



**Center for Clinical Standards and Quality/Survey & Certification Group**

**Ref: S&C: 14-36-ALL**  
**REVISED 10.28.16**

**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  
*\*\*\*Additional Information has been added to Breaches to Be Referred. This policy memorandum supersedes policy memorandum S&C: 14-36-ALL\*\*\**

**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 *must* refer them *as directed* 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, the Centers for Medicare & Medicaid Services (CMS) strongly encourages them to notify the appropriate State public health officials to make the referral of information about serious infection control breaches on the part of healthcare providers they survey in that state. Contact information for each state's health departments is identified on the Centers For Disease Control & Prevention's (CDC's) website at: <https://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; but not limited to, medication injection practices and disinfection and sterilization of medical devices and equipment, pose a risk of blood borne pathogen transmission that warrants engagement of public health authorities to conduct a risk assessment and, if necessary, to implement the process of patient notification. These functions are outside the jurisdiction of the 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 infection control breaches described below, in addition to taking appropriate

enforcement action to ensure the deficient 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 infection control breaches, that could potentially expose patients to the blood or bodily fluids of another, are identified during any survey of a Medicare or Medicaid-certified provider/supplier, the SA or AO *must* make the appropriate State public health authority aware of the deficient practice. Examples of such infection control breaches *that must be reported* are unsafe injection practices and use of sharps, including:

- Using the same needle for more than one individual;
- Using the same syringe, pen or injection device (e.g. pre-filled, manufactured, insulin or any other *medication or biological*) for more than one individual;
- Re-using a needle or syringe which has already been used to administer medication *or a biological* 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.

*The SA or AO should also refer other infection control breaches in addition to those described above if recommended by their State public health authorities or if they believe the breaches require public health assessment and management. Examples of such infection control breaches include, but are not limited to, the following:*

- *Improper cleaning and disinfection of endoscopy equipment; and,*
- *Improper cleaning and sterilization of surgical instruments.*

The 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 points 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.

AOs are expected to refer identified infection control breaches to the appropriate State’s HAI Prevention Coordinator, State Epidemiologist or other state public health contact.

State public health contact information may be found on the CDC’s website on the webpage titled, “Healthcare Acquired Infections (HAIs)/State Based HAI Prevention” at <http://www.cdc.gov/HAI/state-based/index.html>.

**Contact:** Questions concerning this memorandum may be addressed to [hospitalscg@cms.hhs.gov](mailto: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/  
David R. Wright

cc: Survey and Certification Regional Office Management  
Centers for Disease Control and Prevention  
CMS-Approved Accrediting Organizations