

State and Federal Regulatory Requirements

ACH IP Course, 2022

Infection Prevention Training for ACH
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

- Reporting HAIs became law for hospitals in 2006 & 2008
- Disclosure to the public is intended as a driver for infection prevention; encourages healthcare providers to take action
- Reporting publicly allows the consumer to assess quality of healthcare for each facility
- Informing the public can drive demand for higher quality healthcare
- Requirement to report HAIs to CMS became law in 2014 for SNFs

[SNF Quality Reporting Program \(QRP\) Public Reporting](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Public-Reporting)

(www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Public-Reporting)

Regulatory Agency Overview

Federal	State	Local
Centers for Medicare and Medicaid Services (CMS)	California Department of Public Health <ul style="list-style-type: none">• Licensing & Certification• Reportable Diseases and conditions• Medical Waste	Local public health officers and departments <ul style="list-style-type: none">• Communicable Disease reporting
Occupational Health and Safety Administration (OSHA)	Cal-OSHA	<ul style="list-style-type: none">• Environmental Health

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)
- Do not issue citations
 - Act as CMS surveyors and provide information to CMS

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 statutes, 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)

[CDPH General Acute Care Relicensing Survey](http://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/GeneralAcuteCareRelicensingSurvey.aspx)

(www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/GeneralAcuteCareRelicensingSurvey.aspx)

Skilled Nursing Facility Surveys

- CDPH surveys SNFs every 6–16 months
 - SNF can be surveyed out of schedule, sooner than usual
 - Focus on facilities with prior outbreaks
- Surveyors assess compliance with state and federal standards
- Investigate complaints of abuse and infectious disease concerns
 - SNF visited immediately
- Revisits if high risk findings are reported

[CDPH Licensing & Certification Regulations](#)

(www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/Regulations.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)

- Communicates with healthcare facilities about laws and regulations
- Sent to inform facilities of
 - New requirements
 - Change of requirement in healthcare
 - Clarify an existing law/regulation
 - Scope of practice clarifications
 - Provide guidance and information
- The absence of an AFL does not absolve a facility from complying with the law

LICENSING AND CERTIFICATION PROGRAM

[CDPH Licensing & Certification AFLs](#)

(www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/All-Facilities-Letters-Listing.aspx)

All Facilities Letters

✓	Name	LetterDate	LetterRecipient	LetterSubject
▲AFLDate : 2022 (3)				
	AFL-22-02	... January 14, 2022	Skilled Nursing Facilities	Notice of Testing Supply Availability and Distribution Process
	AFL-22-01	... January 7, 2022	All Facilities	Centralization of Program Flexibility Application Process
	AFL-21-08	... January 8, 2022	General Acute Care Hospitals (GACHs) Acute Psychiatric Hospitals (APHs) Skilled Nursing Facilities (SNFs)	Guidance on Quarantine and Isolation for Health Care Personnel (HCP) Exposed to SARS-CoV-2 and Return to Work for HCP with COVID-19 (This AFL supersedes AFL 21-08.6)
▲AFLDate : 2021 (79)				
	AFL-21-55	... December 23, 2021	Skilled Nursing Facilities (SNFs)	Deployment of Risk and Safety Solutions (RSS) for Complaint/Facility Reported Incident (FRI) Investigations
	AFL-21-54	... December 23, 2021	General Acute Care Hospitals (GACH)	Assembly Bill (AB) 532 and AB 1020 - Health Care Debt and Fair Billing Policies
	AFL-21-53	... December 17, 2021	Hospice Providers	Senate Bill (SB) 664 - Hospice Licensure: Moratorium on New Licenses

California HAI and Public Reporting Laws

- HAI requirements were passed as Senate Bills 739, 1058, 158 and 1311 in 2006, 2008 and 2014, respectively
- Health and Safety Code 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](http://www.oal.ca.gov) (www.oal.ca.gov)

[Official CA Legislative Information](http://www.leginfo.ca.gov) www.leginfo.ca.gov

California HAI Reporting Requirements

- Follow California **acute care hospital** requirements and NHSN rules for reporting healthcare associated infections (HAI)
 - CLABSI – each in-patient hospital location
 - 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

Central line insertion practices (CLIP) reporting requirement was discontinued June 2021

[AFL 21-08](http://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-18.aspx) (www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-18.aspx)

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 \geq 200 licensed beds

Title 22: Infection Control

[*Division 5, Chap 1, Article 7, Sec 70739](#)

(govt.westlaw.com/calregs/Document/IB44FB28B5B6111EC9451000D3A7C4BC3?viewType=FullText&listSource=Search&originationContext=Search+Result&transitionType=SearchItem&contextData=(sc.Search)&navigationPath=Search%2fv1%2fresults%2fnavigation%2fi0ad720f100000185b7dde7c70342eec3%3fpccid%3d79cd9bee7a6e4d7fbeb07664c8bd568%26Nav%3dREGULATION_PUBLICVIEW%26fragmentIdentifier%3dIB44FB28B5B6111EC9451000D3A7C4BC3%26startIndex%3d1%26transitionType%3dSearchItem%26contextData%3d%2528sc.Default%2529%26originationContext%3dSearch%2520Result&list=REGULATION_PUBLICVIEW&rank=1&t_T1=22&t_T2=70739&t_S1=CA+ADC+s)

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) form is used to report all conditions except TB
 - Local public health should be consulted for particular requirements, forms, method of reporting

[Title 17: Public Health, *Division 1, Chap 4, Article 1, Sec 2500](#)

(govt.westlaw.com/calregs/Document/I01D4328129FA11EDA5B6DDCDF7AC13B6?viewType=FullText&listSource=Search&originationContext=Search+Result&transitionType=SearchItem&contextData=(sc.Search)&navigationPath=Search%2fv1%2fresults%2fnavigation%2fi0ad720f200000185b7e4ab11c543c3e4%3fpccid%3d3d37f48bbad14c4e96325d096d46c1da%26Nav%3dREGULATION_PUBLICVIEW%26fragmentIdentifier%3di01D4328129FA11EDA5B6DDCDF7AC13B6%26startIndex%3d101%26transitionType%3dSearchItem%26contextData%3d%2528sc.Default%2529%26originationContext%3dSearch%2520Result&list=REGULATION_PUBLICVIEW&rank=110&t_querytext=Reportable+Diseases+and+Conditions)

[CDPH Reportable Disease and Conditions Morbidity Report \(PDF\)](#)

(www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph110a.pdf)



Cal/OSHA

- Protection of the worker with guidance to keep workers healthy and safe in the state of California
 - Department of Industrial Relations
 - Division of Occupational Safety and Health
 - Develops regulations for workplace safety and health
 - Bloodborne Pathogen Standard
 - Aerosol-Transmissible Diseases Standard
 - Respiratory Protection Standard
 - Regulations must be as stringent (or more) than federal regulations
- [Cal/OSHA](http://www.dir.ca.gov/dosh/) (www.dir.ca.gov/dosh/)

California 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**
(www.law.cornell.edu/cfr/text/42/part-482/subpart-C)
 - **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

CMS Conditions of Participation (CoP)

Interpretive Guidelines for Infection Control

- Hospitals must have an active infection control program and someone overseeing it
- Hospitals must be sanitary
- 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](#) (PDF)

([www.cms.gov/Regulations-and-](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf)

[Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf](http://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)
(www.cms.hhs.gov)
- [CMS Regulations & Guidance](http://www.cms.hhs.gov/home/regsguidance.asp)
(www.cms.hhs.gov/home/regsguidance.asp)
- [CMS Hospital Center](http://www.cms.hhs.gov/center/hospital.asp)
(www.cms.hhs.gov/center/hospital.asp)
- [Conditions of Participations \(CoPs\)](http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html?redirect=/CFCsAndCoPs/06_Hospitals.asp)
(www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html?redirect=/CFCsAndCoPs/06_Hospitals.asp)
- [Interpretive Guidelines](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/SOM107AP_a_hospitals.pdf) (PDF)
(www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/SOM107AP_a_hospitals.pdf)

Current CMS NHSN Acute Care Hospital Reporting Requirements

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
	SSI: HYST	Inpatient HYST Procedures	January 2012
	MRSA Bacteremia LabID Event	FacWideIN	January 2013
	<i>C. difficile</i> 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
	Healthcare Personnel COVID-19 Vaccination	All Healthcare Personnel	October 2021

[Healthcare Facility HAI Reporting Requirements to CMS via NHSN \(PDF\)](https://www.cdc.gov/nhsn/pdfs/cms/cms-reporting-requirements.pdf)
(www.cdc.gov/nhsn/pdfs/cms/cms-reporting-requirements.pdf) (October 2022)

CMS Value-Based Purchasing Program

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

[CMS Value Based Purchasing \(PDF\)](#)

(www.cms.gov/files/document/snf-vbp-faqs-august-2020.pdf)



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

AFL 20-84 (SNF)

- Refers to AB 81, AB 2644 - CDPH incorporating Quality and Accountability Supplemental Payment (QASP) effective January 1, 2021
 - Incorporates infection prevention program and COVID-19 mitigation requirements into QASP
 - QASP assesses SNF quality and bases payment on quality measures

[AFL 20-84](#)

(cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-84.aspx)

AFL 20-84

- Requires a full time Infection Preventionist in SNFs
 - Training requirements – minimum of 14 hours initial IP training
 - Attend IP education – minimum of 10 hours annually
 - Designated IP (or shared by 2 to cover full time) for each facility
 - Describes the IP Program Functions
 - Management, staff education, regulatory requirements, performance improvement and committees, occupational health, IPC policies and protocol

AFL 20-85 and AFL 21-51 (SNF)

- Requires full time IP
 - Must have professional training as a licensed nurse, medical technologist, microbiologist, epidemiologist, public health professional, or other health care related field (may job share)
 - Hours specified for IP LVN or RN hours cannot include hours spent in direct care services
 - Provide annual training for HCP in the facility
- Reporting communicable diseases during a declared emergency
 - Disease or suspect disease related death reported within 24 hours
 - Refers to AFL 20-43.3 Daily Reporting requires data entry into NHSN

[AFL 20-85](http://cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-85.aspx) (cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-85.aspx)

[AFL 21-51](http://cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-51.aspx) (cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-51.aspx)

Summary

- There are many mandates and influencers that affect infection prevention programs and practices
- The IP must be familiar and stay informed to facilitate facility compliance
- IPs need to know the laws and regulations for which healthcare facilities are accountable

Questions?

For more information,
please contact

HAIPprogram@cdph.ca.gov

Include “ACH IP Basics Class” in
the subject line

Post Test

Now that you have
completed this module,
Click on the “Post Test” link
when it pops up
To Return to and take the
post test

If the Post Test link does not pop up, you will be sent a link via e-mail