Preventable Harm:

California Fails to Follow Through With Patient Safety Laws

March 2010

I. INTRODUCTION

More than 10 years after the Institute of Medicine (IOM) first estimated that nearly 100,000 Americans die every year from preventable medical errors, little progress has been made to implement the key reforms recommended by the IOM to improve patient safety.[1] Since 2006, California lawmakers have passed six new laws aimed at shining the public spotlight on medical errors and hospital-acquired infections and holding hospitals accountable for improving patient safety. [2] But a review by Consumers Union has determined that the California Department of Public Health (CDPH) has been slow to implement many of the key provisions of these new patient safety laws.

The statistics that helped spur the passage of these patient safety laws in California are staggering. An estimated 240,000 California patients develop infections in hospitals each year, resulting in an estimated 13,500 deaths per year at a cost of $3.1 billion.[3] Nationally, nearly two million patients suffer from hospital-acquired infections every year.[4] Medical errors kill as many as 10,000 Californians each year and injure 140,000.[5] These errors include a class of adverse events known as "never-events" because they can always be prevented and should never happen.

Consumers deserve to know how well hospitals prevent errors and infections. They deserve to be assured that the government is fulfilling its role of protecting the public. Our review found that CDPH has fallen short in a number of key areas, failing to implement several statutory provisions and ignoring the spirit of the law.

II. OVERVIEW:

Consumers Union submitted a letter to the Department on December 28, 2009, requesting information that would help clarify the status of implementing patient safety laws, but the Department has not answered our letter.[6] On February 16, 2010, we submitted an official request for this information under California's Public Records Act.[7] CDPH responded, stating it needed more time to answer. The Department has missed the deadline required by law for responding to the public records request. We have not received the information we requested so far. Our findings below reflect the lack of publicly available information from CDPH and the lack of response to our specific information requests. This report is based upon our review of the CDPH website, a meeting with CDPH staff on December 16, 2009, and a review of Healthcare-Associated Infection Advisory

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[1] Consumers Union, "To Err Is Human, To Delay Is Deadly," May 2009; http://www.safepatientproject.org/2009/05/to_err_is_human_to_delay_is_de.html
[2] SB 1312 (2006), SB 739 (2006), SB 1301 (2006), SB 1058 (2008), SB 158 (2008), and SB 541 (2008)
[3] SB 739 (2006) and CDPH HAI Plan, http://www.cdph.ca.gov/services/boards/Documents/CDPHHAIPlan.pdf
[4] CDC Estimates of Healthcare-Associated Infections http://www.cdc.gov/ncidod/dhqp/hai.html
[5] California Health Care Foundation http://www.chcf.org/press/view.cfm?itemID=21578
[6] Letter from Consumers Union to Kathleen Billingsley, RN, December 29, 2009, http://www.safepatientproject.org/pdf/CU%20Billingsley%20Letter%20Dec%202009.pdf
[7] Public Records Act Request from Consumers Union, February 16, 2010, http://www.safepatientproject.org/pdf/CU%20February%2016%202010%20PRA.pdf

Committee minutes and "All Facilities Letters" from 2007-2009. In the arena of patient safety, it is unclear whether the Department has the organization or commitment to comply with what the legislature has mandated and what Californians deserve.

Hospital-Acquired Infections (HAIs)—Consumers Union found that the Department:

- Disbanded the statutorily-required Healthcare-Associated Infection Advisory Committee in January 2009.
- Has collected information on patient and healthcare worker vaccinations, but has not released it to the public.
- Has not published data for each hospital on measures to reduce central line associated bloodstream infections and surgical site infections.
- Has delayed implementing an HAI program to organize and focus its efforts to reduce HAI rates in California.
- Has not promulgated administrative regulations that incorporate Centers for Disease Control and Prevention (CDC) guidelines on HAI prevention.
- It is unclear whether the department is ensuring that hospitals screen patients for Methicillin-resistant *Staphylococcus aureus* (MRSA) or adopt mandated HAI prevention measures into their infection control plans.
- It is unclear whether the department is enforcing hospital infection reporting or ensuring that hospitals take steps proven to reduce hospital-acquired infections.

Medical Errors, also known as "adverse events"—Consumers Union found that the Department:

- Has begun assessing fines to hospitals in which adverse events occur and is posting that information on the internet.
- Is collecting adverse event reports from hospitals but is not making the information readily accessible to the public.
- Is aware of underreporting by hospitals, but it is not clear what steps it is taking to ensure reporting compliance.
- Has not promulgated regulations establishing criteria for administrative penalties when a hospital's failure to comply with the law severely harms a patient or puts a patient in severe danger.
- It is unclear whether the Department is routinely inspecting hospitals to ensure that they have patient safety plans in place.
- It is unclear whether the Department is ensuring that hospitals are informing patients when medical errors occur.

III. Hospital-Acquired Infections

A. Inspections

- What is required: During regular inspections, required by law to occur once every three years, the Department must evaluate hospitals' compliance with mandated

HAI reporting and prevention practices.[8] These range from implementing CDC guidelines on preventing central line and surgical infections[9] to quarterly reporting of *Clostridium difficile* ("*C.diff*") infections.[10]

- When it must be done: Beginning in January 2009.
- Status: We are unsure whether hospitals are being inspected as required. We are concerned that the Department is not ensuring that hospitals have infection prevention measures in place and that they may not be submitting required infection rates and prevention measures to the Department. Consumers Union has submitted a Public Records Act request with the Department to obtain survey checklists and survey information for hospitals that have been inspected.

B. Department HAI Surveillance, Prevention, and Control Programs

- What is required: Under the 2006 hospital infection law, the Department is required to have a program devoted to HAI surveillance and prevention and to appoint a Healthcare-Associated Infection Advisory Committee. [11] The program was to prepare Department staff to evaluate hospitals for HAI prevention and require hospitals to take steps like limiting the overuse of antibiotics. The Committee was created to assist in implementation of the law, including making certain recommendations. In 2008, these requirements were expanded.[12] The Department is now required to designate infection prevention professionals as consultants to the licensing and certification program within the Department and prepare an electronic reporting system for HAI by January 1, 2011.[13]
- When it must be done: Appoint the advisory committee by July 1, 2007. The 2006 law provisions were to be implemented by January 2008; the 2008 law provisions regarding the infection program by January 2009 and the electronic HAI reporting system by January 1, 2011.
- Status: The Department appointed the Healthcare-Associated Infection Advisory Committee, which met in 2007 and 2008 to discuss implementation issues, but was disbanded by CDPH in January 2009.[14] CDPH began creating an HAI surveillance and prevention program in September 2009, 21 months late, in response to a federal requirement to develop a 5-year state HAI plan in order to receive federal funding.[15, 16] The Department reports that it has just completed hiring new staff. It is questionable whether the Department's outlined plan meets

[8] SB 739 (2006).
[9] SB 739 (2006).
[10] SB 1058 (2008).
[11] SB 739 (2006).
[12] SB 158 (2008).
[13] The law also requires CDPH to hire infection control professionals as consultants to the licensing and certification program and to train Department evaluator nurses on how to assess hospitals' compliance with state and federal regulations.
[14] Minutes of January 12, 2009 HAI Advisory Committee Meeting http://www.cdph.ca.gov/services/boards/Pages/HAI_AC.aspx
[15] CDPH HAI Plan http://www.cdph.ca.gov/services/boards/Documents/CDPHHAIPlan.pdf
[16] Fiscal Year 2009 Budget Omnibus Bill, signed March 11, 2009, requires states receiving Preventive Services Block Grant funds to certify that they will submit an HAI plan. http://www.cdc.gov/hai/recoveryAct/PDF/Oct09/2-0930HAI_ELC_GranteePresentationJY.pdf

the state requirements. Instead of training its own staff and monitoring hospitals to comply with HAI laws, the plan written by the Department emphasizes training hospital staff and coordinating efforts to help hospitals learn from each other. Furthermore, the plan suggests that only central line bloodstream infections and *C-diff* will be targeted, rather than MRSA or other infections. The program appears to lack a focus on enforcement of requirements of state law.

C.MRSA Screening and Infection Prevention

- What is required: The Department is required to establish a program to ensure that hospitals are screening certain high-risk patients for MRSA and that a mandated group of procedures are included in all hospitals' infection control policies.[17] Attending physicians must advise patients who are found to be carrying MRSA and patients with MRSA infections are to be given information upon discharge.
- When it must be done: By January 2009.
- Status: It is unclear whether the Department is ensuring that patients are being screened for MRSA, that patients are being informed as required, or that hospitals' infection control plans are in compliance with the law.

D. Public Reporting

(1) **Rates of Influenza Vaccination of Healthcare Workers and Personnel**
CDPH is required to publicly report influenza vaccination/declination rates by facility for patients and health care workers within six months of receiving the data.[18] Hospitals were required to report this data to CDPH by January 1, 2008. In January 2009, at the last HAI Advisory Committee, CDPH staff acknowledged having 2007-08 immunization data for health care workers and stated that they did not see why it could not be posted.[19] Yet to date no influenza vaccination data is on the CDPH website. Enormous attention has been focused on a potential H1N1 epidemic, and CDPH asserts that it has directed education and preparedness efforts toward the public for that. Yet tremendous potential for spreading—or curbing—H1N1 and routine influenza viruses lies in hospital settings where immune-compromised patients reside in close proximity to each other.

(2) **Reporting to NHSN of HAI rates and prevention measures**
Hospitals are mandated to report to the Department and to the CDC's National Healthcare Safety Network (NHSN) on their compliance with CDC guidelines to prevent central line and surgical site infections.[20] CDPH communicated to hospitals the requirement to use NHSN for reporting through an "All Facilities Letter" (AFL) in 2007.[21] According to the Department, not all hospitals in California are, in fact,

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[17] SB 1058 (2008).
[18] SB 739 (2006).
[19] Minutes of January 12, 2009 HAI Advisory Committee Meeting, p. 5
http://www.cdph.ca.gov/services/boards/Documents/HAIACMM01-12-09.pdf
[20] SB 739 (2006).
[21] CDPH AFL 07-3, November 27, 2007
http://ww2.cdph.ca.gov/services/boards/Documents/AFL0737NHSN.pdf

reporting to NHSN.[22] But to our knowledge, the Department has not taken action to enforce this statutory duty.

(3) **Rates of implementation of CDC guidelines to prevent central line and surgical site infections**

CDPH has failed to publicly post the important information on whether hospitals are complying with CDC protocols to prevent deadly central line blood stream and surgical infections, which was supposed to have been done by July 1, 2008.[23] Additional infection prevention and outcome measures were supposed to be phased in. The Department is required to issue public reports within 6 months of receiving the information. It should be noted that the federal government posts the surgical infection prevention information that the Department is required to publish. [24]

(4) **Rates of MRSA and other HAI**

Hospitals must also report to the Department and NHSN the incidence of bloodstream infections caused by MRSA, *C-diff*, and Vancomycin-resistant enterococcal; certain surgical site infections; and central line-associated bloodstream infections.[25] All of this information is to be used to develop public reports of infection rates that are to be posted on the Department's website on January 1, 2011, except surgical site infection rates, which are to be published on January 1, 2012. In January 2008, the MRSA Reporting Subcommittee to the HAI Advisory Committee made a specific, consensus-based recommendation that hospitals be required to report all laboratory-confirmed MRSA bloodstream infections for inpatients and that those rates be publicly reported.[26] CDPH drafted an "All Facilities Letter" to that effect, dated October 9, 2008, stating that such reporting was to begin January 1, 2009 using the NHSN or other method for reporting.[27] That AFL does not appear to have been finalized.

E. Administrative Regulations

- What is required: The Department was to revise existing hospital infection regulations and adopt new ones as necessary to incorporate current CDC guidelines and standards for HAI prevention.[28]
- When it must be done: Regulations should have been in place by January 1, 2008.
- Status: These regulations are nowhere to be found, leading us to believe they were never promulgated as required. Consumers Union has submitted a Public Records Act request for these regulations to determine whether they exist.

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[22] Meeting Minutes of the HAI Advisory Committee, January 12, 2009 http://www.cdph.ca.gov/services/boards/Documents/HAIACMM01-12-09.pdf
[23] SB 739 (2006)
[24] http://www.hospitalcompare.hhs.gov
[25] SB 1058 (2008)
[26] MRSA Reporting Subcommittee Recommendations http://www.cdph.ca.gov/services/boards/Documents/MRSASubRec12908final.pdf
[27] CDPH Draft AFL 08-19, October 9, 2008 http://www.cdph.ca.gov/services/boards/Documents/DRAFTAFL08_19ReportingofCLABSIs.pdf
[28] SB 738 (2006).

IV. MEDICAL ERRORS, ALSO KNOWN AS "ADVERSE EVENTS"

A. Reporting, Inspections, and Penalties

What is required: Hospitals must report adverse events to the Department, which is required to investigate them.[29] The adverse events specified by the law are the 27 "never events" identified by the National Quality Forum.[30] Examples of some events in California range from prostate removal of the wrong patient to sponges left in a patient's abdomen during surgery. A list of detailed reports of events for which the Department has fined hospitals is posted on the CDPH website.[31] By January 1, 2009 until January 1, 2015, CDPH is required to make information from adverse event reports and inspections "readily accessible to consumers throughout California."[32] In addition, the Department is required to "compile and make available to entities deemed appropriate by the department" data regarding reports of substantiated events and outcomes of investigations of reported adverse events. By 2015 the Department is required to post this information on its website. The Department is also authorized to fine hospitals when noncompliance with requirements of licensure results in patient harm.[33] The combined reporting, investigation, and fining process should proceed along the following flowchart

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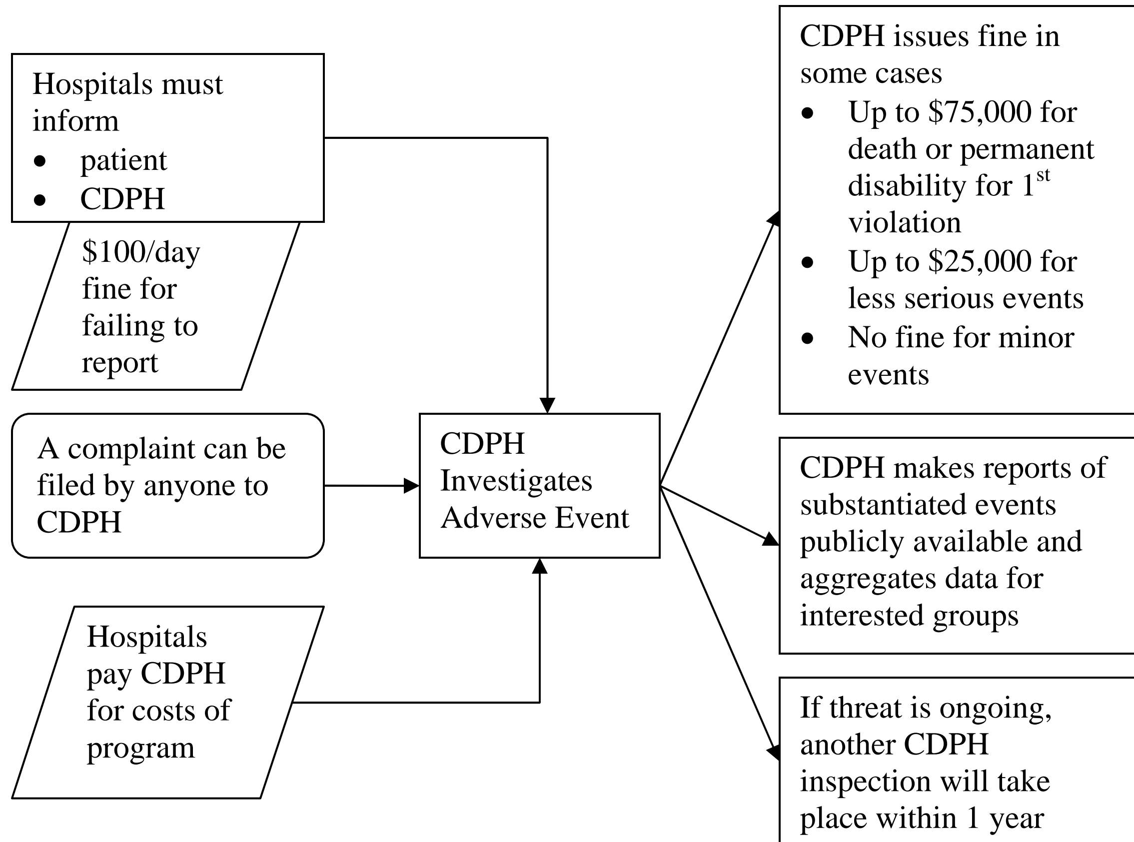
[29] SB 1301 (2006).
[30] NQF officially refers to these as "serious reportable events." http://www.qualityforum.org/Projects/s-z/SRE_Maintenance_2006/Fact_Sheet_-_Serious_Reportable_Events_in_Healthcare_2005-2006_Update.aspx
[31] http://www.cdph.ca.gov/certlic/facilities/Pages/Counties.aspx
[32] SB 1301 (2006).
[33] SB 1312 (2006), SB 541 (2008).

Adverse Event Reporting, Inspection, & Penalty Process



- When it must be done: Fines, referred to in the law as "administrative penalties," could be assessed for events taking place on or after January 2007. Hospitals are required to report adverse events to the Department starting July 2007. The Department is to make data and reports of adverse events readily accessible to Californians by January 2009. CDPH is to publish hospital-specific reports on their website by January 2015.
- Status: The Department is receiving, investigating, and reporting adverse events. However, there are several flaws in the current system. CDPH is aware that not all hospitals are reporting in compliance with law.[34] Yet its only actions seem to be to "…encourage all hospital providers to regularly review the reporting mandates with all appropriate hospital staff…"[35] and to "invite hospitals to join the department in promoting successful prevention of adverse events statewide, through sharing of best practices policies.[36]"

[34] CDPH All Facilities Letter 09-05 http://www.cdph.ca.gov/certlic/facilities/Documents/LNC-AFL-09-05.pdf
[35] Id.
[36] DCPH All Facilities Letter 09-11 http://www.cdph.ca.gov/certlic/facilities/Documents/LNC-AFL-09-11.pdf

The Department has not made it clear to consumers how they may report an event to the Department or where they can find information on reported events. From the information available on the CDPH website, it is unclear the types of events and how many events have actually occurred, since most of the information lacks detail. Finally, the entire database is difficult to find on the website, and it is not easily accessible for the average consumer.[37]

We cannot determine whether the Department is making reports available to interested organizations. Consumers Union requested the information by letter in December 2009 and again in a formal Public Records Request in February 2010; to date, we have received no information. CDPH is regularly posting information about fines assessed against hospitals and this site is the richest source of information available, allowing the public to view the actual investigation documents.[38]

B. Hospital Patient Safety Plans

- What is required: The Department is required to inspect hospitals to ensure that they develop, implement, and comply with a patient safety plan. Each hospital's plan must establish accountability and a system for reporting of harmful events, analysis when events occur, and ongoing patient safety training.[39] These plans are supposed to contribute to the culture of safety within hospitals that the IOM reported as impeding safety improvement.[40] The Department is required to conduct unannounced inspections of general acute care hospitals at least once every three years to ensure that they are in compliance with the requirements of state laws.[41]
- When it must be done: Unannounced inspections of hospitals were required by January 2007. Hospital patient safety plans were required starting January 2009.
- Status: It is unknown whether hospitals are being inspected by the Department for patient safety plan requirements. Consumers Union has submitted a Public Records Act request to obtain hospital survey checklists to see if they include checks for patient safety plans and their requirements.

C. Informing Patients of Adverse Events

- What is required: A hospital must inform a patient or the party responsible for a patient that an adverse event has occurred within five days (if the threat is not ongoing) or within 24 hours (if the event is an ongoing or emergent threat).[42]
- When it must be done: For events occurring during or after January 2007.
- Status: It is unclear how the Department is making sure that hospitals are informing patients of adverse events. Consumers Union has inquired of the CDPH

[37] http://hfcis.cdph.ca.gov/default.aspx
[38] http://www.cdph.ca.gov/certlic/facilities/Pages/Counties.aspx
[39] SB 158 (2008).
[40] Institute of Medicine. To Err is Human: Building a Safer Health System. National Academy Press, 1999. http://www.nap.edu/openbook.php?record_id=9728&page=4
[41] SB 1312 (2006).
[42] SB 1301 (2006).

whether there is a standard form, or other method, used by hospitals to report adverse events to patients.

D. Regulations on Administrative Penalties and Mandatory Reporting

- What is required: The Department is required to promulgate regulations establishing criteria to assess an administrative penalty against a health facility for adverse events when a facility's failure to comply with requirements of licensure results in harm to a patient, visitor, or personnel.[43]
- When it must be done: Regulations on administrative penalties: January 2007.
- Status: The regulations required by SB 1312 are nowhere to be found. While some administrative penalties have been issued, it is unclear whether these penalties are being issued arbitrarily or consistently because of the failure of the Department to establish criteria for assessing penalties as mandated.[44]

V. CONCLUSION:

The Little Hoover Commission, in its "First Year Check-Up" on the Department of Public Health, noted that:

> The Legislature has taken the initiative in pushing the department to reduce healthcare acquired infections through a series of incremental bills. This is an area in which the department should have led the state's efforts to halt the spread of these preventable infections that kill thousands of Californians. The failure of the department to drive this cultural change speaks to the political timidity and underscores the need for the director to take on a greater public advocacy role than the leadership has been willing to embrace.[45]

Consumers Union calls upon the Department to take up the mantle of leadership to prevent the harm done to hundreds of thousands of California patients each year due to medical errors and hospital-acquired infections. The Department must ensure that all hospitals are implementing practices to reduce medical harm; reinstate the HAI Advisory Committee; establish a stronger HAI program that will also ensure MRSA screening; release information to the public on medical errors and HAI infection rates and prevention practices; and begin adopting regulations that incorporate CDC recommendations to prevent HAI. The Department must follow through on requiring hospitals to establish patient safety plans; must ensure that patients are informed when adverse events occur; and must establish regulations on administrative penalties and adverse event reporting. Consumers Union calls upon the Department to fulfill its responsibilities not just to establish minimum compliance with the law, but also to promote best practices in healthcare safety in order to protect California patients.

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[43] SB 1312 (2006).
[44] http://www.cdph.ca.gov/certlic/facilities/Pages/Counties.aspx
[45] Cover letter of Little Hoover Commission Report, "First Year Check-up: Strategies for a Stronger Public Health Department" Dated January 22, 2009 from Daniel Hancock, Little Hoover Commission Chair, to the Governor and legislative leadership http://www.lhc.ca.gov/studies/194/report194.html