State and Federal Regulatory Requirements

Basics of Infection Prevention
2-Day Mini-Course
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 control-related regulations

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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

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THE AGENCIES

Health Care Regulatory Agencies

National	State-level	Local
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

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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

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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

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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)

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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)

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What is the PSLS?

- GACH*Survey to determine compliance with Statutes enacted since 2006.
  - End of Life Care
  - Brain Death
  - Hospital Services
  - Patient Safety & Infection Control
  - Discharge Planning
  - Dietary
  - Immunizations
  - Fair Pricing

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AFL 11-01 Patient Safety Licensing Survey,
www.cdph.ca.gov/PROGRAMS/LNC/Pages/PSLS

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* GACH – General Acute Care Hospital including LTACH (Long Term Acute Care Hospitals)

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) added
- Institute for Healthcare Improvement (IHI)
- National Quality Forum (NQF)
- Professional organizations and societies (SHEA, APIC, CSTE, IDSA)

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FEDERAL REGS

Federal CMS Title 42 Regulations

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

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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

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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.

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CMS CoP Interpretive Guidelines for Infection Control – **READ THEM!**

- 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". Link also on slide 18

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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
    http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R37SOMA.pdf

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CMS HAI Reporting Requirements - via NHSN

CMS Reporting Program	HAI Event	Reporting Specifications	Reporting Start Date
Hospital Inpatient Quality Reporting (IQR) Program	CLABSI	Adult, Pediatric, and Neonatal ICUs	January 2011
	CAUTI	Adult and Pediatric ICUs	January 2012
	SSI:COLO	Inpatient COLO Procedures	January 2012
	SSSI:HYST	Inpatient HYST Procedures	January 2012
	MRSA Bacteremia LabID Event	FacWideIN	January 2013
	C. difficile LabID Event	FacWideIN	January 2013
	Healthcare Personnel Influenza Vaccination	All Inpatient Healthcare Personnel	January 2013
	Medicare Beneficiary Number	All Medicare Patients Reported into NHSN	July 2014
	CLABSI	Adult & Pediatric Medical, Surgical, & Medical/Surgical Wards	January 2015
	CAUTI	Adult & Pediatric Medical, Surgical, & Medical/Surgical Wards	January 2015
Hospital Outpatient Quality Reporting (OQR) Program	Healthcare Personnel Influenza Vaccination	All Outpatient Healthcare Personnel	October 2014
ESRD Quality Incentive Program (QIP	Dialysis Event (includes Positive blood culture, IV antimicrobial start, and signs of vascular access infection)	Outpatient Hemodidalysis Facilities	January 2012
	Healthcare Personnel Influenza Vaccination	All Healthcare Personnel	October 2015

CMS HAI Reporting Requirements - via NHSN

CMS Reporting Program	HAI Event	Reporting Specifications	Reporting Start Date
Long Term Care Hospital* Quality Reporting (LTCHQR) Program	CLABSI	Adult & Pediatric LTAC ICUs & Wards	October 2012
	CAUTI	Adult & Pediatric LTAC ICUs & Wards	October 2012
	Healthcare Personnel Influenza Vaccination	All Inpatient Healthcare Personnel	October 2014
	MRSA Bacteremia LabID Event	FacWideIN	January 2015
	C. difficile LabID Event	FacWideIN	January 2015
	VAE	Adult LTAC ICUs and Wards	January 2016
Inpatient Rehabilitation Facility Quality Reporting (IRFQR) Program	CAUTI	Adult & Pediatric IRF Wards	October 2012
	Healthcare Personnel Influenza Vaccination	All Inpatient Healthcare Personnel	October 2014
	MRSA Bacteremia LabID Event	FacWideIN	January 2015
	C. difficile LabID Event	FacWideIN	January 2015
Ambulatory Surgery Centers Quality Reporting (ASCQR) Program	Healthcare Personnel Influenza Vaccination	All Inpatient Healthcare Personnel	October 2014
PPS-Exempt Cancer hospital Quality Reporting (PCHQR) Program	CLABSI	All Bedded Inpatient Locations	January 2013
	CAUTI	All Bedded Inpatient Locations	January 2013
	SSI:COLO	Inpatient COLO Procedures	January 2014
	SSI:HYST	Inpatient HYST Procedures	January 2014
Inpatient Psychiatric facility Quality Reporting (IPFQR) Program	Healthcare Personnel Influenza Vaccination	All Inpatient Healthcare Personnel	October 2015

*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.

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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).

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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)**

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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)

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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

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Where to Find AFLs and What They Cover

www.cdph.ca.gov/certlic/facilities/Pages/LnCAFL.aspx

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
- MERS
- Five on ebola preparedness, FAQ, waste management
- SB 1311 Antimicrobial Stewardship

2015

- Management of influenza in LTC and congregate living facilities

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

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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

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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, 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 juridiction 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)]

✆ ! = Report immediately by telephone (designated by a ♦ in regulations).

† = 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 ♠ in regulations.)

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

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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

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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

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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

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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

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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 reapportioning) 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!

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Questions?

For more information, please contact any HAI Liaison Team member.

Thank you

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