



State of California—Health and Human Services Agency  
**California Department of Public Health**



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VIA ELECTRONIC MAIL AND FIRST CLASS MAIL

Lisa McGiffert  
506 W. 14<sup>th</sup> Street, Suite A  
Austin, TX 78701

**Re: Response to Petition Requesting Action to Reduce Hospital-Associated Infections through More Rigorous Oversight**

Dear Ms. McGiffert:

Thank you for contacting the California Department of Public Health (CDPH). CDPH has received and reviewed your petition dated January 23, 2017. Pursuant to the requirements of Government Code section 11340.7, CDPH issues the following response to the petition.

The action you have requested specifically concerns the requirements for oversight and enforcement action related to healthcare-associated infections (HAI) in hospitals. The petition requests that:

1. CDPH require that the HAI Program share real time hospital infection data with the Licensing and Certification (L&C) Program, in a format that is most usable to the L&C Program;
2. CDPH require that the L&C Program review each hospital's infection data in preparation for conducting the agency's routine state licensure inspection of that hospital every three years and when investigating complaints involving infections;
3. Each hospital identified in the data from the HAI Program annual reports as having significantly high infection rates in any category of infections triggers a timely "complaint" with the L&C Program about that specific type of infection and causes an investigation of the hospital's infection prevention practices. CDPH should begin this process based on 2015 hospital infection data. These investigations should include an infection preventionist and plans of correction relating to infection control should be developed with the assistance of the CDPH HAI Program;
4. CDPH impose fines when hospitals fail to report infections caused by the use of contaminated devices that cause serious disability or death;
5. CDPH impose "immediate jeopardy"-related penalties in situations where hospitals' noncompliance with infection prevention measures have caused, or is likely to cause, serious injury or death to one or more patients. In determining the amount of the penalty, CDPH should find that hospitals with significantly higher infection rates compared to other hospitals, especially those with higher rates over multiple years, are demonstrating a widespread problem or a pattern of deficiencies;

6. CDPH prioritize hospitals with significantly high infection rates when scheduling state licensure inspections. Further, those hospitals that had significantly high infection rates in any type of infection in both 2014 and 2015 and have not been inspected in the past three or more years should be given priority in catching up on these overdue inspections; and
7. CDPH comply with the statutory requirement that all hospitals be inspected every three years, including conducting the patient safety licensing survey.

To support these requests, you reference your review of media publications, CDPH annual reports of HAI in California hospitals, HAI Advisory Committee meeting summaries, communication with CDPH staff, and existing laws and regulations.

Based on your review, you state at that end of your petition:

CDPH should demonstrate its commitment to its mission to optimize the health and well-being of the people of California by making policy changes to improve its infection control oversight through better coordination and cooperation between the two programs in its Center for Healthcare Quality: the CDPH Healthcare-Associated Infections (HAI) Program responsible for public reporting of infection rates and for improving infection prevention efforts in California's hospitals and the Licensing and Certification (L&C) Program, responsible for regulating hospitals throughout the state.

Pursuant to Government Code section 11340.6, any interested person may petition CDPH requesting the adoption, amendment, or repeal of a regulation. The petition must state, clearly and concisely: the substance or nature of the regulation, amendment, or repeal requested; the reason for the request; and reference to the authority of the state agency to take the action requested. Your petition does not state clearly and concisely a specific request for adoption, amendment or repeal of regulation. Nonetheless, CDPH employs a broad interpretation of the section 11340.6 criteria and has interpreted your request as an administrative petition.

### **Background:**

Existing law requires California hospitals to report specific HAI data to CDPH using the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) surveillance system. Specifically, Health and Safety Code section 1288.55 (a) states:

(1) Each health facility, as defined in paragraph (3) of subdivision (a) of section 1255.8, shall quarterly report all cases of health-care-associated MRSA (Methicillin resistant *Staphylococcus aureus*) bloodstream infection, health-care-associated clostridium difficile infection, and health-care-associated Vancomycin-resistant enterococcal bloodstream infection, and the number of inpatient days; (2) Each health facility shall report quarterly to the department all central line associated bloodstream infections and the total central line days; and (3) Each health facility shall report quarterly to the department all health-care-associated surgical site infections of deep or organ space surgical sites, health-care-associated infections of orthopedic surgical sites, cardiac surgical sites, and gastrointestinal surgical sites designated as clean and clean-contaminated, and the number of surgeries involving deep or organ space, and orthopedic, cardiac, and gastrointestinal surgeries designated clean and clean-contaminated.

Surveillance data provide information to estimate disease burden and monitor trends over time. CDC states the purposes of NHSN HAI surveillance data are to:

[A]nalyze and report collected data to permit recognition of trends; provide facilities with risk-adjusted metrics that can be used for inter-facility comparisons and local quality improvement activities; assist facilities in developing surveillance and analysis methods that permit timely recognition of patient and healthcare worker safety problems and prompt intervention with appropriate measures; and comply with legal requirements for mandatory reporting of healthcare facility-specific adverse event, prevention practice adherence, and other public health data.

(<https://www.cdc.gov/nhsn/PDFs/PurposesEligibilityRequirementsConfidentiality.pdf>)

Pursuant to Health and Safety Code section 1288.55 subdivisions (b) and (e), CDPH posts and provides to the public on its website an annual report of hospital HAI incidence rates to the Governor and Legislature. These annual reports also inform hospital providers, public health officials, regulators, and the public about HAI incidence and trends in California hospitals.

HAI Program staff members review reported data throughout the calendar year, communicate with hospitals that have missing, incomplete, or aberrant data, and prompt corrections. At the end of each surveillance year (after March 31<sup>st</sup>), the HAI Program downloads a final data set, removes from the final data set hospitals with incomplete reporting, analyzes the data, and writes a summary report of key findings to accompany the data tables. Since 2010, CDPH has published hospital HAI surveillance data annually.

CDPH publishes the data in multiple formats via a public website. CDPH published the most recent data on the internet as a report titled, "Healthcare-Associated Infections in California Hospitals Annual Report," along with data tables (<http://www.cdph.ca.gov/programs/hai/Documents/2015-HAI%20in%20CA%20Hospitals%20Annual%20Report%202015%209.12.16.pdf>), as an interactive map titled, "My Hospital's Infections" (<http://gis.cdph.ca.gov/HAI/map/>), and as a set of downloadable data files on the California Health and Human Services (CHHS) open data portal (<https://chhs.data.ca.gov/browse?tags=healthcare>).

#### **I. HAI Program Sharing Real Time Hospital Infection Data with Licensing and Certification (L&C) Program**

Petitioner requests that the HAI program share real time and up-to-date hospital infection data with L&C in a usable format so that L&C can better regulate hospitals with significant infection rates. Currently, the HAI program does not receive data directly from hospitals. Hospitals report to the CDC NHSN surveillance system which is then accessed by the HAI program. Unfortunately, the manner in which hospitals report to and the HAI program receives data from the NHSN is not designed or intended for real time regulatory public health intervention or regulatory action.

NHSN HAI data are not public health case reports that can support or inform action in real time. They are surveillance data, reported without patient identifiers that require analysis in aggregate to demonstrate temporal trends. The HAI Program does not analyze hospital-specific quarterly data because quarterly analysis and comparisons would not provide meaningful information due to normal data variation during a calendar year. Nonetheless, CDPH agrees with Petitioner's point that there is value if the HAI program is able to share real time hospital infection data with L&C and will work towards seeing if improvements can be made.



## **II. L&C Program Reviewing Each Hospital's Infection Data in Preparation for Conducting Routine State Licensure Inspections**

Petitioner requests that the L&C Program review each hospital's infection data in preparation for conducting the agency's routine state licensure inspection. Beginning in 2016, as part of hospital relicensing surveys and during the pre-survey preparation stage, nurse surveyors identify any compliance concerns including the data about a hospital's HAI rates. The HAI Program is currently developing a simplified format for sharing hospital-specific HAI data and trends with L&C Program surveyors that will be available later this year. The HAI Program also plans to incorporate this simplified hospital-specific HAI data format into the annual HAI report published on the internet starting in 2018.

## **III. Using Significantly High Infection Rates to Trigger a Complaint Investigation by the L&C Program.**

Petitioner requests that timely complaint investigations be initiated by the L&C Program when hospitals identified in the HAI Program annual reports have significantly high infection rates. As indicated above, the HAI surveillance data are currently not designed or intended to be reported and used for regulatory action. L&C does not initiate complaint investigations based solely on HAI surveillance data used to evaluate temporal trends. Nonetheless, L&C prioritizes hospitals demonstrating a pattern of high infection rates when developing the annual relicensing survey schedule (*See Section V*).

## **IV. Include an Infection Preventionist to Assist in the Investigation and Plan of Correction**

Petitioner requests that L&C's complaint investigations should include an infection preventionist and that a hospital's plan of correction relating to infection control should be developed with the assistance of the CDPH HAI Program. The L&C Medical Consultant Unit currently employs two nurse consultants who are experts in infection control and prevention issues. These expert consultants support L&C surveyors tasked with conducting investigations. The consultants also provide infection surveillance, prevention, and control training to all surveyors, develop policies and procedures to address common and emerging HAI, and participate in surveys at hospitals to assess compliance with state and federal infection control requirements. In 2016, L&C infection control nurse consultants directly participated in 24 hospital surveys.

Additionally, since its inception in December 2009, the HAI Program has worked collaboratively with L&C infection control nurse consultants to develop content and provide infection prevention education for nurse surveyors. In 2010, HAI Program staff developed infection prevention content that was incorporated into the L&C new surveyor academy. HAI Program public health medical consultants frequently consult and share infection prevention expertise with L&C staff for investigations of potential HAI-related outbreaks and unusual disease occurrences. Furthermore, the HAI Program employs regionally-based infection preventionists to provide local support and education to L&C district offices.

During January to May of 2016, HAI Program infection preventionists provided education, including a review of published annual hospital HAI data, to 661 L&C surveyors and other staff members at 15 L&C district offices (the LA offices were combined). The HAI Program provides statewide webinar-based training to L&C staff. In November 2016, the HAI Program educated L&C staff about the national investigation of *M. chimaera* infections following open chest surgery. In January 2017, it provided an overview of the evidence-based care practices most important for preventing the four most common HAI. These presentations are available to L&C staff for self-study.

The HAI Program also employs experienced infection preventionist contractors, supported by CDC funding, to conduct non-regulatory, consultative onsite infection prevention assessments at hospitals and other healthcare facilities. The scope of the funding for these contractors is limited to non-regulatory

functions. L&C surveyors, on the other hand, serve a regulatory function by citing hospitals for deficiencies when they find a hospital to be noncompliant with federal or state regulations.

**V. Imposing Fines and Immediate Jeopardy-Related Penalties in Situations where Hospitals' Noncompliance with Infection Prevention Measures have Caused, or are Likely to Cause, Serious Injury or Death**

Petitioner requests that L&C impose "immediate jeopardy"-related penalties in situations where a hospital's noncompliance with infection prevention measures has caused, or is likely to cause, serious injury or death to one or more patients. California law provides authority to L&C to assess administrative penalties against hospitals for deficiencies that constitute an immediate jeopardy violation. Specifically, Health & Safety Code section 1280.3 (g) defines "immediate jeopardy" as "a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient." If L&C staff find a hospital is out of compliance with federal or state infection control regulations and determines HAI have caused or are likely to cause serious injury or death, L&C may assess an administrative penalty. L&C has full discretion to consider all factors when determining the amount of an administrative penalty.

Despite this authority to assess administrative penalties, limitations in existing law present challenges for L&C. Specifically, Health & Safety Code section 1279.1(b) requires hospitals to report adverse events to L&C and lists 28 specific types of adverse events and "adverse events that cause the death or serious disability of a patient, personnel, or visitor." However, the law provides no specifics related to how hospitals should determine "cause." For patients with serious or complex medical conditions, confirming that a death is "caused" by HAI is especially difficult. Death often occurs with patients at the highest risk for HAI, who have long hospitalizations, often requiring care that requires invasive medical devices and procedures. To address this issue, L&C is developing regulations to provide more guidance to hospitals on how they report adverse events.

**VI. Prioritizing Hospitals with Significantly High Infection Rates when Scheduling State Licensure Inspections**

Petitioner requests that CDPH prioritize hospitals with significantly high infection rates when scheduling state licensure inspections. L&C agrees that hospital infection rates should be factored in L&C selection decisions prior to scheduling relicensing surveys. In October 2016, prior to the publication of the 2015 HAI data report, the HAI Program provided L&C a list of hospitals with high HAI incidence in consecutive years to consider as priorities when developing the 2017 relicensing survey schedule. L&C will annually repeat and refine this process of using hospital HAI incidence data to inform relicensing survey decision-making. Going forward, the HAI program will provide L&C staff a list of hospitals that have high HAI incidence based on annual HAI data analysis, prior to the annual report publication.

**VII. Complying with the Statutory Requirements that All Hospitals be Inspected Every Three Years, including Conducting the Patient Safety Licensing Survey**

Finally, Petitioner requests that CDPH comply with the statutory requirement that all hospitals be inspected every three years, including conducting the patient safety licensing survey. Beginning in March 2016, L&C began using a new general acute care hospital state relicensing survey tool to develop a schedule to ensure that every hospital will have a state relicensing survey over the next three years and a relicensing survey every three years thereafter. L&C continues to incorporate all elements of the patient safety licensing survey into the new, comprehensive relicensing survey. Prioritization for relicensing surveys currently takes into consideration a hospital's HAI data and time since its last survey. This prioritization will occur until all hospitals are resurveyed every three years. In addition, federal recertification surveys occur every 36 months.

### VIII. Conclusion

CDPH appreciates and shares your interest and desire to improve the regulation of hospitals with respect to HAI. CDPH is dedicated to its mission to optimize the health and well-being of all Californians and will aim to improve its infection control oversight through better coordination and cooperation between the HAI and L&C programs. As described above, CDPH is working to:

- Continually improve the exchange of information between the HAI and L&C Programs so that L&C surveyors have usable real time HAI data to better oversee and regulate hospitals;
- Continue to consider administrative penalties for immediate jeopardy violations that may be related to noncompliance with infection control regulations resulting in HAI;
- Incorporate and use hospital HAI data to prioritize relicensing surveys; and
- Ensure that every hospital will have a state relicensing survey every three years as required by statute.

Please direct any further correspondence with CDPH on this matter to my attention.

Sincerely,



Scott Vivona  
Acting Deputy Director