

# RHC Updates to Emergency Drugs, Program Evaluation and Emergency Preparedness

GRHA

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Jekyll Island, Georgia

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Consulting  
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Three Recent  
Changes that  
Effect RHCs

- One change to  
**Appendix G:  
Interpretive Guidance  
for Surveyors**
- Two changes to  
**42 CFR § 491  
Conditions of RHC  
Certification**

# Emergency Kit Drugs

**Ref: QSO-19-18- RHC**

**September 3, 2019**

Emergency Drugs  
42 CFR 491:9(c)3

(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.**

## **Ref: QSO-19-18- RHC**

“After further view of the regulatory language, we believe the use of “such as” in relation to the drug/biological types described at 42 CFR 491.9(c)(3), does provide some flexibility to RHCs. Therefore, we are revising Appendix G. Specifically, when determining which drugs and biologicals to have available in order to provide medical emergency procedures as a first response to common life-threatening injuries and acute illnesses, an RHC must consider each of the categories listed in regulation. While each category of drugs and biologicals must be considered, all are not required to be stored. An RHC must have those drugs and biologicals that are necessary to provide its medical emergency procedures to common life-threatening injuries and acute illnesses. In making this determination, the RHC should consider, among other things, accepted medical standards of practice, community history and the medical history of its patients. The RHC should have written policies and procedures for determining what drug/biologicals are stored to provide such emergency services. The policy and procedures should also reflect the process for determining which drugs/biologicals to store, including who is responsible for making this determination. They should be able to provide a complete list of which drugs/biologicals are stored and in what quantities.”

# New Interpretive Guideline for Evidence of Compliance with Appendix G

## **J-0136**

**(Rev. 177, Issued: 01-26-18, Effective: 01-26-18, Implementation: 01-26-18)**

### **[§ 491.9(c) Direct services]**

**(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 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 as a first response to common life-threatening injuries and acute illnesses at all times the clinic operates. The clinic maintains the types and quantity of drugs and biologicals *commonly* 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* RHC must maintain a supply of *commonly used* drugs and biologicals adequate to handle the volume and type of *medical* emergencies it typically encounters. The following are categories of drugs and biologicals commonly used in life saving procedures:

- Analgesics;
- Local Anesthetics;
- Antibiotics;
- Anticonvulsants; and
- Antidotes, emetics, serums & toxoids.

*While 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 particular 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). Nonetheless, when determining which drugs and biologicals it has available for purposes of addressing common life-threatening injuries and acute illnesses, the RHC should consider, among other things, the community history, the medical history of its patients and accepted standards of practice. The clinic should 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.*

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-18-RHC.pdf>

## **Survey Procedures § 491.9(c)(3)**

**Review the RHC's written policies and procedures to determine the types and quantities of drugs/biologicals it stores for medical emergency purposes,**

**Review all of the drugs/biologicals that are stored and available in the RHC, including in what quantities, to verify the RHC maintains a supply of commonly used drugs and biologicals adequate to handle the volume and type of medical emergencies it typically encounters.**

**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?**

**Any findings as a result of the inquiry, may lead to noncompliance under 42 CFR 491.9(b).**

# Steps to Compliance with New Emergency Drug Guidance



**Step 1: Redesign  
Processes and  
Revise Written  
Policies to Reflect  
New Drug  
Selection Process**

- ✓ Design new processes and procedures to implement the emergency drug selection and documentation of the selection process.
- ✓ Determine if your written policies for provision of emergency services and the emergency kit required revision to align with new Appendix G language.
- ✓ Educate providers, clinical staff and key personnel on the changes.

**Step 2:  
Determine which  
Emergencies You  
Need to be able  
to Treat**

- ✓ Review which emergencies the RHC has treated in the past:
  - ✓ Medical emergencies
  - ✓ Injuries
  - ✓ Critical Care
  
- ✓ Evaluate which emergencies you would most likely need to treat:
  - ✓ Based on location, geography, demographics of service area
  - ✓ Based on emergency risk assessments

# Have a process for determining which emergencies you are most likely to treat in your RHC

## Emergency Kit, Drugs and Biologicals Assessment Tool

RHC Name: \_\_\_\_\_ Date: \_\_\_\_\_

42 CFR 491.9(c)(3)

Direct Services

**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.

**Appendix G:** While 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 particular 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). Nonetheless, when determining which drugs and biologicals it has available for purposes of addressing common life-threatening injuries and acute illnesses, the RHC should consider, among other things, the community history, the medical history of its patients and accepted standards of practice. The clinic should 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.

**Instructions:** Complete this assessment form to assist in determining which emergency drugs and supplies should be considered by the RHC medical director and medical staff.

### Section 1: Type of RHC

Independent       Provider-based On Hospital Campus       Provider-based Off Campus: Distance \_\_\_\_\_

1. Does hospital code team respond to RHC?     Yes     No     N/A if independent RHC
2. Does RHC have AED?     Yes     No (Not required by federal regulation)
3. Are RHC providers ACLS trained?     Yes     No

### Section 2: Closest Facilities with Emergency Services

Hospital Name	Distance from RHC	Type A ED, Type B ED or Other Facility
_____	_____	_____
_____	_____	_____

**Section 3: EMS/ACLS Providers**

- Is there dependable/timely EMS service to/from RHC?     Yes     No    EMS Provider: \_\_\_\_\_
- Does the RHC have transport agreement with EMS?     Yes     No    EMS Provider: \_\_\_\_\_
- Does EMS have ACLS?     Yes     No    EMS Provider: \_\_\_\_\_
- Is Air Ambulance available?     Yes     No    EMS Provider: \_\_\_\_\_

**Section 4: History of Treating Life-threatening Emergencies in the RHC**

What emergency treatment has the RHC given in the past?    Is the RHC a new practice without tx history?     Yes     No  
 If no treatment history is available, complete assessment based on predictions. Note "estimated or predicted" as frequency.

Type of Emergency Care	Treatment/Supplies/Drugs Typically Given	Frequency over Time
<input type="checkbox"/> Lacerations/Closure/Repair	_____	_____
<input type="checkbox"/> Puncture Wounds	_____	_____
<input type="checkbox"/> Fractures/Dislocations	_____	_____
<input type="checkbox"/> Other Traumatic Injury	_____	_____
<input type="checkbox"/> Chest Pain	_____	_____
<input type="checkbox"/> Cardiac Emergency	_____	_____
<input type="checkbox"/> Respiratory Distress	_____	_____
<input type="checkbox"/> Animal Bites	_____	_____
<input type="checkbox"/> Human Bites	_____	_____
<input type="checkbox"/> Insect Bites	_____	_____
<input type="checkbox"/> Venomous Snake Bites	_____	_____
<input type="checkbox"/> Anaphylaxis	_____	_____
<input type="checkbox"/> Hypertensive Emergency	_____	_____
<input type="checkbox"/> Loss of Consciousness	_____	_____
<input type="checkbox"/> Convulsions/Seizures	_____	_____
<input type="checkbox"/> Suicide/Intentional Injury	_____	_____
<input type="checkbox"/> Accidental Poisoning/Overdose	_____	_____
<input type="checkbox"/> Anaphylactic Shock	_____	_____
<input type="checkbox"/> Diabetic Emergency	_____	_____
<input type="checkbox"/> Mental Health Emergency	_____	_____
<input type="checkbox"/> _____	_____	_____
<input type="checkbox"/> _____	_____	_____

# Have medical staff and key personnel sign off

## Section 5: Populations Serviced

Adults Only    Pediatrics Only    Adults and Peds    Geriatrics    Other Specified Populations: \_\_\_\_\_

## Section 6: Regional Considerations:

List any regional/geographic factors which make the treatment of certain types of medical emergencies more or less probable. For example: no venomous snakes in state; high tourist/recreational area; agricultural area, etc.

## Section 7: Medical Staff Preference/Comments/Concerns:

List any provider preferences, comments or issues concerning the provision of direct emergency care in the RHC. For example: best practices, transport times, drug storage, handling and administration, provider and licensed professional staff training.

## Section 8: Attestation/Acknowledgement

The following staff and providers participated in the completion of this assessment.

<u>Name</u>	<u>Credential/Title</u>	<u>Signature</u>	<u>Date</u>

## Step 3: Medical Staff Decides on Which Drugs to Stock

- ✓ Based on the assessments, the medical director and RHC providers should decide which drugs from each category they will stock and in what quantities.
- ✓ Document this decision-making process.
- ✓ If the medical staff decides not to stock a category of drug (anti-venom, for example), document the reason why the providers do not think it is necessary to stock.

# Have a master list of drugs, supplies and quantities

## Rural Health Clinic Emergency Drug, Biological and Supplies Master List

The medical director, physicians, nurse practitioners, and physician assistants have agreed that the following items and drugs shall be kept as emergency drugs and biologicals for the treatment of life-threatening conditions as required by 42 CFR 491.9. Note: Only the category of drug is referenced in the regulation. Commonly used drugs are listed but are not a requirement. The RHC providers may decide which of a category or class of drug is to be stocked as part of the emergency kit and supplies. You may decide **NOT** to stock a category of drug or a specific drug if you have determined it is not applicable to your RHC based on your assessment.

**Note: Not all items listed are required by 42 CFR 491.**

### Drugs and Biologicals Needed to Provide Emergency Care

Analgesics (check all that apply and indicate route, dosage and quantity to stock for emergency kit)

Drug	Route	Dosage	Quantity	Comment
<input type="checkbox"/> Acetaminophen (Tylenol)	Oral	_____	_____	_____
<input type="checkbox"/> Ibuprofen (Motrin)	Oral	_____	_____	_____
<input type="checkbox"/> Aspirin	Oral	_____	_____	_____
<input type="checkbox"/> Aspirin, Baby	Oral	_____	_____	_____
<input type="checkbox"/> Naproxen (Aleve)	Oral	_____	_____	_____
<input type="checkbox"/> Ketorolac (Toradol)	IM	_____	_____	_____
<input type="checkbox"/> Other: _____	_____	_____	_____	_____

Anesthetic

<input type="checkbox"/> Lidocaine (Xylocaine)	Topical	_____	_____	_____
<input type="checkbox"/> Lidocaine (Xylocaine)	SubQ	_____	_____	_____
<input type="checkbox"/> Marcaine (Bupivacaine) with epi	As block	_____	_____	_____
<input type="checkbox"/> Marcaine (Bupivacaine) w/o epi	Infiltration	_____	_____	_____
<input type="checkbox"/> Viscous Lidocaine (for Magic Mouthwash)	Oral	_____	_____	_____
<input type="checkbox"/> Ethyl Chloride Spray (Pre-Injection)	Topical	_____	_____	_____
<input type="checkbox"/> Other: _____	_____	_____	_____	_____

Antibiotics

<input type="checkbox"/> Ceftriaxone (Rocephin)	IM	_____	_____	_____
<input type="checkbox"/> Penicillin G	IM	_____	_____	_____
<input type="checkbox"/> Other: _____	_____	_____	_____	_____

- Inventory List Shall be included on the outside or within the emergency kit.
- Emergency Kit Shall be stored securely to prohibit unauthorized access.

### Attestation and Acknowledgement

This master list of emergency drugs, biologicals and medical supplies has been reviewed and approved by the RHC medical director, physicians, nurse practitioners, and physician assistants based on the emergency assessment that has been done. This list shall be reviewed at least annually as part of the annual RHC program evaluation and policy review.

Approved by,

Name	Credential/Title	Signature	Date

- Licensed Professional Staff Oriented to Contents and Location of Emergency Drugs and Supplies.
- For PBRHC Only: Routed to Pharmacy \_\_\_\_\_
- For PBRHC Only: Routed to Compliance/MEC \_\_\_\_\_

**Have appropriate sign-offs**

## Other Steps

- **Label Outside of Emergency Kit or Cart**
- **Include Emergency Kit in Routine Periodic Inventory of Drugs.**
- **Watch for expiration dates for both drugs and supplies**
- **Review Steps 1 & 2 at least annually or whenever your demographics or environment change.**

# RHC Policy Review and Program Evaluation Change

**Effective November 29, 2019**

**42 CFR §491.9 Revision**

**42 CFR §491.11 Revision**

# Policy Review and Program Evaluation



## Organizational Structure and Ownership

J Tag References: J-0060,  
J-0061, J-0062, J-0081,  
J-0084, J-0086

Policy Type: Administrative

Policy Number:  
110.00

§ References: 491.7, 491.8,  
491.9

Adopted or Revised Date: 9/27/2019

**Policy Declaration:** This  
clinic is identified as Cros

**Policy Purpose:** The pu  
organizational structure o  
is designed to give detaile  
clinic.

Our Town RHC



Rural Health Clinic  
Annual Evaluation  
Report

Conducted by

**inQuiseek** LLC  
Consulting

*The requirements for review and  
evaluation have not changed. Only the  
frequency has changed.*

*If you are behind, catch up now.*

# **Policy Review and Program Evaluations are now Biannual Requirements**

**d. Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Review of Patient Care Policies**

***We are revising the requirement at § 491.9(b)(4) that RHC and FQHC patient care policies be reviewed at least annually by a group of professional personnel, to review every other year in order to reduce the frequency of policy reviews. e. RHC and FQHC Program Evaluation***

***We are revising the requirement at § 491.11(a) by changing the frequency of the required RHC or FQHC evaluation from annually to every other year.***

Final Rule published in FR on September 30, 2019

<https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-20736.pdf>

Is foregoing any type of annual review of policies or program evaluation wise?

Although there has been a statutory change to the RHC regulation, is it wise to skip policy or program evaluations on an annual basis.

- Changes in medical staff, providers, managers, key personnel?
- Changes in policies or procedure may occur more often than biannually.
- RHCs can fall out of compliance in other areas without a periodic review process.
- Best practice would include maintaining some type of review and evaluation processes even it is not longer required to be formally documented.

# RHC Emergency Preparedness Changes

**Effective November 29, 2019**

**42 CFR §491.12 Revision**

Final Rule published in FR on September 30, 2019

<https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-20736.pdf>

## Revisions to 42 CFR §491.12

- Changes to frequency of review of emergency preparedness plan
- Changes to frequency of testing requirements
- Changes to frequency of training requirements
- Changes to the **documentation** requirements for local, state, federal and tribal collaboration.

## § 491.12 Emergency preparedness

(a) **Emergency plan.** The RHC or FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. •••

(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: •••

(c) **Communication plan.** The RHC or FQHC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following: •••

**(d) Training and testing.** The RHC or FQHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section.

The training and testing program must be reviewed and updated at least every 2 years. (1) •••

(ii) Provide emergency preparedness training at least every 2 years.

**(v) *If the emergency preparedness policies and procedures are significantly updated, the RHC/FQHC must conduct training on the updated policies and procedures.*** •••

**2) Testing.** The RHC or FQHC must conduct exercises to test the emergency plan at least annually. The RHC or FQHC must do the following:

**(i) Participate in a full-scale exercise that is community-based every 2 years; or**

**(A) When a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years; or.**

**(A) When a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years; or**

**(B) If the RHC or FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC or FQHC is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.**

**(ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to following: ••**

**(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or**

**(B) A mock disaster drill; or**

**(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.**

**(iii) Analyze the RHC or FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC or FQHC's emergency plan, as needed.**

*It is no longer necessary to document collaborative efforts with other facilities and agencies. However, the requirement to collaborate is still in force.*

p. Emergency Preparedness Requirements: Requirements for Emergency Plans

***We are removing the requirements from our emergency preparedness rules for Medicare and Medicaid providers and suppliers that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials, and that facilities document their participation in collaborative and cooperative planning efforts.***

Final Rule published in FR on September 30, 2019

<https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-20736.pdf>

<b>EPP Requirement</b>	<b>Before 11/29/2019</b>	<b>After 11/29/2019</b>
<b>EP Risk Assessments (Internal and Community)</b>	<b>Annually</b>	<b>Biannually or when there is a significant change</b>
<b>Review of EPP</b>	<b>Annually</b>	<b>Biannually or when there is a significant change</b>
<b>Employee Training</b>	<b>Upon Hire and Annually</b>	<b>Upon Hire and Biannually if no significant change</b>
<b>Community Wide or Facility Wide Testing Activity</b>	<b>Once Annually</b>	<b>Once biannually or if there is significant change. Activation counts as a facility wide exercise.</b>
<b>Tabletop or drill testing as alternative exercise</b>	<b>Once annually</b>	<b>Once biannually on year when full-scale is not done.</b>
<b>Collaboration with Others</b>	<b>Annually and documented</b>	<b>Biannually but not documented</b>

## Other EPP Tips

- Document employee training
- After Action Reports still required for any testing activity or exercise and for any activation of the EPP (severe weather, loss of utilities, community emergencies.)
- Full-scale and tabletops must be on alternate years.
- Plan review and revision needed if there is a significant change in the EPP.
- Training required on hire, biannually and when there is a major change in EPP.

# Georgia RHC Survey Findings

# Citation Frequency Report

## Selection Criteria

**Display Options:** Display all results  
**Provider and Supplier Type(s):** Rural Health Clinics  
**State:** Georgia  
**Year Type:** Fiscal Year  
**Year:** 2018  
**Quarter:** Full Year

**2018 CMS Fiscal Year**

Tag #	Tag Description	# Citations	% Providers Cited	% Surveys Cited
<b>Totals represent the # of providers and surveys that meet the selection criteria specified above.</b>			Georgia Active Providers = 91	Total Number of Surveys = 12
E0004	Develop EP Plan, Review and Update Annually	2	2.2%	16.7%
E0013	Development of EP Policies and Procedures	2	2.2%	16.7%
E0037	EP Training Program	2	2.2%	16.7%
J0042	PHYSICAL PLANT AND ENVIRONMENT	2	2.2%	16.7%
J0161	PROGRAM EVALUATION	2	2.2%	16.7%
J0043	PHYSICAL PLANT AND ENVIRONMENT	1	1.1%	8.3%
J0123	STAFFING AND STAFF RESPONSIBILITIES	1	1.1%	8.3%

# Citation Frequency Report

## Selection Criteria

**Display Options:** Display all results  
**Provider and Supplier Type(s):** Rural Health Clinics  
**State:** Georgia  
**Year Type:** Fiscal Year  
**Year:** 2019  
**Quarter:** Full Year

**2019 CMS Fiscal Year**

Tag #	Tag Description	# Citations	% Providers Cited	% Surveys Cited
<b>Totals represent the # of providers and surveys that meet the selection criteria specified above.</b>			Georgia Active Providers = 90	Total Number of Surveys = 11
E0037	EP Training Program	2	2.2%	18.2%
J0042	PHYSICAL PLANT AND ENVIRONMENT	2	2.2%	18.2%
J0082	STAFFING AND STAFF RESPONSIBILITIES	2	2.2%	18.2%

**No survey findings reported for Fiscal Year 2020 entered into QCOR database as of 10/25/2019.**

# Overdue Recertification Surveys

## Selection Criteria

**Months Since Last Survey Date:** 36  
**Provider and Supplier Type(s):** Rural Health Clinics

Region	Number of Late Surveys	% of Active Providers
(I) Boston	37	56.1%
(III) Philadelphia	64	39.8%
(IV) Atlanta	500	45.8%
Alabama	46	40.0%
Florida	84	52.2%
<b>Georgia</b>	<b>62</b>	<b>69.7%</b>
Georgia (001)	15	N/A
Georgia All (GAA)	45	N/A
Georgia South (GAS)	2	N/A

**Questions?**  
**Comments?**  
**A Survey Experience to Share?**





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