharps are secured throughout clinic – should be attached to the wall and high enough so children cannot reach.			
J20.16	Treatment trays are free of dust and debris.			
J20.17	Nothing under the exam room sinks.			
J20.18	Closed trash containers are utilized in patient care areas and biohazard stickers are placed on hazardous waste baskets.			
TCT	Clinic has written cleaning policies and procedures for patient rooms.			
TCT	Equipment is cleaned and disinfected prior to each patient's use.			
TCT	No equipment is located/stored on the floor.			
TCT	Clinic has documented universal precautions and training on hand washing (sinks, alcohol-based gels, signs, etc) and the utilization of gloves.			
TCT	Clinic has an OSHA Spill Kit and Eye Wash faucet.			



Physical, Plant, and Environment Preventative Maintenance

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level Three
 Date: **Date of Inspection**

J21/J22: Physical Plant and Environment – Maintenance. The clinic has a preventative maintenance program to ensure that: All essential mechanical, electrical, and patient care equipment is maintained in safe operating conditions.

PREVENTATIVE MAINTENANCE				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J22.1	Written equipment management policy includes a listing of equipment, how the equipment is organized, labeled, and tested. No equipment is on the floor.			
J22.2	Adult and pediatric scales are balanced at least annually.			
J22.3	Patient care equipment is appropriately calibrated per manufacturer’s guidelines.			
J22.4	AED is maintained and tested in accordance with manufacturer recommendations.			
J22.5	Equipment testing log or checklist is current and available to the surveyor.			
TCT	Clinic has written cleaning policies and procedures for equipment.			
TCT	Clinic has a list of all equipment by manufacturer, model, and serial number.			
TCT	Clinic has a process for tracking preventive maintenance due dates.			



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Physical, Plant, and Environment Drugs and Biologicals

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level Three
 Date: **Date of Inspection**

J23: Drugs and biologicals are appropriately stored.

DRUGS AND BIOLOGICALS				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J23.1	All medications are stored in locked cabinets, cupboards, and/or drawers. No patient access.			
J23.2	Medications are locked up at the end of each day.			
J23.3	Medications, biological, and sterile supplies are inventoried monthly for expiration date.			
J23.4	Multi-injectable vials, ointments, and solutions are dated when opened and discarded in accordance with hospital or clinic policy.			
J23.5	Expired medications, biologicals, and supplies are discarded in accordance with hospital or clinic policy.			
J23.6	Refrigerator and freezer temperatures are recorded daily; and twice daily if storing vaccines. (VFC)			
J23.7	The clinic does not store medications in the door of the refrigerator or freezer.			
J23.8	Sample medications are logged out when dispensed to include: Date, Patient Name, Medication, Lot #, Expiration Date, Amt. Dispensed, and NDC #.			
J23.9	Controlled substances are inventoried on a weekly basis and stored dispensed in accordance with State Pharmacy regulations.			



Physical, Plant, and Environment Emergency Procedures – Drills

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level Three
 Date: **Date of Inspection**

J25: Physical Plant and Environment – Emergency Procedures. The clinic assures the safety of patients in case of non-medical emergencies by:

J26 Training staff in handling emergencies.

J28: Taking other appropriate measures that are consistent with the conditions of the area in which the clinic is located.

DRILLS & EDUCATION				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J26.1	All staff have participated in emergency training, i.e. fire, evacuation, tornado, acts of terrorism.			
J26.2	Training is documented.			
J26.3	Staff clearly understands their role in the event of an emergency.			
J28.1	Clinic has a tornado evacuation plan.			
TCT	Clinic has personal protective equipment available.			
TCT	Clinic has documented universal precautions and training.			
TCT	Clinic has procedures in place for handling and disposing of infectious waste and how to prevent cross-contamination.			
TCT	Clinic has an organized process for handling on-site and off-site emergencies.			



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Organizational Structure

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level Four
 Date: **Date of Inspection**

- J31: The clinic is under the medical direction of a physician, and has a health care staff that meets the requirements of 491.8.
- J32: The organization’s policies and its lines of authority and responsibilities are clearly set forth in writing.
- J33: The clinic discloses the names and addresses of:
 - J34: Its owners in accordance with Section of the Social Security Act.
 - J35: The person principally responsible for directing the operation of the clinic
 - J36: The person responsible for medical direction

ORGANIZATIONAL STRUCTURE				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J31.1	The medical director is identified.			
J31.2	Staff can identify the clinic’s medical director.			
J32	The clinic organizational chart is current.			
J34	The clinic discloses the names and addresses of its owners in accordance with Section of the Social Security Act.			
J35.1	The practice administrator is clearly identified.			
J35.2	All staff can identify the practice administrator by name.			



Staffing and Staff Responsibilities

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level Five
 Date: **Date of Inspection**

J5: Licensure, certification or registration personnel. Staff of the clinic are licensed, certified or registered in accordance with applicable State and local laws.

J39: The clinic has a health care staff that includes one or more physicians and one or more physician’s assistants or nurse practitioners. The staff meets the following requirements.

STAFFING AND STAFF RESPONSIBILITIES				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J39.1	Clinic physicians are identified.			
J39.2	Clinic physician assistant/nurse practitioners are identified.			
J40.1	Nurse practitioner holds a current state license as a nurse practitioner, if applicable.			
J40.2	Physician assistant holds a current state license as a physician assistant, if applicable.			
J40.3	All physician assistants/nurse practitioners have either a supervisory or collaboration agreement with the supervising/collaborating physician.			
J41.1	A physician, physician’s assistant or nurse practitioner is scheduled at all times during patient care hours.			
J41.2	The physician assistant/nurse practitioner is scheduled to see clinic patients at least 50% of the patient care hours.			
J42.1	The clinic’s schedule reflects appropriate staffing levels.			



Staffing and Staff Responsibilities Medical Director Responsibilities

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level Five
 Date: **Date of Inspection**

J45: Physician responsibilities:

J46: The physician provides medical direction for the clinic’s health care activities and consultation for, and medical supervision of the health care staff.

J47: The physician participates in developing, executing, and periodically reviewing the clinic’s written policies and the services provided to Federal program patients.

J48: The physician periodically reviews the clinic’s patient records, provides medical orders, and provides medical care services to the patients of the clinic.

J49: A physician is present for sufficient periods of time at least once every 2-week period (except in extraordinary circumstances), to provide medical direction, medical care services, consultation, and supervision, and is available through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the clinic.

MEDICAL DIRECTOR RESPONSIBILITIES				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J47.1	A physician participated in the development and review of the clinic’s policies.			
J47.2	The physician’s participation is documented.			
J48.1	The physician has reviewed 15 DOS of each nurse practitioner at least quarterly.			
J48.2	The review is documented and shared with the nurse practitioner.			
J48.3	The documentation is kept separate from the medical record with the clinic’s QAPI records.			
J49.1	Physician meets state requirements for time spent on site.			
J49.2	The physician is scheduled to see patients while at the clinic.			
J49.3	The physician reviews the documented care of the Mid-level practitioner.			



Staffing and Staff Responsibilities Physician’s Assistant and Nurse Practitioner Responsibilities

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level Five
 Date: **Date of Inspection**

J51: The physician’s assistant and the nurse practitioner members of the clinic’s staff: (i) participated in the development execution and periodic review of the written policies governing the services the clinic furnishes; (ii) provide services in accordance with those policies; (iii) arrange for, or refer patients to needed services that cannot be provided at the clinic; (iv) assure that adequate patient health records are maintained and transferred as required when patients are referred ; and (v) participates with a physician in a periodic review of patient’s health records.

PHYSICIAN’S ASSISTANT AND NURSE PRACTITIONER RESPONSIBILITIES				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J51.1	A physician’s assistant or nurse practitioner participated in the development and review of the clinic’s policies.			
J51.2	The physician assistant/nurse practitioner’s participation is documented.			
J51.3	The physician assistant/nurse practitioner participated with the physician in the medical record review. If the review didn’t happen jointly, the physician’s findings were shared with the physician assistant/nurse practitioner.			



Provision of Services

Clinic Name: **NAME OF RHC**
 Rural Health Clinic Survey – Mock Inspection Form
Condition Level Six
 Date: **Date of Inspection**

J53: Basic requirements. The clinic is primarily engaged in providing outpatient health services.

J55: The clinic’s health care services are furnished in accordance with appropriate written policies

J56: The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician’s assistants or nurse practitioners. At least one member of the group is not a member of the clinic’s staff.

J57: 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 the health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic; and (iii) rules for the storage, handling and administration of drugs and biologicals.

J58: These policies are reviewed at least annually by the group of professional personnel.

J60: The clinic staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician’s office or at the entry point into the healthcare delivery system. These include medical history physical examination, assessment of health status, and treatment for a variety of medical conditions.

PROVISION OF SERVICES				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J55.1	Written policies are consistent with clinic operations.			
J56.1	The Advisory Group has met within the past 12 months to review the clinic’s policies.			
J56.2	The Group includes a community representative.			
J57	The policies include medical guidelines and program evaluation/QAPI.			
J60	Clinic policy identifies all the services that are performed onsite through the clinic by clinic providers and personnel either as employees or as contract services.			



Provision of Services Laboratory and Emergency Services

Clinic Name: **NAME OF RHC**

Rural Health Clinic Survey – Mock Inspection Form

Condition Level Six

Date: **Date of Inspection**

J61: Laboratory: The clinic provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including (i) chemical examinations of urine by stick or tablet methods or both (including urine ketones); (ii) hemoglobin or hematocrit; (iii) blood sugar; (iv) examination of stool specimens for occult blood; (v) pregnancy test; and (vi) primary culturing for transmittal to a certified laboratory.

J62: 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 biological commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes, and emetics, serums and toxoids.

LABORATORY AND EMERGENCY SERVICES

JTag	Compliance Item Reviewed	Pass	To Do	Comments
J61.1	External controls are performed on all CLIA waived tests, if applicable.			
J61.2	External control results are logged.			
J61.3	The clinic has the equipment and supplies to perform hemoglobin or hematocrits.			
J61.4	Lab supplies and reagents are inventoried monthly. Expired supplies are disposed of via the bio-hazard receptacle.			
J61.5	The clinic has the ability to perform:			
	Urinalysis			
	Blood Glucose			
	Hemoglobin or Hematocrit			
	Occult Stool			
	Pregnancy			
	Primary Culturing			
J61.6	Lab work surface is clearly marked as “Non-Sterile” or “Sterile”.			
J61.7	The clinic has a process for tracking labs that are referred out.			



JTag	Compliance Item Reviewed	Pass	To Do	Comments
J62.1	The clinic has emergency drugs for each of the following drug classifications:			
	Analgesics			Make sure
	Anesthetics (local)			To have an
	Antibiotics			Emergency Kit
	Anticonvulsants			With medicines
	Antidotes			For a first response
	Emetic			To a medical
	Serums			emergency.
	Toxoids			
J62.2	All clinical staff have current BLS certifications on file.			Make sure ALL staff has current BLS certifications.
J62.3	If patients are allowed into the clinic prior to a provider being on the premises, clerical staff have current BLS certification on file.			
J62.4	Clinic has a spill kit – all staff is aware of its location.			



Patient Health Records

Clinic Name: **NAME OF RHC**

Rural Health Clinic Survey – Mock Inspection Form

Condition Level Seven

Date: **Date of Inspection**

PATIENT HEALTH RECORDS				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J69	The medical policies clearly state who is ultimately accountable for the medical records.	√		
J70	For each patient receiving health care services the clinic maintains a record that includes, as applicable:	√		
	(i) Identification of social data, evidence of consent forms, pertinent medical history, assessment of health status and health care needs of the patient, and a summary of the episode, disposition, and instructions to the patient;	√		REMEMBER: Consent to Treat and HIPAA must be updated annually.
	(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.	√		
J71	The clinic has a confidentiality policy and policies that governs the storage and handling of PHI.	√		
J72.1	The clinic has a patient authorization for release policy.	√		
J73.2	The clinic has all appropriate HIPAA policies related to release of information to:			
	(i) Government entities	√		
	(ii) Law Enforcement	√		
	(iii) Friends and family	√		
	(iv) Other providers involved in treatment via facsimile	√		
	(v) When transporting records from one facility to another	√		
J74	The clinic has a patient authorization for release policy.	√		
J75	The clinic's policy is consistent with state law as pertains to the retention of records.	√		



Program Evaluation

Clinic Name: **NAME OF RHC**

Rural Health Clinic Survey – Mock Inspection Form

Condition Level Eight

Date: **Date of Inspection**

PROGRAM EVALUATION				
JTag	Compliance Item Reviewed	Pass	To Do	Comments
J77	A program evaluation was completed within 12 months.			
J79	A review of the clinic's utilization of services has been performed in the past 12 months that includes:			
J80.1	The clinic's documentation meets the compliance requirements as outlined in J70.			
	(i) Identification and social data			
	(ii) Evidence of consent forms			
	(iii) Pertinent medical history			
	(iv) Assessment of health status and patient needs			
	(v) Summary of the episode, disposition, and instructions to the patient			
	(vi) Reports of physical examinations, diagnostic and laboratory test results, and findings			
	(vii) All physician's orders, reports of treatments and medications and other pertinent information necessary to monitor the patient's progress			
	(viii) Signatures of the physician or others			
J80.2	A summary of the findings has been presented to the Advisory Group within the past 12 months with recommendations for consideration and approval.			
J81.1	The clinic's policies have been reviewed by the clinic's staff and changes have been made as appropriate.			
J81.2	The policies and recommended changes have been presented to the Advisory Group within the past 12 months for consideration and approval.			
J83	The Advisory Group has reviewed this and found utilization to be appropriate.			
J84	The Advisory Group has reviewed this and found that policies were followed.			
J85	Based on the review of utilization of services and clinic policies, changes were made, if applicable.			
J86	Corrective action was taken, if applicable.			



Preparing for the RHC Certification Inspection

RHC Survey Procedures from Appendix G



RHC Inspection Checklist – Survey Procedures

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. The following bullet points from the Interpretative Guidelines for RHCs issued in January 2018 are the source for these procedures. Here is the link:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf

Credentialing 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.
- Review a sample of personnel files of clinical staff to verify that licensure or other required credential information is present and up to date.

Medical Director 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 and has at least one patient visit per year.

Organizational 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 and the names and addresses of the required disclosures are available in the RHCs written records.



Preventive Maintenance Interpretative Guidelines

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.

Physical Plant 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.

Preventive Maintenance 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.



Drugs and Medications -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.

Drugs and Medications Survey Procedures § 491.6(b)(2)

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

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?

Medication Storage



Secured/Organized In Original Containers, Not Expired/Past BUD, No MDV in Immediate Treatment Areas, SDV contents Not Saved



Laboratory

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 offsite 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.

Top 10 Infection Control Tips for Facilities Managers



Cleanliness -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.

As a resource, applicable questions from Part 2 of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf , 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.



First Response to a Medical Emergency

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.

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?



NP/PA 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.

Hours of Operation - 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.

Ancillary Personnel - 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.

Ancillary Personnel -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.



Staffing - 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.

Licensed Providers and Staff

Licensed Staff Member	State of Origin License # (or Certificate #)	Expiration Date	DEA Certificate # (as applicable)	Expiration Date	BLS Exp For Licensed and Certified Patient Care Personnel	Verification & copies of professional license, registration and/or certification is maintained if applicable.



Medical Director 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?

The Medical Director of the Rural Health Clinic should do the following:

- a. Supervise and collaborate with the Nurse Practitioner/ Physician Assistant in accordance with State scope of practice regulations in the state.
- b. Review and sign Nurse Practitioner/Physician Assistant protocols with the NP/PA provider on an annual basis.
- c. Review at least 15 charts per Nurse Practitioner/ Physician Assistant per quarter, communicate those results to the Nurse Practitioner/ Physician Assistant and sign the document that indicates the review took place. Review both active and closed charts. See Examples of Chart Audit Forms.
- d. Participate in the Clinic's needs assessment, quality assurance, utilization review and peer review programs.
- e. Review the RHC Policy and Procedure manual on an annual basis and sign the signature page indicating the review took place.
- f. Participate and review the annual evaluation or program evaluation process and sign the signature page indicating participation.
- g. Review and participate in the development in policies, procedures, training, and drills regarding emergency preparedness especially related to medical emergencies and the proper procedures to be followed in case of a medical emergency and provide guidance on the types of emergency drugs to be maintained at the rural health clinic.

Medical Director - 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?

REFERRAL



Referrals - 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.

Referrals - Survey Procedures § 491.8(c)(2)

- Ask the RHC for the RHC's policies governing which services may be provided by an NP/PA, whether there are any RHC services that are outside the scope of practice of an NP/PA.
- Interview NPs/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?

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.



Provision of Services - 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.

Provision of Services - 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.



Policies and Procedures-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?

Patient Care Policies - 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?



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.

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?

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?

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.

Here is a sample Chart Audit Form that should be used each quarter to record medical record reviews.

Patient Health Records

Medical Record Audit Tool Insert "Y" (YES) if evidence is found, "N" (NO) if evidence of is missing, or "NA" if not applicable. Insert an "M" next the patient number if the patient is a minor child.								
Patient	Patient ID & Social Data	Written Consent to Treat	Medical History	Health Status & Patient Health Needs	Summary & Patient Instructions	Labs Diagnostics & Consult Info	Physicians' Orders & Treatments & Medications (includes allergies)	Signature of Provider & Date
1.								
2.								
3.								
4.								



Program Evaluation

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.

Annual Evaluation - 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?

For More Information

For additional Resources contact Mark Lynn at (423) 243-6185 or marklynnrhc@gmail.com or go to:

- <http://www.ruralhealthclinic.com/certification-materials>
- <http://www.ruralhealthclinic.com/resources/>

For Recordings of our webinars, go to https://www.youtube.com/channel/UCXW4pkwNzDXVTMFrFwMy2_A and subscribe to our YouTube Channel.

Please join our Facebook Group which currently has over 550 members. This is where we post updated RHC information, resources and files to use in managing your rural health clinic, announcements of Technical Assistance webinars, HBS webinars, and HBS seminars.

<https://www.facebook.com/groups/1503414633296362/>



The Centers for Medicare & Medicaid Services (CMS) requires Rural Health Clinics to be in compliance with all components of the Emergency Preparedness final rule: 42 CFR Part 491.12. These components include but are not limited to the following:

Risk assessment and emergency planning: An “all-hazards” risk assessment was performed, and essential components of this assessment have been integrated into the emergency preparedness plan and planning.

- 1. _____ Date the most recent “all hazards” assessment was performed or updated.
- 2. _____ Date the most recent review (revision, if applicable) of the emergency plan.

Policies and Procedures: The facility has developed Policies and Procedures to promote and support the successful outcome of the emergency plan.

- 3. _____ Date the most recent review (revision, if applicable) of the Emergency Policies and Procedures.

Communication Plan: The facility has developed and maintains a comprehensive emergency preparedness communication plan. The communication plan is fully coordinated within the facility, with state and local emergency management agencies, and with other healthcare providers as necessary.

- 4. _____ Date the most recent review (revision, if applicable) of the Communication Plan.

Training and Testing: The facility developed and maintains a training and testing program for emergency preparedness. The program includes initial training of staff and involves personnel as well as refresher courses, drills and exercises. The program includes methods to identify areas of the plan that need improvement and the processes and procedures to enact those improvements. *Dates within this section may only be used once and must be within the previous 12 calendar months. To be considered compliant, providers must submit two test dates or one test date along with a date the facility emergency plan was activated.*

- 5. _____ and _____ Dates of the most recent tests.

- 6. _____ Date of the most recent training of staff on Emergency Preparedness

Contact with Local EMA Official regarding of Emergency Preparedness: The facility is knowledgeable of how to contact the local EMA Director and has consulted with them regarding the content of their emergency preparedness plans.

- 7. _____ Date of the most recent contact with local EMA Director.

For Resources to complete the Emergency Preparedness Process contact Mark Lynn at marklynnrhc@gmail.com or go to <http://www.ruralhealthclinic.com/emergency-preparedness>.



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Preparing for the RHC Certification Inspection

Infection Control for RHCs

Exhibit 351

Ambulatory Surgical Center (ASC) INFECTION CONTROL SURVEYOR WORKSHEET

(Rev: 142, Issued: 07-17-15, Effective: 07-17-15, Implementation: 07-17-15)

Name of State Agency or AO (please specify) _____

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (e.g., the staff person responsible for sterilization should answer the sterilization questions). A minimum of one surgical procedure must be observed during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases. When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS-2567 when deficient practices are observed.

PART 1 – ASC CHARACTERISTICS

1. ASC Name

2. Address, State and Zip Code

_____ Address
_____ City State Zip

3. 10-digit CMS Certification Number

□ □ □ □ □ □ □ □ □ □

4. What year did the ASC open for operation?

□ □ □ □
y y y y

5. Please list date(s) of site visit:

□ □ / □ □ / □ □ □ □ to □ □ / □ □ / □ □ □ □
m m d d y y y Y m m d d y y y y

6. What was the date of the most recent previous federal (CMS) survey:

□ □ / □ □ / □ □ □ □
m m d d y y y y

7. Does the ASC participate in Medicare via accredited "deemed" status? YES NO

7a. If YES, by which CMS-recognized accreditation organization(s)?

- Accreditation Association for Ambulatory Health Care (AAAHC)
- American Associate for Accred. of Ambulatory Surgery Facilities (AAAASF)
- American Osteopathic Association (AOA)
- The Joint Commission (TJC)

7b. If YES, according to the ASC, what was the date of the most recent accreditation survey?

		/			/				
m	m		d	d		y	y	y	y

8. What is the ownership of the facility? Physician-owned
(SELECT only ONE bubble)

Hospital-owned

National corporation (including joint ventures with physicians)

Other (please print):

--

9. What is the primary procedure performed at the ASC (i.e., what procedure type reflects the majority of procedures performed at the ASC)? (Select only ONE bubble)

- Dental
- Endoscopy
- Ear/Nose/Throat
- OB/Gyn
- Ophthalmologic
- Orthopedic
- Pain
- Plastic/reconstructive
- Podiatry

Other (please specify):

--

10. What additional procedures are performed at the ASC? (Select all that apply)

Do not include the procedure type indicated in question 9.

- Dental
- Endoscopy
- Ear/Nose/Throat
- OB/Gyn
- Ophthalmologic
- Orthopedic
- Pain
- Plastic/reconstructive
- Podiatry
- Other (please specify):
- N/A

--

11. Who does the ASC perform procedures on?

(Select only ONE bubble)

Pediatric patients only

Adult patients only

Both pediatric and adult patients

12. What is the average number of procedures performed at the ASC per month?

--	--	--	--	--	--

per month

13. How many Operating Rooms (including procedure rooms) does the ASC have?

- | | | | | | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9+ | |

Number actively maintained:

- | | | | | | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9+ | |

14. Please indicate how the following services are provided: **(fill in all that apply)**

	Contract	Employee	Other	If Other, Please print:
Anesthesia/Analgesia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Environmental Cleaning	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Linen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Nursing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Pharmacy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Sterilization/Reprocessing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Waste Management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

INFECTION CONTROL PROGRAM

15. Does the ASC have an explicit infection control program? YES
 NO

NOTE! If the ASC does not have an explicit infection control program, a condition-level deficiency related to 42 CFR 416.51 **must** be cited.

16. Does the ASC's infection control program follow nationally recognized infection control guidelines? YES
 NO

NOTE! If the ASC does not follow nationally recognized infection control guidelines, a deficiency related to 42 CFR 416.51(b) **must** be cited. Depending on the scope of the lack of compliance with national guidelines, a condition-level citation may also be appropriate.

16a. Is there documentation that the ASC considered and selected nationally-recognized infection control guidelines for its program? YES
 NO

NOTE! If the ASC cannot document that it considered and selected specific guidelines for use in its infection control program, a deficiency related to 42 CFR 416.51(b) **must** be cited. This is the case even if the ASC's infection control practices comply with generally accepted standards of practice/national guidelines. If the ASC neither selected any nationally recognized guidelines nor complies with generally accepted infection control standards of practice, then the ASC should be cited for a condition-level deficiency related to 42 CFR 416.51.

16b. If YES to (a), which nationally-recognized infection control guidelines has the ASC selected for its program?
(Select all that apply)

- CDC/HICPAC Guidelines:
 - Guideline for Isolation Precautions (CDC/HICPAC)
 - Hand hygiene (CDC/HICPAC)
 - Disinfection and Sterilization in Healthcare Facilities (CDC/HICPAC)
 - Environmental Infection Control in Healthcare Facilities (CDC/HICPAC)
- Perioperative Standards and Recommended Practices (AORN)
- Guidelines issued by a specialty surgical society / organization (List)

Please specify (please limit to the space provided):

- Others

Please specify (please limit to the space provided):

17. Does the ASC have a licensed health care professional qualified through training in infection control and designated to direct the ASC's infection control program? YES NO

NOTE! If the ASC cannot document that it has designated a qualified professional with training (not necessarily certification) in infection control to direct its infection control program, a deficiency related to 42 CFR 416.51(b)(1) must be cited. Lack of a designated professional responsible for infection control should be considered for citation of a condition-level deficiency related to 42 CFR 416.51.

17a. If YES, Is this person an: ASC employee
(Select only ONE bubble) ASC contractor

17b. Is this person certified in infection control (i.e., CIC) YES
(Note: §416.50(b)(1) does **not** require that the individual be certified in infection control.) NO

17c. If this person is **NOT** certified in infection control, what type of infection control training has this person received?

17d. On average, how many hours per week does this person spend in the ASC directing the infection control program? hours per week

(Note: §416.51(b)(1) does **not specify the amount of time the person must spend in the ASC directing the infection control program, but it is expected that the designated individual spends sufficient time on-site directing the program, taking into consideration the size of the ASC and the volume of its surgical activity.)**

18. Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC? YES

NOTE! If the ASC does not have a documented identification system, a deficiency related to 42 CFR 416.51(b)(3) must be cited. NO

18a. If YES, how does the ASC obtain this information?
(Select ALL that apply)

- The ASC sends e-mails to patients after discharge
- The ASC follows-up with their patients' primary care providers after discharge
- The ASC relies on the physician performing the procedure to obtain this information at a follow-up visit after discharge, and report it to the ASC
- Other (please specify):

18b. Is there supporting documentation confirming this tracking activity? YES
 NO

NOTE! If the ASC does not have supporting documentation, a deficiency related to 42 CFR 416.51(b)(3) must be cited.

18c. Does the ASC have a policy/procedure in place to comply with State notifiable disease reporting requirements? YES
 NO

NOTE! If the ASC does not have a reporting system, a deficiency must be cited related to 42 CFR 416.51(b)(3). CMS does not specify the means for reporting; generally this would be done by the State health agency.

19. Do staff members receive infection control training? YES

If training is completely absent, then consideration should be given to condition-level citation in relation to 42 CFR 416.51, particularly when the ASC's practices fail to comply with infection control standards of practice. NO

19a. If YES, how do they receive infection control training?
(Select all that apply)

- In-service
- Computer-based training
- Other (please specify):

19b. Which staff members receive infection control training?
(Select all that apply)

- Medical staff
- Nursing staff
- Other staff providing direct patient care
- Staff responsible for on-site sterilization/high-level disinfection
- Cleaning staff
- Other (please specify):

19c. Is training:

- the same for all categories of staff
- different for different categories of staff

19d. Indicate frequency of staff infection control training (Select all that apply)

- Upon hire
- Annually
- Periodically / as needed
- Other (please specify):

19e. Is there documentation confirming that training is provided to all categories of staff listed above?

- YES
- NO

NOTE! If training is not provided to appropriate staff upon hire/granting of privileges, with some refresher training thereafter, a deficiency **must be cited in relation to 42 CFR 416.51(b) and (b)(3).**

20. How many procedures were observed during the site visit?

- 1
- 2
- 3
- 4
- Other

If other, please specify the number:

procedures

PART 2 – INFECTION CONTROL & RELATED PRACTICES

INSTRUCTIONS:

- Please **select ONE bubble** for each “Was Practice Performed?” question, unless otherwise noted.
- If N/A *or unable to observe* is *selected as the* response, please explain why there is no associated observation, or why the question is not applicable, in the *surveyor notes* box. *Surveyors should attempt to assess the practice by interview or document review if unable to observe the actual practice during survey.*
- *During the survey, observations or concerns may prompt the surveyor to request and review specific policies and procedures. Surveyors are expected to use their judgment and review only those documents necessary to investigate their concern(s) or to validate their observations.*

I. Hand Hygiene

Observations are to focus on staff directly involved in patient care (e.g., physicians, nurses, CRNAs, etc.). Hand hygiene should be observed not only during the case being followed, but also while making other observations in the ASC throughout the survey.

Unless otherwise indicated, a “No” response to any question below **must be cited as a deficient practice in relation to 42 CFR 416.51(a).**

Practices to be Assessed	Was Practice Performed?	Surveyor Notes:
A. All patient care areas have <i>readily accessible, in appropriate locations</i> :		
a. Soap and water	<input type="radio"/> Yes <input type="radio"/> No	
b. Alcohol-based hand rubs	<input type="radio"/> Yes <input type="radio"/> No	
I. If alcohol-based hand rub is available in patient care areas, it is installed as required. (There are LSC requirements at 42 CFR 416.44(b)(5) for installation of alcohol-based hand rubs)	<input type="radio"/> Yes <input type="radio"/> No	
B. Staff perform hand hygiene:		
a. After removing gloves	<input type="radio"/> Yes <input type="radio"/> No	
b. Before direct patient contact	<input type="radio"/> Yes <input type="radio"/> No	
c. After direct patient contact	<input type="radio"/> Yes <input type="radio"/> No	
d. Before performing invasive procedures (e.g. placing an IV)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	

- e. After contact with blood, body fluids, or contaminated surfaces (even if gloves are worn) Yes
 No
 Unable to observe

C. Regarding gloves, staff:

- a. Wear gloves for procedures that might involve contact with blood or body fluids Yes
 No
 Unable to observe

- b. Wear gloves when handling potentially contaminated patient equipment Yes
 No
 Unable to observe

- c. Remove gloves before moving to the next tasks and/or patient Yes
 No
 Unable to observe

- D. *Personnel providing direct patient care do not wear artificial fingernails and/ or extenders when having direct contact with patients.* Yes
 No

II. Injection Practices (injectable medications, saline, other infusates)

Observations are to be made of staff preparing and administering medications and performing injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).

Unless otherwise indicated, a "No" response to any question below must be cited as a deficient practice in relation to 42 CFR 416.51(a).

If unable to observe is selected, please clarify in the surveyor notes box why it was not observed and attempt to assess by means of interview or documentation review.

NOTE: Some types of infection control breaches, including some specific to medication administration practices, pose a risk of bloodborne pathogen transmission that warrant engagement of public health authorities. When management review confirms that a survey has identified evidence of one or more of the breaches described in S&C: 14-36-All, in addition to taking appropriate enforcement action to ensure the deficient Medicare practices are corrected, the SA should also make the responsible State public health authority aware of the identified breach.

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. Needles are used for only one patient.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
B. Syringes are used for only one patient (<i>this includes manufactured prefilled syringes</i>).	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
C. The rubber septum on a medication, <i>whether unopened or previously accessed</i> , vial is disinfected with alcohol prior to piercing.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
D. Medication vials are always entered with a new needle.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
E. Medication vials are always entered with a new syringe	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
F. Medications that are pre-drawn are labeled with the date and time of draw, initials of the person drawing, medication name, strength and <i>beyond-use</i> date and time	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
NOTE: A "No" answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs		
G. a. Single dose (single-use) medication vials are used for only one patient	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
b. Bags of IV solutions are used for only one patient (<i>and not as a source of flush solution for multiple patients</i>).	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
c. Medication administration tubing and connectors are used for only one patient	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
<p>H. <i>The ASC has voluntarily adopted a policy that medications labeled for multi-dose use for multiple patients are nevertheless only used for one patient.</i></p>	<p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A</p>	
<p>(Fill in N/A if no multi-dose medications/infusates are used).</p>		
<p>(NOTE: a "No" answer to question H. does not indicate a breach in infection control practices and does not result in a citation. <i>However</i>, a "No" response to either or both of the related questions I and J should be cited).</p>		
<p>If YES, please skip to "K"</p>		
<p>If NO, you must also assess the practices at questions "I and J":</p>		
<p>I. Multi-dose vials are dated when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note: This is different from the expiration date for the vial. The multi-dose vial can be dated with either the date opened or the <i>beyond-use date</i> as per ASC policies and procedures, so long as it is clear what the date represents and the same policy is used consistently throughout the ASC.</p>	<p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i></p>	
<p>J. Multi-dose medication vials used for more than one patient are stored <i>appropriately</i> and <i>do not enter</i> the immediate patient <i>care area</i> (e.g., <i>operating room, anesthesia carts</i>).</p>	<p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i></p>	
<p><i>NOTE: If multi-dose vials enter the immediate patient care area, they must be dedicated for single patient use and discarded immediately after use.</i></p>		
<p>K. All sharps are disposed of in a puncture-resistant sharps container</p>	<p><input type="radio"/> Yes <input type="radio"/> No</p>	
<p>L. Sharps containers are replaced when the fill line is reached</p>	<p><input type="radio"/> Yes <input type="radio"/> No</p>	

III. Single Use Devices, Sterilization, and High Level Disinfection

Pre-cleaning must always be performed prior to sterilization and high-level disinfection

Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)

High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)

Observations are to be made of staff performing equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

Unless otherwise indicated, a "No" response to any question below must be cited as a deficient practice in relation to 42 CFR 416.51(a).

SINGLE-USE DEVICES

(Choose N/A if single-use devices are never reprocessed and used again) (Surveyor to confirm there is a contract or other documentation of an arrangement with a reprocessing facility by viewing it)

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. a. If single-use devices are reprocessed, they are devices that are approved by the FDA for reprocessing	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
b. If single-use devices are reprocessed, they are reprocessed by an FDA-approved reprocessor.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	

STERILIZATION

A. Critical equipment is sterilized	<input type="radio"/> Yes <input type="radio"/> No	
B. Are sterilization procedures performed on-site? (If NO, skip to "F")	<input type="radio"/> Yes <input type="radio"/> No	

(A "No" answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement.)

(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)

- a. If YES to B, please indicate method of sterilization:
- Steam autoclave
 - Peracetic acid
 - Other (please specify):

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
C. Items are pre-cleaned according to manufacturer's instructions or, <i>if the manufacturer does not provide instructions</i> , evidence-based guidelines prior to sterilization	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> <i>Unable to observe</i>	
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> <i>Unable to observe</i>	
b. A chemical indicator (<i>process indicator</i>) is placed <i>correctly, as described in manufacturer's instructions for use, in the instrument packs</i> in every load.	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> <i>Unable to observe</i>	
c. A biological indicator is <i>used</i> at least weekly <i>for each sterilizer and with every load containing implantable items, as evidenced by ASC documentation (i.e., log)</i> .	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> <i>Unable to observe</i>	
d. Each load is monitored with mechanical indicators (e.g. time, temperature, pressure)	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> <i>Unable to observe</i>	
e. Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load	<input type="radio"/> Yes <input type="radio"/> No	
E. Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> <i>Unable to observe</i>	
F. After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised	<input type="radio"/> Yes <input type="radio"/> No	
G. Sterile packages are inspected for integrity and compromised packages are reprocessed	<input type="radio"/> Yes <input type="radio"/> No	

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
<p>H. Is immediate-use steam sterilization (IUSS) performed on-site? If NO, skip to “High Level Disinfection Section”</p>	<p><input type="radio"/> Yes <input type="radio"/> No</p>	
<p>If YES, you must also assess the practices at questions “I - K”: (A “No” answer does not result in a citation)</p>		

I. If IUSS is performed, all of the following criteria are met:

- | | |
|---|---|
| <ul style="list-style-type: none"> • Work practices ensure proper cleaning and decontamination, inspection, and arrangement of the instruments into the recommended sterilizing trays or other containment devices before sterilization. | <p><input type="radio"/> Yes
 <input type="radio"/> No</p> |
| <ul style="list-style-type: none"> • Once clean, the item is placed within a container intended for immediate use. The sterilizer cycle and parameters used are selected according to the manufacturers’ instructions for use for the device, container, and sterilizer. | <p><input type="radio"/> Unable to observe
 <input type="radio"/> N/A</p> |
| <ul style="list-style-type: none"> • The sterilizer function is monitored with monitors (e.g., mechanical, chemical and biologic) that are approved for the cycle being used. | |
| <ul style="list-style-type: none"> • The processed item must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use, the sterile field in an ongoing surgical procedure. | |

Note: “Immediate use” is defined as the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile field. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another. IUSS is not equivalent to “short cycle” sterilization performed in accordance with manufacturers’ IFUs. IUSS must not be a routine or frequent practice in the ASC.

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
<p><i>J. Immediate-use steam sterilization is NOT performed on the following devices:</i></p> <ul style="list-style-type: none"> • <i>Implants.</i> • <i>Post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease or similar disorders.</i> • <i>Devices that have not been validated with the specific cycle employed.</i> • <i>Single-use devices that are sold sterile.</i> 	<input type="radio"/> Yes <input type="radio"/> No	
<p><i>K. Is IUSS performed on a routine basis?</i></p>	<input type="radio"/> Yes <input type="radio"/> No	

(A "Yes" answer must be cited as a deficient practice in relation to 42 CFR 416.51(a).)

HIGH-LEVEL DISINFECTION

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. Semi-critical equipment is high-level disinfected or sterilized	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
B. Is high-level disinfection performed on site? (If NO, Skip to "F")	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	

(A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.)

(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)

<p>a. If answer to B was YES, please indicate method of high-level disinfection:</p>	<input type="radio"/> Manual <input type="radio"/> Automated <input type="radio"/> Other (please specify):	<div style="border: 1px solid black; width: 100%; height: 40px;"></div>
<p>C. Items are pre-cleaned according to manufacturer's instructions or, <i>if the manufacturer does not provide instructions</i>, evidence-based guidelines prior to high-level disinfection</p>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	

Practices to be Assessed	Was Practice Performed?	<i>Surveyor Notes</i>
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
b. High-level disinfection equipment is maintained according to manufacturer instructions	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
c. Chemicals used for high-level disinfection are:		
I. Prepared according to manufacturer instructions	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
II. Tested for appropriate concentration according to manufacturer's instructions	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
III. Replaced according to manufacturer's instructions	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
IV. Documented to have been prepared and replaced according to manufacturer's instructions	<input type="radio"/> Yes <input type="radio"/> No	
d. Instruments requiring high-level disinfection are:		
I. Disinfected for the appropriate length of time as specified by manufacturer's instructions or, <i>if the manufacturer does not provide instructions</i> , evidence-based guidelines	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
II. Disinfected at the appropriate temperature as specified by manufacturer's instructions or, <i>if the manufacturer does not provide instructions</i> , evidence-based guidelines	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
E. Items that undergo high-level disinfection are allowed to dry before use	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
F. Following high-level disinfection, items are <i>placed</i> in a designated clean area in a manner to prevent contamination	<input type="radio"/> Yes <input type="radio"/> No	

IV. Environmental Infection Control

Observations are to be made of staff performing environmental cleaning (e.g., surgical technicians, cleaning staff, etc.)

If unable to observe is selected, please clarify in the surveyor notes box why it was not observed and attempt to assess by means of interview or documentation review.

Unless otherwise indicated, a "No" response to any question below must be cited as a deficient practice in relation to 42 CFR 416.51(a).

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
B. Operating rooms are terminally cleaned daily	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
C. <i>Environmental surfaces in patient care areas are cleaned and disinfected, using an EPA-registered disinfectant on a regular basis (e.g., daily), when spills occur and when surfaces are visibly contaminated.</i>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
D. The ASC has a procedure in place to decontaminate gross spills of blood.	<input type="radio"/> Yes <input type="radio"/> No	

V. Point of Care Devices (e.g., blood glucose meter)

Observations are to be made of staff *performing* fingerstick testing (e.g., nurses)

If *unable to observe* or N/A is selected, please clarify in the *surveyor notes* box why it was not observed or applicable *and attempt to assess by means of interview or documentation review.*

Unless otherwise indicated, a "No" response to any question below must be cited as a deficient practice in relation to 42 CFR 416.51(a).

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
1. Does the ASC <i>use</i> a point-of-care <i>testing</i> device, such as a blood glucose meter? If NO, STOP HERE.	<input type="radio"/> Yes <input type="radio"/> No	

Practices to be Assessed	Was Practice Performed?	<i>Surveyor Notes</i>
A. <i>Hand hygiene is performed before and after performing a finger stick procedure to obtain a sample of blood and using the point-of-care testing device.</i>	<input type="radio"/> Yes <input type="radio"/> No	
B. <i>Gloves are worn by health care personnel when performing a finger stick procedure to obtain a sample of blood, and are removed after the procedure (followed by hand hygiene).</i>	<input type="radio"/> Yes <input type="radio"/> No	
C. <i>Finger stick devices are not used for more than one patient.</i>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <i>Unable to observe</i>	
<i>NOTE: This includes both the lancet and the lancet holding device.</i>		
D. <i>If used for more than one patient, the point-of-care testing device (e.g., blood glucose meter, INR monitor) is cleaned and disinfected after every use according to the manufacturer's instructions.</i>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
<i>NOTE: if the manufacturer does not provide instructions for cleaning and disinfection, then the device should not be used for >1 patient.</i>		