Legislating Medication Safety: The California Experience

Prepared for
CALIFORNIA HEALTHCARE FOUNDATION

by
Convergence Health Consulting

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About the Authors

Convergence Health Consulting is a multi-disciplinary team of professionals supporting health care organizations to advance patient safety, improve quality, strengthen leadership and promote enduring change, and to facilitate a solution oriented dialogue between physicians, hospitals, health plans, purchasers, the public and other health care stakeholders.

About the Foundation

The **California HealthCare Foundation,** based in Oakland, is an independent philanthropy committed to improving California's healthcare delivery and financing systems. For more information on CHCF, visit www.chcf.org.

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Executive Summary

In September 2000, less than one year after the media reported several high-profile deaths resulting from medication error and the Institute of Medicine (IOM) released *To Err is Human,* on medication errors, the California legislature enacted Senate Bill 1875. As a condition of licensure, the new law required all California hospitals to submit a plan to the Department of Health Services (DHS) that would substantially reduce medication-related errors. The plan needed to include technological solutions and had to be submitted by January 1, 2002, with implementation no later than January 1, 2005. Rural hospitals could request an exemption from the technology requirement and hospitals undergoing construction for seismic safety could delay implementation. The law resulted in a set of five "guiding principles" from DHS, which were codified into a subsequent law in early 2002.

About the Report

This report presents a detailed examination of the plans submitted by hospitals to comply with the California patient safety legislation, SB 1875 and SB 801. Under a grant from the California HealthCare Foundation (CHCF), Convergence Health Consulting (CHC) examined the medication safety plans submitted to the Department of Health Services (DHS), the state hospital regulator, by California hospitals pursuant to the law. The researchers looked at the technologies, strategies, and methods hospitals plan to employ to reduce medication-related errors. The research is based on an analysis of the 344 medication safety plans submitted to DHS by California hospitals. (For more information on the research methodology, see Appendix A.)

Two major themes emerged from an analysis of the plans:

Theme 1: SB 1875 succeeded in encouraging many California hospitals to submit far reaching action plans to address the issue of patient safety.

Hospitals responded expansively to legislative requirements. Many hospitals went far beyond minimum requirements, even when the legislation provided specific exemptions.

- Technology solutions were broadly embraced by hospitals. California hospitals plan to implement 2.8 technology

methods by 2005. A third of the hospitals indicate that they will use four or more technology methods.

- The most popular technology planned (46 percent) is computerized physician order entry (CPOE), which enables a prescribing clinician to enter a medication order directly into a software application. The software is designed to detect errors or situations that can lead to an error.

Hospital plans also describe complex non-technology strategies that will be used to reduce medication-related errors. The approaches often leverage standards established by regulatory agencies or other standard-setting bodies and help support and pave the way for technology implementation.

Most California hospitals have sophisticated infrastructures for managing medication safety improvement initiatives.

Theme 2: If California hospitals follow through on these plans as written, they will have set a high standard for quality improvement nationwide. However, hospitals plan only limited efforts to evaluate their strategies for effectiveness.

- Few hospitals plan to measure directly the detection and reduction of errors.
- Most hospitals will rely on self-reporting as the primary error detection method. However, voluntary error reporting historically underdetects errors and their causes. To provide a true picture of progress, this method will require a supportive and nurturing hospital culture that distinguishes between errors caused by poorly designed systems and negligent or incompetent behavior of staff.
- Importantly, hospitals rarely describe what level of participation they expect from their physicians. In particular, descriptions of CPOE deployment usually do not address the percentage of physicians expected to use the technology described. Because not all CPOE systems are created equal, error reduction using CPOE will vary, depending on the strength of error detection software and the level of physician participation. However, hospitals seldom discuss these issues in their plans.

Policy Implications

There are wide ranging implications for hospitals, policymakers, researchers, consumers, and other stakeholders in the patient safety movement that emerge from the analysis of the plans.

- Since the business case for medication safety practices is poorly developed, external forces are crucial for their widespread adoption.
- Hospitals focus the most attention where external requirements overlap in order to leverage their efforts for multiple audiences.
- Legislation can help hospitals prioritize specific patient safety activities.
- Because error measurement (also called "failure detection") strategies are in their infancy, progress towards a uniform framework and metrics for safety measurement should be a priority.
- While CPOE offers tremendous promise in reducing medication-related errors, the ability of hospitals to ensure that clinicians use high-yield systems appropriately remains an open question.

California Senate Bill 1875

In brief, SB 1875 requires all acute care hospitals and surgical centers to:

- Adopt a plan to eliminate or substantially reduce medication-related errors.
- Except for rural hospitals, the plan must include technology "that, based on expert scientific advice and data, has been shown effective."

SB 1875 required each hospital to submit a plan to the Department of Health Services (DHS) by January 1, 2002 (15 months after the law was enacted) for implementation by January 1, 2005. SB 801, as amended, authorizes DHS to specify the requirements of each plan submitted and to monitor its implementation when SB 1875 goes into effect.

SB 1875 defines a medication-related error as an event that:

- Adversely affects hospitalized patients;
- Is related to professional practice, products, procedures; or
- Is related to systems such as prescribing, transcribing, labeling, packaging, compounding, dispensing, and administration, among others.

To assist hospitals with their planning, DHS issued the following guiding principles:

- Establish an organized quality system that addresses the issue of a facility-wide reduction of medication errors.
- Develop a reporting mechanism to ensure that medication-related errors are reviewed.
- Establish a baseline assessment, and, at a minimum, annually review the effectiveness of the plan to reduce medication-related errors.
- Technology implementation shall be part of the plan.
- Review pertinent literature related to the reduction of medication-related errors in the development and ongoing review of the plan.

A table of best practices for medication use was also included in the guidelines.

The text of the final SB 1875 legislation can be found at http://info.sen.ca.gov/pub/99-00/bill/sen/sb_1851-1900/sb_1875_bill_20000928_chaptered.pdf.

Note: Under a grant from CHCF, hospitals also received technical assistance in complying with SB 1875 and SB 801 through a collaborative program operated by the California Institute for Health System Performance (CIHSP). CIHSP produced a *Compendium of Medication Safety Practices,*[1] which led to the development of a model plan (with a formatting template) and Frequently Asked Questions document that were sent to all California hospitals.

California Senate Bill 801

The guiding principles subsequently were codified into SB 801, which requires each facility to:

- Evaluate the organization's weaknesses or deficiencies that could contribute to medication errors.
- Review the plan's effectiveness at least annually.
- Modify the plan as warranted.
- Describe the planned technology and how it reduces medication-related errors.
- Include a system to proactively identify actual or potential medication errors.
- Include a multidisciplinary process to regularly analyze all identified actual or potential medication-related errors and describe how the analysis will be utilized to change current procedures and systems.

The final SB 801 legislation can be found at: http://info.sen.ca.gov/pub/01-02/bill/sen/sb_0801-0850/sb_801_bill_20020321_chaptered.pdf.

I. Background

"The increase in the number of hospitals turning to a system like CPOE to meet the new regulations and reduce medication errors is a good example of what can happen when regulators and purchasers coordinate and streamline compliance requirements."

— Lark Galloway-Gilliam
Executive Director
Community Health Councils, Inc.

Concerns Over Patient Safety Converge

Passage of SB 1875 and SB 801 followed on the heels of high-profile accidental patient deaths and an alarming report by the Institute of Medicine (IOM) in 1999[2] suggesting that at least 44,000 and perhaps as many as 98,000 individuals may die each year in U.S hospitals as a result of medical errors. Although the earliest work on quantifying the magnitude of medical errors in California hospitals dates from 1975,[3] the issue of patient safety has generally escaped notice in Sacramento.[4] A measure of the impact of inadequate attention to patient safety is that between 1978 and 1999, an estimated 2 million preventable deaths occurred in hospitals nationally, which extrapolates to more than 210,000 accidental patient deaths in California. From another perspective, between nine and 22 preventable deaths occurred at every community hospital, every year, during this 20-year period.[5]

The IOM report and the widespread media attention on patient safety galvanized action on several fronts. A Presidential Commission on Quality and Safety was created; the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) made sweeping changes in its medication safety inspections at accredited hospitals; and other state legislatures, along with California, began crafting new laws that would safeguard patient safety.

The Context of Patient Safety Legislation

While legislation was being drafted in California, various initiatives began in the state involving patient safety. One example is the Stanford Patient Safety Consortium. With a grant from the Agency for Healthcare Research and Quality (AHRQ), the Center for Health Policy/Center for Primary Care and Outcomes Research at Stanford University formed a partnership with some 20 California hospitals to conduct research on successful safety practices with national patient safety experts, JCAHO, the Institute for Safe Medical Practices (ISMP), and the Palo Alto Veterans Administration Patient Safety Center of Inquiry.

Specifically, the project developed and tested a sophisticated safety culture survey instrument, evaluated participating hospitals' results on the ISMP Self-Assessment Tool, and held meetings to discuss consortium results along with patient safety

improvement activities at each hospital.[6] Another aspect of the project involved the use of publicly available data to create a new set of patient safety indicators.[7]

Health care purchasers entered the patient safety arena shortly after the legislation was passed. Hospitals in California generally do not contract directly with the purchasers of health care. Nevertheless, many California facilities responded positively when the Leapfrog Group, a consortium of major health care purchasers, selected California in the rollout of a national program to improve patient safety. The Pacific Business Group on Health, a Leapfrog member, coordinated the California effort, resulting in 48 percent of invited hospitals voluntarily agreeing to participate in the program.[8] Among the Leapfrog requirements was implementation of CPOE, which also meets the technology requirement of SB 1875.

Concurrent with these developments, a state budget crisis was developing that threatened enforcement of the new legislation by DHS. Faced with personnel reductions, as well as constraints imposed by a legal analysis citing the lack of enforcement provisions in SB 1875, DHS did not officially review plans until SB 801 was enacted on March 28, 2002, after the 90-day deadline mandated in the original legislation. Once SB 801 was enacted, DHS reviewed all submitted plans expeditiously and called hospitals that had only a few or minor deficiencies with their plans to facilitate the revision process. Later, they notified in writing those hospitals that did not substantially meet the requirements, giving them a 90-day completion deadline. A small minority of hospitals required multiple revisions before their plans were approved by DHS.

National Groups Call for Change

The National Quality Forum, a national private-public partnership, also published a study describing the development of consensus, evidence-based best practices involving medication safety.[9] The IOM issued another report on health care quality that included a discussion on how hospitals must make health care safer for patients through technology.[10]

AHRQ published a major report examining the evidence for implementing various patient safety practices.[11] The AHRQ report endorsed the use of a variety of patient safety practices including certain medications for specific clinical conditions. However, the report did not find sufficient evidence to support some of the medication safety strategies identified in SB 1875 and the guiding principles as created by DHS.

II. Discussion of Hospitals' Reaction to 1875

"Addressing patient safety has clearly become a top agenda item for California's hospitals. The good news is that almost half of California's hospitals plan to have CPOE in place by 2005. The 'glass half empty' aspect is that many hospitals commited to CPOE have not made the parallel commitment to assuring the effectiveness of these systems."

— Peter Lee, President and CEO
Pacific Business Group on Health

The Nexus of Patient Safety and Technology

Assuming implementation proceeds according to plan, SB 1875 appears to be a legislative success story; few stakeholders envisioned that California hospitals would embrace technology so aggressively. Because of cost and implementation challenges associated with an unfunded mandate, one would have expected hospitals to take a "floor approach" and seek to conform only to the minimum standards required under the law. Instead, hospitals have set out to create an infrastructure much more intricate and sophisticated than the law or the guiding principles required. (See Key Findings on the following page.)

Where the law stated only one technology was required, the average hospital has plans to deploy nearly three times as many technology tools. With exemptions for deployment available, they have been only sparingly used. (For more detailed information on the findings, see Appendix B.)

Why Did Hospitals Behave As They Did?

…Good for Business

One answer might be the potential business opportunities and cost savings to be realized. This is unlikely for several reasons. Although some research[12] suggests that cost savings are associated with error reduction in academic or teaching institutions, forecasting similar results in a community hospital with a different payer mix and cost structure is impossible. A recent analysis suggests that although efficiency, quality, and standardization all improved demonstrably with CPOE, no impact on overall costs was found.[13] Anecdotal reports concerning various patient safety technologies described significant implementation challenges and an unappealing return on investment.

…Good for Community Image

Could improving the public perception of an institution drive the kind of results found in this study? Here the answer is likely modest, at best. With the possible exception of certain rural institutions, most hospitals have a strategy linked to market share. Advertising new technology is a common method of attracting new patients and recruiting top-flight physicians. Bar code scanners and wireless PDAs may be interesting, but

they compare poorly with other cutting-edge technologies that offer earlier diagnosis or better treatment. What institution wants to advertise "fewer failures in the operating room?" In short, while the public endorses safety efforts at local hospitals, it is not likely to be advertised.

Additionally, dollars spent on safety infrastructure compete in a hospital's budget for projects and technologies that physicians may desire. Losing that new scope or some other state-of-the-art clinical technology to a safety technology that may create *more* work for physicians could drive high-margin-producing clinicians to a competitor.

Key Findings of Analysis of Hospital Plans

Technology-based Solutions

- The average hospital will employ 2.8 significant technology tools to reduce medication errors.
- Forty-five percent of hospitals are implementing three technology tools and 32 percent are deploying four or more tools.
- CPOE is the most common technology tool planned for implementation by 2005. Forty-six percent of hospitals plan to install or upgrade CPOE systems by the legislative deadline.
- All 11 children's hospitals, 6 academic medical centers, eight public hospitals, 30 hospitals under 100 beds, and 2 rural hospitals plan to deploy CPOE.
- Pharmacy information systems that allow pharmacists to track, verify, cross-check, and evaluate drug interactions and allergies, is the next most common technology tool planned for installation or significant upgrade.

Non-technology-based Solutions

- Hospitals' use of non-technology strategies is diverse, but also expansively employed to reduce medication errors. Pre-printed order sets are an example of a non-technology approach that reduces medication errors, meets JCAHO requirements, and leads to CPOE implementation.
- Pharmacy practices include modified storage methods, clinical pharmacy rounds, and pharmacy-based protocols. Other non-technology solutions involve nursing practices, prescribing practices, and better access to information.

Hospital Improvement Infrastructure

- Most hospitals have existing committees and reporting structures to implement plans.
- The chief pharmacist is the most frequently cited leader responsible for effective implementation of the medication safety plan; others cited the patient safety officer.
- Small hospitals often use the chief nursing executive as the person responsible for plan deployment.

Measurement of Plan Impact

- Most hospitals describe measures of success as either improvement on the scoring of self-assessment surveys, like the Institute for Safe Medication Practices (ISMP) tool, or by reduced voluntary error reporting. Most hospitals do not quantify the amount of improvement they expect using these approaches.
- Few hospitals directly measure non-reported errors or the direct impact of individual components of their plans.

Note: For a more complete summary of the analysis, see Appendix B.

…It's the Cost of Doing Business

Given the pressure from external sources on reducing preventable errors in hospitals, it is not surprising that hospitals attempt to leverage their activities to meet multiple external demands. With the JCAHO, Leapfrog Group, NQF, AHRQ, IOM, and state government all emphasizing error reduction, where those groups' requirements intersected is where hospitals in California tended to build into their plans. If a hospital does not respond aggressively to reducing medication errors, it runs the risk of being left behind by important stakeholders. In one sense, then, reducing medication errors is now a cost of doing business.

…Regulatory Uncertainty

The most plausible explanation for hospitals' embrace of technology may be found in the structure of the law and the guiding principles promulgated by DHS. The language of SB 1875 is ambiguous. In its technical guidance, DHS noted that effective reporting systems are able to detect more errors, but offered no guidance to hospitals about what it would consider to be a "substantial reduction" in reported errors. Because the measurement of failure is nascent in health care, it is difficult, if not impossible, to predict how well all of the planned tools and practices will be able to accomplish the goal of detecting and eliminating errors. Hospitals apparently decided to make a major investment in technology because the end point is so uncertain and the stakes — possible disciplinary action by DHS — are high.

In addition, technical assistance provided by CIHSP in the form of a compendium of suggested medication practices, a model plan with answers to frequently asked questions, a checklist of medication safety practices, and interactive conference calls, made compliance with the law substantially easier for California hospitals. In particular, one conference call on low-cost methods to reduce errors highlighted many of the non-technology solutions that hospitals could rapidly deploy to improve medication safety in their facilities. This type of technical assistance likely reduced operational and resource concerns by some hospitals, allowing them to focus on meeting the requirements of SB 1875.

…Technology Is Not a Panacea

Many well-accepted safety practices do not require high-tech solutions. Deploying alternative, "low-tech" strategies and tools might have a cumulatively greater impact on patient safety than a transformational technology such as CPOE or bar code point of care, especially if these systems are poorly utilized. If legislative ambiguity and overlapping external pressure stimulated hospitals to embrace technology, as noted earlier, the lack of specificity on the part of the legislature and DHS on how to apply the technology may lead to suboptimal results. Technology also can create new or different kinds of errors requiring additional systems to provide safeguards to patients.

The Lure of Transformational Applications

California hospitals have embraced medication safety technology, often choosing risky, but promising, applications like CPOE. These applications transform an institution's information systems over less risky but also potentially less fruitful incremental upgrades. However, technology creates its own set of problems in the patient safety arena. The new deployments elucidated in many plans submitted by hospitals will require major work flow alterations if their benefits are to be realized fully. Effective change management solutions are required for successful implementation.

In this context, the omission of physician participation in the hospitals' plans to implement CPOE is problematic. Physician participation and the robustness of the CPOE system are two major components of a successful CPOE installation that bear directly on error-reduction

effectiveness. CPOE comes with different functionality and, depending on the level of decision support in the software, produces varying levels of error-reduction. CPOE systems with sophisticated error detection rules and flags are often the most difficult to implement and frequently face fierce physician resistance because of their time-consuming features. However, if physicians bypass the CPOE system by issuing verbal orders or by using clerks to enter their orders from written documents, then many common errors will continue to go undetected and no improvement will have been realized, all at great cost to the institution. Could a hospital not implementing CPOE have a greater impact on error reduction than one implementing such a system poorly or incompletely? The answer is an obvious yes. The impact of CPOE, the most commonly cited technology tool in this study, on the overall impact of medication error reduction in California, remains an open question.[14]

To produce the most complete, integrated, and safe medication delivery system would require technology that connects each step in a continuous feedback loop. Such a solution would include a CPOE system with linkages to a comprehensive electronic medical record. Dispensing would include automated error checks and a limited override capability. Nurses would administer medications with smart pumps and bar code point-of-care units that capture the medication administration record electronically while incorporating automated monitoring and feedback of patient status. This ideal "end-to-end" medication system is several evolutionary steps in the future for most hospitals.

The Uncertainty of Safety Measurement

Some hospitals' plans include metrics for determining if errors have been reduced. However, the weakest links in the evolution of patient safety involve detecting errors and measuring their reduction. Virtually all hospitals in California use error-reporting systems. Most are paper-based and depend on staff voluntarily filling out a form to identify and describe an error whenever it is observed. For a variety of reasons, such low-tech, voluntary reporting systems usually underreport actual and potential errors.[15,16] To be effective, these systems will require a supportive culture and constant nurturing and encouragement by hospital leadership. Overall, reliable safety measurement is at the embryonic stage of development in California's hospitals.

III. Policy Implications

"Clearly, this legislation has focused the energy of California hospitals towards improving medication safety. In their plans, hospitals have made a good first step in the journey to safeguard patients. Now they must implement them effectively."

— Senator Jackie Speier

A Promising Future

Prodded by SB 1875, SB 801, and other regulatory and business forces previously described, California hospitals have chosen to focus on improving their infrastructure where the majority of internal and external requirements intersect. Although SB 1875 encourages hospitals to select a safe patient medication strategy that goes beyond other standards, greater clarity and emphasis on quantitative error reductions in the bill could have reduced the variation among hospital plans and further targeted high-yield medication safety practices. Deploying a CPOE system in itself is not indicative of whether a hospital will successfully reduce medication errors. A CPOE simulation model that is used by the Leapfrog Group to test the effectiveness of the error detection methods in a particular hospital system — a necessary first step — unfortunately does not measure physician participation. Cooperative physicians play a pivotal role as users and custodians of error detection and decision support systems.

The response of California hospitals to this first generation of medication safety legislation has broad implications for both the hospital regulatory process and for the field of medication safety. As hospitals gather both experience and data on various approaches to medication safety, both the field itself and the process by which it is nurtured through regulation can be expected grow in refinement and effectiveness.

1. **Since the business case for medication safety remains poorly developed, external forces are crucial for the widespread adoption of safety practices.** Despite high rates of medical errors that have been documented since the mid-70s, substantial movement in error reduction did not occur until widespread media and public interest, legislation, standard-setting bodies, and other stakeholders elevated the subject and demanded a response.
2. **Hospitals focus the greatest attention where external requirements overlap (JCAHO standards, Leapfrog, etc.) in order to leverage their work for multiple audiences.** Hospitals emphasized those practices where multiple external requirements aligned. To the extent stakeholders can collaborate on a single set of solutions, hospitals will more likely attempt to focus their efforts.

3. **Legislation can help hospitals prioritize specific patient safety activities.** With its emphasis on technology, the mandate from SB 1875 forced hospitals to select a medication safety strategy that went beyond other standards. However, with even greater clarity and emphasis on quantitative error reductions, SB 1875 could have reduced the variation among hospital plans and further targeted high-yield practices. The downside from this approach is that it reduces the number of natural experiments and likely increases the collective opposition to challenging requirements.
4. **Because error measurement strategies are in their infancy, a uniform framework and metrics for safety measurement should be a high priority.** The several self-assessment tools developed to help hospitals understand the gaps in their safety practices should evolve to evaluate systems of care and failure detection.
5. **While CPOE holds tremendous promise for reducing medication-related errors, the power of individual systems and the challenge of ensuring that clinicians use them remains an open question.** Deploying a CPOE system is a key, but not sufficient, indicator of whether a hospital has successfully reduced medication errors. Equally necessary are robust error detection and decision support regarding the most common and dangerous errors. The engagement and participation of physicians is also needed. A CPOE simulation model developed for the Leapfrog group will test the effectiveness of the error detection methods in a particular system, but it does not measure physician participation.

In conclusion, it is clear that patient safety efforts have gained substantial momentum and there are additional opportunities for improvement. By planning for costly and human resource-intensive technologies and safety practices, California hospitals are making significant commitments to improving medication safety. It is also clear that even the earliest adopters of safety practices can make improvements, even by their own standards. As the culture of safety becomes common practice, it is hoped that other non-medication safety activities such as surgical misadventure or nosocomial infection, for example, will be viewed as prime opportunities for improvement.

Appendix A. Methodology

Because DHS did not require a specific format or taxonomy for the plans, the study team created a methodology for abstracting information that would impose a structured format on plan review. In addition to basic hospital demographic information, information was collected on:

- Requests for legislative exemptions.
- Plan objectives.
- Hospital infrastructure (leadership, committees, and systems).
- Reporting and error-detection methodologies.
- Self-assessment tools and results.
- Planned technology and non-technology strategies.
- Methods for hospital dissemination of medication safety practices.

The methodology allocated several fields for each area with pre-determined categories. The methodology also allowed for free text entry when data elements did not conform to any category. An advisory group (which included some members of the original DHS advisory group that created the guiding principles) was formed to provide input on the methodology. The advisory group reviewed the tool and data storage methodology and made minor modifications to individual fields. The methodology was then tested on ten randomly selected plans by the principal investigator and modifications were made in the data entry approach. No fields or category descriptors were modified during the final review of the methodology.

Most fields were populated with any appropriate evidence the hospital supplied in the plan. For example, if the hospital claimed an exemption from the technology requirement, the hospital was credited with an exemption. With the technology and non-technology strategies, however, only those hospitals commited to implementing a specifically defined approach by 2005 were credited with that practice. Likewise, if a technology or medication safety practice was implemented prior to 2002, no credit was given for it unless the hospital planned significant upgrades between 2002 and 2005. This classification mirrored DHS approval rules.

Using the agreed-upon structured format and protocol, two research assistants reviewed each plan for critical elements. Only rarely were data elements not available in the documents. The first 25 plans were reviewed by each research assistant and then again by a senior member of the research team. Any substantial interpretation differences were identified, agreed upon, and corrected as needed. Plan length ranged from three pages to several hundred and it took approximately 30 minutes on average to capture data on each plan. In general, it was easier to capture the appropriate data elements from plans that followed the CIHSP model plan referenced on page 6. Each plan was reviewed at least twice for the technology strategies hospitals identified, and once by a senior member of the team to ensure data integrity.

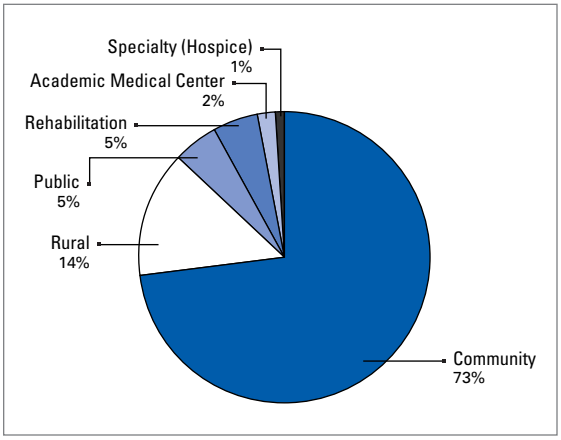
Appendix B. Research Findings

A total of 410 plans were submitted to DHS, representing 98 percent of all licensed acute care hospitals in California. Of these, 66 were unavailable because of hospitals' request for an exemption from public release. Some 14 hospitals requested partial exemptions for release, which allowed them to strike specific language. However, even after specific language was redacted, partially exempted plans still contained all of the elements in the abstraction tool. The researchers ultimately analyzed 344 plans, representing 84 percent of all available plans submitted to DHS.

Types of Hospitals

The plans analyzed by hospital type reflect the overall distribution of hospitals in California. Among the plans not available for review, there was no substantial difference in hospital type (e.g., they did not reflect a particular hospital type, geography, size, or academic status). The study does not distinguish between investor-owned and not-for-profit tax status.

Figure 1. The Predominant Hospital Type Is a Community Hospital



Approximately half of all eligible rural hospitals have taken advantage of the technology exemption in SB 1875, far below the anticipated number of exemptions for potentially costly technology solutions. A possible explanation for why some rural hospitals have opted to implement technology in lieu of an exemption may be the broad definition of applicable technology choices. Some of the available technology choices, such as automated dispensing units, may also drive important operational efficiencies, particularly in a rural setting.

An estimated 50 percent of California hospitals are in the process of seismic-related retrofit or reconstruction[17] and would likely qualify for the seismic construction exemption under SB 1875. Surprisingly, only one hospital requested a delay in implementation because of seismic construction.

Objectives and Priorities

Hospitals were not required to state objectives for their plans by DHS, but the CIHSP model template suggested plan objectives were important to the overall design. Some 72 hospitals have not stated objectives, but the remaining 272 stated multiple objectives. Considering the medication process in the following categories — prescribing/ordering; dispensing; administering; and monitoring — most hospitals cited prescribing/ordering slightly more frequently among their multiple priorities.

Self-Assessment Tools

Hospitals were required to perform an assessment of their medication safety effectiveness. A specific methodology was not required as long as the method contained all of the elements of the medication delivery process. DHS was quite specific that the assessment must be performed at least annually to demonstrate progress in reducing medication-related errors.

Table 1 lists the number of times a particular tool was used by a hospital. Hospitals often employed more than one tool to determine areas of opportunities.

Table 1. Self-Assessment Tools

TOOL	No. of Hospitals
Institute for Safe Medication Practices (ISMP)	237
Hospital Created*	90
CIHSP Medication Safety Checklist	67
CHCF Tool Kit: Addressing Medication Errors	24
VHA	24
Other	27

*Some hospitals only indicated a self-assessment was performed without listing a particular tool and were scored as a hospital-created method.

The ISMP Self-Assessment tool was clearly the most popular method, partly because of its prior endorsement and distribution by the American Hospital Association. Although DHS did not require the plans to include actual results from the self-assessment, some hospitals did submit actual scores in their plans, however too few to draw meaningful conclusions.

Hospital Infrastructure

Most California hospitals have developed an extensive infrastructure to address medication-related errors. Day-to-day accountability is usually specified and reporting relationships indicate a chain of responsibility rising up through senior leadership. (One hospital said "everyone is responsible" for medication safety.) Many hospitals have the governing body conducting oversight of the process.

Table 2 lists the members of the hospital and medical staff involved in leadership roles indicated in the plans.

Table 2. Personnel Responsible for Oversight of Plans

TITLE	No. of Hospitals
Pharmacy Leader	247
CEO/Senior Administrator	142
Senior Nurse Executive	129
Quality/Performance Improvement Leader	99
Senior Physician Executive	90
Patient Safety Officer	68
Risk Manager*	24
Other	17

*Some hospitals combine the roles of risk manager and quality/performance improvement leader.

Clearly, more than one person is involved in the creation and deployment of the plan. Front-line responsibility typically is delegated to a pharmacy leader. In small hospitals, the senior nurse executive is often responsible for plan implementation. A relatively new position, the patient safety officer, is listed in 68 plans (19 percent).

The active committees involved in medication safety are diverse and varied. Most hospitals describe a hierarchal process in which a Medical Executive Committee (MEC) submits the plan upwards to the board for approval, and then delegates execution to another committee, typically a quality or pharmacy-related committee. The committees hail by different names at hospitals, but generally fit into the categories listed in Table 3. The most common committee identified in the sample is the Pharmacy and Therapeutics Committee, which is frequently a subcommittee of a larger quality or performance improvement committee.

Almost half the plans list a specific medication safety committee, which is largely multi-disciplinary in nature (as required by the guiding principles) for implementation responsibility. Many hospitals have combined quality and risk management functions into a single committee. In the table, the category "other" includes plans

listing committee names and descriptions whose function could not be classified. In only a few cases, unique organizational or personnel capabilities within their facility have prompted hospitals to locate the medication safety function in an unusual committee, such as "environment of care" or infection control.

Table 3. Committee Responsibility

COMMITTEE NAME	No. of Hospitals
Pharmacy and Therapeutics Committee	259
Quality/Performance Improvement or Risk Management Committee	212
Medication Safety Committee	159
Patient Safety Committee	69
Medical Executive Committee	63
Other	56

Error Reporting and Detection Systems

Although most hospitals have internal reporting systems, more than 90 percent use paper-based reporting methods. The remainder employ either phone or electronic reporting approaches. Some 87 percent of hospitals describe "near miss" components of their reporting system, but do not elaborate on the definition or the effectiveness of the reporting methodology. Nearly 60 percent of hospitals describe an automated method of surveillance, often associated with a pharmacy information system (PIS). Some hospitals specifically noted this type of PIS upgrade or a specific software program to detect errors automatically as one of their technology strategies for overall medication error reduction.

One quarter of California hospitals use an external reporting service with MedMARx (a reporting system from the United States Pharmacopoeia), and MEDWATCH (from the United States Food and Drug Administration), the two most frequently used services.

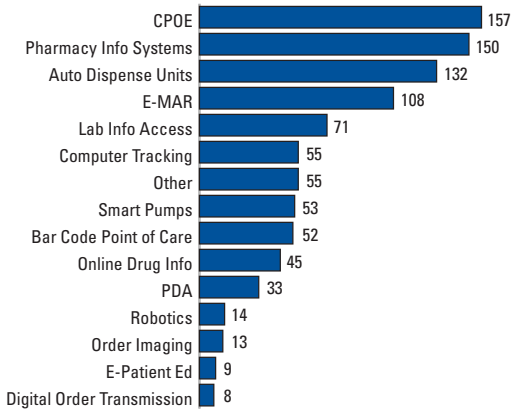
Hospitals also listed methods of proactively detecting errors. Medication alerts (e.g., drug-drug interactions, allergies, lab abnormalities), which are usually associated with PIS or other automated systems, were the most common method to detect error pro-actively (43 percent). Other strategies, such as failure mode and effects analysis (FMEA), drug utilization evaluation (DUE), and direct observation or medication counts, were mentioned much less frequently.

Error Reduction Strategies

Technology Tools

As previously discussed, hospitals responded aggressively to the technology requirements of SB 1875. The typical hospital plans to implement 2.8 technology methods by 2005, while a third will use four or more methods. Figure 1 displays the results of the technologies hospitals plan to deploy by 2005.

Figure 2. Number of Hospitals Planning 2005 Deployment of Technology Tools Cited in SB 1875.*



*Appendix C contains an explanation of terms.

Some 157 hospitals (46) percent plan to complete implementation of a CPOE system by 2005. This compares with approximately four hospitals in California that currently use CPOE to some

degree.[18] The plans did not describe the level or intensity of CPOE functionality nor its effectiveness at reducing errors. In general, hospitals simply stated that CPOE would be implemented by 2005. No mention of the expected level of physician use of a CPOE system was evident in the plans.

The California institutions planning to install or upgrade CPOE include all 11 children's hospitals, six academic medical centers (one academic medical center plan was not made available), eight of 18 public hospitals, 30 hospitals with fewer than 100 acute care beds, and two rural hospitals.

Additions or significant upgrades to PIS represent the second-largest group of technology tools (44 percent), followed by automated dispensing units (ADUs), and electronic medication administration records (E-MARs). Some hospitals have ADUs and plan to add error-checking functionality or linkages to the PIS as a significant upgrade. The E-MAR was often associated with PIS upgrades, but was also seen with independent computer or Web-based systems. Other medication safety technology tools are cited less frequently and are to be used in addition to other devices or tools.

Non-Technology Tools

Hospital plans often describe complex non-technology strategies that will be used to reduce medication-related errors. Some hospitals address every aspect of the medication delivery process by listing multiple best practices described by DHS and medication safety organizations. These techniques usually have correlation with the major categories in the ISMP Self-Assessment Tool and frequently include JCAHO standards.

After reviewing the plans, the research team elected to group these practices into nine categories as listed in Table 4.

Table 4. Non-Technology Tools

CATEGORY	No. of Hospitals
Pharmacy Practices	246
Ordering Systems	231
Nursing Practices	179
Information Access	106
Culture	102
Education	97
Infrastructure	69
Patient Activities	53
Other	2

Examples of specific methods for each category include:

Culture

- Executive interaction with front-line staff regarding patient safety.
- Regular safety culture surveys of hospital staff.
- Showing the video "Beyond Blame."
- Reward systems (pizza parties, cookies, other) for error reporting.
- Newsletters of medication safety activities.
- Change error-reporting forms to remove blame.

Education

- Using screen savers as educational tools.
- Including safety reminders in paychecks.
- Nurses spending time in the pharmacy during orientation.
- Medication safety discussions during new hire orientations.

Information Access

- Reference books on units.
- Infusion posters on units.

Infrastructure

- Creating new committees or job descriptions.
- Building an electronic adverse drug reaction (ADR) hotline.
- Modifying, updating, or developing new policies and procedures (e.g., that pharmacy refer back to physician policy).

Nursing Practices

- High-risk medication double checks.
- Standard administration times, dosing in high-risk medications.
- Standardize infusion pump protocols.
- Reducing/limiting floor stock of medications.

Ordering Systems

- Preprinted order sets.
- Handwriting classes.
- Verbal order policies.
- Correct use of zeroes, abbreviations, etc.
- Pocket cards for dosing and high-risk medications.
- Renal failure dosing protocols.
- Closing the hospital formulary.

Patient Activities

- Using pamphlets and handouts to encourage patient participation in medication management.
- Using nationally developed documents that engage patients in the issue of participating in safety awareness and medication double checks.

Pharmacy Practices

- Better storage of sound-alike, look-alike medications.
- Clinical pharmacy rounds.
- Pharmacy protocols for high-risk medications.
- Relocating pharmacy to clinical units for improved access, improved lighting, and fewer distractions.
- Pharmacy-based IV admixture service.

Other

- Creating work-rest schedules for employees.
- Performing biomedical testing.

Measuring Plan Impact

As discussed previously, most hospitals have not developed specific metrics either for measuring successful implementation or for quantifying error reduction. Some hospitals do create reduction targets for adverse drug events (ADEs), but then specifically rely on self-reporting as the primary error detection method. A few hospitals describe using trigger tools, in which the use of an agent or specific order may indicate a medication error and hence trigger an evaluation, but they infrequently quantify the expected decrease in triggers.

Hospitals often describe implementation dates for different aspects of their plans, but usually do not explain or attempt to quantify what will constitute a successful implementation. Hospitals typically will rely on the annual self-assessment process to determine whether their plans have been effective.

Appendix C. Glossary of Medication Safety Technologies

Automated Dispensing Units (ADUs) — Mobile "cabinets" containing multiple medications for dispensing on the nursing unit. They include software to track medication dispensing and have varying levels of safeguards. The most sophisticated units can be programmed to "lock out" all cabinets except those containing specific medications for specific patients at specific times as determined by the physician's orders. ADUs can also be linked to the hospital pharmacy so new orders can be entered by a nurse on a unit and checked by the pharmacist against a patient profile.

Bar Code Point-of-Care — Bar-coded medications and patient bar-coded identification tags or bracelets scanned by a clinician to ensure the right medication for the right patient, at the right time, route, and dose. Requires compliance from drug manufacturers (recently mandated by the United States Food and Drug Administration) and can also produce electronic medication administration records. Point-of-care implies the patient's bedside, as distinct from some bar-coding systems used in the pharmacy for medication inventory tracking and dispensing.

Computer Tracking — A Web- or computer-based error tracking system. Currently, the majority of errors are reported and tracked with paper-based systems. Computerized tracking allows linkages to other databases and more detailed analyses of errors and trends.

Computerized Physician (Prescriber) Order Entry (CPOE) — Computerized systems where the prescribing clinician directly enters a medication order into a software system. The system can employ several levels of decision support to detect errors or situations that can lead to an error. They can also prohibit certain types of errors (allergies, dosing parameters, age/weight/renal function modifications, etc.) from being entered in the first place.

Digital Order Transmission — Faxing orders from one area in the hospital to the pharmacy (or perhaps a remote pharmacy for rural hospitals). Compared with order imaging, these systems usually do not allow for magnification or further scrutiny of written orders, but can increase the speed of delivery to the pharmacy and potentially reduce transcription errors.

Electronic Patient Education — Providing tailored education to patients, usually prior to discharge, that is computer-based. The most advanced systems include detailed medication information (with warnings). Some types allow for staged learning as the hospital stay progresses.

Electronic Medication Administration Records (E-MAR) — Medication administration records are generated when a patient receives a medication. They document the specific drug, dose, route, and time a medication is administered. They can also function as a prompt and medication scheduler for the clinician. Written MARs can cause errors because of illegibility; incorrect transcription; slips, such as failing to record a medication; and other problems. An E-MAR can be linked to a pharmacy information system or can be generated in a stand-alone computer or Web-based system. Barcode point-of-care systems can also generate E-MARs.

Laboratory Information Access — Laboratory results available through electronic means. These systems increase accessibility to pertinent laboratory information that may alert for potential medication errors (e.g., drug toxicity levels, abnormal renal function, etc.). Access can be through desktop computer access to patient results or may be linked to the pharmacy information system, CPOE, wireless personal digital assistants, or other technologies.

Online Drug Information — Creating computer- and Web-based information regarding medication use, precautions, interactions, and special circumstances for any clinician with such access. Online systems can be internally developed using custom reference tools (which may include the hospital

formulary and prescribing guidelines) or purchased from several vendors.

Order Imaging — Electronic transmission of scanned written orders to the pharmacy with the capability of magnifying, focusing, or comparing specific aspects of the order. These systems allow a pharmacist to thoroughly inspect handwritten orders, potentially reducing transcription errors. They may also improve operational efficiencies and improve the speed of order delivery to the pharmacy.

Personal Digital Assistant (PDA) — Handheld computerized tools that contain information regarding medication use, precautions, interactions, and special circumstances. They may also be interactive with prescription systems that alert for dosing, drug-drug interaction, allergies, or other information depending on the vendor and individual hospital capabilities.

Pharmacy Information Systems (PIS) — Software that facilitates pharmacy activities. At a minimum, these systems consist of databases for medication orders and basic patient information. System upgrades increase the number and types of errors that can be detected, including allergies, drug-drug interactions, dosing parameters (frequency, minimum/maximum), and laboratory alerts, and can also automate the analysis of medication usage and potential errors ("triggers"). More advanced systems can produce electronic medication administration records (E-MAR) and can interface with automated dispensing units (ADUs) and bar code point-of-care administration systems.

Pharmacy Robotics — Mechanical devices used in the pharmacy for packaging, re-packaging, medication bar coding, and sorting for delivery to hospital units. Automating several functions of the pharmacist can reduce some dispensing errors and provide operational efficiencies for high-volume pharmacies.

Smart Pumps — Programmable intravenous infusion pumps with drug libraries that can perform calculations and also apply medication-specific dosing limits. These systems may be amenable to both bag and syringe delivery devices. Combining bar-coded medications with smart pumps can further reduce medication errors.

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