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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-30-ALL

DATE: **May 18, 2012**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Use of Insulin Pens in Health Care Facilities

Memorandum Summary

Insulin Pen devices: The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in the need for post-exposure patient notification. These reports indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients. **Insulin pens are meant for use by a single patient only.** Each patient/resident must have his/her own. Sharing of insulin pens is essentially the same as sharing needles or syringes, and must be cited, consistent with the applicable provider/supplier specific survey guidance, in the same manner as re-use of needles or syringes.

Background

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times by a single patient/resident, using a new needle for each injection. Insulin pens must never be used for more than one patient/resident. Regurgitation of blood into the insulin cartridge after injection will create a risk of bloodborne pathogen transmission if the pen is used for more than one patient/resident, even when the needle is changed [1]. A previous memo (10-28-NH), dated August 27, 2010, similarly identified that point of care testing devices must not be shared between residents because of the risk of bloodborne pathogen transmission.

In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration (FDA) issued an alert for healthcare professionals reminding them that insulin pens are meant for use by a single patient only and are not to be shared between patients [2**].** Despite this alert, patients continue to be placed at risk of bloodborne pathogen exposure through inappropriate use of insulin pens for more than one patient, including an incident in 2011 that required notification of more than 2,000 patients [3]. These events indicate that some healthcare personnel may be unaware of the risk this unsafe practice poses to patients/residents.

Discussion

Any provider or supplier using insulin pens should review the following recommendations of the FDA to prevent transmission of bloodborne infections in the patients/residents under their care.

- Insulin pens containing multiple doses of insulin are meant for single patient/resident use only, and must never be used for more than one person, even when the needle is changed.
- Insulin pens must be clearly labeled with patient/resident's name or other identifiers to verify that the correct pen is used on the correct patient/resident.
- Healthcare facilities should review their policies and procedures and educate their staff regarding safe use of insulin pens.

Reuse of insulin pens is similar to reusing needles or syringes for more than one patient/resident and must direct the surveyor to focus on the overall infection control practices in the facility. The facility plan of correction should include notification of the local health department or state epidemiologist for determination of the need for post-exposure follow-up of patients and residents.

Effective Date: Immediately. Please ensure that state and RO surveyors are incorporating this information into their survey practices.

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

The CDC has updated their website reference material www.cdc.gov/injectionsafety and issued a clinical reminder accessible a http://www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html

References

1. Sonoki K, Yoshinari M, Iwase M, Tashiro K, Iino K, Wakisaka M, Fujishima M. Regurgitation of blood into insulin cartridges in the pen-like injectors. *Diabetes Care*. 2001;24(3):603-4.
2. Information for healthcare professionals: risk of transmission of blood-borne pathogens from shared use of insulin pens (2009). *U.S. Food and Drug Administration Postmarket Drug Safety Information for Patients and Providers*. Accessed November 14, 2011 from http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm133352.htm
3. Important Patient Safety Notification (2011). *Dean Clinic*. Accessed November 14, 2011 from http://www.deancare.com/about-dean/news/2011/important-patient-safety-notification/

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/s/
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cc: Survey and Certification Regional Office Management