

Infection Control Breach Referral Protocol

Background

In May 2014, the Center for Clinical Standards and Quality/Survey & Certification Group of the Center for Medicare and Medicaid Services (CMS) issued a memorandum (S&C:14-36-ALL) to State Survey Agencies mandating that any identified breach of generally accepted infection control standards must be referred to appropriate state authorities for public health assessment and management. [CMS Memo 14-36-ALL](#) provides an additional channel through which public health can become aware of ongoing infection control issues in a variety of healthcare settings.

Public Health Significance

Certain categories of infection control breaches, specifically including, but not limited to, improper medication injection practices and inadequate disinfection and sterilization of medical devices and equipment, present a risk of bloodborne pathogen transmission. This risk necessitates the involvement of public health authorities to conduct a comprehensive risk assessment and, when warranted, to initiate the process of patient notification. These specific functions reside outside the purview of CMS but are within the established authority of the State's public health agencies.

Infection control breaches are divided into two categories based on the qualitative risk assessment:

1. **Category A Breach**

Defined as breaches that have an established precedent for transmission of bloodborne pathogens and involve a gross error or demonstrated high risk procedure (e.g., needle and syringe reuse; syringe reuse to access multi-dose vials; IV fluid reuse; contaminated equipment; improper injection practices; failure to reprocess reusable equipment; IV fluid reuse). These breaches pose a significant risk for bloodborne pathogen and bacterial transmission such as hepatitis B, hepatitis C, and HIV. Examples of Category A breaches include:

- a. Reuse of needles or syringes between patients/residents.
- b. Using a contaminated syringe to draw medication from a multi-dose vial or IV fluid bag.
- c. Not properly cleaning and sterilizing reusable medical instruments between patients.

2. **Category B Breach**

Involve infection control breaches during which the likelihood of blood exposure (e.g., improper reprocessing of reusable medical devices; inadequate cleaning and sterilization; unsafe injection practices; environmental contamination; equipment-

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related issues) resulting from the breach is uncertain, but lower than a Category A breach. Examples of Category B breaches include:

- a. Scope reprocessing performed with incorrect disinfectant solutions or those performed with a shorter duration than is recommended by the manufacturer.
- b. Probes and needles that were sterilized, but retained tissue was not physically removed from the biopsy probe channel.
- c. Not following manufacturer's instructions when using automated equipment.

State Survey Agency (SA) or Accrediting Organizational (AO) Responsibilities

CMS memorandum S&C:14-36-ALL (Appendix A) mandates that SAs or AOs must refer identified breaches of infection control standards to the State Health Department for public health assessment and management. SAs or AOs will notify the Division of Healthcare Quality, Promotion, Prevention and Response (DHQPPR) Director and/or The Centers for Disease Control and Prevention (CDC) via email or letter if a breach is identified.

Some types of infection control breaches that must be reported:

1. Unsafe injection practices.
2. Unsafe use of sharps.
3. Inadequate or inappropriate disinfection and sterilization of medical devices.

State Health Responsibilities

Decisions on how to manage the breach will be made in consultation with the West Virginia Department of Health (DH), Bureau for Public Health (BPH), Office of Epidemiology and Prevention Services (OEPS), DHQPPR Director, designee, other program staff as needed, and may or may not require the CDC. State health responsibilities include the following:

1. Notification Response:
 - a. Calls regarding any infection control breach should be routed to the DHQPPR Director or designee.
 - b. Emails/information sent to the DHQPPR Director will be shared with the DHQPPR Outbreak Team, Office Director and State Epidemiologist.
 - c. The nature of the breach should be noted in the ID Outbreak folder, "Infection Control Breach" subfolder.
 - d. Within the subfolder, a new folder should be created titled "Infection Control Breach {Facility Name} {Date}."
2. Initial Investigation
 - a. Timeframe

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- i. Category A Breach- An on-site Infection Control Assessment and Response (ICAR) visit will be made within three business days from the date of initial notification.
 - ii. Category B Breach- The need and timeframe for an on-site ICAR visit should be determined based on, but not limited to, staff interviews, review of instrument reprocessing, review of procedure, record review, and exposure timeframe.
 - iii. Additional data gathering will ensue in accordance with the type of breach, to include, but not limited to, research of instruments, disinfectants and process, staff interviews.
3. On-going updates will be provided to the OEPS Director about the breach, investigation, and findings. These updates will be provided on a weekly basis and more frequently if warranted.
4. On-site Visits
 - a. Communication and scheduling of visit will be correlated with the facility administrator, infection preventionist or designee.
 - b. Direct observation of practices or disinfection and sterilization will be conducted.
 - c. Verify risk level and notify and involve key stakeholders at local health department, DH leadership, DH's Office of Health Facility Licensure and Certification (OHFLAC), CDC, etc.
 - d. If necessary, cross-referencing with public health records will be conducted.
5. After the on-site visit is complete, decisions on how to manage the breach will be made in consultation with the DHQPPR Director, and/or medical epidemiologist, outbreak team, or other staff leads as required.
6. The OEPS Director will be notified of the investigation findings and recommended actions. Should a patient notification be recommended at any point during the investigation, the State Epidemiologist will be notified of the breach, investigation, and recommendations.

Laboratory Responsibilities

If warranted, DH's Office of Laboratory Services (OLS) will work with the BPH to arrange for specimen collection, testing and prompt reporting in accordance with CDC recommendations.

Local Health Responsibilities

The local health department may be called upon to participate in the on-site visit and/or assistance with specimen collection. If patient notification is deemed necessary, the local health department will be included in all communications.

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Disease Control & Prevention Objectives

The objective for disease control and prevention is to limit the number of patients potentially exposed to blood borne pathogens via contaminated medical equipment by conducting a thorough investigation of the reported breach.

Disease Surveillance Objectives

1. To identify and monitor characteristics of infection control breaches in West Virginia.
2. To identify areas at risk for infection control breaches in West Virginia.
3. To provide appropriate public health interventions and referral for infection control breaches.

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References

1. CMS Memorandum: *Infection Control Breaches Warranting Referral to Public Health Authorities*. October 26, 2016. Retrieved from:
<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-36.pdf>
2. Steps for evaluating an infection control breach. CDC. Date accessed: January 30, 2019.
https://www.cdc.gov/hai/outbreaks/steps_for_eval_ic_breach.html