



health services associates

# DEVELOPING AN RHC OPERATING MANUAL

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# OBJECTIVES

- Attendees will gain an understanding of key items surveyors require to see documentation in regards to compliance.
- Attendees will gain an understanding of preparing an operating RHC manual to assist with managing the RHC
- Attendees will gain an understanding of maintaining this operating RHC manual



# COMPLIANCE

- CMS Form 30 (select the most current)
- Federal Regulations 491.1-491.11
- Surveyors utilize as tool of measurement
- Office must remain compliant to regulations on daily operations.



# CERTIFICATION/RECERTIFICATION

- Certification is the initial application process to become a RHC.
- Recertification is the continual review of compliance that the clinic is functioning under federal regulations as a RHC.
- Both visits are unannounced.
- Operations are to be a standard of practice for every day, not just to become certified.



# UNDERSTANDING THE POC

- POC=Plan of Correction
- This is issued at the time of recertification, if there are any conditions or standards that are found deficient.
- The RHC will have 10 days from the date of the letter (not the date of receiving the letter) to show correction. There is the possibility of another site visit to review corrections and compliance.



# OPERATING MANUAL

- You may create an RHC operating manual which will contain key documentation to evidence clinic compliance.
- **\*\*throughout the presentation**



42 CFR 491.5

- **LOCATION OF  
THE CLINIC**

# LOCATION OF THE CLINIC

- **§ 491.5 Location of Clinic**
- **§ 491.5(d)** The facility meets the shortage area requirements under one of the following criteria.
- **\*\*Copy of current HPSA**
- **\*\*Copy of CMS initial/final tie-in notice**
- **\*\*Documentation stating ownership**
- **\*\*Documentation listing each employee, date of hire and job title.**



42 CFR 491.6

PHYSICAL PLANT  
AND  
ENVIRONMENT

# PHYSICAL PLANT/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)



# PHYSICAL PLANT/ENVIRONMENT

- (1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition; **(J22)**
  - \*\*Copy of current (within one year) inspection of equipment and proof of calibration of weight scales and check on BP equipment/digital thermometers
  - \*\*Copy of AED log with evidence of current monthly battery check, annual maintenance



# PHYSICAL PLANT/ENVIRONMENT

(2) Drugs and biologicals are appropriately stored; (J23) and

**\*\*Copy of policy available regarding handling medications during power outage. Also recommend to place copy of policy of front of medication refrigerator.**

**\*\*Medication and Biologicals policy:**

- Storage and maintenance
- Security
- Inventory
- Disposal of expired medications/biologicals
- Handling of samples and distribution



# PHYSICAL PLANT/ENVIRONMENT

(2) Drugs and biologicals are appropriately stored; (J23) and

**\*\*Copy of template of Frig/Freezer temp log**

**\*\*Copy of template for sample medication distribution**

**\*\*IF clinic has Schedule II medications, copy of document used to monitor and maintain.**



# PHYSICAL PLANT/ENVIRONMENT

- 3) The premises are clean and orderly. (J24)
- \*\*The clinic has a Housekeeping policy and the clinic is maintained in accordance to that policy.
- Recommend that outside janitorial services have contract and that they sign a confidentiality agreement.
- \*\*Sanitation plan for toys, if needed.



# PHYSICAL PLANT/ENVIRONMENT

(c) *Emergency procedures.* The clinic or center assures the safety of patients in case of non-medical emergencies by: **(J25)**

**\*\*Separate manual of MSDS sheets IN PRINT**



# PHYSICAL PLANT/ENVIRONMENT

(1) Training staff in handling emergencies; (J26)

**\*\*Copies of all trainings showing evidence of staff participation**

**Biohazard training**

**\*\*Copy of recent AED training, CPR/BLS trainings, etc.**

**\*\*Completed fire drill reports/tornado drill reports or additional emergency training reports**



# PHYSICAL PLANT/ENVIRONMENT

- (2) Placing exit signs in appropriate locations; and **(J27)**

**\*\*Copy of current floor plan**



# PHYSICAL PLANT/ENVIRONMENT

- (3) Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic or center is located. **(J28)**

**\*\*Completed fire drill reports/tornado drill reports or additional emergency training reports**



PHYSICAL PLANT/ENVIRONMENT

- QUESTIONS

- &

- ANSWERS

42 CFR 491.7 & 491.8

**ORGANIZATIONAL  
STRUCTURE AND  
STAFFING  
RESPONSIBILITIES**

# ORGANIZATIONAL STRUCTURE

## § 491.7 Organizational structure. (J29)

### (a) *Basic requirements.* (J30)

(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.

### (J31)

- **\*\*Copy of current organizational chart—including Medical Director**
- **\*\*Copy of various license/certificates for each staff member, including providers and Medical Director.**



# ORGANIZATIONAL STRUCTURE

- (2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing. **(J32)**
- **\*\*Printed Policy & Procedure manual separate from RHC Operating manual**
- **\*\*Copies of Job Descriptions for each position within the RHC clinic setting, including Medical Director.**



# ORGANIZATIONAL STRUCTURE

## (b) *Disclosure.* (J33)

The clinic or center discloses the names and addresses of:

- (1) Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A-3); (J34)
- (2) The person principally responsible for directing the operation of the clinic or center; and (J35)
- (3) The person responsible for medical direction. (J36)

[57 FR 24983, June 12, 1992]

**\*\*Evidence of “owner” documentation.**

**NOTE: Some surveyors are asking for mailing address of owner. (independents)**



# STAFF RESPONSIBILITIES

## § 491.8 Staffing and staff responsibilities. (J37)

### (a) *Staffing.* (J38)

(1) The clinic or center has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners. (J39)

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center, or under agreement with the clinic or center to carry out the responsibilities required under this section. (J40)

(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker, or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the center. (J40)



# STAFF RESPONSIBILITIES

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

(5) The staff is sufficient to provide the services essential to the operation of the clinic or center. (J42)

**\*\*Copies of job descriptions for ALL positions.**

(6) A physician, nurse practitioner, physician assistant, nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for rural health clinics, a nurse practitioner or a physician assistant is available to furnish patient care services at least 60 percent of the time the clinic operates. (has been changed to 50%) (J41)

**\*\*Sample of provider routine schedule.**



# STAFF RESPONSIBILITIES

## (b) *Physician responsibilities.* (J45)

### (1) The physician:

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. (J46)

**\*\*Evidence of record review and communication between provider/supervisor/medical director and non physician providers**



# STAFF RESPONSIBILITIES

(ii) In conjunction with the physician's 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; and (J47)

(iii) Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center. (J48)

**\*\*Documentation to show evidence of provider participation in policy and procedure review.**

**\*\*Documentation to evidence chart reviews of non physician providers and trail of documented education.**



# STAFF RESPONSIBILITIES

(2) A physician is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances), to provide the medical direction, medical care services, consultation and supervision described in paragraph (b)(1) of this section 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 or center.

**(J49)**

**\*\*Change in requirement to default to State requirement.**

**\*\*Copies of posted office hours.**

**\*\*Copy of provider scheduled hours.**

**\*\*Copy of Supervisory Plan and QA plan**



# STAFF RESPONSIBILITIES

(c) *Physician assistant and nurse practitioner responsibilities. (J50)*

(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.

**\*\*Documentation to show evidence of provider participation**



# STAFF RESPONSIBILITIES

(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;
- (ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic or center; and
- (iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred. **(J51)**

[57 FR 24983, June 12, 1992, as amended at 61 FR 14658, Apr. 3, 1996; 68 FR 74817, Dec. 24, 2003; 71 FR 55346, Sept. 22, 2006]

- \*\*Copies of completed/signed collaboration agreements, waivers, contracts, guidelines of practice limitations.
- \*\*Health Services policies which lists all services rendered within the clinic setting and addresses referral system.
- \*\*Copy of referral policy/log
- \*\*Policy and/or form completed for patient referrals for both diagnostic and consultative services



• QUESTIONS

• &

• ANSWERS

42 CFR 491.9

# PROVISION OF SERVICES

# PROVISION OF SERVICES

## § 491.9 Provision of services. (J52)

(a) *Basic requirements.* (1) All services offered by the clinic or center are furnished in accordance with applicable Federal, State, and local laws; and **(J53)**

(2) The clinic or center is primarily engaged in providing outpatient health services and meets all other conditions of this subpart.

(3) The laboratory requirements in paragraph (c)(2) of this section apply to RHCs, but do not apply to FQHCs.

**\*\*Copies of all CPR/BLS certifications for ALL required staff.**



# 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. **(J54-J55)**

(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. **(J56)**

**\*\*Clinical guidelines or reference material for medical care within the Policy/Procedure Manual.**

**\*\*Show evidence of Community Member involvement in the review**



# PROVISION OF SERVICES

(c) *Direct services* —(1) *General*. The clinic or center staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions. **(J60)**

**\*\*Copy of policy stating Health Services rendered within the clinic.**



# PROVISION OF SERVICES

(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.



# PROVISION OF SERVICES

- 2) *Laboratory*
- \*\*Templates of logs and/or completed current logs (reference)
- \*\*Evidence that required tests are performed and logged, etc
- \*\*Copy of CLIA certificate
- \*\*Copy of Waste Management Certificate/invoice

# PROVISION OF SERVICES

(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)**

**\*\*Emergency First Aid Kit—Document listing all the meds in the kit and their monitoring/use, etc.**



# PROVISION OF SERVICES

(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.

**\*\*Evidence to show lab contracts or tracking processes for labs sent outside of the clinic setting. (either outside lab or hospital, etc)**

**\*\*Copies of MOA's for various services**



• QUESTIONS

• &

• ANSWERS

CFR 42 491.10

**MEDICAL**

**RECORDS**

**REQUIREMENTS**

# MEDICAL RECORDS

## § 491.10 Patient health records. (J66)

### (a) *Records system.* (J67)

(1) The clinic or center maintains a clinical record system in accordance with written policies and procedures. (J68)

(2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized. (J69)



# MEDICAL RECORDS

(3) For each patient receiving health care services, the clinic or center maintains a record that includes, as applicable:

(i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

**\*\*Copy of patient registration forms, include social data, HIPAA form, etc.**

**\*\*Samples of Consent to treat form and Informed Consent forms**



# MEDICAL RECORDS

(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. **(J70)**

**\*\*Copy of forms used in the Medical Record such as Medication List, Problem List, etc.**

**\*\*Documentation showing Name, Print, and Signature/Initials**



# MEDICAL RECORDS

(b) *Protection of record information. (J71)*

(1) The clinic or center maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use. **(J72)**

(2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information. **(J73)**

(3) The patient's written consent is required for release of information not authorized to be released without such consent. **(J74)**

**\*\*Policies for Medical Records, faxing, email,  
Release, etc**



# MEDICAL RECORDS

(c) *Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute. **(J75)**

(Secs. 1102, 1833 and 1902(a)(13), Social Security Act; 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 13951 and 1396a(a)(13)))

[43 FR 30529, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, as amended at 57 FR 24984, June 12, 1992]

**\*\*Medical Records policies regarding the retention of Medical Records.**

**\*\*Transition plan (if needed) from paper to electronic Medical Records**



• QUESTIONS

• &

• ANSWERS

42 CFR 491.11

**ANNUAL  
PROGRAM  
EVALUATION**

# ANNUAL PROGRAM EVALUATION

## § 491.11 Program evaluation. (J76)

(a) The clinic or center carries out, or arranges for, an annual evaluation of its total program. (J77)

(b) The evaluation includes review of: (J78)

(1) The utilization of clinic or center services, including at least the number of patients served and the volume of services; (J79)

(2) A representative sample of both active and closed clinical records; and (J80)

(3) The clinic's or center's health care policies. (J81)

**\*\*Copy of tool or policy for documentation of  
Medical Record review process.**



# ANNUAL PROGRAM EVALUATION

(c) The purpose of the evaluation is to determine whether: **(J82)**

(1) The utilization of services was appropriate; **(J83)**

(2) The established policies were followed; and **(J84)**

(3) Any changes are needed. **(J85)**

(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary. **(J86)**

[71 FR 55346, Sept. 22, 2006]

**\*\*Copy of recent Annual Advisory Committee Meeting minutes.**



• QUESTIONS

• &

• ANSWERS

- CIVIL RIGHTS  
REQUIREMENTS

# CIVIL RIGHTS

- All new applications and CHOWs for provider based RHC's are mandated to complete Civil Rights.
- In the State of Ohio, all new applications and CHOWS for Independent RHC's are mandated to complete Civil Rights.



# CIVIL RIGHTS

- All policies are submitted to the State Office who will then forward to CMS.
- CMS forwards the policies to OCR (Office of Civil Rights).



# OCR POLICIES

- Website: :  
<http://www.hhs.gov/ocr/civilrights/clearance/index.html>
- You may download templates and fill in required information, but make it fit your clinic/corporation.



# FORMS

- The Information Request Form:
  - Please sign and complete this form
  - <http://www.hhs.gov/ocr/civilrights/clearance/index.html>



- Dissemination of Nondiscrimination Policy:
  - Give detail as to how the nondiscrimination policy is communicated with clients, future patients, community, visitors, etc.



# OCR POLICIES

- Limited English Proficiency (LEP) Policy:

- This policy needs to include information with regard to the procedures and policies for communicating with persons who are limited in their use of the English language. (Please see the attachment.)
- If the agency uses staff/employees for language interpretation, please provide a listing of those employees and the languages for which they are fluent.
- Also, provide procedures of what the actions will be if staff/employees are unable to effectively communicate the appropriate information to a patient/client, family member or friend.
- Family and friends are to be utilized only after the patient has been notified that a certified language interpreter will be provided to them at no additional cost. This will assist in ensuring that Private Health Information (PHI) is not communicated to individuals the patient does not want to know such information.
- ***PLEASE NOTE: CHILDREN MAY NOT BE USED AS INTERPRETERS AND SHOULD NOT BE LISTED WITHIN THE CLINIC POLICIES TO INTERPRET***



# OCR POLICIES

- Admissions Policy:

- Please state the criteria a person must meet in order to receive the services provided by your particular agency. (\*\*There is no approved sample for the Admissions Policy.) The policy **does** need to state that patients are admitted without regards to “race, color, national origin, disability and age”



# OCR POLICIES

- Sensory/ Auxiliary Aids Policy:
  - This policy needs to include information with regard to the procedures and policies for communicating with persons with Speech, Hearing, and Visual Impairments.
  - If the agency uses staff/employees for sign-language interpretation, please provide a listing of those employees that are able to effectively communicate using sign-language.
  - Also, provide procedures of what the actions will be if staff/employees are unable to effectively communicate the appropriate information to a patient/client, family member or friend.
  - Family and friends are to be utilized only after the patient has been notified that a certified sign-language interpreter will be provided to them at no additional cost. This will assist in ensuring that Private Health Information (PHI) is not communicated to individuals the patient does not want to know such information.
  - The State Relay Number can be found on this website:  
<http://transition.fcc.gov/cgb/dro/trsphonebk.html>
- *Please use policy sample to ensure that the agency receives clearance. You may adopt the template language and format it as the agency sees fit.*



# STATE SENSORY RELAY

- **OHIO**
- **TRS Provider - Sprint Nextel & Relay Ohio**

Danny Barrett, Account Manager

**Address:** Sprint Nextel, 2 Easton Oval, Columbus, OH 43219

**Customer Service #'s:** 800-325-2223(V/T)

**Access #'s:**

800-750-0750(V/T)

877-750-9097(STS)

Access Website URL: [www.SprintIP.com](http://www.SprintIP.com) and [www.ohiorelay.com](http://www.ohiorelay.com)

Access Information: [www.sprintrelay.com](http://www.sprintrelay.com)



# OCR POLICIES

- Notice of Accessibility:
  - Give detail as to how the clinic is accessible to persons with various impairments.
  - If patients do not come to a physical clinic but are treated in their homes, please state as such.



# OCR POLICIES

- Grievance Procedures:

- Provide statement as to who the Administrator/Section 504 Coordinator is along with contact information
- This is required if the facility has 15+ full/part-time employees. The timeframe to submit grievances needs to be at least 30 days.



# OCR POLICIES

- Separate Restrictions Based on Age Statement: (two samples will be available): one for facilities that do not cater to pediatrics and only accept patients over 18, and one for facilities with no age restrictions)
  - State why the facility does or does not cater to a particular demographic.
  - This is not the same as the statement in the Nondiscrimination Policy.



- QUESTIONS

- AND

- ANSWERS



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