

Understanding and Implementing RHC Rules and Regulations

**2021 Kentucky Rural
Health Clinic Virtual
Summit**

July 23, 2021



Discussion Points

What is Regulatory Compliance?

Where do I find the regulations?

What Policies and Procedures does an RHC need?

How do I stay on top of it all?

What are the top Kentucky RHC Deficiencies?

What exactly is Compliance ?

Regulatory Compliance is adherence to guidelines and requirements which are established by federal, state, and local laws. For Medicare & Medicaid providers, and RHCs, there is both general compliance and facility-specific compliance.



Rules and Regulations

Healthcare is a regulated industry.

Rural Health Clinics are a CMS certified facility type.

The framework for compliance already exists in the federal regulations that created RHCs.

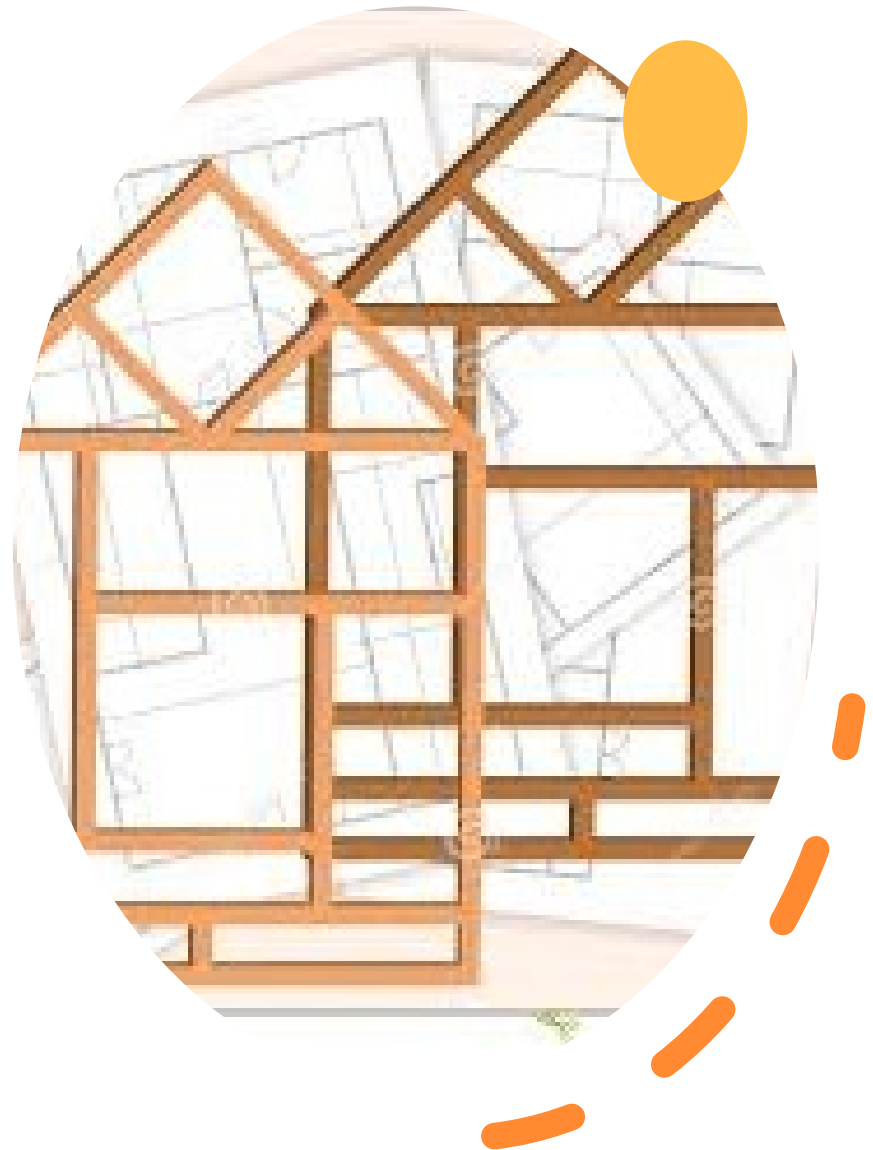


Where do
you start ?



Use the regulations as a compliance blueprint.

- Would you plan a house without a blueprint?
- Would your contractor build the house without ever looking at the plans?
- Federal, State and Local Regulations are the blueprint for any type of facility's compliance.



Federal RHC/FQHC Regulations

- 42 CFR §491

Conditions for certification

- 42 CFR §405

Subpart X

- 42 CFR §413.65

Provider Based Status



Federal Hospital Regulations



- 42 CFR §482
Conditions of Participation
- 42 CFR §412
Inpatient PPS System
- 42 CFR §419
Outpatient PPS System

Federal Regulations Critical Access Hospitals



- **42 CFR §485**

Subpart F

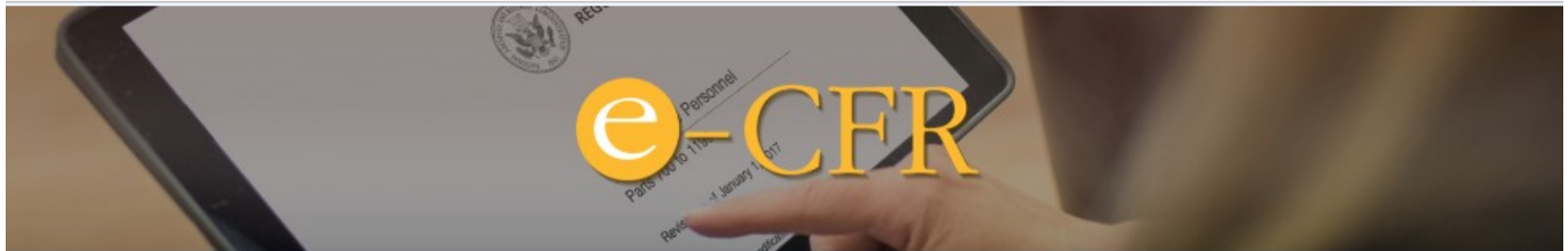
Conditions of Participation

Federal Regulations

Medicare Program



- **42 CFR §405**
Federal Healthcare for the Aged and Disabled
- **42 CFR §420**
Program Integrity-Medicare
- **42 CFR §455**
Program Integrity- Medicaid



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The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. They are CMS' program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives. The CMS program components, providers, contractors, Medicare Advantage organizations and state survey agencies use the IOMs to administer CMS programs. They are also a good source of Medicare and Medicaid information for the general public.

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100-03	Medicare National Coverage Determinations (NCD) Manual
100-04	Medicare Claims Processing Manual
100-05	Medicare Secondary Payer Manual
100-06	Medicare Financial Management Manual
100-07	State Operations Manual
100-08	Medicare Program Integrity Manual
100-09	Medicare Contractor Beneficiary and Provider Communications Manual

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>

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Creating Policies and Evidence for RHC Certification

A true professional not only follows but loves the processes, policies and principles set by his profession.” — Amit Kalantri

Policies are broad statements of compliance which are static unless there is a regulatory change. Less is More.

Processes are more defined by nature are dynamic. They are usually created internally or in conjunction with other guidance. Provide Clarity. Can Be addendums or supplemental documents.

Procedures are specific steps in performing a task. These are dynamic, promote efficiencies in workflow and ensure quality performance. Used for training and internal guidance. Promotes standardization of tasks.

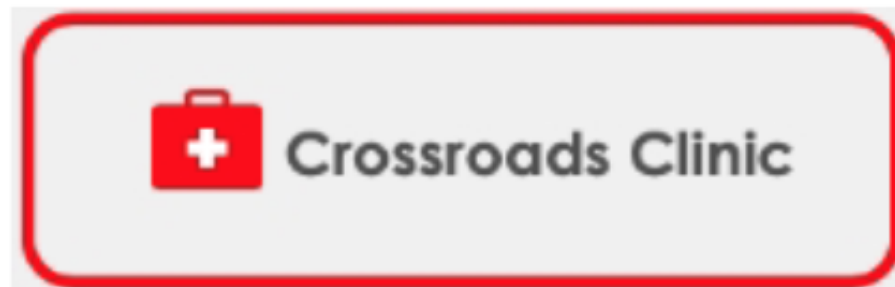
Tips for Policy Development



- Don't make policy writing more difficult than it needs to be. More is not more!
- Use broad language that established compliance without locking you into a rigid process or procedure that might change.
- Organize policies topically or in the order of the survey tags or standards.
- Policies should not be used to manage people but to ensure practical compliance.

Administration (7)	Environmental (16)
<u>Regulatory Compliance</u>	<u>Physical Plant Safety: General</u>
Policy: 100 T V E Evidence (4) <ul style="list-style-type: none"> • Crossroads_100-A_855A • Crossroads_100-B_State License • Crossroads_100-C_CLIA Certificate • Crossroads_100-D_Occupancy License 	Policy: 200 T V E Evidence (3) <ul style="list-style-type: none"> • Crossroads_200-A_Physical Plant Licenses, Inspections, Permits • Crossroads_200-B_Floor Plan Exits • Crossroads_200-C_Insurance Information
<u>Formal Corporate or Organization Compliance Plan</u>	<u>Preventive and Required Maintenance</u>
Policy: 105 T V E Evidence (3) <ul style="list-style-type: none"> • Crossroads_105-A_Compliance Plan • Crossroads_105-B_Standards of Conduct • Crossroads_105-C_Standards of Conduct Notice 	Policy: 210 T V E Evidence (2) <ul style="list-style-type: none"> • Crossroads_210-A_Bio-Med Service Contract • Crossroads_210-B_BioMed Sticker Example_06252019
<u>Organizational Structure and Ownership</u>	<u>Building Sanitation and Cleanliness</u>
Policy: 110 T V E Evidence (1) <ul style="list-style-type: none"> • Crossroads_110-A_Ownership Statement 	Policy: 215 T V E Evidence (1) <ul style="list-style-type: none"> • Crossroads_215-A_Sanitation
<u>Organizational Chart Structure</u>	<u>Storage, Handling & Administration of Drugs, Biologicals, and Pharmaceutic...</u>
Policy: 120 T V E Evidence (4) <ul style="list-style-type: none"> • Crossroads_120-A_Organizational Structure • Crossroads_120-B_Org Chart • Crossroads_120-C_Current Board 	Policy: 220 T V E Evidence (3) <ul style="list-style-type: none"> • Crossroads_220-A_Temperature Logs • Crossroads_220-B_Sample Medications Log • Crossroads_220-C_Safe Injection Poster_06252019

- Systematically Organize Policies
- Number Policies
- Have Standard Format
- Show Effective Dates



Organizational Structure and Ownership

J Tag References: J-0060,
J-0061, J-0062, J-0081,
J-0084, J-0086
§ References: 491.7, 491.8,
491.9

Policy Type: Administrative

Policy Number:
110.00

Adopted or Revised Date: 9/27/2019

Policy Declaration: This is the Organizational Structure and Ownership Policy of the clinic. The clinic is identified as Crossroads Clinic.

Policy Purpose: The purpose of this policy is to disclose in a written document the organizational structure of the Clinic which is Rural Health Clinic (RHC). Furthermore, the policy is designed to give detailed information about the governance, management and staffing of the clinic.

Required Policies for RHCs

- 42 CFR 491, Conditions of Certification for RHCs requires certain written policies and procedures as a minimum.
- Accreditors may require additional levels of compliance.
- The next slides include RHC policies and evidence as required by TCT, one of the RHC accreditation organizations deemed by CMS.
- Similar requirements can be found in SOM Appendix G.

Corporate Compliance for RHCs

The Clinic has a written Corporate Compliance Plan.

The Corporate Compliance Plan contains the following required element

1. Written policies and procedures.
2. Standards of Conduct.
3. A designated compliance officer.
4. Evidence of Internal communication system and methods for reporting noncompliance.
5. Evidence of Quality Improvement techniques: Monitoring and auditing, problem identification, investigation and corrective action.
6. Evidence of Clinic Risk Assessment addresses areas in which the clinic is vulnerable. Proof of Education and Training.
7. Disciplinary and Corrective actions when non-compliance is identified.



Ownership and Organizational Disclosure

- The clinic policies and its line of authorities and responsibilities are clearly set forth in writing. (§491.7(a)(2))
- The clinic has written policies and procedures for identifying categories of practitioners that includes, at a minimum, the following: (§491.8(a))
 - One or more physicians. (§491.8(a)(1)) ADM 5.0.2(a)
 - One or more physician assistants, nurse practitioners, or nurse mid-wife. (§491.8(a)(2)).
- The physician member of the staff may be the owner of the clinic. (§491.8(a)(3))
- The physician assistant, nurse practitioner, nurse mid-wife, clinical social worker or clinical psychologist member of the staff may be the owner or an employee of the clinic, or may furnish services under contract to the clinic. (§491.8(a)(3))



Policy Development and Review

- The clinic has written policies and a mechanism in place for review and approval of policies.
- The physician, in conjunction with the physician assistant and or nurse practitioner participates in developing, executing and periodically reviewing the clinic's written policies and services provided. (§491.8(b)(2))
- There is proof that the staff has been trained on the policies.

Medical Records

- The clinic has written policies & procedures for maintaining patient health records. (§491.10(a)(1))
- The clinic has policies and procedures addressing the protection of record information. (§491.10(b))
- The clinic has written policies and procedures that govern the use and removal of patient health records from the clinic and the conditions for the release of information. (§491.10(b)(2))

Emergency Drugs, Disinfection and Biohazardous Waste

- The Medical Director and other providers will determine the contents of the emergency box. The contents are listed on the exterior of the emergency box and in a written policy.
- The clinic has written policies for a clean and orderly environment that address the following:
 - Techniques for cleaning and disinfecting environment surfaces, carpeting, and furniture.
 - Disposal of regulated waste.

HR Policies and Employee Training

- The clinic has policies and procedures in place for hiring, orienting and training of all employees.
- The clinic has written human resources policies and procedures specifying personnel qualifications, training, experience, and continuing education requirements consistent with the services it provides to beneficiaries.

Job descriptions

Competencies

Evaluations



Program Evaluation and Quality

The clinic has a written policy determining who is to do the program evaluation, how it is to be done and what is reviewed.



The clinic has a written policy and procedure for defining, handling, reviewing and resolving complaints.



When a complaint is received, the clinic provides notice to the complainant that the issue is being investigated within the timeframe identified in the clinic policy.

Equipment Maintenance and Disinfection

- The clinic has written policy and procedures for equipment management.
- The clinic's equipment management policy and procedures clearly state the process for cleaning, maintaining and storing all equipment.
- All equipment is cleaned with a healthcare disinfectant according to manufacturer's directions and kept sanitary prior to each patient's use.
- Environmental surfaces are cleaned with a healthcare disinfectant according to the manufacturer's directions, using products, which will at a minimum kill Hepatitis B and HIV and are registered with the U.S. Environmental Protection Agency (EPA) and/or OSHA.
- Equipment used in the clinic or loaned to patients (e.g. crutches, wheelchairs or walkers) is be cleaned between patients and appropriately stored.
- Clean equipment is segregated from dirty equipment. Equipment/supplies stored on shelves, in cabinets and off the floor.
- Defective and obsolete equipment is appropriately labeled.

Patient Care Policies

- Healthcare services are provided in accordance with written policies, which are consistent with applicable State law. (§491.9(b)(1))
- The patient care policies are initially developed and reviewed biennially by an advisory group that includes, at a minimum, a physician, physician's assistant or nurse practitioner and one person who is not a member of the clinic staff.
- The clinic has a written policy for referring patients to needed services that cannot be provided at the clinic.

Patient Care Policies

The patient care policies include:

- A description of patient care services furnished directly and those furnished through agreement, arrangement or referral. (§491.9(b)(3)(i))
- Guidelines for the medical management of health problems which includes the conditions requiring medical consultation and/or patient referral, maintenance of patient health records, and procedures for the periodic review and evaluation of the services provided by the clinic. (§491.9(b)(3)(ii))
- The clinic will specify in the policy, which reference sources the Medical Director and the non- physician provider have agreed on. The reference maybe textbooks, written polices or electronic software.

Drug Storage and Handling

- The clinic has written policies for the storage, handling and dispensing of drugs, biologicals, and supplies. (§491.9(b)(3)(iii))
- The clinic's written policies include:
 - Requirements that drugs are stored in original manufacturer's containers to maintain proper labeling
 - Requirements that multiple dose vials and single dose vials are stored according to manufacturer guidelines.
 - Requirements that drugs and biologicals dispensed to patients have complete and legible labeling of containers;
 - Requirements for a process to regularly monitor the inventory of clinic drugs, biologicals, and supplies for expiration by the manufacturer's date, beyond use-dating, or evidence of recall, to prevent harmful or ineffective treatment to patients.
 - Requirements for a process to handle outdated, deteriorated, or adulterated drugs, biological, and supplies. Outdated, deteriorated or adulterated drugs, biologicals and supplies are stored separately and the disposal is in compliance with applicable State laws.

Drug Storage and Handling

Requirements for storage in a space that provides proper humidity, temperature and light to maintain quality of drugs and biological that includes the following:

- Refrigerated or frozen medication or vaccines are monitored for storage temperature at least twice daily.
- Temperatures are recorded in a log and staff reports variances in normal findings to clinic leadership.
- No drugs or biological are stored in the door of the refrigerator or freezer.
- Water bottles are placed in the door of the medication refrigerator to promote temperature stability.
- Requirements that current drugs references, antidote information and manufacturer guidelines are available on the premises.

Drug Storage and Handling

- All Controlled Substances are handled, as directed by the Drug Enforcement Agency (DEA) Practitioner's Manual, in a manner that guards against theft and diversion.
- Schedule II drugs are stored in a securely constructed locked compartment, separate from other drugs.
- Schedule III, IV, and V drugs are secured in a substantially constructed cabinet.
- The clinic maintains adequate record keeping of the receipt of controlled drugs and a reconcilable log of the distribution. Should schedule II drugs be administered in the clinic, these drugs are accounted for separately. Any thefts or significant losses have been reported to the DEA.
- Requirements that containers used to dispense drugs and biologicals to patients conform to the Poison Prevention Packaging Act of 1970.
- Requirements that all prescribing and dispensing of drugs shall be in compliance with applicable State laws.

Emergency Preparedness

- The clinic has developed and implemented emergency preparedness policies and procedures that are based on its emergency preparedness plan, risk assessment and communication plan. (42 CFR 491.12(b)).
- The policies and procedures are reviewed and updated, at a minimum, at least every 2 years. (§491.12(b)).

Emergency Preparedness Appendix Z

- Emerging Infectious Disease- Hazard Vulnerability Assessment
- Surge Patients
- Volunteers
- Shelter in Place

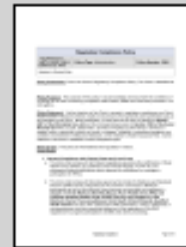
[QSO-21-15-ALL \(cms.gov\)](#)

Identify
Supporting
Evidence
Documents
and Keep
them Up-to-
Date

CMS Tag

J- 0011; J-0012; J-0013

Policy



Evidence (4)



How will you keep it all up- to-date?

Some policy or document management systems have a built-in tickler function.

Spreadsheets, calendars or tickler organizers can all work. Create a format that works for you and your facility.

Set reminders far enough in advance to allow for processing time, approval time, or scheduling.

Build-in accountability so that more than one person is aware of a deadline.

TICKLER LIST

Date	Subject	Evidence
10/5/2019	200-C Replace Declaration Sheet on insurance coverage	200-C Property Insurance All 06132019
10/18/2019	290-A Verify exercises are within one-year	290-A Emergency Preparedness Plan All 06132019
11/1/2019	215-A Review all cleaning contracts	215-A Sanitation and Cleaning Contracts All 06132019
11/8/2019	380-A Review the PHI Release Authorization form	380-A Authorization to Release Health Information All 06132019
11/29/2019	410-A Verify current Employment Application	410-A Employment Application All 06132019
12/1/2019	500-A Replace the Clinic's Annual Evaluation	500-A Annual Program Evaluation All 06132019
12/10/2019	290-C Verify current Training Evidence	290-C Emergency Preparedness Training All 06132019
12/10/2019	400-B Replace Employment Poster	400-B Labor Law OSHA Posters All 06132019
12/15/2019	110-A Review Ownership and Disclosure	110-A Ownership and Disclosure Statement All 06132019
1/2/2020	220-A Replace sample temperature logs with current temperature logs	220-A Temp Logs for Refrigerated and Frozen Medications All 06132019
1/6/2020	100-D Renew state license. A check will be required, Don't delay.	100-D State Licensing LA 06132019
1/10/2020	410-C Update Employee Training Records	410-C Employee Training All 06132019
1/15/2020	130-C Ensure OCR Notice and Taglines are correct	130-C OCR Language Translation Links All 06132019
2/1/2020	100-A Review 855A to make sure the persons on the 855A are still in the same roles	100-A CMS 855A Application All 06132019
2/4/2020	290-B Update Emergency Preparedness Risk Assessment	290-B Emergency Preparedness Risk Assessment All 06132019
2/5/2020	390-A Update HIPAA Risk Assessment	390-A IT Related Documents All 06132019
3/1/2020	600-B Review / Replace Consent Forms	600-B Consent Forms All 06132019
4/1/2020	220-C Verify Medication Safety Poster in on the wall in the Nursing Station	220-C-Medication Safety Poster All 06132019
4/10/2020	200-A Verify current inspections	200-A Physical Plant Licenses, Inspections, and Permits All 06132019

Compliance is both static and dynamic!

- Redesign your “blueprint” as needed.
- Keep training methods fresh.
- Retool monitoring when you have operational changes.
- Balance responsibility and authority.

Don't assume that the written policies or compliance plan you inherited are up-to-date or complete. Even corporate level policies can fail to meet compliance especially when rural health providers are scarce within the system.

Don't wait for a survey deficiency or a payer audit to reveal a gap in compliance.

Revise and Simplify—making sure that the policies and training are following the regulatory blueprint.

Monitoring Changes in Regulations

Sign up

Sign up for newsletters, announcements, newsfeeds and mailing lists.

Set up

Set up email folders for these activities.

Allocate

Allocate time weekly to review updates and clean up the folder.

Attend

Attend state, regional and national meetings.

Develop

Develop relationships with other stakeholders outside your organization.

Join

Join professional associations.



Kentucky Specifics

Kentucky RHC Regulations

Medicaid Provider Type 35

<https://chfs.ky.gov/agencies/dms/dpo/bpb/Pages/ruralhealth.aspx>

<https://chfs.ky.gov/agencies/dms/DMSProviderSummaries/RuralHealthClinicPT35.pdf>

Covered Services

<https://apps.legislature.ky.gov/law/kar/907/001/082.pdf>

KY Reimbursement for RHCs

<https://apps.legislature.ky.gov/law/kar/907/001/055.pdf>

Top Kentucky RHC Deficiencies

Citation Frequency Report

Selection Criteria

Begin Year: 2019
End Year: 2021
Display Options: Display top 25 tags
Provider and Supplier Type(s): Rural Health Clinics
State: Kentucky

Year Type: Year: Quarter:

Citation Frequency Report

State	Tag #	Tag Description	# Citations	% Providers Cited	% Surveys Cited
Totals represent the # of providers and surveys that meet the selection criteria specified above.			Kentucky Active Providers=260		Total Number of Surveys=57
	J0160	PROGRAM EVALUATION Program Evaluation	4	1.5%	7.0%
	J0161	PROGRAM EVALUATION Biennial Evaluation	4	1.5%	7.0%
	E0001	Establishment of the Emergency Program (EP) EPP	2	0.8%	3.5%
	J0136	PROVISION OF SERVICES Emergency Drugs	2	0.8%	3.5%
	J0044	PHYSICAL PLANT AND ENVIRONMENT Preventive Maintenance	1	0.4%	1.8%
	J0123	STAFFING AND STAFF RESPONSIBILITIES Physician Responsibilities	1	0.4%	1.8%

Source: QCOR, 07/20/2021

Resources

OIG Compliance Resource Materials

<https://oig.hhs.gov/compliance/compliance-guidance/compliance-resource-material.asp>

OIG Compliance Plan Tips

<https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf>

RHC Conditions of Certification

<https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol5/xml/CFR-2017-title42-vol5-part491.xml>

CMS IOM Policy Benefit Manual, Chapter 13 (RHC)

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c13.pdf>

CMS IOM Claims Processing Manual, Chapter 9 (RHC)

<https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c09.pdf>

SOM Appendix G

<https://www.cms.gov/files/document/appendix-g-state-operations-manual>

**Questions?
Comments?**



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Shannon serves as the Director of Provider Solutions for the South Carolina Office of Rural Health. She assists private physician offices who desire to convert to Rural Health Clinic status and also provides technical assistance to Rural Health Clinics in maintaining compliance in RHC regulations. Shannon also provides technical assistance in billing and coding, EHR implementation and Practice Management for all RHCs. Shannon is a certified professional coder with the American Academy of Professional a Certified Revenue Cycle Associate. Shannon serves as Secretary/Treasurer for the National Association of Rural Health Clinics. Additionally, she serves as a contractor for NOSORH.



SOUTH CAROLINA OFFICE OF RURAL HEALTH

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