Briefing paper

Department of Public Health:
Implementation of Patient Safety Measures

Patient safety has become an increasingly important topic over the last decade due to increased interest in health care quality, outcomes, and cost containment. The Institute of Medicine 1999 report "To Err is Human: Building a Safer Health System" estimated that as many as 98,000 people die in any given year from medical errors that occur in hospitals - more than die from motor vehicle accidents, breast cancer, or AIDS.

Of particular interest are hospital acquired infections (HAIs), which affect from 5 to10 percent of hospitalized patients, resulting in 2 million infections annually, according to the Centers for Disease Control and Prevention (CDC). The CDC estimates the overall annual direct medical costs of hospital acquired infections to U.S. hospitals range from $28.4 to $33.8 billion in 2007.

Consumer demand for health care information, including data about the performance of health care providers, has also increased steadily over the past decade, according to the CDC. The belief is that giving consumers information about the quality of care they receive will empower them to use the health care system more efficiently, which will result in concerted efforts by providers and facilities to improve patient care.

California has enacted several measures over the past decade to improve the safety of patients in hospital and long-term care settings, including bills to require infection control plans and practices, reporting of adverse events, and adherence to staffing ratios to ensure adequate patient care (see Appendix A). The purpose of this hearing is to examine the implementation of these measures by the California Department of Public Health (DPH).

Hospital acquired infections (HAIs)

HAIs constitute a major public health problem in the United States. Urinary tract infections (generally catheter associated), surgical-site infections, bloodstream infections (mostly associated with the use of an intravascular device), and pneumonia (generally ventilator associated) account for more than 80 percent of all HAIs. The most common organisms that cause HAIs are becoming resistant to the current armament of effective antibiotics, such as Methicillin-resistant *Staphylococcus aureus* (MRSA) and

vancomycin-resistant enterococci (VRE), leaving patients even more vulnerable to their effects. HAIs are one of the top 10 causes of death in the United States. Patients who develop HAIs end up staying longer in the hospital, have higher medical bills, and are more likely to die from their infection (see Appendix B).

Both surveillance and prevention activities are vital in reducing the number of patients affected by HAIs. In 2006, the legislature passed SB 739 (Speier) to establish the Hospital Infectious Disease Control Program, which required DPH and general acute care hospitals to implement various measures relating to disease surveillance and HAI prevention. This was followed by SB 1058 (Alquist) and SB 158 (Florez) in 2008 which expanded the requirements to reduce preventable patient safety events by requiring that hospitals implement certain procedures for the screening, prevention, and reporting of HAIs.

Adverse events

In 2002, the National Quality Forum (NQF) identified 27 adverse events occurring in health care settings that are clearly identifiable and measurable, are significantly influenced by policies and procedures of hospitals, and are of great concern to providers and patients (see Appendix C). They include such events as retention of objects (e.g., sponges) inside a patient after surgery, medication errors, or surgery on the wrong body part. All of these events are easily preventable when systems and safeguards in hospitals become part of the culture of care.

To address this problem, SB 1301 (Alquist) was enacted in 2006. It requires hospitals to report adverse events within specified timeframes to DPH, requires DPH to investigate complaints, and to make information on substantiated adverse events available to the public.

Administrative penalties

Administrative penalties can be a critical tool in enforcing compliance with the law. In order to strengthen the department's enforcement authority, SB 1312 (Alquist, 2006) was enacted to allow DPH to issue administrative penalties against hospitals for violations of licensing provisions. The bill authorized DPH to assess an administrative penalty up to $25,000 for deficiencies constituting an immediate jeopardy to the health or safety of a patient. The bill allowed DPH to raise this to $50,000, upon adoption of regulations, and allowed it to levy an administrative penalty of up to $17.500 for violations that do not constitute immediate jeopardy. SB 541 (Alquist, 2008) increased further the maximum penalties that DPH can levy, for violations incurred after January 1, 2009, to up to $50,000 for a first immediate jeopardy violation, $75,000 for a second and subsequent violation, and $100,000 for a third and subsequent violation (with authority to increase this to $75,000, $100,000, and $125,000 respectively, upon adoption of regulations). The bill also increased the maximum penalty for non-immediate jeopardy violations to $25,000.

Nurse staffing ratios
Numerous studies have documented a direct relationship between low skill mix (i.e., less licensed nursing staff to higher numbers of patients) and increased infections, higher mortality rates, increased illness and errors. In response to concerns about the increasing use of unlicensed personnel and the decreasing use of appropriate levels of nursing staff, AB 394 (Kuehl) was passed in 1999 to establish required nurse-to-patient staffing ratios in general acute care hospitals, acute psychiatric hospitals, and special hospitals, making California the first in the nation to do so. The bill also limits the nursing-related duties that can be performed by unlicensed personnel.

Pursuant to DPH Regulations, the minimum ratios in different units, are as follows: a) one nurse to two patients in critical care units (burn, labor/delivery, recovery, and intensive care); b) one nurse to three patients for step-down units; c) one nurse to four patients for pediatrics, postpartum and antepartum units, emergency room, specialty and telemetry units; d) one nurse to five patients in medical/surgical units; and e) one nurse to six patients in psychiatric units.

National Healthcare Safety Network
General acute care hospitals in California are required to report certain HAIs to the DPH through the CDC's National Healthcare Safety Network (NHSN). The NHSN is a voluntary, secure, internet-based surveillance system that integrates and expands legacy patient and health care personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion (DHQP) at CDC. NHSN also includes a new component for hospitals to monitor adverse reactions and incidents associated with receipt of blood and blood products. Enrollment is open to all types of health care facilities in the United States, including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and long term care facilities.

CDC guidelines on patient safety
In addition to providing the NHSN, the CDC also publishes numerous resources and guidelines for facilities and providers on prevention of HAIs and adverse events. Several of the abovementioned bills require DPH and hospitals to adopt these nationally recognized guidelines and practices. These guidelines include hand washing and cough etiquette protocols; infection surveillance and infection prevention process measures; isolation of influenza patients; mandated vaccinations for health care workers; process measures to prevent ventilator-associate pneumonia; central line insertion practices; and surgical antimicrobial prophylaxis measures.

Non-payment policies for HAIs and adverse events
In order to align financial incentives with patient safety outcomes, the Centers for Medicare and Medicaid Services (CMS) has adopted policies denying Medicare reimbursement for 12 adverse events, which they refer to as hospital acquired conditions (HACs). As part of the Deficit Reduction Act (DRA), signed by President Bush in February of 2006, the Secretary of the Department of Health and Human Services (HHS) was required to take steps to prevent Medicare from paying hospitals for the additional

costs of treating patients who acquire specified conditions during hospitalization. Pursuant to the DRA, for discharges occurring on or after October 1, 2008, hospitals will not receive additional Medicare payment for cases in which one of the selected HACs was not "present on admission." CMS also initiated a process in 2008 to review Medicare coverage of so-called "never events" - including incidents like surgery on the wrong body part, surgery on the wrong patient, and performing the wrong surgery on a patient.

More recently, the Patient Protection and Affordable Care Act (PPACA) signed by President Obama in March of 2010, requires the Secretary of HHS to identify current state practices that prohibit payment for HACs and to incorporate them, or elements of them in regulations governing the Medicaid program, which are required to be effective as of July 1, 2011.

Many health plans are developing similar non-payment policies for the private market. At least 11 states have enacted non-payment policies for HACs through statute or other agreements.

Department of Public Health Licensing and Certification (L&C) Division

There are over 7,000 public and private health care facilities throughout the state, including hospitals, nursing homes, clinics and home health agencies. The DPH L&C Program conducts licensing and certification inspections (surveys) in these facilities to ensure their compliance with minimum federal certification and state licensing requirements in order to protect patient health and safety.

The L&C Program is responsible for investigating complaints from consumers, consumer representatives, the Ombudsmen, and anonymous sources. Certification is a federal prerequisite for health facilities and individual providers wanting to participate in and receive reimbursement from both Medicare and Medicaid (Medi-Cal). DPH is the designated entity under contract with the federal CMS to verify that health facilities meet certification standards. In addition, L&C fees, which are collected from health care facilities, provide the bulk of the funding for L&C's enforcement activities and are placed into the L&C Fund. General Fund support is also provided for some facilities to support L&C functions of state facilities (such as Developmental Centers).

Funding for HAI prevention and control

The 2007 Budget Act added 61 positions to L&C to support the implementation of SB 1301 and 1312. An additional 48 positions were added in the 2008 budget to further support the implementation of Senate Bill 1312.

The Governor proposed an increase of $2 million ($1.6 million General Fund) to support the implementation of the Hospital Acquired Infection Program, which was required to be established by SB 739 in 2007, but later vetoed it indicating that funding would be delayed for one year due to the fiscal crisis of the state. In 2008, the administration restored the vetoed funding but the Legislature deleted it due to the state's fiscal crisis.

Finally, in 2009, $1.4 million (from hospital licensing fees) was approved to implement the HAI program, which is continued in the 2010 budget.