State and Federal Regulatory Requirements

Basics of Infection Prevention
2-Day Mini-Course
October 2016
Objectives

• Describe national, state and local regulatory bodies that oversee infection prevention and HAI public reporting
• Describe policy decisions and requirements for public reporting of HAI
• Discuss interpretation of California statutes and regulations
• Review current infection prevention & control-related regulations
HAI Public Reporting Policies Driven by Call for Transparency

• Public disclosure intended as driver for infection prevention; encourages healthcare providers to take action
• Public reporting favored by consumers as means to assess quality of healthcare
• Better informed public can drive demand for higher quality healthcare
• Assumption: lower costs to hospitals and society

California, like many other US states, passed HAI public reporting laws for hospitals in 2006 & 2008
THE AGENCIES
## Health Care Regulatory Agencies

<table>
<thead>
<tr>
<th>National</th>
<th>State-level</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 |
Centers for Medicare & Medicaid Services (CMS) – Federal Oversight

- CMS provides health insurance through Medicare, Medicaid

- Social Security Act (SSA) requires meeting Conditions of Participation (COP) in order to receive Medicare and Medicaid funds
  - SSA Section 1861

- “Surveys and certifies” health care facilities, including nursing homes, home health agencies, and hospitals
CDPH Licensing and Certification (L&C) – State Oversight

- Headquarters - Sacramento, CA
- 13 District Offices plus LA County (5)
- 600+ Health Facility Evaluator Nurses
- License over 30 different facility types, including
  - General Acute Care Hospitals
  - Long Term Care Facilities (LTCF)
  - Primary Care Clinics
  - Ambulatory Surgery Centers
Accreditation Agencies

Hospital Accrediting Agencies

– Private, independent accreditation organizations with standards; certify compliance with CMS requirements

  • TJC – The Joint Commission (formerly JCAHO)
  • NIAHO – National Integrated Accreditation for Healthcare Organizations (DNV Healthcare)
  • HFAP - Healthcare Facilities Accreditation Program

Ambulatory Surgery Center Certification

– American Association of Ambulatory Surgery Centers (AAASC)
– American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF)
– Accreditation Association for Ambulatory Health Care (AAAHC)
Relationships

• TJC certifies (“Deems”) to CMS that hospitals licensed in California meets federal requirements
  – 80% hospitals accredited by TJC
• Otherwise, State Agency (L&C) certifies to CMS regulations (via a contract with CMS)
• Consolidated Accreditation and Licensing (CALS) surveys – jointly with TJC
• L&C surveys enforce state laws (HSC 1188) and regulations (CCR Title 22)
What is PSLS

• AFL 11-01
  (http://www.cdph.ca.gov/certlic/facilities/Documents/LNC-AFL-11-01.pdf)

• Patient Safety Licensing Survey
  http://www.cdph.ca.gov/programs/LnC/Pages/PSLS.aspx
General Acute Care Relicensing Survey

• Determines statues enacted since 2006
  – End of life care
  – Brain death
  – Hospital Services
  – Patient Safety and Infection Control
  – Discharge Planning
  – Dietary statues
  – Immunizations
  – Fair Pricing
Non-Regulatory “Influencers”

- Centers for Disease Control and Prevention (CDC)
  - HICPAC: Healthcare Infection Control Practices Advisory Committee
- NHSN: National Healthcare Safety Network
- The Joint Commission (TJC)
- Institute for Healthcare Improvement (IHI)
- National Quality Forum (NQF)
- Professional organizations and societies (SHEA, APIC, CSTE, IDSA)
FEDERAL REGS
Federal CMS Title 42 Regulations

Centers for Medicare & Medicaid Services

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
Part 42 Subpart C - Basic Hospital Functions

§ 482.21 Quality Assurance
§ 482.22 Medical Staff
§ 482.23 Nursing services
§ 482.24 Medical record services
§ 482.25 Pharmaceutical services
§ 482.26 Radiologic services
§ 482.27 Laboratory services
§ 482.28 Food and Dietetic services
§ 482.31 Utilization review
§ 482.41 Physical environment
§ 482.42 Infection Control
§ 482.43 Discharge planning
§ 482.45 Organ, tissue, and eye procurement
Part 43 Subpart B - Requirements for Long Term Care Facilities

§ 483.1 Basis and scope.
§ 483.5 Definitions.
§ 483.10 Resident rights.
§ 483.12 Admission, transfer and discharge rights.
§ 483.13 Resident behavior and facility practices.
§ 483.15 Quality of life.
§ 483.20 Resident assessment.
§ 483.25 Quality of care.
§ 483.30 Nursing services.
§ 483.35 Dietary services.
§ 483.40 Physician services.
§ 483.45 Specialized rehabilitative services.
§ 483.55 Dental services.
§ 483.60 Pharmacy services.
§ 483.65 Infection control.
§ 483.70 Physical environment.
§ 483.75 Administration.
CMS CoP Interpretive Guidelines for Infection Control

- Hospitals must be sanitary
- Have active IC Program and someone overseeing it
- Surveillance must be systematic
  - Infections must be “logged”
- Leadership must
  - Ensure problems identified by IC are addressed
  - Take responsibility for corrective action plans when problems identified

  Complete interpretive guidelines (14 pages) on APIC website. Google “APIC interpretive guidelines”.
Finding Federal Regulations

• Centers for Medicare and Medicaid Services (CMS)
  http://www.cms.hhs.gov/
  • Regulations & Guidance
    http://www.cms.hhs.gov/home/regsguidance.asp
  • Hospital Center
    http://www.cms.hhs.gov/center/hospital.asp
  • Conditions of Participations (CoPs)
    http://www.cms.hhs.gov/CFCsAndCoPs/06_Hospitals.asp
  • Interpretive Guidelines
# CMS HAI Reporting Requirements - via NHSN

<table>
<thead>
<tr>
<th>CMS Reporting Program</th>
<th>HAI Event</th>
<th>Reporting Specifications</th>
<th>Reporting Start Date</th>
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<tr>
<td><strong>Hospital Inpatient Quality Reporting (IQR) Program</strong></td>
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<td></td>
<td>CLABSI</td>
<td>Adult, Pediatric, and Neonatal ICUs</td>
<td>January 2011</td>
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<td>CAUTI</td>
<td>Adult and Pediatric ICUs</td>
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<td>SSI:COLO</td>
<td>Inpatient COLO Procedures</td>
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<td>SSSI:HYST</td>
<td>Inpatient HYST Procedures</td>
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<td>MRSA Bacteremia LabID Event</td>
<td>FacWideIN</td>
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<td><em>C. difficile</em> LabID Event</td>
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<td>Healthcare Personnel Influenza Vaccination</td>
<td>All Inpatient Healthcare Personnel</td>
<td>January 2013</td>
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<td></td>
<td>Medicare Beneficiary Number</td>
<td>All Medicare Patients Reported into NHSN</td>
<td>July 2014</td>
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<tr>
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<td>CLABSI</td>
<td>Adult &amp; Pediatric Medical, Surgical, &amp; Medical/Surgical Wards</td>
<td>January 2015</td>
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<tr>
<td></td>
<td>CAUTI</td>
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<td><strong>Hospital Outpatient Quality Reporting (OQR) Program</strong></td>
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<td>Healthcare Personnel Influenza Vaccination</td>
<td>All Outpatient Healthcare Personnel</td>
<td>October 2014</td>
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<tr>
<td><strong>ESRD Quality Incentive Program (QIP)</strong></td>
<td>Dialysis Event (includes Positive blood culture, IV antimicrobial start, and signs of vascular access infection)</td>
<td>Outpatient Hemodialysis Facilities</td>
<td>January 2012</td>
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<td><em><em>Long Term Care Hospital</em> Quality Reporting (LTCHQR) Program</em>*</td>
<td>CLABSI</td>
<td>Adult &amp; Pediatric LTAC ICUs &amp; Wards</td>
<td>October 2012</td>
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<td>VAE</td>
<td>Adult LTAC ICUs and Wards</td>
<td>January 2016</td>
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<td><strong>Inpatient Rehabilitation Facility Quality Reporting (IRFQR) Program</strong></td>
<td>CAUTI</td>
<td>Adult &amp; Pediatric IRF Wards</td>
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<td><strong>Ambulatory Surgery Centers Quality Reporting (ASCQR) Program</strong></td>
<td>Healthcare Personnel Influenza Vaccination</td>
<td>All Inpatient Healthcare Personnel</td>
<td>October 2014</td>
</tr>
<tr>
<td><strong>PPS-Exempt Cancer hospital Quality Reporting (PCHQR) Program</strong></td>
<td>CLABSI</td>
<td>All Bedded Inpatient Locations</td>
<td>January 2013</td>
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<td></td>
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<td><strong>Inpatient Psychiatric facility Quality Reporting (IPFQR) Program</strong></td>
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*Long Term Care hospitals are called Long Term Acute Care Hospitals in NHSN*
CMS – 2010 Affordable Care Act

- Established hospital value-based purchasing plan (HVBP) that rewards hospitals with payments for the quality of care provided beneficiaries.
  - Reimbursement was based on participation; is now shifting by 0.25% annually over 5 year period to a maximum withholding of 2% Medicare reimbursement.
    - Current reduction is 1% Medicare reimbursement.
  - Hospitals are ‘scored’ according to Final Rule: 74% or below will not lose or gain. For scores greater than 75%, hospital will be subject to a payment reduction.
- Publishes a “Final Rule” periodically updating requirements.
The Joint Commission (TJC) National Patient Safety Goal (NPSG) 7: Reduce Risk of HAI

- **NPSG.07.01.01**: Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

- **NPSG.07.03.01**: Implement evidence-based practices to prevent health care-associated infections due to multidrug-resistant organisms in acute care hospitals.

- **NPSG.07.04.01**: Implement evidence-based practices to prevent central line-associated bloodstream infections.

- **NPSG.07.05.01**: Implement evidence-based practices for preventing surgical site infections.

- **NPSG.07.06.01**: Implement evidence-based practices to prevent indwelling catheter-associated urinary tract infections (CAUTI).

TJC certifies (deems) to CMS that GACH licensed in California meets federal requirements. 80% CA hospitals are TJC-accredited.
CALIFORNIA REGS
Terminology

Bills

• Passed by California legislature, make findings and declarations

• 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 - continued

Regulations

• Written by the State Executive branch (usually the affected agency or department, i.e. CDPH) to

  1. **Carry-out** promulgation of what a Bill authorizes or directly requires a Department of the State to do

  2. **Clarify** the requirements of a Bill (far less common)
Terminology - continued

All Facilities Letters (AFL)

• Letters to communicate with healthcare facilities about law and regulations
• Sent to inform facilities of a new requirement or a change of requirement
• Usually incorporate language from the legislation
• The absence of an AFL does not absolve a facility from complying with the law
California Health and Safety Code (HSC)

- HAI requirements were passed as Senate Bills 739, 1058, 158 and 1311 in 2006, 2008 and 2014

- HSC sections that contain HAI requirements are:
  - 1188.45–1188.95 (reporting and prevention requirements, including for an antimicrobial stewardship program)
  - 1255.8 (MRSA patient testing)
  - 1279.7 (Hand hygiene program, connector language)

To find California laws and regulations:

www.oal.ca.gov
www.leginfo.ca.gov
Where to Find AFLs and What They Cover

An All Facility Letter (AFL) is a letter from the Licensing and Certification (L&C) Program to health facilities that are licensed or certified by L&C.

The information contained in the AFL may include
- changes in requirements in healthcare,
- enforcement,
- new technologies,
- scope of practice, or
- general information that affects the health facility.

Examples of Recent AFL Topics:

2014
- Measles
- SB 1311 Antimicrobial Stewardship

2015
- Management of influenza in LTC and congregate living facilities

2016
- SNF – Transfer, Discharge & Readmission Requirements

www.cdph.ca.gov/certlic/facilities/Pages/LnCAFL.aspx
California Title 22 Regulations

Division 5 Licensing and Certification of Health Facilities

- Chapter 1  GACH (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 Code of Regulations – Title 22*

• Requires a written hospital infection control program for the surveillance, prevention, and control of infections.

• Policies and procedures must cover
  • Management of transmission risks within hospital
  • Education
  • A plan for surveillance, including management of outbreaks
  • How to identify biohazardous equipment and materials

• Oversight of the program is vested in a multidisciplinary committee

• There shall be one designated FTE/200 licensed beds

*Title 22, Div 5, Chap 1, Article 7, Sec 70739
Reportable Diseases and Conditions

• All cases of reportable diseases shall be reported to the local health officer in accordance with Section 2500, Article 1, Subchapter 4, Chapter 4, Title 17, California Administrative Code

• Defined as events that threaten welfare, safety, or health of patients, personnel, or visitors
Title 17 – Reportable Diseases and Conditions

Title 17, California Code of Regulations (CCR) §2500, §2593, §2641.5-2643.20, and §2800-2812 Reportable Diseases and Conditions*

§ 2500. REPORTING TO THE LOCAL HEALTH AUTHORITY.

- § 2500(b) It shall be the duty of every health care provider, knowing of or in attendance on a case or suspected case of any of the diseases or condition listed below, to report to the local health officer for the jurisdiction where the patient resides. Where no health care provider is in attendance, any individual having knowledge of a person who is suspected to be suffering from one of the diseases or conditions listed below may make such a report to the local health officer for the jurisdiction where the patient resides.
- § 2500(c) The administrator of each health facility, clinic, or other setting where more than one health care provider may know of a case, a suspected case or an outbreak of disease within the facility shall establish and be responsible for administrative procedures to assure that reports are made to the local officer.
- § 2500(a)(14) “Health care provider” means a physician and surgeon, a veterinarian, a podiatrist, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, a school nurse, an infection control practitioner, a medical examiner, a coroner, or a dentist.

URGENCY REPORTING REQUIREMENTS [17 CCR §2500(h)(i)]

- 1: Report immediately by telephone (designated by a 1 in regulations).
- 1: Report immediately by telephone when two or more cases or suspected cases of foodborne disease from separate households are suspected to have the same source of illness (designated by a 1 in regulations).
- FAX: Report by electronic transmission (including FAX), telephone, or mail within one working day of identification (designated by a + in regulations).
- All other diseases/conditions should be reported by electronic transmission (including FAX), telephone, or mail within seven calendar days of identification.

REPORTABLE COMMUNICABLE DISEASES §2500(j)(1)

- Acquired Immune Deficiency Syndrome (AIDS)
- (HIV infection only: see “Human Immunodeficiency Virus”)
- Amebiasis
- Anaplasmosis/Ehrlichiosis
- Anthrax, human or animal
- Babesiosis
- Botulism (Infant, Foodborne, Wound, Other)
- Brucellosis, animal (except infections due to Brucella canis)
- Brucellosis, human
- Campylobacteriosis
- Q Fever
- Rabies, human or animal
- Relapsing Fever
- Rickettsial Diseases (non-Rocky Mountain Spotted Fever), including
  - Typhus and Typhus-like Illnesses
  - Rocky Mountain Spotted Fever
  - Rubella (German Measles)
  - Rubella Syndrome, Congenital
- Salmonellosis (Other than Typhoid Fever)
- Scoombroid Fish Poisoning
Cal/OSHA

Department of Industrial Relations -->
Division of Occupational Safety and Health -->

Cal/OSHA

– Develops regulations for workplace safety and health
  • Standards Board adopts
– California regulations must be “at least as effective” as federal regulations
Cal-OSHA Bloodborne Pathogens (BBP) Standard*

Purpose: Ensure employees are protected from potential exposure to blood/body fluids

Includes

- Hierarchy of controls (early identification, engineering controls, administrative policies, personal protective equipment)
- Safe practices, risk assessment, medical surveillance of employees
- HBV offered to all employees at risk
- Post exposure management
- Training and record keeping

*CCR, Title 8, Section 5193
Cal-OSHA Aerosol-Transmissible Diseases Standard (ATD)*

Inclusive of any disease that could be “transmitted by particles flying through air and landing in the lungs or on mucous membranes”

- Aerosol, near-aerosol, droplet modes of transmission
- Tuberculosis Standard rolled into this

Extends scope of requirement for to settings outside hospital – across continuum

- Requires specified levels of respiratory protection for certain diseases (be familiar w/ appendices)

Format, requirements similar to BBP Standard

*CCR, Title 8, Section 5199
Cal-OSHA Respiratory Protection Standard*

Any employer that requires a worker to don a respirator must have a Respiratory Protection Program (RPP)

To include

• How to select and care for respirators
• Medical screening
• Fit-testing requirements and methods
• Training and documentation

Concept of RPP was developed initially for use of respirators in industrial settings

*CCR, Title 8, Section 5144
Medical Waste Management Act*

Ensures proper handling and disposal of medical waste throughout California

Biohazardous Waste   See HSC 117635 for complete definition

- (a) Laboratory waste, including human or animal specimen cultures from medical and pathology laboratories
- (b) Human surgery specimens or tissue
- (e) Waste containing discarded materials contaminated with excretion, exudate, or secretions from humans... that are required to be isolated by infection control staff, attending physician and surgeon, ...or local health officer

*Health and Safety Code 117600
Medical Waste Management Act

Enforced by

• CDPH Medical Waste Program
gray counties

-or-

• Local Departments of Environmental Health
  • white counties
Summary

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

• The IP must be familiar with these and facilitate compliance in his/her facility.

Copies or links to this information can be found on the HAI Program website

www.cdph.ca.gov/HAI
HAI Prevention Now

We no longer accept that 2/3 infections are a cost of receiving healthcare. Infections are ever more the exception, not the expected outcome.

We know there are bundles of evidence-based strategies and new technology that, when properly applied in a safety culture, can significantly enhance patient safety.

By apportioning (or reapportioining) dollars to buy specified outcomes, the mantras of prevention and patient safety have become a higher priority to healthcare providers.

We remain committed to our goal: healthier, safer patients!
For more information, please contact any HAI Liaison Team member.

Thank you