Rural Health Clinic
Technical Assistance Webinar

This webinar is brought to you by the National Association of Rural Health Clinics and is supported by cooperative agreement UG6RH28684 from the Federal Office of Rural Health Policy, Health Resources and Services Administration (HRSA). It is intended to serve as a technical assistance resource based on the experience and expertise of independent consultants and guest speakers.
RHC Policies and Procedures

National Association of Rural Health Clinics

October 6, 2022
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1. What Policies and Procedures Are Required?

2. What is new in the P & P World for RHCs?

3. What is Often Missed in P & P Development?
What Policies and Procedures Are Required?
Regulations are the compliance blueprint for building RHC Policies and Procedures.
Understanding the Differences Between Policies, Processes and Procedures

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

**Processes** are more defined by nature and 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.
Required Policies and Procedures can be divided into several categories:

- **Compliance with 42 CFR 491, Conditions of Certification of Rural Health Clinics**
- Compliance with Federal regulations which apply to ALL entities and organizations. For example: Labor Laws
- Compliance with Federal regulations which apply to healthcare organizations and conditions of participation with Centers for Medicare and Medicaid Services. For example: Office of Civil Rights, Stark Laws
- Compliance with Accreditation Organization Standards. For example: The Compliance Team or QuadA standards
- Compliance with state, county/parish or local regulations & laws. For example: RHC licensure, building codes, city ordinances.
Where do you find the regs?
Ecfr.gov
Federal RHC/FQHC Regulations

42 CFR §405
Subpart X

42 CFR §413.65
Provider Based Status

42 CFR §491
Conditions for certification
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
Federal Hospital Regulations

42 CFR §482
Conditions of Participation

42 CFR §412
Inpatient PPS System

42 CFR §419
Outpatient PPS System
What does 42 CFR §491 say?

Policies specifically required in the RHC Conditions for Certification
An RHC should have written policies that are unique to it as a certified healthcare facility. This includes an organizational chart and the organizational structure.

§ 491.7 Organizational structure.

(a) Basic requirements.

(1) The clinic or center is under the medical direction of a physician, and has a health care staff that meets the requirements of § 491.8.

(2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.
§ 491.9 Provision of services.

(b) Patient care policies.

(1) The clinic's or center's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic or center staff.

(3) The policies include:

(i) A description of the services the clinic or center furnishes directly and those furnished through agreement or arrangement.

(ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic or center.

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

(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the RHC or FQHC.
RHCs should have written patient care policies which:

- Ensure that services are provided within State Law
- Are developed by a professional group which includes at least one physician, at least one PA or NP, and an outside member
- Medical Management
  - Guidelines for Patient Care
  - Identification of Direct Services and Services Under Arrangement
  - Identification of Services Referred Out/Referral Processes
  - Maintenance of Medical Records
  - Policy Review Processes and evaluation of services
- Storage, Handling and Administration of Drugs and Biologicals
RHCs should have written policies for maintaining complete medical records and for safeguarding the records. The records must contain all required data elements in §491.10. A designated individual is identified as being responsible for the patient health records. Written Policies should include HIPAA provisions concerning privacy and security of records, release of information and protection of records.

§ 491.10 Patient health records.

(a) Records system.
   (1) The clinic or center maintains a clinical record system in accordance with written policies and procedures.
Policy Review Included in Program Evaluation

A review of written policies and procedures is required as a component of the biennial program evaluation. This includes determining if the policies were followed.

§ 491.11 Program evaluation.

(a) The clinic or center carries out, or arranges for, a biennial evaluation of its total program.

(b) The evaluation includes review of:

(1) The utilization of clinic or center 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 or center's health care policies.
Emergency Preparedness Policies and Procedures

RHCs are required to have written emergency preparedness policies and procedures. These are separate from those of the parent hospital although the plans can be integrated. See the full text of §491.12 for all requirements. Also, refer to Appendix Z.

§ 491.12 Emergency preparedness.

(b) Policies and procedures. The RHC or FQHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:
What Other Policies May Be Needed

Policies that may be required by other federal, state or local laws and by accreditation organizations
Policies Which Are Suggested to Demonstrate General Compliance

• Employment and Human Resource Policies
• Corporate Compliance Plan
• Policies to Ensure Compliance with Federal, State and Local laws
• Office of Civil Rights Policies/ Non-discrimination Policies
• Infection Control Policies/Sterilization & Disinfection Policies
• Environment of Care Policies/ Maintenance of Plant & Equipment
• Quality Assurance and Performance Improvement
• Other Administrative and Financial Policies
• Policies specific to programs, grants and awards (NHSC, for example)
2. What is new in the P & P World for RHCs?
COVID-19 Vaccine Mandate

RHC Specific Policies and Procedures

Revision of 42 CFR §491.8
New in 2022: RHCs must have policies and procedures to ensure that all staff is fully vaccinated for COVID-19 or has been granted valid medical or religious exemptions. See the full text of 491.8(d) for all required policies and procedures.

§ 491.8 Staffing and staff responsibilities.

(d) COVID-19 vaccination of staff. The RHC/FQHC must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.
(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following clinic or center staff, who provide any care, treatment, or other services for the clinic or center and/or its patients:

(i) RHC/FQHC employees;
(ii) Licensed practitioners;
(iii) Students, trainees, and volunteers; and
(iv) Individuals who provide care, treatment, or other services for the clinic or center and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following clinic or center staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the clinic or center that are performed exclusively outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section.
The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the clinic or center and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring that the clinic or center follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID-19;
(iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains;

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the clinic's or center's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

Contingency plans for staff who are not fully vaccinated for COVID-19.

COVID-19 VACCINE MANDATE P & P

- Vaccine-Related Hiring Processes/Definition of Staff
- Tracking and Record-keeping of Vaccination & Booster Status
- Processes for Receiving and Granting Exemptions Under Guidelines
- Education of Staff and Vaccine Awareness
- Accommodation of Staff with Approved Exemptions
- Increased Infection Control
- Contingency Plan
Transitioning Out of PHE
Getting Back to Normal with P & P

Processes and Procedures have been dynamic for the past two years with many changes to how RHCs do business. Many RHCs have been developed during the PHE and may not know what normal P & P should look like. Things to consider:

• Review 42 CFR §491 and other CMS Guidance to make sure you understand what is required.
• Review current processes and procedures to determine what will change back after the blanket waivers end.
• Revise internal documents including policies, procedures, training and orientation materials.
• RETRAIN staff and providers.
• Evaluate policy effectiveness and implementation.
Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs): CMS Flexibilities to Fight COVID-19

At the beginning of the COVID-19 Public Health Emergency (PHE), CMS used emergency waiver authorities and various regulatory authorities to enable flexibilities so providers could rapidly respond to people impacted by COVID-19. CMS has developed a cross-cutting initiative to use a comprehensive, streamlined approach to reestablish certain health and safety standards and other financial and program requirements at the eventual end of the COVID-19 public health emergency.

This CMS cross-cutting initiative aims to evaluate CMS-issued PHE blanket waivers and flexibilities to prepare the health care system for operation after the PHE. This review is being done in three concurrent phases:

Waivers or Flexibilities That Have Already Ended are indicated in red text

- **Provider Enrollment:** During the PHE, CMS has established toll-free hotlines for physicians, non-physician practitioners, and Part A certified providers and suppliers who have established isolation facilities to enroll and receive temporary Medicare billing privileges. **When the PHE ends, the hotlines will be shut down.** Additionally, CMS has provided the following flexibilities for provider enrollment:
  
  - **Screening requirements:**
    - **Site Visits:** CMS waived provider enrollment site visits for moderate and high-risk providers/suppliers. *(This waiver terminated on 07-06-2020 and CMS, in accordance with 42 C.F.R. §§ 424.517 and 424.518, resumed all provider enrollment site visits.)*
    - **Fingerprint-based criminal background checks:** CMS waived the requirement for fingerprint-based criminal background checks for 5% or greater owners of newly enrolling high risk categories of providers and suppliers (e.g., newly-enrolling Home Health Agencies, DMEPOS suppliers, Medicare Diabetes Prevention Programs, Opioid Treatment Programs). *(This waiver terminated on 10/31/2021 and CMS, in accordance with 42 C.F.R. § 424.518, resumed requesting fingerprints for all newly enrolling high risk providers and suppliers.)*
  
  - **Application Fees:** CMS waived the collection of application fees for institutional providers who are initially enrolling, revalidating, or adding a new practice location. *(This waiver terminated on 10/31/2021 and CMS, in accordance with 42 C.F.R. § 424.514, resumed collecting application fees.)*
The document has been revised and updated to include information about when the waiver will end or how it will be transitioned.

**Temporary Expansion Sites**

- Temporary Expansion Locations: CMS has been waiving the requirements at 42 CFR §491.5(a)(3)(iii), which require RHCs and FQHCs to be independently considered for Medicare approval if services are furnished in more than one permanent location. Due to the current PHE, CMS has temporarily waived this requirement, removing the location restrictions, to allow flexibility for existing RHCs/FQHCs to expand service locations to meet the needs of Medicare beneficiaries. This flexibility includes areas that may be outside of the location requirements, at 42 CFR §491.5(a)(1) and (2), for the duration of the PHE. CMS will end this waiver at the conclusion of the PHE.

Published 8/18/2022
RHC Federal Regs & Guidance

42 CFR § 491

CMS Policy Benefit Manual, Chapter 13

CMS Claims Processing Manual, Chapter 9

State Operations Manual, Appendix G
2023 Upcoming Changes

Changes to RHC Policies may be required due to changes in general HHS/CMS regulations.
Be Looking for More Guidance on:

Information Blocking

• May require changes to medical records or privacy & security policies
• May require changes in processes and procedures related to the release of information (PHI)
• May require changes in processing and procedures for provider review of data and portal management

No Surprises Act/Pricing Transparency Regulations

• May require additional change to financial or administrative polices
• May require changes in front desk or revenue cycle processes and procedures
3. What is Often Missed in P & P Development?
Common Problems with RHC Policies and Procedures

- Clinic NOT Following Its Own Policies
- Wrong Policies/Missing Policies
- Too Many Policies/Unnecessary/Too Long
- No Proof of Policy Review

This slide is illustrative and not scientific
Common Problems with RHC Policies and Procedures

- Not Well Organized or Accessible
- Staff and Providers Not Trained on Policies
- Missing Evidence Documents
- Providers Not Involved in Policy Development

This slide is illustrative and not scientific
Lack of Provider Involvement in Policy Development and/or No Provider Review of Policies
§ 491.8 Staffing and staff responsibilities.

(b) *Physician responsibilities.* The physician performs the following:

1. Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff.

2. In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and the services provided to Federal program patients.
§ 491.8 Staffing and staff responsibilities.

(c) **Physician assistant and nurse practitioner responsibilities.**

(1) The physician assistant and the nurse practitioner members of the clinic's or center's staff:

   (i) Participate in the development, execution and periodic review of the written policies governing the services the clinic or center furnishes;

   (ii) Participate with a physician in a periodic review of the patients' health records.

(2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:

   (i) Provides services in accordance with the clinic's or center's policies.
Have a Policy Development and Review Attestation with all required signatures.
Policy Organization, Training & Tracking
<table>
<thead>
<tr>
<th>Administration (7)</th>
<th>Environmental (18)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory Compliance</strong></td>
<td><strong>Physical Plant Safety: General</strong></td>
</tr>
<tr>
<td>Policy: 100 Evidence (4)</td>
<td>Policy: 200 Evidence (3)</td>
</tr>
</tbody>
</table>
- Crossroads.100-A.General |
- Crossroads.100-B.State License |
- Crossroads.100-C.CLA Certificate |
- Crossroads.100-D.Occupancy License |
- Crossroads.200-A.Physical Plant Licenses, Inspections, Permits |
- Crossroads.200-B.Floor Plan Exits |
- Crossroads.200-C.Insurance Information |
| **Formal Corporate or Organization Compliance Plan** | **Preventive and Required Maintenance** |
| Policy: 105 Evidence (3) | Policy: 210 Evidence (2) |
- Crossroads.105-A.Compliance Plan |
- Crossroads.105-B.Standards of Conduct |
- Crossroads.105-C.Standards of Conduct Notice |
- Crossroads.210-A.Bio-Med Service Contract |
- Crossroads.210-B.BioMed Supplier Example.06282010 |
| **Organizational Structure and Ownership** | **Building Sanitation and Cleanliness** |
| Policy: 110 Evidence (1) | Policy: 215 Evidence (1) |
- Crossroads.110-A.Ownership Statement |
- Crossroads.215-A.Sanitation |
| **Organizational Chart Structure** | **Storage, Handling & Administration of Drugs, Biologicals, and Pharmaceutical...** |
| Policy: 120 Evidence (4) | Policy: 220 Evidence (3) |
- Crossroads.120-A.Organizational Structure |
- Crossroads.120-B. Org Chart |
- Crossroads.120-C.Current Board |
- Crossroads.220-A.Temperature Logs |
- Crossroads.220-B.Samples Medications Log |
- Crossroads.220-C.Injection Post.06252010 |

### Policy Organization and Policy Format Examples

- Systematically Organize Policies
- Number Policies
- Have Standard Format
- Show Effective Dates
Use a standard format for all written policies.

<table>
<thead>
<tr>
<th>Organizational Structure and Ownership</th>
</tr>
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<tbody>
<tr>
<td><strong>J Tag References:</strong> J-0060, J-0061, J-0062, J-0081, J-0084, J-0086</td>
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<tr>
<td><strong>Policy Type:</strong> Administrative</td>
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<td><strong>Policy Number:</strong> 110.00</td>
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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.
Identify Supporting Evidence Documents and Correlate Them to Related Policies
Have a system for tracking staff training and policy review
Have a system for tracking evidence documents and due dates

** TICKLER LIST **

<table>
<thead>
<tr>
<th>Date</th>
<th>Subject</th>
<th>Evidence</th>
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<tbody>
<tr>
<td>10/21/19</td>
<td>200-C Replace Declaration Sheet on insurance coverage</td>
<td>200-C Property Insurance All 06/13/2019</td>
</tr>
<tr>
<td>10/18/19</td>
<td>180-A Verify exercises are within one year</td>
<td>180-A Emergency Operations Plan All 06/13/2019</td>
</tr>
<tr>
<td>11/12/19</td>
<td>215-A Review all cleaning contracts</td>
<td>215-K Sanitation and Cleaning Contracts All 06/13/2019</td>
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<td>11/18/19</td>
<td>160-A Review the PHI Release Authorization form</td>
<td>180-A Authorization to Release Health Information All 06/12/2019</td>
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<td>12/3/2019</td>
<td>100-A Replace the Client's Annual Evaluation</td>
<td>100-A Annual Program Evaluation All 06/13/2019</td>
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<td>12/14/2019</td>
<td>290-C Verify current Training Evidence</td>
<td>290-C Emergency Preparedness Training All 06/13/2019</td>
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<td>12/10/19</td>
<td>410-B Replace Employment Poster</td>
<td>460-B Labor Law OSHA Posters All 06/13/2019</td>
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<tr>
<td>12/15/19</td>
<td>110-A Review Ownership and Disclosure</td>
<td>110-A Ownership and Disclosure Statements All 06/13/2019</td>
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<td>12/2/2020</td>
<td>220-A Replace sample temperature logs with current temperature logs</td>
<td>220-A Temperature Logs for Refrigerated and Frozen Medications All 06/13/2019</td>
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<tr>
<td>1/6/2021</td>
<td>100-D Renew waste license. A check will be required, Don't delay.</td>
<td>100-D State Licensing LA 06/13/2019</td>
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<tr>
<td>2/1/2020</td>
<td>410-C Update Employee Training Records</td>
<td>410-C Employee Training All 06/13/2019</td>
</tr>
<tr>
<td>1/31/2020</td>
<td>130-C Ensure OSHA Notice and Taglines are correct</td>
<td>130-C OSHA Language Translation Links All 06/13/2019</td>
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<tr>
<td>2/23/2020</td>
<td>160-A Review 655A to make sure the persons on the 655A are still in the same roles</td>
<td>160-A CMS 655A Application All 06/13/2019</td>
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<tr>
<td>3/13/2020</td>
<td>305-A Update IFPA Risk Assessment</td>
<td>305-A IT Related Documents All 06/13/2019</td>
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<tr>
<td>3/11/2020</td>
<td>600-B Review / Replace Contact Forms</td>
<td>600-B Contact Forms All 06/13/2019</td>
</tr>
<tr>
<td>4/10/2020</td>
<td>220-C Verify Medication Safety Poster in on the wall in the Nursing Station</td>
<td>220-C Medication Safety Poster All 06/13/2019</td>
</tr>
<tr>
<td>4/10/2020</td>
<td>200-A Verify current Inspections</td>
<td>200-A Physical Plan, Licenses, Inspections, and Permits All 06/13/2019</td>
</tr>
</tbody>
</table>
Have the Right Policies
Read and Know Your Policies
Follow Your Policies
Review Your Policies
Questions
Session Presenters

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