

State and Federal Regulatory Requirements

Infection Preventionist Training for Skilled Nursing Facilities
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 the purpose of CDPH All Facilities Letters (AFL)
- Review current infection control-related regulations

HAI Public Reporting Policies Driven by Call for Transparency

- 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
- Reporting HAIs became law for hospitals in 2006 & 2008
- Requirement to report HAIs to CMS became law in 2014 for SNFs

[CMS SNF Quality Reporting Program 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 health office and health department
Occupational Health and Safety Administration (OSHA)	Cal-OSHA	Environmental Health Communicable Disease reporting

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 (GACH)
 - Skilled nursing facilities (SNF)

Federal Oversight: Centers for Medicare and Medicaid Services (CMS)

- Provision of health insurance through Medicare and Medicaid
- Surveys and certification health care facilities, including nursing homes, home health agencies, and hospitals
- Requirement by Social Security Administration (SSA) to meet conditions of participation (CoP) by the facility, in order to receive Medicare and Medicaid funds (SSA Section 1861)

[Electronic Code of Federal Regulations](http://www.ecfr.gov/cgi-bin/text-idx?SID=7db07035274456a040371c5839d77a1d&mc=true&tpl=/ecfrbrowse/Title42/42tab_02.tpl)

(www.ecfr.gov/cgi-bin/text-idx?SID=7db07035274456a040371c5839d77a1d&mc=true&tpl=/ecfrbrowse/Title42/42tab_02.tpl)

Accreditation Agencies

- Certifies compliance with CMS conditions of participation
- Private, independent accreditation organizations
 - The Joint Commission (TJC)
 - National Integrated Accreditation for Healthcare Organizations (NIAHO; DNV Healthcare)
 - Healthcare Facilities Accreditation Program (HFAP)
- No citations come from these directly
 - Act as CMS surveyors
 - Information from these surveyors is provided to CMS, who determines penalties

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

- The Joint Commission Certifies or “deems” to CMS that facilities licensed in California they have surveyed met federal requirements
- Inspections by L&C reported to CMS via a contract with CMS
- Enforcement after L&C surveys of state laws (HSC 1188) and regulations (CCR Title 22)
- Surveys by Consolidated Accreditation and Licensing (CALs) conducted jointly with TJC

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/GeneralAcuteCareRelicensing](http://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/GeneralAcuteCareRelicensingSurvey.aspx)

Skilled Nursing Facility Surveys

- Surveys of SNFS are conducted by CDPH at least every 6–16 months
 - Assess compliance with state and federal standards
 - Focus on facilities with outbreaks
 - SNF will be surveyed out of schedule, sooner than usual
 - Complaints of abuse and infectious disease concerns
 - SNF will be visited immediately
 - Revisits by other agencies if high risk findings are reported

[CDPH L&C 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 Executive Branch, agency or department such as CDPH to:
 - Carry out what a bill authorizes or directly requires a State department to do
 - Clarify requirements of a bill (less common)

CDPH All Facility Letters (AFL)

- Communicates with healthcare facilities about laws and regulations
- Sent to inform facilities of
 - new requirement or technologies
 - change of requirement in healthcare
 - clarify an existing law/regulation
 - Enforcement actions
 - Scope of practice clarifications
- General information that affects health facility
- The absence of an AFL does not absolve a facility from complying with the law

LICENSING AND CERTIFICATION PROGRAM

All Facilities Letters - 2020

It is recommended to use Google Chrome, Microsoft Edge, or Firefox as your web browser when opening the AFL. Internet Explorer may not work correctly.

*All Facilities Letters are listed in ascending order by release date, with updated AFLs listed directly after their original version

Bulletin Number	Facility Type Affected	Subject	Release Date
AFL 20-01 (PDF)	Skilled Nursing Facilities	Reminder of Mandatory use of "Census and Direct Care Service Hours Per Patient Day (DHPPD)" (CDPH Form 612) and "Nursing Staffing Assignment and Sign-in Sheet (DHPPD Salaried/Dual Role/Nurse Assistant)" (CDPH Form 530)	01/06/2020
AFL 20-02 (PDF)	All Facilities	Changes to the Application Review Process	01/06/2020
AFL 20-03 (PDF)	Skilled Nursing Facilities	Announcement: Online Application Period for Patient Needs Waiver (PNW) and Workforce Shortage Waiver (WSW)	01/06/2020
AFL 20-83	Skilled Nursing Facilities Intermediate Care Facilities	Interdisciplinary Team (IDT) Authorized Medical Interventions for Residents Unable to Provide Informed Consent and Without a Health Care Decision Maker	10/30/2020
AFL 20-84	Skilled Nursing Facilities	Infection Prevention Recommendations and Incorporation into the Quality and Accountability Supplemental Payment (QASP) Program	11/04/2020
AFL 20-85	Skilled Nursing Facilities	Assembly Bill (AB) 2644 – Skilled Nursing Facilities: Infection Preventionists and Communicable Disease Reporting	11/09/2020
AFL 20-86.1	Long-Term Care Facilities	Coronavirus Disease 2019 (COVID-19) Infection Control Recommendations during Holiday Celebrations	11/20/2020

Antibiotic Stewardship (ABS) for SNF

- AFL 15-30: Requires adoption of ABS policy for each SNF
 - [SB 361](http://oal.ca.gov/) (oal.ca.gov/): Failure to comply will result in enforcement actions per HSC section 1423
 - Authority by HSC section 1275.4
- ABS to align with the 7 Core Elements of Antibiotic Stewardship for Nursing Homes:
 1. Leadership commitment – Safe antibiotic use support
 2. Accountability – physician, nursing, or pharmacist leads
 3. Drug expertise – pharmacist or consultant pharmacists
 4. Action – at least one policy or procedure for antibiotic use
 5. Tracking – at least one process measure of use or outcome from antibiotic use
 6. Reporting – regular feedback on antibiotic use
 7. Education – resources to clinicians, nursing, residents, families

[CDC Nursing Homes and Assisted Living LTCFs](http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html)

(www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html)



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
- Requires a full time Infection Preventionist
 - 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 protocols

[AFL 20-84](#)

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



AFL 20-85 (SNF)

Notifies SNF of AB 2644 requiring full time IP

- Requires full time IP
 - Must be LVN or RN (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](#)

(www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-85.aspx)

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

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 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 infection control program for the surveillance, prevention, and control of infections
- Covered by policies and procedures:
 - Management of transmission risks
 - Education
 - Surveillance plan, including outbreak management
 - Biohazardous equipment and materials identification
- Oversight of the program is part of a multidisciplinary committee
- Care of residents with infectious diseases⁺

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

⁺Title 22, Div 5, Chap 3, Article 3, Sec 72321

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
 - Consult with local health for their particular requirements, forms, method of reporting

[Reporting of Communicable Diseases](#)

([govt.westlaw.com/calregs/Document/I805AD6B0FB1711DEACA9F33E9EE53480?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)](http://govt.westlaw.com/calregs/Document/I805AD6B0FB1711DEACA9F33E9EE53480?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default)))

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

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

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

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](#)

(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**
 - **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 42 Subpart B: Requirements for LTCF

§483.5 Definitions

§483.10 Resident Rights

§483.12 Freedom from Abuse, Neglect, and Exploitation

§483.15 Admission Transfer and Discharge Rights

§483.20 Resident Assessment

§483.21 Comprehensive Person-Centered Care Plans

§483.24 Quality of Life

§483.25 Quality of Care

§483.30 Physician Services

§483.35 Nursing Services

§483.40 Behavioral health services

§483.45 Pharmacy Services

§483.50 Laboratory Radiology and Other Diagnostic Services

§483.55 Dental Services

§483.60 Food and Nutrition Services

§483.65 Specialized Rehabilitative Services

§483.70 Administration

§483.75 Quality Assurance and Performance Improvement

§483.80 Infection Control
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§483.85 Compliance and Ethics Program

§483.90 Physical Environment

§483.95 Training Requirements

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

- Develop and maintain Infection control program
- Provide a safe, sanitary environment
- Prevent the development and transmission of communicable diseases
- Surveillance must be systematic (i.e., infections must be logged)
- Support by leadership:
 - Ensure problems identified by infection control are addressed
 - Take responsibility for corrective action plans when problems are identified

[CMS Nursing Homes](#)

(www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes)

[CMS Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals](#) (PDF)

(www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf)

Finding Federal Regulations

[Centers for Medicare and Medicaid Services \(CMS\)](#)

(www.cms.gov)

[CMS Regulations & Guidance](#)

(www.cms.gov/home/regsguidance.asp)

[CMS Hospital Center](#)

(www.cms.gov/Center/Provider-Type/Hospital-Center?redirect=/center/hospital.asp)

[CMS 1716-P LTC Prospective Payment – Proposed Rule](#)

(www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Proposed-Rule-Home-Page-Items/FY2020-IPPS-Proposed-Rule-Regulations)

[CMS Conditions of Participations \(CoPs\)](#)

(www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index?redirect=/CFCsAndCoPs/06_Hospitals.asp)

[CMS Interpretive Guidelines](#) (PDF) revised 2-21-2020

(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
Hospital Inpatient Quality Reporting (IQR) Program	CLABSI	Adult, Pediatric, and Neonatal ICUs
	CAUTI	Adult and Pediatric ICUs
	SSI: COLO	Inpatient COLO Procedures
	SSI: HYST	Inpatient HYST Procedures
	MRSA Bacteremia LabID Event	FacWideIN
	<i>C. difficile</i> LabID Event	FacWideIN
	Healthcare Personnel Influenza Vaccination	All Inpatient Healthcare Personnel
	Medicare Beneficiary Number	All Medicare Patients Reported into NHSN
	CLABSI	Adult & Pediatric Medical, Surgical, & Medical/Surgical Wards
	CAUTI	Adult & Pediatric Medical, Surgical, & Medical/Surgical Wards

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

(www.cdc.gov/nhsn/pdfs/cms/cms-reporting-requirements.pdf) January 2019)

Current CMS NHSN LTAC Reporting Requirements

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
		<i>As of October 1, 2018, LTCHQR no longer requires LTACs to submit MRSA Bacteremia LabID event data</i>	
	C. difficile LabID Event	FacWideIN	January 2015
	VAE	Adult LTAC ICUs & Wards	January 2016
<i>As of October 1, 2018, LTCHQR no longer requires LTACs to submit VAE event data</i>			
* Long Term Care Hospitals are called Long Term Acute Care Hospitals in NHSN			

LTAC - Still required by CDPH to report MRSA and VRE Bacteremia

[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)

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](#)

(www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing)

[SNF Value-Based Purchasing Program: FAQs](#) (PDF)

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

Summary

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

Questions?

For more information,
please contact

HAIProgram@cdph.ca.gov

Include “SNF IP Training
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

Learning Stream

and take the post test

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