
State and Federal Regulatory Requirements

Last Updated 2019

Basics of Infection Prevention
Healthcare-Associated Infections Program
Center for Health Care Quality
California Department of Public Health



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
- Review current infection control-related regulations

HAI Public Reporting Policies Driven by Call for Transparency

- Public disclosure intended as a driver for infection prevention; encourages healthcare providers to take action
- Public reporting is favored by consumers as a means to assess quality of healthcare
- Better informed public can drive demand for higher quality healthcare
- Assumption: lower costs to hospitals and society
- California passed HAI public reporting laws for hospitals in 2006 & 2008

State Oversight: CDPH Licensing and Certification (L&C)

- Headquartered in Sacramento, CA
- 18 district offices
- >600 health facility evaluator nurses (HFEN)
- Licenses facilities to operate in California, including
 - General acute care hospitals
 - Skilled nursing facilities (SNF)

Federal Oversight: 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)

Accreditation Agencies - Hospitals

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

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)

Relationships

- TJC certifies to CMS that hospitals licensed in California meet federal requirements
 - 80% California hospitals are accredited by TJC
- Consolidated Accreditation and Licensing (CALs) surveys jointly with TJC
- L&C inspects to CMS regulations via a contract with CMS
- L&C surveys enforce state laws (HSC 1188) and regulations (CCR Title 22)

General Acute Care Relicensing Survey

- Purpose is to promote quality of care in hospitals, verify compliance with state regulations and statues, and ensure a program wide consistency in the hospital survey methodology.
 - Implemented March 2016
 - Survey every 3 years, 3-5 day survey
 - Evaluates hospital's compliance with statutory and regulatory requirements
 - Surveyors will select patients from various service areas
 - 6%-10% of the current inpatient census will be selected for record review (minimum of 30)

<https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/GeneralAcuteCareRelicensingSurvey.aspx>



Skilled Nursing Facility Surveys

- CDPH surveys SNF at least once every 6–16 months (average 12 months)
 - Survey assesses compliance with state and federal standards
 - Complaints or reportable events can initiate survey

LTC Survey Information

<http://hfcis.cdph.ca.gov/aboutus.aspx>

California Law and Regulations Terminology

- **Bills** are passed by California legislature
 - If signed by governor, bill becomes a statute or law
 - Laws related to health become part of the California Health and Safety Code (HSC)
- **Regulations** are written by the appropriate State agency or department (such as CDPH) to:
 - Carry out what a bill authorizes or directly requires a State department to do
 - Clarify bill requirements

CDPH All Facility Letters (AFL)

- Communicate with healthcare facilities about laws and regulations
- Sent to inform facilities of a new requirement, change of requirement, or to clarify an existing law/regulation
- 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, respectively
- HSC sections that contain HAI requirements:
 - 1188.45–1188.95: reporting and prevention requirements, including an antimicrobial stewardship program
 - 1255.8: MRSA patient testing
 - 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 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
 - Education
 - Surveillance plan, including outbreak management
 - Biohazardous equipment and materials identification
- Oversight of the program is vested in a multidisciplinary committee
- There shall be one designated infection control FTE ≥ 200 licensed beds

*Title 22, Div 5, Chap 1, Article 7, Sec 70739

California HAI Reporting Requirements

- Follow California acute care hospital requirements and NHSN rules for reporting healthcare associated infections (HAI)
 - CLABSI – all in-patient hospital locations
 - CLIP - for lines inserted in ICUs
 - MRSA and VRE – all positive blood stream infections for all inpatients, ED and 24 hour observation units
 - CDI – using LabID, all inpatient, ED and 24 hour observation units
 - 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

<https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph110a.pdf>

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*

- Ensures proper handling and disposal of medical waste throughout California
- Biohazardous waste
 - a) Laboratory waste, including human or animal specimen cultures from medical and pathology laboratories
 - b) Human surgery specimens or tissue
 - c) Waste containing discarded materials contaminated with excretion, exudate, or secretions from humans...required to be isolated by infection control staff, attending physician and surgeon, ...or local health officer

*Health and Safety Code 117600 and 117635

Federal Regulations -CMS Title 42

- Subchapter G Standards and Certification
 - Part 482 Conditions of Participation For Hospitals
 - Part 483 Requirements For States And LTC
 - 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 LTCF

- § 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**
(F Tag 441 Infection Prevention & Control is here)
- § 483.70 Physical environment
- § 483.75 Administration

CMS Conditions of Participation (CoP) Interpretive Guidelines for Infection Control

- Hospitals must be sanitary
- Hospitals must have an active infection control program and someone overseeing it
- Surveillance must be systematic (i.e., infections must be logged)
- Leadership must:
 - Ensure problems identified by infection control are addressed
 - Take responsibility for corrective action plans when problems are identified

Interpretive Guidelines

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf



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>

Conditions of Participations (CoPs)

https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html?redirect=/CFCsAndCoPs/06_Hospitals.asp

Interpretive Guidelines

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/SOM107AP_a_hospitals.pdf

CMS NHSN Reporting Requirements

CMS Reporting Program	HAI Event
Hospital Inpatient Quality Reporting (IQR) Program	CLABSI
	CAUTI
	SSI:COLO
	SSSI:HYST
	MRSA Bacteremia LabID Event
	<i>C. difficile</i> LabID Event
	Healthcare Personnel Influenza Vaccination
	Medicare Beneficiary Number
	CLABSI
	CAUTI
Hospital Outpatient Quality Reporting (OQR) Program	Healthcare Personnel Influenza Vaccination
ESRD Quality Incentive Program (QIP)	Dialysis Event (includes Positive blood culture, IV antimicrobial start, and signs of vascular access infection)
	Healthcare Personnel Influenza Vaccination

<https://www.cdc.gov/nhsn/pdfs/cms/cms-reporting-requirements.pdf>

CMS Reporting Program	HAI Event
Long Term Care Hospital* Quality Reporting (LTCHQR) Program	CLABSI
	CAUTI
	Healthcare Personnel Influenza Vaccination
	MRSA Bacteremia LabID Event
	<i>C. difficile</i> LabID Event
Inpatient Rehabilitation Facility Quality Reporting (IRFQR) Program	CAUTI
	Healthcare Personnel Influenza Vaccination
	MRSA Bacteremia LabID Event
	<i>C. difficile</i> LabID Event
Ambulatory Surgery Centers Quality Reporting (ASCQR) Program	Healthcare Personnel Influenza Vaccination
PPS-Exempt Cancer hospital Quality Reporting (PCHQR) Program	CLABSI
	CAUTI
	SSI:COLO
	SSI:HYST
Inpatient Psychiatric facility Quality Reporting (IPFQR) Program	Healthcare Personnel Influenza Vaccination

*Long Term Care hospitals are called Long Term Acute Care Hospitals in NHSN

CMS Value-Based Purchasing Program

- Facilities participating in CMS quality/incentive reporting programs are required to track and report HAI to NHSN; NHSN shares data with CMS
- CMS penalizes hospitals who do not show improvement of healthcare acquired conditions
 - Conditions include CLABSI, CDI, MRSA, and CAUTI
 - Up to 2% of Medicare claims dollars can be withheld

CMS Value Based Purchasing

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing.html>

Non-Regulatory Influencers

- 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)

Summary

- There are many mandates and influencers that affect infection prevention practices
- The IP must become and stay familiar with mandates and influencers to facilitate compliance in their facility

Questions?

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

Or email

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