Association of Professionals in Infection Control and Epidemiology
Greater New York Chapter Conference 2019

DOH Survey Process and Infection Control Overview

October 13, 2019
Who We Are

Office of Primary Care and Health Systems Management

Center for Health Care Provider Services and Oversight

Division of Hospitals and Diagnostic and Treatment Centers (DHDTC)
Where We Work

- Metropolitan Area – New York City Office (includes orange and pink sections)
- Metropolitan Area – Long Island
- Capital District - Albany
- Central New York – Syracuse
- Western New York – Buffalo Office
- Western New York – Rochester

Regional Office Contact Info: [www.health.ny.gov/facilities/cons/more information/regional offices.htm](http://www.health.ny.gov/facilities/cons/more information/regional offices.htm)
DHDTTC Activities

- Conduct State surveys and serve as the federal State Agency (SA) to qualify facilities for Medicare and Medicaid.
- DHDTTC receives federal budget dollars to do federal surveys, including certification, recertification and validation surveys, and federal allegation (complaint) surveys.
- DHDTTC must survey against the federal Conditions of Participation (COPs) as outlined in the CMS State Operations Manual (SOM).
DHDTC Activities

- Issue Statements of Deficiencies (SOD) and in some cases requires a Plan of Correction (POC) due to regulatory violations.
- Conducts State licensure surveys for new facilities applying through the Certificate of Need Process.
- Investigate and cite for non-compliance with State-only regulations.
- Most hospitals and Ambulatory Surgery Centers (ASCs) are accredited, DHDTC only responsible for surveys of non-accredited facilities, complaint investigations and validation surveys.
Complaint Investigations

• Most complaints fall into one of the federal COPs and are handled as federal allegations, using the federal Centers for Medicare and Medicaid Services (CMS) triage process.

• CMS allows States to triage complaints by level of severity and frequency.

• For complaints that do not meet severity and frequency thresholds, the complainant is told to contact the Accrediting Organization with their complaint.
# Facility Types

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>State Licensure</th>
<th>Federal Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Diagnostic and Treatment Centers (D&amp;TCs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freestanding Clinics</td>
<td>Yes</td>
<td>No (Not required)</td>
</tr>
<tr>
<td>Hospital Extension Clinics</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>ESRD (Dialysis) Centers</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Ambulatory Surgery Centers (ASCs)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Rural Health Centers</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>FQHCs</td>
<td>Yes</td>
<td>No (HRSA)</td>
</tr>
<tr>
<td>Comprehensive Outpatient Rehab Facilities</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Community Mental Health Centers</td>
<td>Yes (OMH)</td>
<td>Yes</td>
</tr>
<tr>
<td>Psychiatric Residential Treatment Facilities</td>
<td>Yes (OMH)</td>
<td>Yes</td>
</tr>
<tr>
<td>Occupational/PT/Speech</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Conditions of Participation-Hospitals

There are 21 federal Conditions of Participation or COPs for hospitals. Each condition has multiple standards that must be met.

- Compliance with Federal State and Local Laws
- Governing Body
- Patient’s Rights
- Quality Assessment and Performance Improvement
- Medical Staff
- Nursing Services
- Medical Record Services
- Pharmaceutical Services
- Radiologic Services
- Food and Dietetic Services
- Utilization Review
- Physical Environment
- Infection Control
- Discharge Planning
- Surgical Services
- Anesthesia Services
- Nuclear Medicine Services
- Outpatient Services
- Emergency Services
- Rehabilitation Services
- Respiratory Services
Conditions of Participation-ASCs

There are 16 Conditions for Coverage (CFCs) for ASCs, each with multiple standards.

- Compliance with State Licensure Law
- Governing Body and Management
- Surgical Services
- Quality Assessment and Performance Improvement
- Environment
- Medical Staff
- Nursing Service
- Medical Records
- Pharmaceutical Services
- Laboratory and Radiologic Services
- Patient Rights
- Infection Control
- Patient Admission, Assessment and Discharge
- Emergency Preparedness
Conditions of Participation-ESRDs

ESRDs are also subject to 16 federal CFCs, each with multiple standards.

- Compliance with Federal, State, and local laws and regulations
- Infection control
- Water and dialysate quality
- Reuse of hemodialyzers and bloodlines
- Physical environment
- Patients’ rights
- Patient assessment
- Patient plan of care
- Care at home

- Quality assessment and performance improvement.
- Special purpose renal dialysis facilities
- Laboratory services
- Personnel qualifications
- Responsibilities of the medical director
- Medical records
- Governance
Regulatory Tags and Interpretive Guidance

- Hospitals
  https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Hospitals.html

- Ambulatory Surgery Centers (ASCs)
  https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/ASCs.html

- End Stage Renal Dialysis (ESRD)
  https://www.cms.gov/Medicare/Provider-Enrollment-and-certification/guidanceforlawsandregulations/dialysis.html
Regulatory Tags and Interpretive Guidance

In addition to the applicable COPs and CFCs, all facilities are subject to Life Safety Code and Emergency Preparedness Requirements:

- **Life Safety Code**
  [https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/LSC.html](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/LSC.html)

- **Emergency Preparedness**
Survey Tools

• CMS Infection Control Checklist

• Distributed by CMS on November 26, 2014 as part of Survey and Certification (S&C) Memorandum 15-02

• Available at the following link:

Survey Findings

• Standard Level Findings
  o Hospital considered to be in “substantial compliance”
  o No POC required
  o Surveillance process ends

• Condition Level Findings
  o Serious level of non-compliance (systemic failure involving one or multiple patients). Can be considered Immediate Jeopardy (IJ) if meets criteria for harm or likelihood of harm.
  o Multiple standard level findings in one or more COPs or CFCs
  o POC and follow-up survey required
## Infection Control Citations-Hospitals

January 1, 2018-September 20, 2019

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Tag</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Condition Level</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-0747 Infection Control</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td><strong>Standard Level</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-0748 Infection Control Officers</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>A-0749 Infection Control Program</td>
<td></td>
<td>23</td>
</tr>
<tr>
<td>A-0756 Infection Control Leadership Responsibilities</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>35</td>
</tr>
</tbody>
</table>
# Infection Control Citations-ASCs

**January 1, 2018-September 20, 2019**

<table>
<thead>
<tr>
<th>ASC</th>
<th>Tag</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Condition Level</strong></td>
<td>Q-240 Infection Control</td>
<td>1</td>
</tr>
<tr>
<td><strong>Standard Level</strong></td>
<td>Q-241 Sanitary Environment</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>Q-0242 Infection Control Program</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Q-0244 Infection Control Program Quality Assurance and Performance Improvement (QAPI)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Q-0245 Infection Control Program</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>25</td>
</tr>
</tbody>
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## Infection Control Citations-ESRDs

January 1, 2018-September 20, 2019

<table>
<thead>
<tr>
<th>ESRD</th>
<th>Tag</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Condition for Coverage</strong></td>
<td>V-110 Infection Control</td>
<td>7</td>
</tr>
<tr>
<td><strong>Standard Level</strong></td>
<td>V-111 Sanitary environment</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>V-113 Gloves/hand hygiene</td>
<td>52</td>
</tr>
<tr>
<td></td>
<td>V-114 Sinks available</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>V-115 Gowns, shields/masks-no eating/drinking by staff</td>
<td>38</td>
</tr>
</tbody>
</table>
Infection Control Citations-ESRDs (continued)

January 1, 2018-September 20, 2019

<table>
<thead>
<tr>
<th>ESRD</th>
<th>Tag</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Level</td>
<td>V-116 Items at station disposable, dedicated or disinfected</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>V-117 Separate clean/dirty areas; medication prep area; no common carts</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>V-119 Supply cart distance from station/no supplies in pockets</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>V-121 Handling infectious waste</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>V-122 Disinfect surfaces/equipment</td>
<td>42</td>
</tr>
</tbody>
</table>
# Infection Control Citations-ESRDs (continued)

**January 1, 2018-September 20, 2019**

<table>
<thead>
<tr>
<th>ESRD</th>
<th>Tag</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Level</td>
<td>V-124 Review test results/HBV status</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>V-126 HBV vaccination for patients and staff</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>V-127 Test patients for HBV/post last dose of vaccine</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>V-128 Isolation of HBV positive patients</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>V-130-Isolation of HBV positive patients (separate equipment, supplies, meds)</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>V-131 Staff cannot care for HBV positive and HBV negative patients at the same time</td>
<td>4</td>
</tr>
</tbody>
</table>
## Infection Control Citations-ESRDs (continued)

January 1, 2018-September 20, 2019

<table>
<thead>
<tr>
<th>ESRD</th>
<th>Tag</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Level</td>
<td>V-132 Education to staff on infection control policies/practices</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>V-142 Monitor and implement biohazard and infection control policies/practices</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>V-143 Aseptic technique for IV meds</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>V-146 Staff report IC breaches</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>V-147 Reporting of communicable diseases</td>
<td>22</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>302</td>
</tr>
</tbody>
</table>
Hospitals - Examples of Condition Level Findings

• The facility failed to ensure that Infection Control Officers developed comprehensive and accurate policies and procedures to educate staff in infection control practice and the prevention and transmission of infection and failed to provide orientation for medical students and education on the principles and practices for preventing transmission of infectious agents within the hospital.

• Patient care and cleaning staff observed failing to wash hands, perform hand hygiene between glove changes, use PPE properly. Patient care staff not following sterile procedure for dressing changes or disinfecting glucose meters properly between patients; cleaning staff not using proper cleansers or cleaning rooms thoroughly.

• OR found to be infested with mice, cross-contamination between cleaning of an OR and terminal cleaning of an isolation room; inappropriate transport of soiled linen; inappropriate transport of a filled suction canister; lack of hand hygiene; failure to disinfect medication caps.
ASCs-Examples of Condition Level Findings

• Contaminated intravenous supplies stored with clean supplies; pathology specimens without biohazard labeling; inappropriate flow of traffic in the scope reprocessing area; lack of endoscope pre-cleaning; lack of cleaning for procedure room floors; lack of anesthesia cart cleaning between patient use.

• Failure of staff to follow standard infection control practices for hand hygiene and use of personal protective equipment (PPE); failure to designate a health care professional trained in the principles and methods of infection control to lead the facility’s infection control program; failure to follow-up on discharged patients to identify and track facility-associated infections; failure to adequately monitor compliance with hand hygiene; failure to perform tests to ensure the proper functioning of the instrument sterilizer; failure to wrap sterilized instruments in a sterile area.
ESRD-Immediate Jeopardy Findings

Immediate Jeopardy identified in two ESRD federal recertification surveys:

Case #1
- Patients in the isolation room could not be easily seen by the staff nor could the patient's call bell be heard by the staff. Staff assigned to care for the isolation patient were also caring for HBV susceptible patients at the same time. Record review identified that the staff assignments did not include consideration of the patient's HBV antibody status.

Case #2
- Facility failed to isolate two patients who tested positive for HBV antigen, staff caring for HBV positive patients caring for HBV susceptible patients at the same time, potentially placing thirty-five dialysis patients at risk.
ESRD-Examples of Condition Level Findings

- Staff observed not wearing gloves or washing hands during procedures, including during central venous catheter site care and when drawing blood from dialysis access site; staff observed washing hands in the “dirty” sink.
- No disinfection or incomplete disinfection of treatment chairs, IV poles, blood pressure cuffs, and other equipment used by multiple patients, staff caring for both HBV positive and HBV susceptible patients at the same time.
- Staff observed failing to disinfect the injection ports prior to administering intravenous medications, and entering IV saline bags attached to hemodialysis machines to withdraw saline to flush lines.
- Policies not in place, policies in place but not being followed, staff not educated on proper policies and practices (as evidenced by staff interviews); infection preventivist did not observe/monitor staff for compliance.
Enforcement

- Failure to achieve substantial compliance in one or more COPs can result in termination of Medicare Participation. CMS process:
  - 30 days notice
  - Public notification of termination
  - Opportunity to regain compliance before termination occurs.
- Negative publicity-SODs are available on the Association for Healthcare Journalists website, Hospital Acquired Infection rates included in Health Profiles website.
- Exposure events can require notification to patients and additional clinical interventions, e.g., prophylaxis, laboratory testing to determine exposure.
Enforcement

- Authorization for fines (Civil Money Penalties) at federal level is limited to EMTALA.

- Authorization for fines at State level-federal citations are crosswalked to applicable state regulations.
  - $2,000 per citation (usually IJs)
  - $5,000 for repeat citations
  - $10,000 for harm
DISCUSSION AND QUESTIONS