

Welcome to *California*



State and Federal Regulatory Requirements



Basics of Infection Prevention
2-Day Mini-Course
2013

Objectives

- List national, state and local regulatory bodies that oversee infection prevention
- Describe policy decisions and requirements for public reporting of HAI
- Discuss interpretation of California statutes and regulations
- Review current infection control-related regulations



THE AGENCIES



Health Care Regulatory Agencies

National	State-level	Local
Centers for Medicare & Medicaid Services (CMS)	California Department of Public Health <ul style="list-style-type: none"> • 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)
 - DHHS requires that state health agencies enforce



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
 - GACH (general acute care hospitals)
 - SNF
 - 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 the Accreditation of Ambulatory Surgical Facilities (**AAAASF**)
- Accreditation Association for Ambulatory Health Care (**AAAHC**)



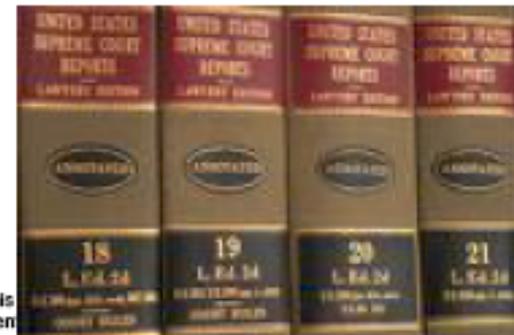
Relationships

- TJC certifies (“Deems”) to CMS that GACH licensed in California meets federal requirements
 - 80% hospitals TJC accredited
- 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 (e.g. SB 1058) and regulations (CCR Title 22)



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

- * GACH – General Acute Care Hospital; in CA, this also includes 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
- Institute for Healthcare Improvement (**IHI**)
- National Quality Forum (**NQF**)
- Professional organizations and societies (**SHEA, APIC, CSTE, IDSA**)



THE POLICIES



Increasing Expectations for HAI Prevention

1999 - Institute of Medicine published "To Err is Human"

- Launched the patient safety movement

2005 - Budget Reconciliation Act - Non-payment for 'preventable' infections

- Mediastinitis post CABG, hip arthroplasty SSI, CLABSI, CAUTI

2006 and 2008 - CA Legislature passed laws requiring public reporting of HAIs

- Mandated use of NHSN

2010 - CMS Inpatient Prospective Payment System (IPPS)

- Pay for reporting → pay for performance

Also March 2010 - Patient Protection and Affordable Care Act

- Strategies to improve care quality while decreasing costs



Demand for HAI 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



CMS HAI Reporting Requirements - via NHSN

HAI Event	Facility Type	Start Date
CLABSI	Acute Care Hospitals Adult, Pediatric, Neonatal ICUs	January 2011
CAUTI	Acute Care Hospitals Adult and Pediatric ICUs	January 2012
SSI	Acute Care Hospitals Colon surgery, Abdominal Hyst.	January 2012
I.V. antimicrobial start	Dialysis Facilities	January 2012
Positive blood culture	Dialysis Facilities	January 2012
Signs of vascular access infection	Dialysis Facilities	January 2012
CLABSI	Long Term Care Hospitals *	October 2012
CAUTI	Long Term Care Hospitals *	October 2012
CAUTI	Inpatient Rehabilitation Facilities	October 2012
MRSA Bacteremia LabID Event	Acute Care Hospitals	January 2013
<i>C. difficile</i> LabID Event	Acute Care Hospitals	January 2013
HCW Influenza Vaccination	Acute Care Hospitals	January 2013
HCW Influenza Vaccination	ASCs	October 2014
SSI (<i>future proposal</i>)	Outpatient Surgery/ASCs	TBD
* Long Term Care Hospitals are called Long Term Acute Care Hospitals in NHSN		

FEDERAL REGS



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

www.premierinc.com/safety/topics/guidelines/cms-guidelines-4-infection.jsp #CMS_Infection_control_interpretive_guidelines



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 Long Term Care Facilities

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



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 17



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.



The Joint Commission 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).



CALIFORNIA REGS



Finding California Laws, Regulations

Office of Administrative Law (OAL) Website

<http://www.oal.ca.gov/>

Sponsored Links *

- [California Code of Regulations](#)
- [Legislative Information](#)
- [California Codes](#)

* Not maintained by OAL



Terminology

The California legislature passes **Bills**

- Bills make findings and declarations, and declare intent
- Words to look for when reading Bills
 - “Shall” – requires someone to do something
 - “May” – authorizes someone to do something
 - “Shall not” – prohibits someone from doing something



Legislative bills set **Statute**

Search Bills - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Print Mail W Wordpad

Address http://www.leginfo.ca.gov/bilinfo.html Go Links

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BILL INFORMATION

Daily Updates [Assembly Bills](#) [Senate Bills](#)

The full text of bills, resolutions, and constitutional amendments, and their status, history, votes, analyses, and veto messages are available. If you know the bill, select the session, and House of origin, and type the bill number to retrieve this information. To search, select the session, and House of origin, and type the keywords and/or author name(s). An [Index](#) is available which lists all bills introduced in the Assembly and Senate.

SESSION (2007-2008)PRIOR HOUSE BOTH Limit to: All hits

Search by: (choose only one option)

Bill Number or Author(s) or Keyword(s):

1058

Clear Search

Home Page Feedback Help Subscription List

Done Internet

Start Microsoft PowerPoint - [...] Search Bills - Microsof... bookworm - Google Imag... Inbox - Microsoft Outlook 2:05 PM

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)

- Purpose: To inform facilities of a new requirement or a change of requirement
- Usually incorporates language from the legislation
- The absence of an AFL does not absolve a facility from complying with the law

Note: When enforcing, L&C is not allowed to interpret legislation in a manner that would expand or contract its meaning



The HAI Program Website posts all HAI-related AFLs

en Español
 → Su salud en su idioma

Most Popular Links

- Birth, Death, & Marriage Certificates
- Licensing and Certification
- WIC

Quick Links

- About Us
- Decisions Pending & Opportunities for Public Participation
- Diseases & Conditions
- Job Opportunities
- Local Health Services
- Newsroom
- Public Availability of Documents

Home > Programs > Healthcare Associated Infections Program > **HAI Program Archives**

AFL's, Legislation, and Regulations

AFLs 2012	AFLs 2008
<ul style="list-style-type: none"> → New AFL 12-46: Implementation Date Extension for Incompatible Line Connectors November 1st → New AFL 12-38 Medi-Cal Provider-Preventable Conditions Reporting CMS Reporting → AFL 12-15: Revised Requirements for Reporting Surgical Site Infections (SSI) March 14, 2012 	<ul style="list-style-type: none"> → AFL 08-17: New Regulatory Requirements for Compliance with Senate Bill 739 -- Reporting of Influenza Vaccination/Declination of Employees and Healthcare Personnel (PDF, New Window) → AFL 08-10: New Regulatory Requirements for Compliance with Senate Bill 739--Joining CDPH Group, CLIP Reporting (PDF, New Window) → CLIP Implementation Discussion - AFL 08-10 (PDF, New Window)
AFLs 2011	AFLs 2007
<ul style="list-style-type: none"> → AFL 11-38: Surgical Site Infection (SSI) Pre-Notice Meeting for Regulations Governing SSI Reporting Requirements → AFL 11-32: Surgical Site Infection (PDF, New Window) → AFL 11-23: Surgical Site Infection Reporting (PDF, New Window) → AFL 11-01: Patient Safety Licensing Survey (PDF, New Window) 	<ul style="list-style-type: none"> → AFL 07-37: Mandated Use of the National Health and Safety Network to Comply with Senate Bill 739 on the Reporting of Hospital Acquired Infections Process Measures (PDF, New Window) → AFL 07-06: Compliance with Senate Bill 739 on Hospital Acquired Infections (HAI) (PDF, New Window)
AFLs 2010	Legislation Archives
<ul style="list-style-type: none"> → AFL 10-35: Mandatory Reporting of Influenza Vaccination/Declination of Hospital Personnel (PDF, New Window) 	<ul style="list-style-type: none"> → SB 158 Chaptered (PDF, New Window) → SB 1058 Chaptered (PDF, New Window) → SB 739 Chaptered (PDF, New Window)
Resources	

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, 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)]

Ⓞ ! = 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.)

Senate Bill 739 Requirements*

HSC 1288.6 – Implement policies to prevent CLABSI... in ICUs

HSC 1288.7

- Annually offer influenza **vaccination to employees**
- Institute **respiratory hygiene** and cough etiquette protocols
- Develop capacity to **isolate influenza patients**
- Develop **seasonal influenza plan...**collaboration with public health in event of a pandemic



*Health & Safety Code Chapter 2, Division 2

SB 739 Requirements - continued

HSC 1288.8

- Develop a process for **evaluating the judicious use of antibiotics**
- Report specified process measures through NHSN (Report **CLIP** from ICU)

HSC 1288.9

- Develop and report compliance with measures for prevention of SSI (**SCIP**)
- Develop and implement policies and procedures to **prevent VAP**



Senate Bill 158 Requirements

HSC 1279.6* – Hospitals must have a **patient safety plan**...encourages a **culture of safety**

HSC 1279.7* – Hospital must have a **hand hygiene program**

HSC 1288.6 – 3-year **evaluation of IP program**, including program resources. Updated annually

HSC 1288.95 – Staff **education**, including IC Chair, clinicians, hospital staff, and housekeeping

*Applies to general acute care, acute psychiatry, skilled nursing facilities, and specialty hospitals (e.g., maternal-child)



Senate Bill 1058 Requirements

HSC 1255.8 – MRSA testing of specified patients, timely patient education, re-testing of negative patients prior to discharge

- Delineates specifics for cleaning... include in infection control policy
- Infection control officer to head IC efforts; name publicly available upon request

HSC 1288.55

- Reporting **MRSA/VRE BSI, C. diff infections**
- **SSI** from “deep and organ/space surgical sites, cardiac, orthopedic, and gastrointestinal” surgical procedures



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



Remember IPs don't (and can't) own all infection prevention responsibilities alone

Per SB 739, each hospital... with participation of senior health care facility leadership... at least once every three years must **“prepare a written report that examines the hospital’s existing resources and evaluates the quality and effectiveness of the hospital’s infection surveillance and prevention program.”**

Report to include **“an estimate of the need and recommendations for additional resources for infection prevention and control programs”**

If more resources are needed, inform administration in a professional and collegial way

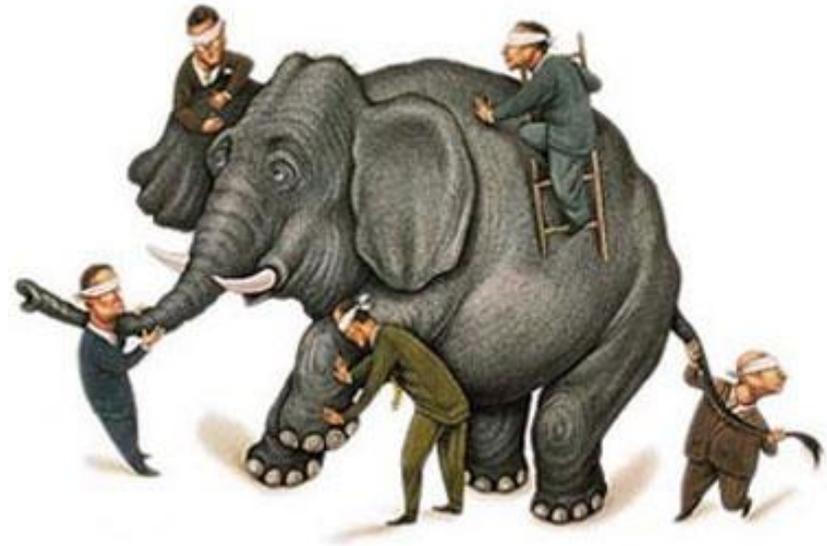


Regulatory Survival 101

What MUST you do?

- Know what to report to whom by when
- Endeavor not to re-invent the wheel
- Continue to breathe (every day)

Work collaboratively; while you may be responsible for the program, others may have easier access to needed pieces of this puzzle



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!



Questions?

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

Thank you



California HAI Prevention Activities Timeline

2003 - Little Hoover Report

2005 - HAI Advisory Working Group
"White Paper"

2006 - SB 739 passed

2007 - HAI-Advisory Committee formed

2008 - Start of mandatory reporting of CLIP through NHSN
- SB 1058, 158 passed

2009 - SB 1058/158 take effect

- H1N1 pandemic
- Startup of CDPH HAI Program, Dec 9

2010 - Startup of HAI Infection Prevention Liaison Program (ARRA funded)

- HAI reporting thru NHSN, April
- CMS IPPS Rule

2011 - Reporting of 29 surgical procedures thru NHSN

