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

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

Transmittal 194

Date: October 25, 2019

**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: October 25, 2019
IMPLEMENTATION DATE: October 25, 2019

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) Direct services]

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:

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

J-0136

(Rev.194, Issued: 10-25-19, Effective; 10-25-19, Implementation: 10-25-19)

[§ 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).*