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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.

Background

Point-of-care testing is diagnostic testing that is performed at or near the site of resident care. This may be accomplished through use of portable, handheld instruments such as blood glucose meters or prothrombin time meters. This testing may involve obtaining a blood specimen from the resident using a fingerstick device. The guidance in this document regarding fingerstick devices and blood glucose meters is applicable to other point-of-care devices where a blood specimen is obtained (e.g., prothrombin time meters).

Deficiency Identification

- Fingerstick devices must never be used for more than one resident. Although the package instructions for some fingerstick devices may indicate or imply the potential for multiple patient use, surveyors and health care workers must adhere to this CMS guidance regarding the avoidance of multiple patient use of fingerstick devices, consistent with recent statements of the CDC and the FDA.
- Point-of-care devices, such as blood glucose meters, can become contaminated with blood and, if used for multiple residents, must be cleaned and disinfected after each use according to manufacturer's instructions.
- If the manufacturer does not specify steps for cleaning and disinfection between uses of a point-of-care device, then the device generally should not be used for more than one resident. In the case of point-of-care devices where there are no manufacturers' instructions for cleaning between uses, we strongly advise nursing homes not to share the devices among residents. In such cases involving sampled residents (or when triggered for further investigation) where there are no manufacturer's instructions, surveyors will inquire as to the methods used for cleaning and disinfection between shared uses and will cite a deficiency for such a practice unless the nursing home can clearly establish that commonly accepted safe infection control practices are being followed (through authoritative references to published research, CDC recommendations, recommendations of professional societies, or similar references to commonly accepted professional practices).

According to the interpretive guidance and investigative protocol F441, for sampled residents or when triggered for further investigation, nursing home surveyors should determine whether point-of-care equipment (such as blood glucose meters) used for more than one resident are appropriately cleaned and disinfected after each use following manufacturer's recommendations.

If the manufacturer's recommendations do not specify agents for cleaning and disinfection between uses, the device generally should not be used for more than one resident. In such a case of shared use of a point-of-care device for which there are no manufacturer's instructions for cleaning and the inquiry is triggered or sampled, inquire as to: (a) the methods used for cleaning and disinfection, (b) the basis for the methods used, as expressed in published research, CDC guidance, recommendations of professional societies, or similar authoritative references, and (c) cite a deficiency if the practice is not grounded in such research, communication from the manufacturer that provides direction for cleaning/disinfection and product compatibility[1], professional recommendations, CDC guidance, guidance from the U.S. Food and Drug Administration (FDA), or other sources of commonly accepted professional infection control practice.

The example provided in the infection control examples of Appendix PP combined reuse of fingerstick devices (e.g., pen-like devices) and the cleaning and disinfection of blood glucose

[1] Manufacturers' instructions may derive from package inserts, published literature, communications between the manufacturer and the nursing home or other parties, or any other form of communication from the manufacturer that identifies cleaning agents, methods, and assurance of compatibility between agents used and the product itself.

meters together in one sentence, which has led to some confusion about how to assess scope and severity for this requirement.

Deficiency Severity Determination

The reuse of fingerstick devices for more than one resident should be treated as immediate jeopardy.

Failure to clean and disinfect blood glucose meters used for more than one resident is a deficiency in infection control that warrants corrective action, but may not constitute immediate jeopardy. This deficiency should warrant further investigation following the interpretive guidelines, investigative protocol, and severity determination information at F441 to determine level of severity.

Next Steps

CMS will be revising the example related to the use of blood glucose meters in appendix PP to state the following:

> *An example of a negative outcome that occurred or has the potential to occur at Severity Level 4 as a result of the facility's deficient practices may include:*
>
> *The facility failed to follow Standard Precautions during the performance of routine testing of blood glucose. The facility reused fingerstick devices for more than one resident. This practice of re-using fingerstick devices for more than one resident created an Immediate Jeopardy to resident health by potentially exposing residents who required blood glucose testing to the spread of bloodborne infections in the facility.*

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information must be shared with all survey and certification staff, surveyors, managers, and the State and CMS regional office training coordinators.

Additional Resource Material

Both the CDC and FDA have updated their website reference material this week, accessible at:

http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html
http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

Below are additional references which offer information about hepatitis, point-of-care devices, and/or blood glucose meter practices.

http://www.cdc.gov/hepatitis/Settings/GlucoseMonitoring.htm

http://www.cdc.gov/ncidod/dhqp/bp_hepatitisb_prevent.html
http://www.cdc.gov/ncidod/dhqp/bp_hepatitisc_prevent.html

http://www3.interscience.wiley.com/cgi-bin/fulltext/123236683/PDFSTART
http://journalofdst.org/March2009/Articles/VOL-3-2-ORG3-THOMPSON.pdf
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5409a2.htm
http://www.cdc.gov/mmwr/preview/mmwrhtml/00046679.htm

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management
U.S. Center for Disease Control and Prevention
U.S. Food and Drug Administration