

CMS Standards for Infection Prevention for Fingertick and Point of Care Testing Devices

Karen Hoffmann RN, MS, CIC, FSHEA
Infection Preventionist
Survey and Certification Group (SCG)
CCSQ/CMS



March 6, 2013



Laboratory and Radiologic Services

Standard: Lab Services part 493

- POC testing is considered a laboratory service requiring a waived test certificate.
- Under the laboratory and radiologic services CfC, §416.49(a) states the requirements for laboratory services in ASCs.
- *§416.49(a) Standard: Laboratory Services*
- *If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter...*

<http://wwwn.cdc.gov/dls/waivedtests/>

<https://www.cms.gov/CLIA/downloads/HowObtainCLIACertificate.pdf>

493.15 Laboratories performing waived tests

493.15(e) Laboratories eligible for a certificate of waiver must -
(1) Follow manufacturers' instructions for performing the test;

493.1100 Standard: Facilities

493.1100(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements

(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

493.1254(a)(1) Standard: Maintenance and function checks

(a) *Unmodified manufacturer's equipment, instruments, or test systems.* The laboratory must perform and document the following:

(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

CMS Nursing Home Infection Control Standards: Section 483.65 - F411

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850



Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 10-28-NH

DATE: August 27, 2010
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Point of Care Devices and Infection Control in Nursing Homes

Memorandum Summary

Infection Control Standards for Nursing Homes at §483.65 - F441 –Determining Compliance: The following practices are deficiencies in infection control:

- Reusing fingerstick devices (e.g., pen-like devices) for more than one resident;
- Using a blood glucose meter (or other point-of-care device) for more than one resident without cleaning and disinfecting it after use.

If a surveyor observes a facility doing either of the above, the surveyor should follow the interpretive guidelines, investigative protocol, and severity determination information at F441 to determine the severity of the deficiency.

Scope & Severity: CMS is revising the example in Appendix PP to make a distinction between (a) reuse of fingerstick devices for more than one resident (immediate jeopardy) and (b) use of a blood glucose meter for more than one resident without proper cleaning and disinfection, so that scope and severity can be correctly assessed.

CMS

CENTERS for MEDICARE & MEDICAID SERVICES



CMS ASC Infection Control Standards

Section: 416.51 CfC

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

(a) Sanitary environment.-- must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

(b) Infection control program--must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. (i.e. CDC Guidelines, ASA, AORN, and USP)

CMS INFECTION CONTROL ASC AUDIT TOOL

A 16-page audit tool listing items that must be assessed during the on-site survey, in order to determine compliance with the infection control

- Observation, interview, or both
- Patient tracer methodology used

Condition for Coverage available for download from:

<http://www.cms.gov/SurveycertificationGenInfo/>

Excerpt from ASC infection control surveyor tool

V. Point of Care Devices (e.g., blood glucose meter)
**Observations are to be made of staff who perform
fingerstick testing (e.g., nurses)**

Practices to be assessed:

A. A new single-use, auto-disabling lancing device is used for each patient

- Yes
- No
- N/A

B. The glucose meter is not used on more than one patient unless the manufacturer's instructions indicate this is permissible

- Yes
- No
- N/A

C. The glucose meter is cleaned and disinfected after every use.

- Yes

CMS Hospital Infection Control Regulations: Section 482.42

Sec. 482.42 CoP: Infection Control:

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases.

There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

Hospital Patient Safety Initiative

- Significantly reduce harm and HAIs in the hospital setting
- SCG with CDC assistance has developed new tool to help surveyors assess the Infection Control Conditions of Participation
- Hospital Infection Control Infection tool- *pilot in progress- final in 2013*

CMS Infection Control *pilot* Tool for Hospitals

Section 4. E Point of Care Devices (e.g. Blood Glucose Meter, INR Monitor)

Elements to be assessed	Manner of Assessment Code (check all that apply) & Surveyor Notes			Manner of Assessment Code (check all that apply) & Surveyor Notes		
Point of care devices are used in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:						
4. E.1 Hand hygiene is performed before and after the procedure.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	
4. E.2 Gloves are worn by healthcare personnel when performing the finger stick procedure to obtain the sample of blood and are removed after the procedure (followed by hand hygiene).	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	
4. E.3 Finger stick devices are not used for more than one patient. Note: This includes both the lancet and the lancet holding device.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	
4. E.4 If used for more than one patient, the point-of-care device is cleaned and disinfected after every use according to manufacturer's instructions. Note: if manufacturer does not provide instructions for cleaning and disinfection, then the device should not be used for >1 patient.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	
4. E.5 Insulin pens are used for only one patient	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	

If no to any of 4.E.1 through 4.E.5, the hospital would be at risk on a non-PSI, non-pilot survey for a deficiency citation related to 42 CFR 482.42(a)(1) (Tag A-0749)

Interview = 1

Observation = 2

Infection Control Document Review = 3

Medical Record Review = 4

Other Document Review = 5

Page 32 of 42

CMS Infection Control *pilot* Tool for Hospitals - POC Devices

POC Devices: elements to be assessed: Policies and procedures developed and implemented.

4.E.1. HH performed before and after procedure.

4.E.2. Gloves worn during finger stick (followed by HH).

4.E.3. Finger stick devices are not used for more than one patient. (*Note: includes lancet and holding device*).

4.E.4. If used for more than one patient POC device is cleaned and disinfected after every use according to manufacturer's instructions.

4.E.5. Insulin pens are used for only one patient. (*citable for deficiency under 42 CFR 482.42(a)(1)*)

<http://www.cms.gov/sitesearch/searchresults.html?q=infection%20control%20PSI%20survey%20tool>

Manufacturer Instructions

Deficient practice if determine that health care personnel use the following:

- Disinfectant products that are not effective against viral bloodborne pathogens (refer to EPA list)
- Cleaning and disinfectant products that have not been specified by the device manufacturer to be compatible with their device

CDC, MMWR Weekly March 11, 2005

When No Manufacturer Instructions for Cleaning and Disinfection Exist

Surveyors will investigate the following:

- methods for cleaning and disinfection of meters follow standards of practice by authoritative references to published research, CDC or FDA guidance, recommendations of professional societies, or similar references to commonly accepted professional practices.
- cleaning agents and disinfectants are shown by the device manufacturer to be compatible with their device

Summary

- CMS recognizes the risk of POC devices for cross-transmission.
- CMS has offered trainings to surveyors to increase awareness of risk of POC devices.
- CMS has worked with its partners to develop IC surveyor tools that includes POC devices.
- The CMS IC tools offers guidance for surveyors and use as an assessment tool for healthcare facilities.

Acknowledgements

CMS

Daniel Schwartz, MD, MBA

Thank you!