INTRODUCTION

More than one decade after the Institute of Medicine (IOM) first approximated that virtually 100,000 Americans die each year from preventable clinical mistakes, little development has actually been made to execute the key reforms advised by the IOM to boost patient safety and security.

1 Because 2006, The golden state legislators have passed six new laws focused on shining the public limelight on clinical errors and hospital-acquired infections as well as holding health centers liable for boosting patient safety and security.

2 But an evaluation by Consumers Union has established that the California Department of Public Health (CDPH) has been slow to execute much of the essential stipulations of these new patient security regulations.

The statistics that helped spur the flow of these individual safety and security legislations in California are shocking.

An estimated 240,000 The golden state patients create infections in healthcare facilities each year, resulting in an approximated 13,500 deaths annually at an expense of $3.1 billion.3 Country wide, almost 2 million patients struggle with hospital-acquired infections every year.4 Clinical errors eliminate as numerous as 10,000 Californians annually and also hurt 140,000.

1. 5 These errors consist of a class of damaging events referred to as "never-events" since they can always be protected against and also ought to never happen.
2. Customers should have to know just how well medical facilities protect against mistakes and also infections. They should have to be guaranteed that the federal government is satisfying its duty of safeguarding the general public.

Our testimonial located that CDPH has fallen short in a number of key areas, falling short to implement a number of legal stipulations and also disregarding the spirit of the regulation. II. OVERVIEW: Consumers Union submitted a letter to the Department on December 28, 2009, inquiring that would assist clear up the condition of applying client security legislations, however the Division has actually not addressed our letter.

6 On February 16, 2010, we sent a main ask for this information under California's Public Records Act.7 CDPH reacted, stating it needed even more time to address. The Division has actually missed the deadline required by law for replying to the public records demand. We have actually not received the info we asked for up until now.

Our findings listed below mirror the lack of openly available info from CDPH as well as the lack of feedback to our certain information requests. This record is based upon our review of the CDPH site, a meeting with CDPH personnel on December 16, 2009, and also a testimonial of Healthcare-Associated Infection Advisory

1 **Consumers Union, "To Err Is Human, To Delay Is Deadly," May 2009;** Hospital-Acquired Infections (HAIs)-- Consumers Union found that the Department: - Dissolved the statutorily-required Healthcare-Associated Infection Advisory Committee in January 2009. - Has collected information on patient as well as medical care employee vaccinations, but has not released it to the general public.

Has not published data for every medical facility on procedures to decrease central line associated blood stream infections and also medical website infections. - Has actually delayed carrying out an HAI program to organize and concentrate its efforts to lower HAI rates in California. - Has actually not promulgated administrative policies that incorporate Centers for Condition Control as well as Avoidance (CDC) guidelines on HAI avoidance.

It is vague whether the division is ensuring that healthcare facilities screen patients for Methicillin-resistant Staphylococcus aureus (MRSA) or embrace mandated HAI prevention determines into their infection control strategies. - It is uncertain whether the division is applying healthcare facility infection coverage or making sure that health centers take actions verified to minimize hospital-acquired infections.

Clinical Mistakes, additionally known as "damaging occasions"

Consumers Union located that the Department: - Has actually started examining penalties to healthcare facilities in which adverse events happen as well as is publishing that details on the internet. - Is gathering damaging occasion records from healthcare facilities but is not making the info easily accessible to the general public.

Is aware of underreporting by healthcare facilities, but it is not clear what tips it is taking to ensure reporting compliance. - Has not promulgated laws establishing standards for management charges when a health center's failure to comply with the regulation drastically harms a patient or places a patient in extreme danger.

It is unclear whether the Department is regularly inspecting hospitals to make certain that they have individual safety and security strategies in position. - It is uncertain whether the Division is guaranteeing that health centers are educating individuals when clinical mistakes occur. III. Hospital-Acquired Infections A.

Evaluations - What is needed: During routine evaluations, called for by law to take place when every three years, the Division should review hospitals' conformity with mandated 3 HAI reporting and prevention techniques.

8 These variety from executing CDC standards on stopping central line as well as surgical infections9 to quarterly coverage of Clostridium difficile (" C.diff") infections.10 - When it have to be done: Beginning in January 2009.

Condition: We are not sure whether healthcare facilities are being checked as called for. We are worried that the Department is not making sure that health centers have infection prevention steps in position which they may not be sending necessary infection rates and also avoidance actions to the Department.

Consumers Union has actually sent a Public Records Act demand with the Division to get survey checklists and also study details for hospitals that have been evaluated. B. Division HAI Surveillance, Prevention, and also Control Programs - What is needed: Under the 2006 hospital infection legislation, the Division is called for to have actually a program dedicated to HAI security and also avoidance and to appoint a Healthcare-Associated Infection Advisory Board. 11 The program was to prepare Division staff to evaluate medical facilities for HAI avoidance and also call for hospitals to take actions like restricting the overuse of antibiotics.

The Board was developed to help in execution of the regulation, consisting of making certain suggestions. In 2008, these needs were broadened.12 The Division is now needed to assign infection avoidance professionals as specialists to the licensing and qualification program within the Department as well as prepare an electronic coverage system for HAI by January 1, 2011.

13 - When it needs to be done: Appoint the advisory committee by July 1, 2007. The 2006 law provisions were to be executed by January 2008; the 2008 law provisions relating to the infection program by January 2009 and also the digital HAI reporting system by January 1, 2011.

- *Status: The Department appointed the Healthcare-Associated Infection Advisory Committee, which met in 2007 and also 2008 to talk about application concerns, however was dissolved by CDPH in January 2009.*

14 CDPH began producing an HAI surveillance and avoidance program in September 2009, 21 months late, in action to a federal need to establish a 5-year state HAI strategy in order to receive government funding.15, 16 The Department reports that it has actually simply completed hiring new team. It is questionable whether the Department's laid out strategy satisfies

8 SB 739 (2006). 9 SB 739 (2006). 10 SB 1058 (2008). 11 SB 739 (2006). 12 SB 158 (2008). 13 The regulation also calls for CDPH to hire infection control professionals as specialists to the licensing and also accreditation program and to educate Division critic registered nurses on exactly how to assess hospitals' compliance with state and also federal regulations.

14 Minutes of January 12, 2009 HAI Advisory Board Meeting
http://www.cdph.ca.gov/services/boards/Pages/HAI_AC.aspx 15 CDPH HAI Strategy http://www.cdph.ca.gov/services/boards/Documents/CDPHHAIPlan.pdf 16 Fiscal Year 2009 Spending Plan Omnibus Bill, signed March 11, 2009, needs states receiving Preventive Services Block Give funds to accredit that they will send an HAI strategy. http://www.cdc.gov/hai/recoveryAct/PDF/Oct09/2-0930HAI_ELC_GranteePresentationJY.pdf 4 the state needs.

Rather than training its own staff and also tracking hospitals to abide by HAI legislations, the plan composed by the Division emphasizes training medical facility staff and working with initiatives to assist health centers learn from each other.

Furthermore, the plan suggests that only central line blood stream infections as well as C-diff will be targeted, as opposed to MRSA or various other infections.

The program shows up to lack a concentrate on enforcement of requirements of state law. C.MRSA Testing and Infection Prevention - What is required: The Division is needed to establish a program to ensure that healthcare facilities are evaluating particular risky clients for MRSA and that a mandated team of treatments are included in all health centers' infection control plans.17 Going to physicians need to recommend individuals that are located to be bring MRSA and patients with MRSA infections are to be provided info upon discharge.

When it need to be done: By January 2009. - Condition: It is uncertain whether the Division is ensuring that individuals are being screened for MRSA, that people are being informed as needed, or that medical facilities' infection control plans are in compliance with the legislation. D. Public Reporting (1) Prices of Flu Vaccination of Healthcare Employees and Employee CDPH is called for to openly report flu

vaccination/declination prices by center for individuals and also healthcare workers within 6 months of getting the information.

18 Health centers were required to report this data to CDPH by January 1, 2008. In January 2009, at the last HAI Advisory Committee, CDPH team recognized having 2007- 08 booster shot information for health care employees as well as mentioned that they did not see why it can not be posted.19 Yet to day no flu inoculation information is on the CDPH web site.

Substantial attention has been concentrated on a potential H1N1 epidemic, and also CDPH insists that it has actually directed education and learning as well as readiness initiatives towards the public for that. Yet tremendous potential for dispersing-- or suppressing-- H1N1 as well as regular influenza viruses lies in health center settings where immune-compromised people live near to every other.

(2) Reporting to NHSN of HAI prices as well as avoidance measures Healthcare facilities are mandated to report to the Division and also to the CDC's National Health care Safety and security Network (NHSN) on their conformity with CDC standards to prevent central line as well as surgical website infections.20 CDPH connected to health centers the demand to use NHSN for reporting via an "All Facilities Letter" (AFL) in 2007.21 According to the Department, not all medical facilities in The golden state are, in fact,

17 SB 1058 (2008). 18 SB 739 (2006).

19 Minutes of January 12, 2009 HAI Advisory Board Fulfilling, 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 5 reporting to NHSN.22 Yet to our expertise, the Division has not acted to enforce this legal responsibility.

(3) Rates of application of CDC guidelines to prevent main line and surgical website infections CDPH has stopped working to publicly post the essential information on whether medical facilities are following CDC procedures to prevent harmful central line blood stream and surgical infections, which was meant to have been done by July 1, 2008.

23 Additional infection avoidance and outcome actions were supposed to be phased in.

The Department is needed to provide public reports within 6 months of receiving the info. It must be kept in mind that the federal government posts the surgical infection avoidance info that the Department is required to publish.

24 (4) Fees of MRSA and also other HAI Hospitals need to additionally report to the Department and NHSN the incidence of bloodstream infections brought on by MRSA, C-diff, and Vancomycin-resistant enterococcal; specific surgical website infections; as well as central line-associated blood stream infections.

25 Every one of this information is to be utilized to establish public records of infection prices that are to be uploaded on the Division's website on January 1, 2011, other than medical website infection rates, which are to be published on January 1, 2012.

In January 2008, the MRSA Coverage Subcommittee to the HAI Advisory Committee made a certain, consensus-based suggestion that hospitals be called for to report all laboratoryconfirmed MRSA blood stream infections for inpatients and that those rates be publicly reported.

26 CDPH prepared an "All Facilities Letter" to that effect, dated October 9, 2008, mentioning that such reporting was to start January 1, 2009 making use of the NHSN or other technique for reporting.27 That AFL does not appear to have been finalized. E. Administrative Regulations –

What is required: The Department was to change existing hospital infection regulations and take on brand-new ones as essential to include current CDC guidelines and also standards for HAI prevention.28 - When it should be done: Laws should have been in place by January 1, 2008. - Status: These regulations are nowhere to be found, leading us to believe they were never promoted as required. Consumers Union has sent a Public Records Act ask for these guidelines to identify whether they exist.

22 Satisfying 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 Coverage 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). 6 IV.

MEDICAL ERRORS, ALSO KNOWN AS "ADVERSE OCCASIONS" A. Reporting, Examinations, and also Fines What is required: Health centers need to report damaging occasions to the Department, which is required to explore them.29 The negative events specified by the regulation are the 27 "never ever events" determined by the National Quality Online Forum.

- 30 Examples of some events in California range from prostate elimination of the wrong individual to sponges left in a person's abdomen throughout surgical treatment.
- A checklist of thorough records of occasions for which the Department has actually fined hospitals is uploaded on the CDPH web site.

31 By January 1, 2009 up until January 1, 2015, CDPH is needed to make information from adverse occasion reports and evaluations "easily available to customers throughout The golden state." 32 On top of that, the Department is called for to "assemble as well as provide to entities considered proper by the division" information relating to records of validated occasions as well as end results of examinations of reported adverse events. By 2015 the Department is called for to publish this info on its website.

The Division is likewise licensed to great healthcare facilities when noncompliance with demands of licensure cause individual harm.33 The consolidated coverage, examination, and also fining procedure ought to proceed along the complying with flowchart

29 SB 1301 (2006). 30 NQF formally describes these as "serious reportable events." http://www.qualityforum.org/Projects/sz/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). 7 - When it should be done: Penalties, referred to in the regulation as "management charges," could be analyzed for occasions occurring on or after January 2007. Health centers are called for to report adverse events to the Department starting July 2007. The Division is to make data and records of unfavorable occasions conveniently obtainable to Californians by January 2009. CDPH is to release hospital-specific records on their web site by January 2015.

Status: The Department is getting, checking out, and reporting unfavorable occasions. Nonetheless, there are a number of imperfections in the existing system. CDPH knows that not all medical facilities are reporting in conformity with law.34 Yet its only actions appear to be to "... encourage all hospital providers to frequently examine the reporting mandates with all ideal healthcare facility team ..." 35 and also to "welcome hospitals to join the department in advertising effective prevention of damaging events statewide, via sharing of finest practices plans.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 A complaint can be submitted by anybody to CDPH Investigates Negative Occasion Health centers have to notify - client - CDPH makes records of validated occasions openly available as well as aggregates data for interested teams CDPH issues fine sometimes .

As much as $75,000 for fatality or permanent disability for first violation - Approximately $25,000 for much less significant events - No fine for small occasions If risk is recurring, another CDPH assessment will take place within 1 year $100/day fine for stopping working to report Medical facilities pay CDPH for costs of program Unfavorable Occasion Reporting, Evaluation, & Charge Process 8 The Department has actually not made it clear to consumers exactly how they may report an occasion to the Department or where they can find info on reported events.

From the information offered on the CDPH internet site, it is unclear the kinds of occasions and the number of events have in fact taken place, because the majority of the information does not have information. Lastly, the entire data source is difficult to discover on the website, as well as it is not conveniently obtainable for the ordinary customer.

37 We can not establish whether the Department is making reports readily available to interested companies.

Consumers Union requested the details by letter in December 2009 and also once again in a formal Public Records Demand in February 2010; to day, we have actually received no details. CDPH is on a regular basis publishing information regarding penalties assessed versus medical facilities and this site is the richest source of info readily available, enabling the public to check out the actual investigation files.38 B.

Health center Client Safety And Security Plans - What is needed: The Department is needed to inspect health centers to make sure that they develop, execute, and abide by a client safety and security strategy. Each health center's plan should develop liability and a system for coverage of damaging events, evaluation when events occur, and continuous client security training.

39 These strategies are supposed to contribute to the culture of safety and security within healthcare facilities that the IOM reported as restraining security improvement.40 The Division is needed to carry out unannounced inspections of basic severe care health centers a minimum of as soon as every three years to ensure that they are in conformity with the needs of state legislations.

41 - When it should be done: Unannounced examinations of medical facilities were needed by January 2007. Medical facility patient safety and security plans were required starting January 2009. - Status: It is unknown whether hospitals are being examined by the Department for patient safety and security

strategy demands. Consumers Union has submitted a Public Records Act request to get medical facility survey lists to see if they include checks for individual safety plans and their needs. C.

Informing People of Adverse Events - What is needed: A hospital has to notify an individual or the event in charge of a client that a negative occasion has actually taken place within five days (if the risk is not recurring) or within 24 hours (if the event is a recurring or emergent threat).42 - When it must be done: For events taking place during or after January 2007. - Standing: It is vague how the Department is making sure that medical facilities are notifying people of adverse events. Consumers Union has asked of the CDPH.

Rules on Administrative Penalties as well as Mandatory Reporting - What is required: The Department is required to promulgate policies establishing requirements to assess an administrative fine against a health facility for damaging events when a facility's failing to follow requirements of licensure results in damage to an individual, visitor, or workers.43 - When it have to be done: Regulations on administrative fines: January 2007. - Status: The regulations called for by SB 1312 are no place to be located.

While some administrative fines have been issued, it is vague whether these charges are being provided randomly or regularly due to the failing of the Division to establish standards for examining charges as mandated.44 V.

VERDICT: The Little Hoover Commission, in its "First Year Examination" on the Department of Public Health, noted that: The Legislature has taken the initiative in pushing the department to minimize health care gotten infections through a collection of incremental costs. This is an area in which the division should have led the state's initiatives to halt the spread of these avoidable infections that kill hundreds of Californians.

1. The failure of the division to drive this cultural adjustment speaks with the political timidity and highlights the demand for the supervisor to handle a greater public campaigning for duty than the leadership has actually agreed to accept.
2. 45 Consumers Union calls upon the Department to use up the mantle of management to avoid the harm done to numerous hundreds of California clients yearly because of medical errors and hospital-acquired infections.

The Division needs to ensure that all hospitals are carrying out practices to decrease medical injury; restore the HAI Advisory Committee; establish a stronger HAI program that will likewise make certain MRSA screening; release info to the public on clinical errors and HAI infection rates as well as prevention practices; and start adopting policies that include CDC recommendations to stop HAI.

The Department should follow through on needing medical facilities to develop person security plans; have to make certain that individuals are notified when adverse events take place; and also must develop policies on management penalties and negative occasion coverage. Consumers Union contacts the Division to meet its responsibilities not just to establish minimum compliance with the legislation, but likewise to promote finest practices in health care security in order to safeguard The golden state patients.