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INFORMATIONAL LETTER #2014-11

DATE: July 2, 2014

TO: ADMINISTRATORS
- AMBULATORY SURGERY CENTERS
- HOSPICE AGENCIES
- HOSPITALS
- CRITICAL ACCESS HOSPITALS
- LONG TERM CARE FACILITIES
- HOME HEALTH AGENCIES
- RURAL HEALTH CLINICS
- END STAGE RENAL DIALYSIS FACILITIES

FROM: DEBBY RANSOM, R.N., R.H.I.T., Chief
Bureau of Facility Standards

SUBJECT: **CMS S&C Letter #14-36**
INFECTION CONTROL BREACHES WHICH WARRANT REFERRAL TO PUBLIC HEALTH AUTHORIEIS

The CMS Survey & Certification Letter #14-36, Infection Control Breaches which Warrant Referral to Public Health Authorities, is being distributed to all Health Care Facilities in Idaho.

If you have any questions, please contact our office at 208/334-6626.

Debby Ransom

DEBBY RANSOM, R.N., R.H.I.T., Chief
Bureau of Facility Standards

DR/nm
Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-36-All

DATE: **May 30, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Infection Control Breaches Which Warrant Referral to Public Health Authorities

Memorandum Summary

- ***Infection Control Breaches Warranting Referral to Public Health Authorities:*** If State Survey Agencies (SAs) or Accrediting Organizations (AOs) identify any of the breaches of generally accepted infection control standards listed in this memorandum, they should refer them to appropriate State authorities for public health assessment and management.

- ***Identification of Public Health Contact:*** SAs should consult with their State's Healthcare Associated Infections (HAI) Prevention Coordinator or State Epidemiologist on the preferred referral process. Since AOs operate in multiple States, they do not have to confer with State public health officials to set up referral processes, but are expected to refer identified breaches to the appropriate State public health contact identified at: http://www.cdc.gov/HAI/state-based/index.html

Background:

Medicare regulations for the various certified provider/supplier types require adherence to generally recognized standards for infection control practices. Surveyors evaluate the implementation of these practices as a component of the survey process.

Some types of infection control breaches, including some specific to medication administration practices, pose a risk of bloodborne pathogen transmission that warrant engagement of public health authorities to conduct risk assessment and, if necessary, to implement the process of patient notification. These functions are outside the jurisdiction of the Centers for Medicare & Medicaid Services (CMS), but do fall within the authority of State public health agencies. When a SA or AO confirms that a survey has identified evidence of one or more of the breaches described below, in addition to taking appropriate enforcement action to ensure the deficient

Medicare practices are corrected, the SA or AO should also make the responsible State public health authority aware of the identified breach.

CMS Regulatory Authorities:

Pertinent regulations include, but are not limited to, the following:

42 CFR §416.51 for ambulatory surgical centers (ASCs), "The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.... (b)...The ASC 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...."

42 CFR §418.60 for hospices, "The hospice must maintain and document an effective infection control program that protects patients, families, visitors, and hospice personnel by preventing and controlling infections and communicable diseases. (a) ...The hospice must follow accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions."

42 CFR §482.42 for hospitals, "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."

42 CFR §483.65 for skilled nursing facilities and nursing facilities, "The facility must establish and maintain an infection control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection."

42 CFR §484.12(c) for home health agencies (HHAs), "The HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA."

42 CFR §485.635(a)(3)(vi) for critical access hospitals (CAHs), CAH policies must include "A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel."

42 CFR §491.9(b)(3)(iii) for rural health clinics (RHCs) and Federally Qualified Health Centers, the patient care policies include "Rules for the storage, handling, and administration of drugs and biologicals." [relates to safe injection practices]

42 CFR §494.30 for dialysis facilities, "The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. (a)... The facility must demonstrate that it follows standard infection control precautions.... (b)...The facility must .... (2) Ensure

that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules…."

Breaches to Be Referred

When one or more of the following infection control breaches is identified during any survey of a Medicare- and/or Medicaid-certified provider/supplier, the SA or AO should make the appropriate State public health authority aware of the deficient practice:

- Using the same needle for more than one individual;
- Using the same (pre-filled/manufactured/insulin or any other) syringe, pen or injection device for more than one individual;
- Re-using a needle or syringe which has already been used to administer medication to an individual to subsequently enter a medication container (e.g., vial, bag), and then using contents from that medication container for another individual;
- Using the same lancing/fingerstick device for more than one individual, even if the lancet is changed.

SAs may refer other infection control breaches in addition to those described above if recommended by their State public health authorities. AOs also have the discretion to refer additional breaches they believe require public health assessment and management.

The Centers for Disease Control & Prevention (CDC) works closely with States on HAI prevention activities, and many States have designated HAI Prevention Coordinators.

- SAs should consult with their State's HAI Prevention Coordinator, State Epidemiologist and/or other appropriate public health point of contact to develop an efficient and effective referral process for these and any other serious infection control breaches that public health authorities identify as requiring their intervention.
- Since AOs operate in multiple States, they do not have to confer with State public health officials to set up referral processes, but are expected to refer identified breaches to the appropriate State public health contact.

State public health contact information may be found in the State-based HAI Prevention Activities map at http://www.cdc.gov/HAI/state-based/index.html

Questions concerning this memorandum may be addressed to hospitalscg@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management
Centers for Disease Control and Prevention