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Offering quality consulting & management services to the medical community...

Rural Health Clinic

Policy & Procedure

Policy & Procedure

Policy

A set of principles adopted to guide decisions and achieve reasonable outcomes.

Procedures

A document that supports policy. Procedures describe in detail the who, what, where, when and how required to establish accountability supporting the implementation of a policy.

Policy is implemented through procedures



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Policy & Procedure

Creation:

- ✓ **Header**
- ✓ **Policy or Purpose statement**
- ✓ **Define**
- ✓ **Procedures**
- ✓ **Conduct & Reporting**



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Where do we start?



Title 42 Part 491

“The Framework”

§491.4

Compliance with Federal, State and local laws.

- (a) Clinic licensure;**
- (b) Clinic personnel are licensed, certified or registered in accordance with applicable laws.**



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42 CFR §491.7

Organizational Structure

Basic Requirements:

- 1) The clinic is under the medical direction of a physician, and has a health care staff that meets the requirements of §491.8;
- 2) Policies and lines of authority and responsibilities are clearly set forth in writing.

Disclosure:

- 1) Owners;
- 2) Person principally responsible for directing the operation of the clinic;
- 3) Person responsible for medical direction.



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42 CFR §491.8(b)

Staffing & Physician Responsibilities

Staffing requirements*;

Physician responsibilities:

- 1) Medical supervision of the health care staff;
- 2) In conjunction with the NP and/or PA member(s), participate in developing, executing, and periodically reviewing policies and services provided to Federal program patients;
- 3) Periodically review patient records, provides medical orders and care services to patients of the clinic.



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42 CFR §491.8(c), (c)(2)

Physician Assistant (PA) and Nurse Practitioner (NP) Responsibilities

- (i) Participate in the development, execution and periodic review of the policies;**
- (ii) Participate with the physician in a periodic review of the patients' records.**
- (iii) Arrange for patient referral of services not provided in the clinic;**
- (iv) Assures patient health records are maintained and transferred upon referral.**



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42 CFR §491.9(b)(3)

Services

Policies include:

- (i) A description of services (arrangement or agreement);**
- (ii) Guidelines for 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 periodic review and evaluation of services furnished;**
- (iii) Rules for storage, handling, and administration of drugs and biologicals.**
- (iv) Biennial review.***



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42 CFR §491.9(b)(2)

Policy:

Policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more PAs or NPs.

****At least one member is not a member of the clinic.***



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42 CFR §491.6(a), (b)

“The Big Three”

Physical Plant and Environment

Construction – Ensure access to and safety;

Maintenance – The clinic has a preventive maintenance program:

- 1) Equipment;**
- 2) Drug and biological storage;**
- 3) Clean and orderly.**



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42 CFR §491.9(c)(2)

Laboratory services for immediate diagnosis (part 493);

- (i) Chemical examination of urine by stick or tablet;**
- (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.**



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42 CFR §491.9(c)(3)

Emergency – The clinic provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as: (“The A Team”)

- (i) Analgesics;**
- (ii) Anesthetics (local);**
- (iii) Antibiotics;**
- (iv) Anticonvulsants;**
- (v) Antidotes and emetics; and**
- (vi) Serums and toxoids.**



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CMS Memo - Guidance

Ref: QSO-19-18-RHC

September 3, 2019

The current guidance...an RHC must maintain a supply of drugs and biologicals adequate to handle the volume and type of emergencies it typically encounters for each of the listed categories.

If a RHC generally handles only a small volume/type of a specific emergency, store a small volume of a particular drug/biological.



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CMS Memo

Ref: Interpretive Guidance §491.9(c)(3) – J-0136

The RHC's patient care policies are expected to address which drugs and biologicals it maintains for emergencies and in what quantities.

The RHC must maintain a supply of **commonly** used drugs and biologicals adequate to handle the volume and type of medical emergencies it typically encounters.



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CMS Memo

Ref: Interpretive Guidance §491.9(c)(3) – J-0136

Each category of drugs and biologicals must be considered, all are not required to be stored.

For example, it is appropriate for a RHC to store a small volume of a drug/biological, if it generally handles only a small volume/type of a specific emergency.

Likewise, it may be acceptable if the clinic did not store a particular drug/biological because it is located in a region of the country where a specific type of emergency is not common (e.g., snake bites).



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CMS Memo

Ref: Interpretive Guidance §491.9(c)(3) – J-0136

...when determining which drugs and biologicals...the RHC should consider...community history, the medical history of its patients and accepted standards of practice.

Have written policies and procedures for determining what drug/biologicals are stored and that address the process for determining which drugs/biologicals to store, including identifying who is responsible for making this determination.

The RHC should be able to provide a complete list of the drugs/biologicals that are stored and in what quantities.



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42 CFR §491.9(d)

“Related to...”

Services provided through agreement or arrangement:

- (i) Inpatient hospital care;**
- (ii) Physician(s) services; and**
- (iii) Additional and specialized diagnostic and laboratory services.**

****If not in writing, there is evidence patients referred are being accepted and treated.***



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42 CFR §491.10(a)

Records system

- (1) The clinic maintains a clinical record system...
- (2) A designated member of the professional staff is responsible...;

In the medical record:

- (i) Identification and social data, consent forms, pertinent medical history, assessment of health status and needs of the patient, episode summary, disposition, and instructions to the patient;
- (ii) Documented physical examination, diagnostic and lab results;
- (iii) All physician's orders, treatments, medications...;
- (iv) Signatures.



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42 CFR §491.10(b)

Protection of information:

- (1) Confidentiality and safeguards against lost, destruction or unauthorized use;**
- (2) Policy and Procedure for the use and removal; conditions for release of information;**
- (3) Written consent.**
- (4) Retention of records.**



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42 CFR §491.11

Annual Program Evaluation

- (1) Utilization of clinic services;
- (2) Chart review;
- (3) Policy review.

****Findings; Corrective action(s).***



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Rural Health Clinic Regulations

§491.11 Annual Program Evaluation

RIN 0938-AT23 Effective: 11/29/2019

Rural Health Clinics' and Federally Qualified Health Centers' Annual Program Evaluation requirements in 42 CFR 491.11(a) and the policy review will be revised to a biennial requirement.

<https://www.federalregister.gov/d/2019-20736/p-118>



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42 CFR §491.12

Emergency Preparedness

- (a) Emergency Plan;
- (b) Policies and procedures;
- (c) Communication Plan;
- (d) Training and testing; and
- (e) Integrated health systems.



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Rural Health Clinic Regulations

§491.12 Emergency Preparedness

RIN 0938-AT23 Effective: 11/29/2019

The emergency preparedness program training will be revised to a biennial requirement; except in cases of initial staffing and significant policy updates.

The annual review of the emergency preparedness program policies will be revised to a biennial (every other year) requirement.



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Rural Health Clinic Regulations

§491.12 Emergency Preparedness

RIN 0938-AT23 Effective: 11/29/2019

The requirement to document efforts to contact local, tribal, regional, state and Federal emergency preparedness officials...will be removed. However, a process to collaborate and cooperate must still be included in your emergency policies.



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Rural Health Clinic Regulations

§491.12 Emergency Preparedness

RIN 0938-AT23 Effective: 11/29/2019

The emergency preparedness program testing will be revised to one (1) community-based full-scale exercise, if available, or an individual facility-based functional exercise required biennially, and in opposite years, an additional exercise is required, and you may choose the exercise method (full-scale community or facility-based or tabletop).

<https://www.federalregister.gov/d/2019-20736/p-113>



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RHC Policy Overview

Compliance

- ◇ **Compliance Plan**
- ◇ **Program Evaluation**
- ◇ **Emergency Preparedness**

Administration

- ◇ **Organization**
- ◇ **Personnel**
- ◇ **Records Management**

Patient-Care

- ◇ **Medical Guidelines**
- ◇ **Services**
- ◇ **Physical Plant**
- ◇ **Laboratory**
- ◇ **Emergency Procedures**
- ◇ **Drug/Biological Management**



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Are we done yet?

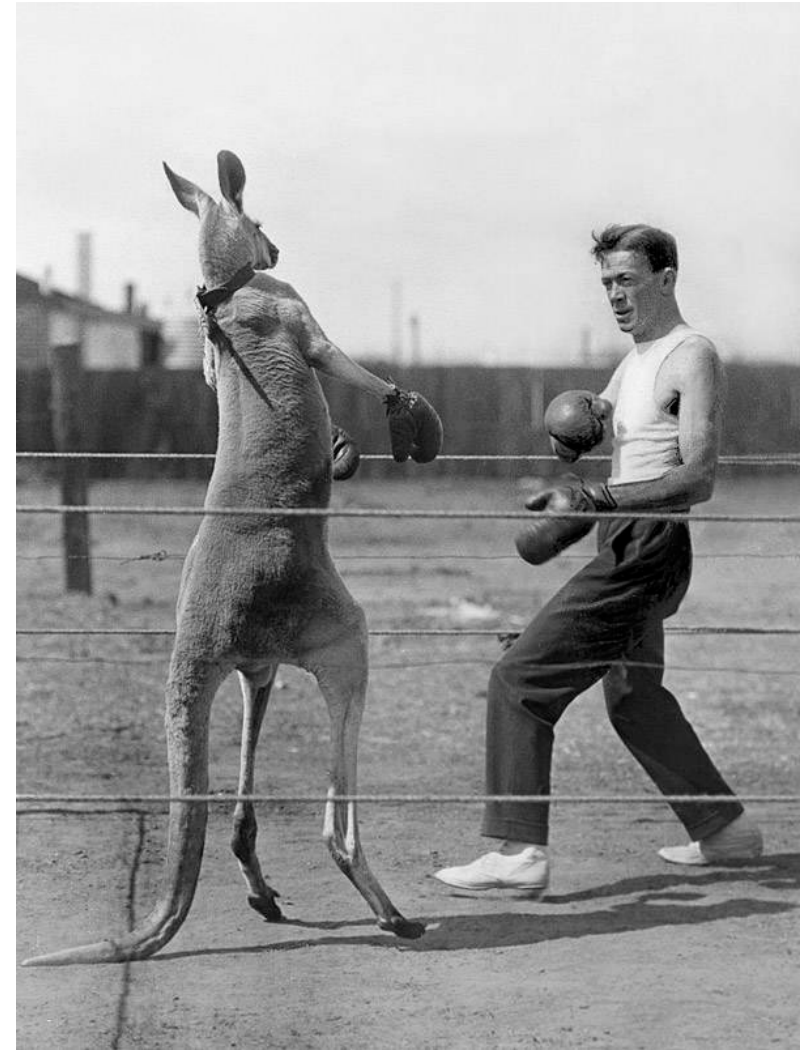
- ❑ Administrative, organizational and compliance* policies
- ❑ Human resources (OIG)
- ❑ Financial & Billing
- ❑ Office of Civil Rights
- ❑ Physical Plant and Safety (OSHA / ADA)
- ❑ Patient & Diagnostic services*
- ❑ HIPAA
- ❑ Other*



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Paper vs. Electronic

- **Policy Manual Index**
- **'Point-to' Policies**
- **Access**
- **Training**



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◆ Credentialing & Enrollment, Medical Billing, RHC Services ◆

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