Administrative Petition
from Consumers Union Safe Patient Project and Activist Network
Calling on the California Department of Public Health
to Require Hospitals to Take Actions to Reduce Hospital-Associated Infections
through More Rigorous Oversight

I. Executive Summary

An increasing number of superbug infections that are resistant to many antibiotics create a compelling need for diligence in preventing infections. The California Department of Public Health (CDPH) recently reported that 19,847 infections occurred in hospital patients in 2015; these data draw only a limited picture because California hospitals are *not* required to report *all* hospital-associated infection types to CDPH. It is estimated that each year a total of between 72,000 and 87,000 California patients acquire infections while hospitalized and that between 7,500 and 9,000 of those patients die during their hospitalizations.

In recognition of the danger posed by superbugs and hospital-associated infections the state of California enacted a series of laws to address this urgent healthcare problem. In particular, in 2008, a law known as "Nile's Law" specified that the protection of hospital patients is of paramount importance to the citizens of this state and required the California Department of Public Health to collect and publicly report hospital infection rates.

As required by law, the CDPH Healthcare Associated Infections (HAI) Program publicly reports these data annually including the identification of hospitals with significantly higher rates of infections than other hospitals; usually the data are one or two years old by the time they are publicly reported. While the CDPH HAI Program *offers* infection control support to these outlier hospitals, it is entirely within each low-performing hospital's discretion whether to act on proposed visits/advice/recommendations from the HAI Program.

On the other hand, all California acute care hospitals are required to be surveyed for state licensure every three years. The CDPH Licensing and Certification (L&C) Program conducts these inspections[1] and has enforcement authority to identify deficiencies, require plans of correction, fine hospitals and take other actions based on the results of the inspections. To the detriment of patients, leadership at CDPH has deliberately created a "firewall" between the CDPH HAI Program and the CDPH L&C Program, which prevents the timely sharing of hospital infection data between the two programs, including identifying which hospitals have significantly higher infection rates that might warrant enforcement actions. Under current CDPH policy, its L&C Program lacks access to the HAI Program infection data (other than that which is made publicly available on the CDPH website one to two years after it is collected).[2]

Over the three years of data that were examined for this petition, nearly 60 percent of the state's acute care hospitals had significantly higher infection rates, compared to other California hospitals, in at least one type of infection (such as MRSA, *C. difficile* or surgical infections). In

[1] In this report, we will use the term "inspection" to refer to these statutorily required "state licensure surveys."
[2] See page 11 of this report for discussion of recent verbal communications with CDPH staff regarding changes to this policy based on advocacy by consumer members of the Healthcare Associated Infections Advisory Committee.

2015, the most recent year of available data, 159 hospitals had significantly high infection rates in at least one type of infection required to be reported to CDPH. Many hospitals had significantly high infection rates of multiple types of infections or over multiple years. For example:

- 59 hospitals had significantly high infection rates in more than one type of infection for 2015 and 35 of those had high rates in three or more types of infections;
- 95 hospitals had significantly high infection rates in at least one type of infection for the years 2014 and 2015; and
- 65 hospitals reported significantly high infection rates in at least one type of infection for more than three years in a row (2013, 2014, and 2015).

Further, despite the three-year requirement for state licensure inspections of California hospitals, 131 California acute care hospitals were not inspected during the more than five-year period of January 1, 2011 to June 18, 2016. Among these uninspected hospitals, 80 had infection rates that were significantly higher than other hospitals in the state.

Through this petition, the Consumers Union Safe Patient Project is calling on CDPH to take the following steps to reduce patient infections:

- Eliminate the firewall and require that the HAI Program share real-time hospital infection data with the L&C Program.
- Require that the L&C program:
  - review hospital infection data prior to conducting routine state licensure inspections;
  - treat significantly high infection rates as it does hospital complaints, thus triggering an investigation of the hospital's infection prevention practices;
  - use its fining authorities against hospitals that fail to report infections related to adverse events or that place patients in immediate jeopardy;
  - prioritize hospitals with significantly high infection rates when scheduling state licensure inspections, with an emphasis on those hospitals that CDPH has not inspected in the past five years; and
  - inspect California hospitals every three years, as required by law.

Hospital-associated infections have increased each year, causing untold suffering for tens of thousands of patients and needless deaths. These infections are preventable. Consumers Union Safe Patient Project's recommendation is to adopt straightforward, common-sense policies that CDPH should immediately put into place. This petition provides for the background for our request, and provides citations to legal authorities supporting these recommendations as well as further detail regarding our recommendations.

II. Parties

A. Petitioners

Consumers Union Safe Patient Project (CUSPP), a nationwide campaign, has organized a California Network of patient safety activists (the CUSPP Network). CUSPP has been working in California on issues relating to hospital safety (hospital-associated infections and medical errors) since 2003. Members of the CUSPP Network monitor agency meetings, testify at legislative hearings and participate as consumer representatives of various health-related state committees. CUSPP monitors the work of the California Department of Public Health's (CDPH) Center for Healthcare Quality's Healthcare Associated Infections Program and the CDPH Licensing and Certification Program. Numerous CUSPP Network members have served as consumer representatives of the Healthcare Associated Infections Program's Advisory Committee since its inception.

B. Respondent

Karen Smith, MD, MPH is the Director of the California Department of Public Health, the mission of which is to "optimize the health and well-being of the people in California."[3]

III. Statement of Facts

Dangerous infections that are resistant to antibiotics
are spreading and growing stronger, with dire consequences.
Medical experts say it's a mess of our own making
and the clock is ticking on when and how we must solve this.

– Consumer Reports August 2015, cover story,
"How to Stop a Superbug"/"The Rise of Superbugs"

Background

The number of dangerous – often lethal – healthcare-associated infections (HAIs) identified at California acute care hospitals reflects a serious patient safety problem. According to a February 2016 California Department of Public Health (CDPH) report, these infections "remain a significant, and in some cases, a growing health problem in California."[4] The increasing number of superbug infections that are resistant to many antibiotics creates an ever more compelling need for diligence in preventing infections. Research has identified effective approaches to reducing HAIs and protocols have been developed by the federal Centers for Disease Control and Prevention (CDC) and numerous professional epidemiological organizations. However, hospitals do not always implement these protocols or provide the resources and staff needed to ensure that they are used consistently with every patient.

In 2008, the California State Legislature passed Nile's Law, in recognition of the critical importance for a government public health agency to track these infections and report them to

[3] https://www.cdph.ca.gov/Pages/AboutUs.aspx.
[4] "California Department of Public Health, Healthcare-Associated Infections in California Hospitals Annual Report for January to December 2014," page 1, Key Findings and Public Health Action, published February, 2016; http://www.cdph.ca.gov/programs/hai/Pages/HAIReportsAndPrevention.aspx.

the public. Since 2010, reports have been published by the CDPH Healthcare Associated Infections (HAI) Program whose responsibility is "to oversee the prevention, surveillance and reporting of healthcare-associated infections."[5] However, the HAI Program lacks enforcement authority over hospitals and is unable to take such action regarding hospitals with significantly high infection rates.[6]

In contrast, the CDPH Licensing and Certification (L&C) Program *does* have enforcement authority and *could* use data, reported by the HAI Program, in its regular state licensure inspections of hospitals and in its response to complaints to ensure that effective infection prevention and control practices are in place, especially among hospitals with high infection rates. But these two Programs within CDPH do not routinely share infection data collected from hospitals or communicate about hospital infection rates; such collaboration could improve the safety of California patients.

Based on research and data published by the CDC, California hospital data reported to CDPH, and statements by leadership at CDPH, the numbers paint a dim picture of the risks for patients:

- According to CDC estimates, one in 25 hospital patients contracted at least one infection during their hospital stay, adding up to 722,000 infections a year nationally. Approximately 75,000 patients with infections died during their hospitalizations.[7]
- CDPH staff estimates that CA acute care hospital patients represent 10% – 12% of this national prevalence estimate, and thus estimate that a total of 72,000 - 87,000 patients suffer with HAIs each year in California and that 7,500 - 9,000 patients with HAIs die during their hospitalizations each year in California.[8]
- California hospitals reported to CDPH that 19,847 of the following infections occurred in their patients in 2015: [9] Methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections, *Clostridium difficile* infections (*C.difficile*), Vancomycin-resistant Enterococci (VRE) bloodstream infections, central line associated bloodstream infections (CLABSI), and surgical site infections associated with 29 types of surgeries[10] This data draw a limited picture because California hospitals are *not* required to report *all* HAI types to CDPH.

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[5] http://www.cdph.ca.gov/programs/hai/Pages/default.aspx.

[6] CDPH reports hospital infection incidence using the CDC National Healthcare Safety Network (NHSN) risk-adjustment method called the standardized infection ratio (SIR). The SIR is calculated by comparing the number of HAI that occurred and were reported by the hospital with the number of HAI that were predicted based on national baseline data. Throughout this petition we use the term "significantly high infection rates" to describe hospitals with SIRs that are statistically significantly higher when compared to other California hospitals.

[7] Newest national estimates from CDC 2011 HAI prevalence survey published in 2014; http://www.cdc.gov/hai/surveillance/.

[8] August 1, 2016 e-mail communication between Lynn Janssen, Chief, Healthcare-Associated Infections Program, Center for Healthcare Quality, California Department of Public Health and Carole Moss, member, CDHP HAI Advisory Committee.

[9], "California Department of Public Health, Healthcare-Associated Infections in California Hospitals Annual Report for January to December 2015" published December 16, 2016 http://www.cdph.ca.gov/programs/hai/Pages/HAIReportsAndPrevention.aspx

[10] See CDPH All Facilities Letter 11-32, April 27, 2011 for list of surgical procedures for which infection reporting is required; http://www.cdph.ca.gov/certlic/facilities/Documents/LNC-AFL-12-15.pdf.

- In the fifth CDPH HAI report regarding California hospital infections in 2015[11]– the most recently publicly reported California hospital infection data – 19,847 infections were reported.[12] That reflects an increase from 19,200 in 2014[13] and 18,780 in 2013.[14] While some types of infections are decreasing, the overall number is moving in the wrong direction. Consumers Union and other experts believe these numbers could drop dramatically if appropriate policies were put in place by CDPH, thus avoiding much suffering among California patients.
- CDPH leadership estimates that annual direct medical costs of HAIs in California hospitals are approximately $3.1 - $3.7 billion.[15]

It is important to remember each of these numbers reflects real people who have suffered great harm, and even sometimes died.

- In 2006, Nile Moss, 15 years old, entered a California hospital for a series of medical tests. Upon returning home he began to have flu-like symptoms. As his mother Carole put it, "within 48 hours, his life on earth came to an end." She and her husband Ty later learned that Nile died of a MRSA infection, something they had never heard about and for which they had not been prepared. Carole Moss worked to get public reporting of MRSA and other infections and served for nine years as a member of the CDPH HAI Advisory Committee.
- Ten years ago Alicia Cole barely survived near fatal sepsis and necrotizing fasciitis, following routine fibroid removal surgery at a Southern California hospital. Ms. Cole has since worked to raise awareness of these infections and now serves as a member of President Obama's Council on Combatting Antibiotic Resistant Bacteria and the CDPH HAI Advisory Committee.
- Following transplant surgery, Dan Greulich fell prey to a superbug infections that eventually led to his death: his seven-month hospital bill was $5.7 million.[16] His widow, Rae Greulich, has served as a member of the CDPH HAI Advisory Committee.

[11] Five California reports using the CDC/NHSN system have been published, beginning in 2011. CDPH published a report in 2010 using other methods.
[12] "California Department of Public Health, Healthcare-Associated Infections in California Hospitals Annual Report for January to December 2015," published December 16, 2016; http://www.cdph.ca.gov/programs/hai/Pages/HAIReportsAndPrevention.aspx.
[13] "California Department of Public Health, Healthcare-Associated Infections in California Hospitals Annual Report for January to December 2014," published February 10, 2016; http://www.cdph.ca.gov/programs/hai/Pages/HAIReportsAndPrevention.aspx.
[14] "California Department of Public Health, Healthcare-Associated Infections in California Hospitals Annual Report for January to December 2013," http://www.cdph.ca.gov/programs/hai/Pages/HAIReportsAndPrevention.aspx.
[15] August 1, 2016, e-mail communication between Lynn Janssen, Chief, Healthcare-Associated Infections Program, Center for Healthcare Quality, California Department of Public Health and Carole Moss, member, CDHP HAI Advisory Committee citing CDC HAI cost analysis published in 2009; and http://www.cdc.gov/HAI/pdfs/hai/Scott_CostPaper.pdf,
[16] http://www.reuters.com/investigates/special-report/usa-uncounted-costs/.

- In Los Angeles in late 2014 and early 2015, fifteen patients were sickened, including three who died, during a CRE superbug outbreak involving contaminated duodenoscopes at Ronald Reagan UCLA Medical Center.[17]

Health care-acquired infections are preventable

Effective infection control requires a comprehensive, hospital-wide approach to stop infections from happening. According to the HAI Program's most recent publication on this topic, "[i]nfections that occur as a result of healthcare are largely preventable if healthcare providers adhere consistently to recommended infection prevention practices. Improvement in HAI prevention is not occurring uniformly across all California hospitals."[18] Standard practices have been developed based on clinical research and adopted by the CDC as Guidance for preventing specific types of infections. Many of these have been translated by professional organizations such as the Society for Healthcare Epidemiology of America into compendia of prevention strategies that provide easy references for hospital personnel.[19]

Further, in recent years, numerous federal programs have funded state collaborations with hospital associations to provide training to hospital staff. For example, Dr. Peter Pronovost of Johns Hopkins developed and tested a simple checklist that led to significant reductions in central line associated bloodstream infections, which can be deadly for many patients who require these lines to deliver medicine, nourishment, and liquids.[20] A public-private initiative taught that checklist across the country and many participating hospitals are now successfully preventing these infections.

The federal Partnership for Patients program – designed to reduce infections and other types of medical harm through collaborative public-private partnerships to identify and share best practices, tools and resources – demonstrated reductions in various infections in 2014 and 2015.[21] The program recently announced more funding for such training. In California, the HAI Advisory Committee recently adopted motions by its Environmental Subcommittee recommending that the state require hospitals follow CDC best practices in environmental cleaning, including monitoring and verification of compliance in place by 2018.

Many prevention protocols involve simple actions – washing hands, ensuring sterile insertion of central lines and urinary catheters, raising the head of the bed of a ventilator patient, following instructions for cleaning medical instruments – but the challenge is in ensuring these simple acts are done correctly 100% of the time. This requires a full investment by hospital leadership to

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[17] Los Angeles Times, "State found lapses in infection control at UCLA and Cedars-Sinai," Melody Petersen, May 15, 2016, http://www.latimes.com/business/la-fi-infections-ucla-cedars-hospitals-20160515-snap-story.html; and CDPH inspection findings: http://documents.latimes.com/ucla-medical-center-inspection-report/ and http://documents.latimes.com/cedars-sinai-medical-center-inspection-report/.

[18] "California Department of Public Health, Healthcare-Associated Infections in California Hospitals Annual Report for January to December 2015," page 12; December 20, 2016 http://www.cdph.ca.gov/programs/hai/Pages/HAIReportsAndPrevention.aspx

[19] http://www.shea-online.org/priority-topics/compendium-of-strategies-to-prevent-hais

[20] http://www.hopkinsmedicine.org/armstrong_institute/training_services/cusp_offerings/cusp_guidance.html.

[21] https://www.hhs.gov/about/news/2014/12/02/efforts-improve-patient-safety-result-1-3-million-fewer-patient-harms-50000-lives-saved-and-12-billion-in-health-spending-avoided.html and https://www.hhs.gov/about/news/2015/12/01/national-patient-safety-efforts-save-lives-and-costs.html.

ensure that the facility has sufficient nursing and cleaning staff, proper training and appropriate materials/equipment. Hospitals reported to have significantly higher infection rates compared to their peers might indicate a breakdown in infection control and thus call for a response from our oversight system. In our opinion, a proactive response from the CDPH L&C Program is warranted in such situations.

Role of California Department of Public Health in addressing HAI in California hospitals

CDPH is organized into five centers dedicated to various aspects of public health. One of those centers, the Center for Health Care Quality, operates:

- the Healthcare-Associated Infections Program (HAI Program), which is responsible for public reporting of infection rates and for improving infection prevention in California's hospitals; and
- the Licensing and Certification Program (L&C Program), which is responsible for licensing and regulating health care facilities throughout the state.[22]

HAI Program: Gathering hospital infection data; limitations on addressing problems

California law requires that acute care hospitals report data for certain healthcare-associated infections to the CDC National Healthcare Safety Network; these data are then risk-adjusted so fair comparisons can be made among diverse hospitals and publicly reported by the CDPH HAI Program. The data are also publicly reported (along with the hospitals from every state) by the federal Centers for Medicaid and Medicare Services (CMS) on its Hospital Compare website. While these data are submitted by hospitals each quarter to CDC and CDPH, the reports are one to two years old when they are finally made publicly available on the CDPH HAI website.

As part of its public reporting of California hospital infection data, the HAI Program identifies hospitals with significantly high rates of infection and designates some of these hospitals as "targeted for public health outreach." In February 2015, Lynn Janssen, Chief, HAI Program, reported at the HAI Advisory Committee meeting regarding 2013 data that, "[i]mprovement is not occurring uniformly across hospitals. The HAI Program's Data for Action strategy is now in its second year. …hospitals with significantly high rates have been identified and will receive detailed letters and an *offer* from a Liaison IP [Infection Preventionist] to provide on-site prevention assistance consultation."[23] [Emphasis added]

Consumers Union analyzed the data accompanying the release of CDPH's most recent three Annual Reports, which covered data for 2013, 2014 and 2015[24] and found that California hospitals are not adequately addressing dangerous infections. Over the course of three years, nearly 60 percent of the state's acute care hospitals had infection rates that were significantly

[22] https://www.cdph.ca.gov/programs/Pages/CenterHealthcareQuality.aspx.
[23] Healthcare-Associated Infections Advisory Committee Meeting, Sacramento, California, February 12, 2015, Summary Meeting Minutes HAI Program updates – L Janssen, Chief, HAI Program, page 3.
[24] http://www.cdph.ca.gov/programs/hai/Pages/HAIReportsAndPrevention.aspx and https://chhs.data.ca.gov/browse?q=hospital+infection

higher when compared to other California hospitals at least once in a specific type of infection – such as MRSA, *C. difficile* or surgical infections. (*See* Appendix A)

In 2015 alone, the most recent year of data available, 159 hospitals had significantly high infection rates in at least one type of infection that is required to be reported to CDPH. Many hospitals had significantly high infection rates in multiple types of infections or over multiple years:

- 59 hospitals had significantly high infection rates in more than one type of infection for 2015 and 35 of those had high rates in three or more types of infections;
- 95 hospitals had significantly high infection rates in at least one type of infection for the years 2014 and 2015; and
- 65 hospitals reported significantly high infection rates in at least one type of infection three years in a row (2013, 2014, and 2015).

While most of the hospitals with high infection rates had them once or twice over the period studied, our analysis found that some hospitals stood out as being consistently and significantly worse at controlling infections in patients. The following hospitals had repeatedly high rates in CDPH's reports for 2013-2015:

- University of California San Diego Medical Center had significantly high infection rates in each of the three years, totaling high infection rates in various types of infections 12 times.
- Riverside Community Hospital had significantly high infection rates in each of the three years, totaling high infection rates in various types of infections 11 times.
- Ronald Reagan UCLA Medical Center had significantly high infection rates in each of the three years, totaling high infection rates in various types of infections 10 times.
- Long Beach Memorial Medical Center had significantly high infection rates in each of the three years, totaling high infection rates in various types of infections 10 times.
- Providence Saint Joseph Medical Center, Los Angeles, had significantly high infection rates in each of the three years, totaling high infection rates in various types of infections nine times.
- USC Kenneth Norris Jr. Cancer Hospital had significantly high infection rates in each of the three years, totaling high infection rates in various types of infections nine times.
- Stanford Health Care had significantly high infection rates in each of the three years, totaling high infection rates in various types of infections nine times.

When the HAI Program *offers* infection control support to hospitals, it is completely in each low-performing hospital's discretion whether to accept or to refuse to act on proposed visits, advice, or recommendations from the HAI Program. As a February 5, 2016, sample letter from CDPH to a low performing hospital stated: "The purpose of this letter is to inform you that your hospital's infection incidence was found to be significantly higher than the California or national comparison. The CDPH HAI Program is *offering* assistance to help assess your infection prevention practices and develop an action plan for preventing HAI." [Emphasis added]

The HAI Program's effectiveness in improving safety is clearly limited when hospitals with the worse infection rates are able to refuse appropriate intervention by CDPH.

L&C Program – authority to conduct state licensure inspections and address deficiencies

The CDPH L&C Program has the legal authority to inspect hospitals routinely, respond to complaints and enforce the hospital licensing laws. California hospitals are required to be inspected every three years. L&C Program surveyors who conduct state hospital inspections may rely on all related California laws and regulations, including laws and regulations related to infection control.[25] The California Hospital Association advises its members: "The California Department of Public Health (CDPH) Licensing and Certification surveyors may visit a hospital at any time to determine whether the hospital is in compliance with state licensing requirements. Visits may result from a complaint by a patient, employee or other third party; a newspaper article; or a report by the hospital itself regarding an unusual occurrence, privacy breach or adverse event."[26]

Hospitals found to be out-of-compliance with the law during L&C Program inspections may be cited for violations/deficiencies, required to submit plans of corrections, have their licenses revoked and be fined. The same applies for compliance violations found when the L&C Program goes into a hospital to investigate a complaint. If that complaint involves an infection, the L&C Program looks into the organization and effectiveness of the hospital's infection control.

Examples of the L&C Program's documentation of violations and of plans of correction required for two California hospitals regarding infection control can be found at the following links (page 12 of this petition also includes examples of violations found during investigations): http://documents.latimes.com/ucla-medical-center-inspection-report/ and http://documents.latimes.com/cedars-sinai-medical-center-inspection-report/ .

CDPH constructed "firewall," creates dangerous situation

An unreasonable and counter-productive firewall has been established between the CDPH HAI Program and the CDPH enforcement arm, the L&C Program, with respect to sharing hospital infection data. According to Lynn Janssen, Chief, HAI Program: "This firewall was established by Kathleen Billingsley (former CDPH Chief Deputy Director of Policy and Programs) when the HAI Program was formed in 2009; we continue to approach facilities on a voluntary basis."[27]

While the HAI Program only offers *voluntary* infection prevention assistance, the L&C Program has the authority to conduct state licensure inspections and require hospitals to address deficiencies related to high infection rates. But the existence of the above-referenced "firewall" within CDPH, between its HAI Program and its L&C Program, and created by CDPH leadership,

[25] General Acute Care Hospital Relicensing Survey, Regulations with Survey Procedures, May 24, 2016, page 2, https://www.cdph.ca.gov/programs/LnC/Documents/GACHRLS_Regulations_with_Survey_Procedures.pdf.
[26] http://www.calhospital.org/cdph-licensing-enforcement.
[27] April 28, 2016, e-mail communication between Lynn Janssen, Chief, Healthcare-Associated Infections Program, Center for Healthcare Quality, California Department of Public Health and Carole Moss, member, CDPH Healthcare Associated Infections Advisory Committee.

has led to a lack of coordination and cooperation between these two Programs, and ultimately a barrier to opportunities to reduce harm to patients.[28]

While nothing prevents the L&C Program from looking at the one- to two-year old public reports once they are produced and publicly reported by the HAI Program on its webpage, it is also clear that *there is no defensible rationale for the L&C Program **not** to have access to the most up-to-date data at all times. L&C should not have to wait for the infection data to be publicly posted on the CDPH website*. According to a presentation by CDPH L&C Program staff, they consult numerous databases prior to conducting state licensure inspections, including those related to adverse events, medication errors and administrative penalties but – unreasonably – not infection data collected by the HAI Program.[29]

This important hospital infection data is not shared between the two programs that form CDPH's Center Health Care Quality based on a theory that to do so might cause low-performing hospitals to refuse to cooperate with the HAI Program's voluntary infection-control efforts. As expressed by Ms. Janssen: "The relationship between our non-regulatory HAI Program and the regulatory L&C program is also a little tricky. If facilities think that everything we assist them with or provide consultation on will be shared with L&C, they will no longer work with the HAI Program."[30] While it is unclear how much consultation these poorly performing hospitals are allowing, it is clear that CDPH has a responsibility to ensure the public that licensed hospitals provide safe care to their patients. When hospitals report significantly high infection rates, sometimes over multiple years, something beyond "consultation" should be done to protect patients.

Contrary to this interpretation by the HAI Program, the law intended for these two programs to collaborate as it specifically requires CDPH to establish a program to designate infection prevention professionals to serve as consultants to the L&C Program and to provide education and training to department health facility evaluators to "effectively survey hospitals for compliance with infection surveillance, prevention, and control recommendations, as well as state and federal statutes and regulations." [Health and Safety Code Section 1288.8 (e)(1)(2)].

HAI Advisory Committee members – unsuccessfully – previously called on CDPH to dismantle its internal "firewall"

[28] According to "California Department of Public Health, Healthcare-Associated Infections in California Hospitals Annual Report for January to December 2015," page 3, despite state law requiring hospitals to submit infection data to CDPH, in 2015, twenty hospitals failed to report any infection data. In a verbal statement, Lynn Janssen, Chief, HAI Program, told Consumers Union staff that the HAI Program turns the names of these non-reporting hospitals over to L&C Program. Since these hospitals are in violation of state law, Janssen further advised that the L&C Program takes enforcement action against these hospitals, including fines and a requirement of a plan of correction.

[29] Slide #13 of presentation titled "General Acute Care Hospital Relicensing Surveys," Patricia Dixon, R.N., California Department of Public Health, Licensing and Certification Program, April 2016. General Acute Care Hospital Relicensing Surveys," Patricia Dixon, R.N., California Department of Public Health, Licensing and Certification Program, April 2016.

[30] April 28, 2016, e-mail communication between Lynn Janssen, Chief, Healthcare-Associated Infections Program, Center for Healthcare Quality, California Department of Public Health and Carole Moss, member, CDPH Healthcare Associated Infections Advisory Committee.

Considering the low rate at which California hospitals are being inspected and the existing backlog of state inspections, it is particularly critical that the hospitals scheduled for inspection each year be carefully chosen. *Using timely infection data to prioritize low-performing/high-infection rate hospitals for L&C Program inspections could help to identify root causes of infections at low performing hospitals and likely reduce future infections and save lives.* Further, if the L&C Program engages the infection control experts in the HAI Program in establishing an action plan to correct deficiencies, the result may be longer lasting, ultimately reducing harm and saving the lives of patients through fewer infections.

When a problem with a hospital becomes a prominent news story, the L&C Program has the authority to follow up with an investigation just as it can when triggered by a complaint. According to the Los Angeles Times, "After 'super bug' outbreaks…state health inspectors descended on two of Los Angeles' largest hospitals and found numerous safety violations that appeared to put far more patients at risk."[31] But when a hospital is identified as having an infection control problem through the HAI Program's infection data (*i.e.*, it is revealed as being significantly worse in controlling infections than other California hospitals), the L&C Program does not go into the hospital to check for possible infection control violations. *In fact, the L&C Program is not even made aware of the hospital's performance and does not have access to the infection data collected by CDPH.*

At the May 12, 2016, meeting of the HAI Advisory Committee in Oakland, California, Advisory Committee member Carole Moss motioned that: "*The CDPH licensing and certification program will have access to all hospital-acquired infection data*, now collected as part of SB 1058 Alquist, 2008, Niles Law AKA the Healthcare Facility Infection Prevention Act and SB 158 Florez, 2008, *as the data are received from the state of California quarterly reports* and will move forward with correcting the problems that are contributing to hospital-acquired infections harming and ending the lives of many." [Emphasis added] The motion received only two votes from consumer representatives on the Committee and failed to pass.[32]

One has to wonder what the estimated 70,000 patients and documented 19,200 patients would make of CDPH's "firewall" policy. Would they agree that hospitals with significant problems in infection control should have control over when and if CDPH staff comes into their facilities to identify problems that could be corrected, improved and surely save lives? Or would they want the CDPH staff to use its oversight authority to check out that hospital's infection control efforts and require that changes be made to make the hospital safer?

In October 2016, HAI advisory committee members Carole Moss and Alicia Cole met with Karen Smith, Director of CDPH, and were given verbal assurances that CDPH would begin sharing infection data between the HAI Program and the L&C Program prior to the state licensure inspections required to be done every three years. Similar verbal statements were given

[31] Los Angeles Times, "State found lapses in infection control at UCLA and Cedars-Sinai, Melody Petersen, May 15, 2016, http://www.latimes.com/business/la-fi-infections-ucla-cedars-hospitals-20160515-snap-story.html and CDPH inspection findings: http://documents.latimes.com/ucla-medical-center-inspection-report/ and http://documents.latimes.com/cedars-sinai-medical-center-inspection-report/.

[32] Healthcare-Associated Infections Advisory Committee Meeting, Sacramento, California, May 12, 2016, Summary Meeting Minutes, page 9.

to Consumers Union staff in December 2016 by Lynn Janssen, Chief, HAI Program, as well as an indication that they were working with L&C to prioritize inspections of hospitals with significantly high infection rates. While these actions are a step in the right direction, we have seen no written policies regarding the L&C Program having real time access to infection data when they are preparing for scheduled inspections or investigating complaints involving infections.

Timely state licensure inspections not undertaken[33]

The rate at which the L&C Program actually inspects California hospitals is far less frequent than is required by state law – every three years. Between January 1, 2011 and June 18, 2016 CDPH had failed to conduct a licensure inspection at 131 of California's acute care hospitals despite the three-year statutory inspection requirement (See Appendix B).[34] According to the "California Department of Public Health Licensing and Certification Program Initial Assessment and Gap Analysis Report," in state fiscal year 2012 – 2013, all 431 California hospitals were required to each be inspected every three years.

To comply with this state mandate would require that 140 hospitals be inspected that fiscal year; however, only 69 – about half that number – were inspected.[35] In addition to the state licensure inspections, CDPH is supposed to conduct Patient Safety Licensing Surveys (that include infection control issues) and Medication Error Reduction Plan surveys to ensure that related mandates are being followed by hospitals. In a revamped inspection process implemented in March 2016, CDPH merged these two surveys with the every three-year state licensure inspection.[36]

Of the 131 hospitals that went five years without inspections by the L&C Program, Consumers Union's analysis of infection reports in 2013, 2014, and 2015,[37] revealed that 80 had significantly higher infection rates than other hospitals in at least one category of infections over those years and 49 had significantly higher rates in two or more categories. (It should be noted that many hospitals that ***did*** have timely inspections also reported high infection rates during these years.)

But the L&C Program was unaware of these patterns because it did not consider hospital infection data when scheduling state inspections. Having approximately one-third of California hospitals uninspected for over five years provides evidence of a problem in CDPH's oversight

[33] These inspections, required by state law, should not be confused with accreditation surveys conducted by The Joint Commission and other similar accrediting agencies to certify hospitals eligible to care for Medicare patients. The Joint Commission conducts periodic surveys to evaluate the hospital and to provide education and guidance to the hospital to improve its performance. The findings of these surveys are not public, although cursory information is available at https://www.qualitycheck.org/.

[34] CDPH response to Public Record Act request by Carole Moss, member, Healthcare Associated Infections Advisory Committee; August 15, 2016, e-mail communication between Carole Moss and Eric Creer, Public Records Coordinator, CDPH L&C Program.

[35] California Department of Public Health Licensing and Certification Program Initial Assessment and Gap Analysis Report, Hubbert Systems Consulting, August 2014, page 54, Table 7.

[36] https://www.cdph.ca.gov/programs/LnC/Pages/PSLS.aspx and https://www.cdph.ca.gov/programs/LnC/Pages/GeneralAcuteCareRelicensingSurvey.aspx.

[37] http://www.cdph.ca.gov/programs/hai/Pages/HAIReportsAndPrevention.aspx.

structure. A process of prioritizing hospitals for future inspection schedules based on infection data from the HAI Program could improve patient safety.

These data provide a guide to harm reduction. Where should CDPH put its resources toward catching up on overdue inspections? On those with high infection rates or those with low or average infection rates? In addition it should focus on hospitals that indicate a pattern of problems through high infection rates repeatedly in recent years.

The situation at Ronald Reagan UCLA Medical Center provides a good illustration regarding the potential impact of uncoordinated oversight. In consecutive CDPH HAI Program's Annual Reports – 2013 data, 2014 data and 2015 data – the hospital was listed among "Hospitals with Significantly High HAI Incidence." According to Consumers Union's analysis of California hospitals designated by CDPH as having significantly high infection rates, Ronald Reagan UCLA Medical Center's rates were found to be significantly high in 10 infection categories during the past three years – one of four hospitals with the worst infection records in the state (See Appendix A). But the HAI Program had no authority to require the hospital to take action based on this data. Despite state law that requires hospital inspections every three years, Ronald Reagan UCLA Medical Center had not been inspected for five years (See Appendix B).[38]

When CDPH finally investigated a complaint at this facility in March 2015, following a CRE infection outbreak and deaths, they declared an "immediate jeopardy"[39] situation after finding many practices that violated infection control protocols:

- failure by a key quality assurance committee to quickly investigate medical errors so problems can be fixed;
- failure to designate a person to evaluate whether staff were safely disinfecting the scopes following the CRE outbreak;
- staff using contaminated water and a tainted liquid cleaner dispenser to ready scopes and other devices for the next patients;
- nurses using a cleaning product without being aware that the liquid had to remain on the surface for three minutes to work;
- failure to safely store disinfected scopes to keep them free of bacteria;
- failure to ensure the sterility of surgical instruments and supplies, and operating room beds;
- failure to perform environmental cultures to detect the presence of microbes following the CRE outbreak; and
- a doctor failing to wash his hands before touching a patient.[40]

[38] CDPH response to Public Record Act request by Carole Moss, member, CDPH HAI Advisory Committee; August 15, 2016, e-mail communication between Carole Moss and Eric Creer, Public Records Coordinator, CDPH L&C Program.

[39] Immediate jeopardy means 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 [Health & Safety Code section 1280.3 (g)].

[40] Los Angeles Times, "State found lapses in infection control at UCLA and Cedars-Sinai, Melody Petersen, May 15, 2016, http://www.latimes.com/business/la-fi-infections-ucla-cedars-hospitals-20160515-snap-story.html; CDPH inspection findings: http://documents.latimes.com/ucla-medical-center-inspection-report/

If CDPH's L&C Program had been aware of UCLA's poor history of infection control sooner, perhaps they would have conducted thorough, timely, routine inspections sooner, thus, potentially, saving lives.

CDPH's important authority to assess financial penalties with regard to hospital-associated infections

California law requires hospitals to report to CDPH certain adverse events that result in patient death or serious disability, including those associated with the use of a contaminated device, such as the duodenoscopes associated with CRE infections at Ronald Reagan UCLA Medical Center.[41] When a facility fails to report these adverse events in a timely manner as established by the law, CDPH can assess a civil penalty up to $100 per day for each day that the event is not reported.[42]

CDPH also has the authority to assess administrative penalties against hospitals when a facility's noncompliance with licensure requirements has caused, or is likely to cause, serious injury or death to the patient.[43] In determining the amount of the penalty for an "immediate jeopardy" deficiency, CDPH is required to assess the severity of the event and consider, among other things, whether the noncompliance is isolated, a pattern, or widespread.[44]

Hospitals have been cited for immediate jeopardy penalties connected with infection related events; a hospital with multiple years of significantly higher infection rates certainly reflects a widespread problem or a pattern of deficiencies to be considered when determining the amount of the penalty.

CDPH should exercise its full fining authority to make hospitals accountable for harming patients and to require timely action by hospitals to prevent patient infections in the future.

IV. Right to Petition

This petition is filed pursuant to the California Constitution, which guarantees the public the right to petition the government for redress of grievances. Cal. Const. Art. 1, Section 3. Additionally, this petition is filed pursuant to the Government Code. Cal. Gov. Code section 11340.6. This provision mandates that within 30 days, the state agency must either deny this petition in writing indicating why the agency has reached its decision or schedule a public hearing. (Cal. Gov. Code Section 11340.7)

IV. Legal Claim

CDPH mission

[41] Health & Safety Code section 1279.1(2).
[42] Health & Safety Code 1279.1 and 1280.4.
[43] Health & Safety Code section 1280.3.
[44] California code of regulations, title 22, division 5, chapter 1, article 10, section 70954 (b) (1) (2) (c) (2).

The mission of the California Department of Public Health is to optimize the health and well-being of the people in California.[45]

CDPH Center for Health Care Quality

CDPH is organized into five centers dedicated to various aspects of public health. One of those centers, the Center for Health Care Quality, operates:

- the Healthcare-Associated Infections Program, which is responsible for public reporting of infection rates and for infection prevention measures in California's hospitals; and
- the Licensing and Certification Program, which is responsible for licensing and regulating health care facilities throughout the state, including regular state licensure inspections and responding to complaints.

Key California statutes related to CDPH hospital infection control responsibility/authority

California law includes a statutory scheme – key provisions of which are outlined below – designed to monitor and address infections occurring in California acute care hospitals through CDPH action.

Legislative intent

In enacting Niles Law[46] in 2008, the California legislature found that:

- the protection of patients in California health facilities is of paramount importance to the citizens of this state; and
- CDPH needed to establish and maintain a comprehensive inspection and reporting system for health facilities to ensure that California health facilities comply with state laws and regulations designed to reduce the incidence of healthcare-associated infections [Health and Safety Code Section 1 (a) (1) (4)].

Infection monitoring and control – advisory committee, public reporting, surveillance and protection

CDPH is required by law to operate a health care-associated infection program [Health and Safety Code Section 1255.8(g)]. CDPH was required to appoint a Healthcare Associated Infections Advisory Committee to make recommendations related to the reporting of infections by acute care hospitals to CDPH (Health and Safety Code Section 1288.5).

California law requires that acute care hospitals report the following healthcare-associated infections to CDPH: Methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections, *Clostridium difficile* infections (*C.difficile*), Vancomycin-resistant Enterococci (VRE) bloodstream infections, central line associated bloodstream infections (CLABSI), and surgical

[45] http://www.cdph.ca.gov/pages/AboutUs.aspx.
[46] SB 1058 (Alquist), 2008, http://www.leginfo.ca.gov/pub/07-08/bill/sen/sb_1051-1100/sb_1058_bill_20080925_chaptered.html.

site infections associated with 29 types of surgeries[47] [Health and Safety Code Section 1288.55(a)(1)(2)(3)]. CDPH is required to post on its website the rate of these infections[48] at each California hospital [Health and Safety Code Section 1288.55(b)].

California law requires that these publicly reported infection rates be risk-adjusted, so hospitals with different patient mixes can be compared to each other; other adjustments include the type of hospital and specific factors involved with various types of infections. Hospitals report these data to the CDC's National Health Safety Network and the risk-adjusted data is then provided to CDPH [Health and Safety Code Section 1288.55(c)].

CDPH is required to establish an infection surveillance, prevention and control program to designate infection prevention professionals to serve as consultants to the L&C Program [Health and Safety Code Section 1288.8 (e)(1)(2)].

Hospital inspections – addressing and preventing infections

The L&C Program has the authority to inspect and license health facilities (Health and Safety Code Section 1254). California acute care hospitals are required to be periodically inspected no less than every three years (Health and Safety Code Section 1279).

CDPH is required to provide training to surveyors so they can evaluate hospital compliance with existing policies and procedures to prevent HAI during the statutorily required licensing inspections every three years. [Health and Safety Code Section 1288.8 (e)(2)]. Inspections may cover the statutory requirements included in Health and Safety Code Division 2, Chapter 2 Articles 1 through 10, which include, among other things, laws governing infection control at California general acute care hospitals.

All California Code of Regulations, Title 22, governing general acute care hospital requirements may be used to complete relicensing inspections, including provisions related to hospitals' infection control programs (CCR Section 70739).

Hospitals that are found during L&C Program inspections to be out-of-compliance with the law may be cited for violations/deficiencies, required to submit plans of correction, have their licenses revoked and/or be required to pay an administrative penalty for a finding of "immediate jeopardy" (Health and Safety Code Section 1280.3) or a civil penalty for failure to report adverse events (Health and Safety Code Section 1280.4).

CDPH fining authority regarding hospital-associated infections

California law requires hospitals to report adverse events to CDPH, including adverse events associated with the use of a contaminated device that results in patient death or serious disability [Health & Safety Code section 1279.1(2)]. Failure of facilities to report these adverse events in a timely manner may result in a civil penalty [Health & Safety Code 1279.1 (a) and 1280.4].

[47] See CDPH All Facilities Letter 11-32, April 27. 2011 for list of surgical procedures for which infection reporting is required; http://www.cdph.ca.gov/certlic/facilities/Documents/LNC-AFL-12-15.pdf.
[48] CDPH reports a "standardized infection ratio" or SIR, which was developed by the CDC and is used nationwide.

California law also gives CDPH the authority to assess administrative penalties against hospitals for deficiencies that constitute an immediate jeopardy violation. [Health & Safety Code section 1280.3 (a)]. Immediate jeopardy means 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 [Health & Safety Code section 1280.3 (g)]

Related regulations provide that in determining the amount of an initial penalty CDPH is required to consider factors including: patient's physical and mental health; the probability and severity of the risk that the violation presents to patients. Additionally CDPH is required to determine whether the noncompliance is isolated, a pattern, or widespread. [California code of regulations, title 22, division 5, chapter 1, article 10, section 70954 (b) (1) (2) (c) (2)].

VI. Relief

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.

The HAI Program collects and publicly reports California hospital infection data in a form that compares hospitals. *As a matter of policy, the HAI Program withholds this information regarding hospital infection rates from the L&C Program. Thus, this information is not available to the L&C Program until it becomes available to the general public; sometimes the data is more than two years old at that point.* There is nothing in law or regulation prohibiting or otherwise encumbering the HAI Program from sharing this important data with the L&C Program in a timley manner, in fact the law includes provisions that require collaboration between the two programs.

A more coordinated policy would support improved infection control practices at California hospitals, better prevent the spread of serious infections and protect patients. The L&C Program should have access to HAI Program hospital infection rate data in real time and use the data to inform surveyors conducting regular state licensure inspections and investigating complaints, as well as in prioritizing the hospitals to be inspected.

California hospitals are required to be inspected every three years, however, currently the L&C Program has fallen dramatically behind in performing inspections; this should be corrected. CDPH should use its full authority to inspect and fine hospitals with significantly high infection rates.

WHEREFORE, Petitioners pray that:

1. CDPH require that the HAI Program share real time hospital infection data with the 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 (See Appendix A) 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.
7. CDPH comply with the statutory requirement that all hospitals be inspected every three years, including conducting the patient safety licensing survey.

Please address follow-up to Maryann O'Sullivan, project consultant, maryannosullivan1@gmail.com; 510-757-7942.

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Appendix A
Consumers Union Safe Patient Project Analysis CDPH Data 2013 – 2015 includes all hospitals with significantly high infection rates in each infection category.

Appendix B
CDPH data indicating California acute care hospitals without state licensure inspections for the more than five-year period between January 1, 2011 and June 18, 2016.