State and Federal Regulatory Requirements

Last Updated 2017
Objectives

• Describe national, state, and local regulatory bodies that oversee infection prevention and HAI public reporting
• Describe the Federal and State requirements for HAI public reporting
• Review California statute and regulation terminology
• Review current infection control-related regulations
HAI Public Reporting

- Public reporting is favored by consumers as a means to assess quality of healthcare
- Public disclosure intended as driver for infection prevention; encourages healthcare providers to take action
- Better informed public can drive demand for higher quality healthcare
- California passed HAI public reporting laws for hospitals in 2006 & 2008
## Health Care Regulatory Agencies

<table>
<thead>
<tr>
<th>National</th>
<th>State</th>
<th>Local</th>
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</table>
| Centers for Medicare & Medicaid Services (CMS) | California Department of Public Health  
  - Licensing & Certification  
  - Reportable Diseases and Conditions  
  - Medical Waste Program | Your local Health Officer and Health Department |
| Occupational Health and Safety Administration (OSHA) | Cal-OSHA | Environmental Health Communicable Diseases reporting |
Federal: Centers for Medicare and Medicaid Services (CMS)

- CMS provides health insurance through Medicare and Medicaid
- CMS surveys and certifies health care facilities, including nursing homes, home health agencies, and hospitals
- Social Security Act (SSA) requires meeting conditions of participation (CoP) in order to receive Medicare and Medicaid funds (SSA Section 1861)
State: CDPH Licensing and Certification (L&C)

• Headquartered in Sacramento, CA
• 18 district offices
• > 600 health facility evaluator nurses
• License over 30 different facility types, including:
  • General acute care hospitals (GACH)
  • Long term care facilities (LTCF)
  • Primary care clinics
  • Ambulatory surgery centers (ASC)
Accreditation Agencies - Hospitals

- Private, independent accreditation organizations
  - The Joint Commission (TJC; formerly JCAHO)
  - National Integrated Accreditation for Healthcare Organizations (NIAHO; DNV Healthcare)
  - Healthcare Facilities Accreditation Program (HFAP)
- Certify compliance with CMS conditions of participation
Accreditation Agencies – Ambulatory Surgery Centers

• American Association of Ambulatory Surgery Centers (AAASC)

• American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF)

• Accreditation Association for Ambulatory Health Care (AAAHC)
Regulatory Surveys and Accreditation

- California L&C performs relicensing surveys and complaint investigations per State Health and Safety codes and Title 22 regulations
  - General Acute Care Hospital Relicensing Survey implemented in Mar 2016
  - Merged Medication Error Reduction Plan (MERP) survey and Patient Safety Licensing Survey (PSLS)
- California L&C also provides surveys and complaint validation for federal regulations through a contract with CMS
- TJC certifies to CMS that hospitals licensed in California meet federal requirements
  - 80% CA hospitals are accredited by TJC
Non-Regulatory Agencies

• Centers for Disease Control and Prevention (CDC)
  • Healthcare Infection Control Practices Advisory Committee (HICPAC)
  • National Healthcare Safety Network (NHSN)
• Institute for Healthcare Improvement (IHI)
• National Quality Forum (NQF)
• Professional organizations and societies (e.g., SHEA, APIC, CSTE, IDSA)
Federal Regulations – CMS Title 42

- Subchapter G Standards and Certification
  - Part 482 Conditions of Participation For Hospitals
    - 482.42 Condition of Participation: Infection Control
  - Part 483 Requirements For States and LTCF
    - 483.65 Condition of Participation: Infection Control
  - Part 484 Home Health Services
  - Part 493 Laboratory Requirements
  - Part 494 Conditions for Coverage for End-stage Renal Disease Facilities
Finding Federal Regulations

Centers for Medicare and Medicaid Services (CMS)
http://www.cms.hhs.gov/

CMS Regulations & Guidance
http://www.cms.hhs.gov/home/regsguidance.asp

CMS Hospital Center
http://www.cms.hhs.gov/center/hospital.asp

CMS Conditions of Participations (CoPs)

CMS Interpretive Guidelines
Healthcare Facility HAI Reporting Requirements to CMS via NHSN

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<tr>
<th>CMS Reporting Program</th>
<th>HAI Event</th>
<th>Reporting Specifications</th>
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<tr>
<td>Long Term Care Hospital Quality Reporting (LTCHQR) Program</td>
<td>CLABS</td>
<td>Adult &amp; Pediatric LTAC ICUs &amp; Wards</td>
<td>October 2012</td>
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<td>MRSA Bacteremia LabID Event</td>
<td>FacWideln</td>
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<td>Adult LTAC ICUs and Wards</td>
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<td>Inpatient Rehabilitation Facility Quality Reporting (IRFQR) Program</td>
<td>CAUTI</td>
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<td>Ambulatory Surgery Centers Quality Reporting (ASCQR) Program</td>
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<td>PPS-Exempt Cancer hospital Quality Reporting (PCHQR) Program</td>
<td>CLABS</td>
<td>All Bedded Inpatient Locations</td>
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<tr>
<td>Inpatient Psychiatric facility Quality Reporting (IPFQR) Program</td>
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<td>All Inpatient Healthcare Personnel</td>
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*Long Term Care hospitals are called Long Term Acute Care Hospitals in NHSN.*
CMS Value-Based Purchasing (VBP) Program

• Penalizes hospitals who do not show improvement with healthcare acquired conditions
• Conditions include CLABSI, CDI, MRSA, and CAUTI events that are reported into NHSN
• Up to 1% of Medicare claims dollars can be withheld

CMS Value-Based Purchasing (VBP) Program
California HAI-Related Laws and Regulations
Terminology

Bills

• Passed by California legislature
• If signed by governor, legislative bills become statute or law
• Laws related to health become part of the California Health and Safety Code (HSC)
Terminology - 2

Regulations

• Written by the State Executive branch (e.g., CDPH) to
  • Carry out what a bill authorizes or directly requires a department of the State to do
  • Clarify the requirements of a law
Terminology -3

All Facility Letters (AFL)

- Letters to communicate with healthcare facilities about laws and regulations
- Sent to inform facilities of
  - A new requirement
  - A change of requirement,
  - A reminder of a requirement
- The absence of an AFL does not absolve a facility from complying with the law
California Health and Safety Code (HSC)

- HAI laws were passed as Senate Bills 739, 1058, 158, and 1311 in 2006, 2008 and 2014, respectively.
- HSC sections that contain HAI requirements:
  - 1288.45–1288.95: HAI reporting and prevention requirements including antimicrobial stewardship
  - 1255.8: MRSA patient testing
  - 1279.1: Adverse event reporting
  - 1279.7: Hand hygiene program, connector language

To find California laws and regulations:
Office of Administrative Law, www.oal.ca.gov
Official CA Legislative Information, www.leginfo.ca.gov
California Title 22 Regulations

Division 5 Licensing and Certification of Health Facilities

- Chapter 1 General Acute Care Hospital
  - Article 7 Administration
- Chapter 2 Acute Psychiatric Hospital
- Chapter 3 Skilled Nursing Facilities
- Chapter 4 Intermediate Care Facilities
- Chapter 7 Primary Care Clinics
  - Chapter 7.1 Specialty Clinics
    - Article 6 Hemodialyzer Reuse
- Chapter 12 Correctional Treatment
California Reporting Requirements

• Using NHSN
• Follow California requirements and NHSN rules for reporting the following:
  • CLABSI – all in-patient hospital locations
  • CLIP - for lines inserted in ICUs
  • MRSA and VRE – all positive blood stream infections for inpatients
  • CDI – using LabID, all inpatient, ED and observation admits
  • SSI - for 28 procedure categories
Reportable Diseases and Conditions – Title 17

• All cases of reportable diseases shall be reported to the local health officer
  • Reportable conditions may vary by local health jurisdiction
  • California Confidential Morbidity Report (CMR) – used to report all conditions except TB

Confidential Morbidity Report
Cal-OSHA

- Department of Industrial Relations
  - Division of Occupational Safety and Health
    - Cal-OSHA

- Develops regulations for workplace safety and health
  - Bloodborne Pathogen Standard
  - Aerosol-Transmissible Diseases Standard
  - Respiratory Protection Standard
Medical Waste Management Act – HSC 117600-118360

• Ensures proper handling and disposal of medical waste throughout California

• Enforced by State or local public health agencies

• Identify who enforces the program in your county
  
  https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/Local-Enforcement-Agencies.aspx

CDPH Medical Waste Management Program

https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/MedicalWaste.aspx
Summary

• There are many mandates and influencers that affect infection prevention practices

• The IP must be familiar with mandates and regulations to facilitate compliance
Questions?

For more information, please contact any HAI Program Team member

Or email HAIProgram@cdph.ca.gov