



Center for Clinical Standards and Quality /Quality, Safety & Oversight Group

Ref: QSO-19-18- RHC

DATE: September 3, 2019

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Rural Health Clinic (RHC) Guidance Updating Emergency Medicine Availability—State Operations Manual (SOM) Appendix G- Advanced Copy

Memorandum Summary

- ***RHC Appendix G Revision:*** The Centers for Medicare & Medicaid Services (CMS) is updating the medical emergency guidance as it pertains to the availability of drugs and biologicals commonly used in life saving procedures.

Background

On December 22, 2017, CMS issued a comprehensive revision to the SOM, Appendix G for RHCs. As part of the revision, we provided additional guidance pertaining to the medical emergency requirements which are codified at 42 CFR 491.9(c)(3). The regulation requires RHCs to provide medical emergency procedures as a first response to common life-threatening injuries and acute illness. In addition, it requires RHCs to have available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids. Since the regulation utilizes the term “such as” when identifying the types of drugs/biologicals the RHC must have available, there have been questions as to whether the RHC must maintain items from *each category type* listed or if the categories were provided as examples. Additionally, it has been brought to our attention that the example provided in the current guidance implies all RHCs are required to store snake bite anti-venom, regardless of whether or not there was a specific risk in the RHC’s geographic area.

Discussion

The current guidance clarifies that 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*. It further states, if an RHC generally handles only a small volume/type of a specific emergency, it is appropriate for the RHC to store a small volume of a particular drug/biological. As an example, we used snake bites as a medical emergency to which storing a small volume of an antidote would be acceptable.

CMS understands the potential financial burden to which RHCs may face as a result of the current guidance. 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. Since RHCs and federally qualified health centers (FQHCs) share the same regulatory requirements as it relates to emergency procedures under 42 CFR 491.9(c)(3), this revision will also apply to FQHCs.

An advance copy of the revised Appendix G, Tag J-0136, which provide additional details is attached. At a later date, the on-line SOM will be revised, and may include further minor changes.

Contact: Questions concerning this memorandum may be addressed to: RHC-FQHC SCG@cms.hhs.gov

Effective Date: Immediately. This guidance should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright
Director

Attachment – Revised Appendix G, Interpretive Guidelines for RHCs, Tag J-0136

cc: Survey and Certification Regional Office Management

CMS Manual System
Pub. 100-07 State Operations
Provider Certification

**Department of Health &
Human Services (DHHS)**
**Centers for Medicare &
Medicaid Services (CMS)**

Transmittal

Date:

ADVANCE COPY

SUBJECT: Revisions to State Operations Manual (SOM) Appendix G, Guidance for Surveyors: Rural Health Clinics

I. SUMMARY OF CHANGES: Appendix G has been revised to update the medical emergency guidance as it pertains to the availability of drugs and biologicals commonly used in life saving procedures.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|--------------|---|
| R | Appendix G/Part II Regulations and Interpretive Guidelines/J-0136 §491.9(c)(3) |
| | |

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2015 operating budgets.

IV. ATTACHMENTS:

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|----------|--------------------------------------|
| | Business Requirements |
| X | Manual Instruction |
| | Confidential Requirements |
| | One-Time Notification |
| | Recurring Update Notification |

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.

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).*