



**Department
of Health**

**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










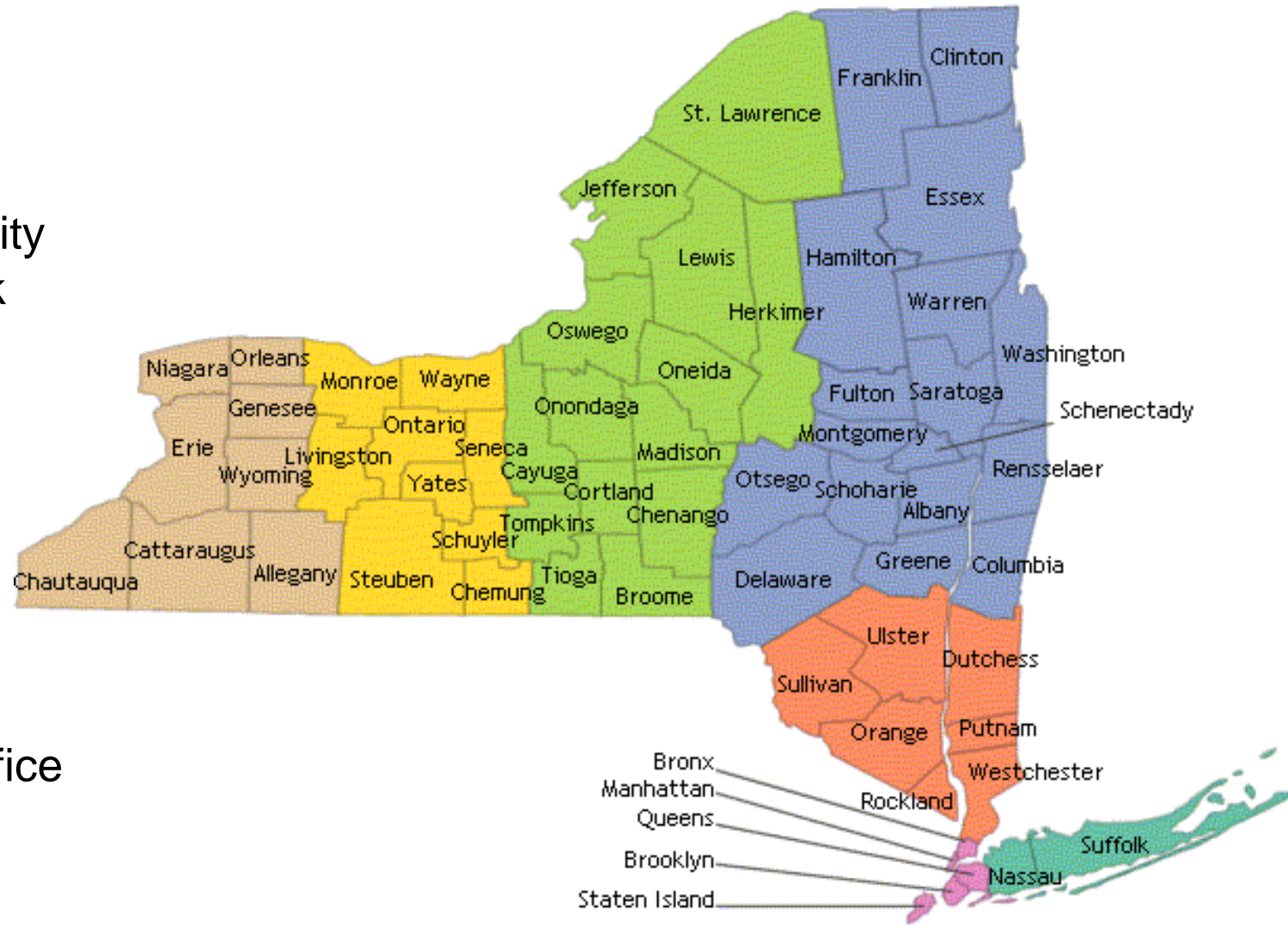
Center for Health Care Provider Services and Oversight



Division of Hospitals and Diagnostic and Treatment Centers
(DHDTTC)

Where We Work

-  Metropolitan Area – New York City Office (includes orange and pink sections)
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-  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

DHDTC Activities

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

DHDTTC 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, DHDTTC 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

Facility Type	State Licensure	Federal Certification
Hospitals	Yes	Yes
Diagnostic and Treatment Centers (D&TCs)		
Freestanding Clinics	Yes	No (Not required)
Hospital Extension Clinics	Yes	Yes
ESRD (Dialysis) Centers	Yes	Yes
Ambulatory Surgery Centers (ASCs)	Yes	Yes
Rural Health Centers	Yes	Yes
FQHCs	Yes	No (HRSA)
Comprehensive Outpatient Rehab Facilities	Yes	Yes
Community Mental Health Centers	Yes (OMH)	Yes
Psychiatric Residential Treatment Facilities	Yes (OMH)	Yes
Occupational/PT/Speech	Yes	Yes

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>

- Emergency Preparedness

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html>



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:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Memo.pdf>

Survey Findings

- Standard Level Findings
 - Hospital considered to be in “substantial compliance”
 - No POC required
 - Surveillance process ends
- Condition Level Findings
 - 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.
 - Multiple standard level findings in one or more COPs or CFCs
 - POC and follow-up survey required

Infection Control Citations-Hospitals

January 1, 2018-September 20, 2019

Hospital	Tag	#
Condition Level	A-0747 Infection Control	5
Standard Level	A-0748 Infection Control Officers	5
	A-0749 Infection Control Program	23
	A-0756 Infection Control Leadership Responsibilities	2
	Total	35

Infection Control Citations-ASCs

January 1, 2018-September 20, 2019

ASC	Tag	#
Condition Level	Q-240 Infection Control	1
Standard Level	Q-241 Sanitary Environment	14
	Q-0242 Infection Control Program	8
	Q-0244 Infection Control Program Quality Assurance and Performance Improvement (QAPI)	1
	Q-0245 Infection Control Program	1
	Total	25

Infection Control Citations-ESRDs

January 1, 2018-September 20, 2019

ESRD	Tag	#
Condition for Coverage	V-110 Infection Control	7
Standard Level	V-111 Sanitary environment	7
	V-113 Gloves/hand hygiene	52
	V-114 Sinks available	5
	V-115 Gowns, shields/masks-no eating/drinking by staff	38

Infection Control Citations-ESRDs (continued)

January 1, 2018-September 20, 2019

ESRD	Tag	#
Standard Level	V-116 Items at station disposable, dedicated or disinfected	30
	V-117 Separate clean/dirty areas; medication prep area; no common carts	12
	V-119 Supply cart distance from station/no supplies in pockets	8
	V-121 Handling infectious waste	15
	V-122 Disinfect surfaces/equipment	42

Infection Control Citations-ESRDs (continued)

January 1, 2018-September 20, 2019

ESRD	Tag	#
Standard Level	V-124 Review test results/HBV status	1
	V-126 HBV vaccination for patients and staff	5
	V-127 Test patients for HBV/post last dose of vaccine	1
	V-128 Isolation of HBV positive patients	4
	V-130-Isolation of HBV positive patients (separate equipment, supplies, meds)	7
	V-131 Staff cannot care for HBV positive and HBV negative patients at the same time	4

Infection Control Citations-ESRDs (continued)

January 1, 2018-September 20, 2019

ESRD	Tag	#
Standard Level	V-132 Education to staff on infection control policies/practices	14
	V-142 Monitor and implement biohazard and infection control policies/practices	9
	V-143 Aseptic technique for IV meds	18
	V-146 Staff report IC breaches	1
	V-147 Reporting of communicable diseases	22
Total		302

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