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**Circular Letter: DHCQ 10-11-540**

**TO:** Long Term Care Facility Administrators  
Health Care Facilities  
Other Interested Parties

**FROM:** Alice Bonner, Ph.D., RN  
Director, Bureau of Health Care Safety and Quality

**RE:** Infection Prevention during Blood Glucose Monitoring and Insulin Administration

**DATE:** November 24, 2010

The purpose of this letter is to highlight the recent notice issued by the Centers for Medicare and Medicaid (CMS) regarding the infection control requirements when health care professionals are assisting with blood glucose monitoring and/or insulin administration. The Centers for Medicare and Medicaid (CMS) issued a Survey and Certification letter [S&C Ref: 10-28-NH] on August 27, 2010 notifying state agency directors that multiple patient use of fingerstick devices is considered an immediate jeopardy situation if found to be the practice in a skilled nursing/nursing facility. Due to the information referenced by CDC/FDA/CMS in their notices and on their websites regarding the serious infection control implications, we are also advising other health care facilities of this serious potential threat to patient safety. We recommend that you immediately review the practices of your staff and your policies and procedures in accordance with these requirements.

[The CMS SNF/NF S&C letter may be found at the following website<sup>1</sup>:  
[https://www.cms.gov/surveyscertificationgeninfo/downloads/SCLetter10\\_28.pdf](https://www.cms.gov/surveyscertificationgeninfo/downloads/SCLetter10_28.pdf) ]

The CDC requirement issued on August 26, 2010 is summarized here:

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<sup>1</sup> For your information, all CMS survey and certification memorandums for all provider types may be accessed at the following website: <http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp>

***“The Centers for Disease Control and Prevention (CDC) has become increasingly concerned about the risks for transmitting hepatitis B virus (HBV) and other infectious diseases during assisted blood glucose (blood sugar) monitoring and insulin administration.***

***CDC is alerting all persons who assist others with blood glucose monitoring and/or insulin administration of the following infection control requirements:***

- ***Fingerstick devices should never be used for more than one person***
- ***Whenever possible, blood glucose meters should not be shared. If they must be shared, the device should be cleaned and disinfected after every use, per manufacturer’s instructions. If the manufacturer does not specify how the device should be cleaned and disinfected then it should not be shared.***
- ***Insulin pens and other medication cartridges and syringes are for single-patient-use only and should never be used for more than one person.***

***...These recommendations apply not only to licensed healthcare facilities but also to any setting where fingerstick procedures are performed and/or insulin is administered, including assisted living or residential care facilities, clinics, health fairs, shelters, detention facilities, schools, and camps. Protection from bloodborne viruses and other infections is a basic requirement and expectation anywhere healthcare is provided.”***

***[The complete explanation of these requirements with clinical references may be found at the CDC website at: <http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html> ]***

CDC states this simple rule for safe care which applies in any setting where assisted monitoring of blood glucose is performed and with the use of any fingerstick device, be it a single use device, or designed for reuse.

***“Fingerstick devices should NEVER be used for more than one person.”***

The **Food and Drug Administration (FDA)** also addressed this infection control standard on 8/10/10. The complete alert may be found at their website. The FDA addressed the use of any fingerstick device including those previously approved for multiple patient uses. The FDA website reads:

***“CDC and FDA have noted a progressive increase in the reports of bloodborne infection transmission over the past 10 to 15 years (primarily hepatitis B virus), resulting from the shared use of fingerstick and point of care (POC) blood testing devices. The infections are occurring in a variety of health care settings; however, the Agencies note a significant increase in hepatitis B virus infection outbreaks related to the shared use of multiuse fingerstick devices and POC blood testing devices in long term care/assisted living settings.***

***The FDA recommendations complement those issued by CDC and are summarized here:***

***FDA and CDC recommend that health care professionals and patients take the following immediate precautions:***

1. ***Fingerstick devices should NEVER be used for more than one person.***

2. *Auto-disabling, single-use fingerstick devices should be used for assisted monitoring of blood glucose. These devices are designed to be used only once, after which the blade is retracted, capped or otherwise made unusable. These may also be called "safety" lancets.*
3. *Whenever possible, POC blood testing devices, such as blood glucose meters and PT/INR anticoagulation meters, should be used only on one patient and not shared. If dedicating POC blood testing devices to a single patient is not possible, the devices should be properly cleaned and disinfected after every use as described in the device labeling.*
4. *Change gloves between patients, even when patient-dedicated POC blood testing devices and single-use, self-disabling fingerstick devices are used by healthcare personnel.*

*Some legally marketed fingerstick devices have been cleared for use on more than one patient. Shortly, FDA will issue a separate communication describing the actions the Agency will take to assure that these devices are labeled for use on only one patient to reduce the risk of bloodborne infection transmission."*

[The complete text of the FDA recommendations may be found on their website at:  
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm> ]

Attached to this letter is a copy of a clinical reminder issued by the CDC which you may find useful. This clinical reminder may also be downloaded from the CDC website at:  
[http://www.cdc.gov/injectionsafety/PDF/Clinical\\_Reminder\\_Fingerstick\\_Devices\\_RiskBBP.pdf](http://www.cdc.gov/injectionsafety/PDF/Clinical_Reminder_Fingerstick_Devices_RiskBBP.pdf)

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

<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>  
[http://www.cdc.gov/ncidod/dhqp/bp\\_hepatitisb\\_prevent.html](http://www.cdc.gov/ncidod/dhqp/bp_hepatitisb_prevent.html)  
[http://www.cdc.gov/ncidod/dhqp/bp\\_hepatitisc\\_prevent.html](http://www.cdc.gov/ncidod/dhqp/bp_hepatitisc_prevent.html)  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5409a2.htm>  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/00046679.htm>  
<http://www.journalofdst.org/September2010/PDF/VOL-4-5-EDT1-KLONOFF.pdf>  
<http://www3.interscience.wiley.com/cgi-bin/fulltext/123236683/PDFSTART>  
<http://journalofdst.org/March2009/Articles/VOL-3-2-ORG3-THOMPSON.pdf>

If you have additional questions after reviewing these resources, please contact Paul DiNatale at the Department of Public Health at 617-753-7345. Thank you very much.

Cc: Lauren Smith, MD, MA DPH Medical Director  
John Auerbach, MA Commissioner of Public Health  
Al DeMaria, MD, Bureau of Infectious Disease