Prescription for Improving Patient Safety: Addressing Medication Errors

A report from
The Medication Errors Panel
Pursuant to California Senate Concurrent Resolution 49 (2005)

March 2007

About the Medication Errors Panel:

Recognizing the significant and growing public health concern of medication errors, Senator Jackie Speier authored Senate Concurrent Resolution (SCR) 49 (2005), sponsored by the California Pharmacists Association. Adopted September 14, 2005, the Resolution called for the creation of an expert panel to study the causes of medication errors in the outpatient setting and to recommend changes to the health care system that would reduce errors associated with prescription and over-the-counter medication use.

The Medication Errors Panel, assembled in 2006, consisted of two Senators, two Assembly members and 13 persons representing academia, consumer advocacy groups, health professions (medicine, nursing, public health and pharmacy), health plans, the pharmaceutical industry, and community pharmacies. Throughout 2006, Panel members gave a tremendous effort to this study and met at the state capitol 12 times to hear and discuss testimony from 32 invited speakers who included many widely respected state and national leaders in the fields of pharmacy practice, medicine, medical technology, healthcare regulation, academia, and the pharmaceutical industry.

The following is the report of the Panel complete with its consensus recommendations.

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EXECUTIVE SUMMARY

The Problem of Medication Errors

A medication error is any preventable event occurring in the medication-use process, including prescribing, transcribing, dispensing, using and monitoring, that results in inappropriate medication use or patient harm. These errors and their consequences present a significant public health threat to Californians.

While most consumers and healthcare providers do not often associate poor health outcomes with adverse drug events – frequently the result of medication errors – the human and financial costs of the problem are staggering.

The most recent estimate of costs associated with drug-related morbidity and mortality in the US exceeds $177 billion per year. Amazingly, this amount is significantly greater than the amount actually spent on prescription drugs during the same year. In terms of patient harm, the Institute of Medicine projects that at least 1.5 million Americans are sickened, injured or killed each year by medication errors. Extrapolating these figures to California suggests that on an annual basis, the problem costs our state $17.7 billion dollars and causes harm to 150,000 Californians.

Perhaps the most concerning aspect of these errors is that the tremendous human and financial costs are not the result of some serious disease, but rather, well-intentioned attempts to treat or prevent illness.

In an effort to address this significant and growing problem, in 2005 Senator Jackie Speier authored Senate Concurrent Resolution 49, sponsored by the California Pharmacists Association. This resolution, adopted September 14, 2005, called for the creation of an expert panel to 1) study the causes of medication errors in the community setting, and 2) recommend changes in the health care system that would reduce errors associated with over-the-counter and prescription medications in the outpatient setting.

The Panel, assembled in 2006, consisted of two Senators, two Assembly members and 13 persons representing academia, consumer advocacy groups, health professions (medicine, nursing, public health and pharmacy), health plans, the pharmaceutical industry, and community pharmacies. Throughout 2006, the Panel met at the state capitol 12 times to hear and discuss testimony from 32 leaders in the fields of pharmacy practice, medicine, medical technology, healthcare regulation, academia, and the pharmaceutical industry.

Reducing Errors through a "Systems Approach"

Testimony provided to the Panel indicated that efforts to address errors are best targeted not at a particular group of individual "wrong doers," but rather at faulty systems, processes, and conditions that either lead people to make mistakes or fail to prevent them. Consequently the Panel took a "systems approach" for studying the problem and developing its recommendations.

After spending considerable time examining each part of the medication-use process – prescribing, dispensing, using (administering/self-administering) and monitoring – and the inter-relationships of each component, the Panel identified four key medication-use systems/processes and three key stakeholder groups which served as the focus of its recommendations.

Key Processes and Stakeholders

The four key processes which the Panel believes could be better designed to reduce and prevent medication errors are those related to:

1) **The transcription and transmission of prescriptions** (i.e. the methods prescribers use to document a prescription order and communicate that order to the pharmacy where it will be filled).
2) **The education of the consumer** regarding the purpose of the treatment, the effective use of the medication, and the monitoring of signs and symptoms that may indicate efficacy or toxicity.
3) **Healthcare provider payments and incentives** which can directly or indirectly influence providers to pursue behaviors designed to reduce medication errors.
4) **Healthcare provider training and licensure** which could foster a better understanding among providers about the seriousness of medication errors and the behaviors to adopt that will reduce them.

The three key stakeholder groups which the Panel believes will be critical in affecting the necessary changes to these processes are:

1) **Consumers and consumer oriented organizations** such as the California Department of Consumer Affairs; advocacy organizations (e.g. AARP, American Heart Association); community-based organizations; and private and public foundations.
2) **Healthcare providers and related organizations** such as academic institutions, professional societies and advocacy groups, and licensing/oversight Boards.
3) **Healthcare purchasers, payers, regulators and related organizations** such as the State of California, its Department of Health Services and the Medi-Cal program; private purchasers of health care such as employers; commercial insurance companies which administer health benefits for both public and private sector purchasers; the

California Departments of Insurance and Managed Health Care which regulate these insurance companies; pharmacy benefit managers which focus specifically on the administration of pharmacy benefits; and of course, the Legislature and Administration of the State of California which possess the potential to influence and/or establish accountability for these groups.

Based on the analysis of these four key processes and three key stakeholder groups, the Panel developed 11 consensus recommendations within five subject areas, and a twelfth recommendation to further consider and address issues that went beyond the scope of the Panel's purpose.

Recommendations

A. **Communication Improvements,** with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients. Specific recommendations are:

1) Improve legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies to use electronic prescribing.

2) Require that the intended use of the medication be included on all prescriptions and require that the intended use of the medication be included on the medication label unless disapproved by the prescriber or patient.

3) Improve access to and awareness of language translation services by pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.

4) *Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain medication consultation from a pharmacist.*

B. **Consumer Education** to increase consumer awareness regarding the proper use – and dangers of misuse – of prescription and over-the-counter medications. Specific recommendations are:

5) Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.

6) Establish an on-going public education campaign to prevent medication errors, targeting outpatients and persons in community settings.

7) Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.

C. **Pharmacy Standards and Incentives,** with a focus on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety. Specific recommendations are:

8) Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.

9) Establish standards for Medication Therapy Management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers.

D. **Training and Education for Healthcare Providers** on various medication safety practices. The specific recommendation is:

10) Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.

E. **Research,** with a focus on obtaining information about the incidence, nature, and frequency of medication errors in the community setting. The specific recommendation is:

11) Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.

In addition to these five subject areas, the Panel identified a sixth that needs to be addressed but which it determined was beyond its scope. This issue relates to the many obstacles that pharmacists face in providing drug consultation to their patients which encompasses a variety of factors such as manpower shortages and the lack of payment systems to cover the time and expense associated with these tasks. Before additional duties can be imposed on pharmacists practicing in outpatient settings, the Panel recognizes that these issues must be addressed. Therefore the Panel put forth a twelfth recommendation:

12) Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.

SECTION I: REPORT OF THE PANEL

Background & Overview

The Problem of Medication Errors

For the purpose of its work, the SCR 49 Panel defined a medication error as "any preventable event occurring in the medication-use process, including prescribing[1], transcribing, dispensing, using and monitoring, which results in inappropriate medication use or patient harm."

Errors involving prescription and over-the-counter medications represent an enormous public health problem. When an error occurs, the best possible outcome is for a medication to simply not elicit an adverse result. Even under this best-case scenario, medication errors have a significant negative impact on the US healthcare system, contributing to increasing costs for consumers, employers and other persons who pay for health care. Even worse than the financial cost is the harm to consumers' health and well-being caused by medication errors, which can range from mild to life-threatening and even death.

The scope and severity of medication errors and the related consequences have been documented by many health researchers. For the year 2000, experts estimated the overall cost of drug-related morbidity and mortality to be in excess of $177.4 billion.[2] That amount greatly exceeds the $120.8 billion spent on prescription drugs during that year.[3] In terms of patient harm from medication errors, the Institute of Medicine (IOM) estimates that at least 1.5 million Americans are sickened, injured or killed each year by medication errors.[4] Extrapolating these figures to California suggests that on an annual basis, the problem costs our state $17.7 billion dollars and causes harm to 150,000 Californians.

Perhaps the most disturbing aspect of medication errors is that these tremendous human and financial costs are not the result of some serious disease, but rather well-intentioned efforts to treat or prevent illness.

The Importance of Addressing Errors in Community Settings

When imagining places where medication is dispensed and taken or "administered," many people think of hospitals or other health care facilities. But, in fact, the vast majority of medications are taken by out-patients in "community settings," including homes, schools, offices, independent living facilities, and children or adult day care centers. Last year, over 5,000 licensed "community" pharmacies in California filled about 400 million prescriptions for community dwelling individuals.

In community settings a person often has a prescription written by his or her health care provider, usually a doctor, and has it filled at a community pharmacy, often a neighborhood drug-store, supermarket or other retail outlet. After a consumer receives medication from a community pharmacy, they or their caregiver is largely left on their own to take/administer the medication and monitor for signs and symptoms of efficacy or toxicity.

Compounding the problem of medication errors in community settings are the increasing numbers of consumers that buy and use over-the-counter medicines, herbals or other alternative treatments. While many consumers believe the "all-natural" or non-prescription status of these therapies suggests inherent safety, these products do have the potential to cause adverse effects and interact with prescription medications or each other.

In spite of incredible potential for medication errors to occur in the community setting, much of the attention paid to the problem thus far has focused on hospital and other institutional settings. In fact, there are already many state and national efforts underway aimed at reducing errors in these settings. This, coupled with evidence regarding the magnitude of the problem outside of institutional settings, led the Panel to focus on making recommendations about medication errors that occur in the community.

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[1] While the Panel identified drug and dose selection as a process (i.e. prescribing) where errors can occur, its analysis and recommendations were focused on the areas of the medication-use process that occur *after* the point where prescribers consciously make such decisions.

[2] Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. J Am Pharm Assoc 2001;41:192-9.

[3] US Office of the Actuary National Health Expenditure Data. 2000

[4] Institute of Medicine (IOM). (2007). *Preventing medication errors: Quality chasm series.* P. Aspden, J. Wolcott, J. L. Bootman, & L. R. Cronenwett (Eds.). Washington, DC: The National Academies Press.

U.S. and California Medication Error Data

There is no organization responsible for maintaining comprehensive data about medication errors in the United States or California. Several national organizations collect information related to medication errors, but their data is not comprehensive and has many limitations – it may focus on health care professionals, not consumers or on health care facilities, not community settings – or organizations may mix data about medication errors with other data – for example, data about "medical" errors or "adverse drug events." Also, organizations often define "medication error" differently, creating challenges with combining or comparing data.

Finding medication error data specific to California is even more challenging. One could extrapolate from data at the State's Board of Pharmacy and Medical Board, although neither body is charged with actively monitoring medication errors or collecting comprehensive error data. They simply document and respond, as appropriate, to complaints made by health care professionals or consumers about medication errors and other issues related to their areas of oversight.

California-specific research studies identified by the Panel did not include information about community-settings, only hospitals and residential care settings. National organizations, including the federal Food and Drug Administration (FDA) and the nonprofit Institute for Safe Medication Practices (ISMP), contacted by the Medication Errors Panel staff were unable to report medication error data specific to California.

Types of Medication Errors

In the community setting, there are three general types of medication errors that can occur: those related to the prescribing process; those that occur when the medication is dispensed at the pharmacy; and those related to the consumer's use of the medication.

Prescribing Errors

The first step in obtaining a prescription medication occurs when a consumer visits a physician, or other health care professional with prescribing authority, and receives a prescription.

In order to avoid selecting a drug that could be inappropriate or harmful to a patient, it is important for the prescriber to have access to the patient's complete health information record at the time the patient is being seen. The patient information should include all medicines the patient is taking, lab test results, other physicians the patient has seen, and any past hospitalizations or drug allergies.

The Panel heard testimony that prescribers in California often do not have ready access to vital patient information at the time that a prescription is written. This is largely due to continued reliance on paper-based documentation systems which lend themselves to having important patient information be missing, inaccessible, illegible and inaccurate – all of which can contribute to prescribing errors.

While the Panel identified drug and dose selection as a place where errors can occur, it decided to focus its analysis and recommendations on areas of the medication-use system that occur *after* the point where such decisions are made. From a prescribing standpoint, this includes practices related to the transcription and transmission of prescription information which may contribute to patients not receiving the intended medication or dose. More information on these types of errors is included in the next section of this report.

Dispensing Errors

Dispensing errors occur when a patient is given a medication other than the one intended by the prescriber. These types of errors are often the result of sound/alike or look/alike drugs, according to testimony provided by Patricia Harris, Executive Officer of the California Board of Pharmacy. Ms. Harris noted that an increasingly reported mistake is the dispensing of the "right drug" to the "wrong person," often the result of similar names shared by several members of a family, many of whom may speak limited English.

To help address errors such as these, the California Board of Pharmacy created a requirement in 2002 for every pharmacy to adopt a quality assurance program. Such programs require pharmacies to document and identify the cause of any errors that occur, and develop systems and workflow processes designed to prevent the same type of error from occurring in the future.

The Panel heard testimony regarding other types of dispensing errors from Michael Cohen, RPh, ScD, founder and director of the Institute for Safe Medication Practices (ISMP). His data is based on voluntary reports of errors received by the ISMP from health practitioners and consumers nationally over many years. A summary of all the major medication error causes identified by

ISMP is listed in Table 1. Causes of dispensing errors include confusing drug names, labels, and/or packaging (look/sound alike problems); environmental, staffing, or workflow issues (poor lighting, excessive noise, workload, interruptions); lack of quality control or independent verification systems; missing patient information (allergies, age, weight, pregnancy); and missing drug information (outdated references, inadequate computer screening).

In relation to the last two causes, it is pertinent to note a California regulation which requires pharmacies to maintain records on all patients who have prescriptions filled at their pharmacy for at least one year. These records must include "patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent".[5] For the purposes of creating as complete a record as possible in one location, the Board of Pharmacy recommends that consumers use only one pharmacy when feasible.

By reviewing patient records, a dispensing pharmacist can determine whether a new medication the patient is being prescribed is appropriate and compatible (not contraindicated or in conflict with) with other medications the patient is already taking. Reviewing patient records in this way is called Drug Utilization Review (DUR) and is a very important safety feature.

Administration/Medication Use Errors

A key characteristic of the community setting that contributes to medication errors is that medications are administered by patients or other persons who are not health care professionals trained to do so. This is in sharp contrast to inpatient hospital settings where prescribers write orders for medications on patients' medical charts and drugs are subsequently administered by health care professionals. In hospitals, patients are often passive, and rely on others for their treatment. In community settings the opposite is true, and medication use is almost completely dependent upon consumer knowledge and motivation which can often be lacking. In fact, it has been estimated that people who are prescribed self-administered medications typically take less than half the prescribed doses.[6]

Many consumers simply do not understand what medications they are taking, their importance, their contraindications, or proper usage. In addition, consumers may not be asked by their health care professionals what non-prescription medications or supplements they are taking and may not know the importance of volunteering this information to avoid problems such as therapeutic duplications or interactions.

Because the majority of medication errors in community settings are made by consumers, it is clear that real progress will require significant efforts to improve consumers' knowledge, skills and motivation to use their medications correctly. Health care professionals and others involved with prescribing, dispensing, administering and monitoring medication use in community settings can all help achieve these goals.

TABLE 1: Institute of Safe Medication Practices' Major Causes of Medication Errors

- **Critical patient information is missing** (allergies, age, weight, pregnancy, etc.)
- **Critical drug information is missing** (outdated references, inadequate computer screening, etc.)
- **Miscommunication of drug order** (illegible, incomplete, misheard, etc.)
- **Drug name, label, packaging problem** (look/sound alike, faulty drug identification)
- **Drug storage or delivery problem**
- **Drug delivery device problem** (poor device design, IV administration of oral syringe contents, etc.)
- **Environmental, staffing, workflow** (lighting, noise, workload, interruptions, etc.)
- **Lack of staff education**
- **Patient education problem** (Lack on patient consultation, non-compliance)
- **Lack of quality control or independent check systems in pharmacy**
- **Physician knowledge is lacking** (when a drug comes to market that replaces an existing one or several ones, i.e., a combination drug may mean that a person takes it once a week instead of daily)

[5] California Code of Regulations, Title 16, Section 1707.1

[6] Haynes RB, Yao X, Degani A, Kripalani S, Garg AX, McDonald HP. Interventions for enhancing medication adherence. Cochrane Database Syst Rev 2005;(4):CD000011.

Working Towards Patient Safety: A Systems Approach

Several experts who testified to the Panel cited multiple reports indicating that efforts to address errors are best targeted not at a particular group of individual "wrong doers," but rather at faulty systems, processes, and conditions that either lead people to make mistakes or fail to prevent them. The Panel consequently agreed to take a "systems approach" for studying the problem and developing its recommendations.

As a result, the Panel spent considerable time examining each part of the medication-use process – prescribing, dispensing, using (administering/self-administering) and monitoring – and the inter-relationships of each component. The Panel determined the medication-use system to be quite complex involving a multitude of stakeholders. A detailed explanation of the entire system is beyond the scope of this report, but through its work, the Panel identified four key processes and three key stakeholder groups which served as the focus of its recommendations.

Key Medication Use Processes

Prescription, Transcription and Transmission Processes

Once a prescriber decides what medication and dose to prescribe, he or she must find a way to communicate that information to the pharmacy where the patient will have their prescription filled. It is through this communication where a significant proportion of prescription errors occur.

Often, prescribing information is communicated via handwritten prescriptions which employ the use of Latin abbreviations that can sometimes be confusing. These prescriptions can be illegibly written and may be submitted to pharmacies via fax which can further contribute to legibility problems. The most frequent problems of this sort are related to medication names (particularly for drugs that have "look-alike" names such as those in Table 2), and medication strengths.

Table 2: Look-alike/Sound-alike Drug Name Examples

Seroquel 200mg	**Serzone 200 mg**
Aciphex	**Aricept**
Hydroxyzine	**Hydralazine**
Zyprexa 10mg	**Zyrtec 10mg**
Quinine 324mg	**Quinidine 324mg**

Alternatively, the prescription can be communicated to a pharmacy verbally over the telephone but this mode of communication is not without its own challenges, such as the confusion of "sound alike" drugs (see examples in Table 2). These problems can be exacerbated through the use of non-professional medical office staff who may not be familiar with drug names and medical terminology. It should also be noted that whenever a person other than the prescriber is used to communicate prescription information over the telephone, they are almost always reading information that was written by another individual, which of course is subject to the same legibility issues as hard-copy prescriptions.

Electronic or "e-prescribing" is, most broadly, the transmission of prescription information from a prescriber to a pharmacy using computer technology. While recent efforts have been made by some prescribers and pharmacies to adopt e-prescribing, medical offices has been slow to do so, predominantly because of high-costs and a lack of incentives for providers to change their practices. Compounding the situation is the fact that state and federal e-prescribing standards have not been set or are inconsistent or conflicting.

Even when medical offices have the technology to facilitate e-prescribing, most do not fully employ it. Rather, they simply use their electronic record systems to send computer generated prescriptions via fax.

While some persons may consider the transmission of a prescription from a computer to a fax machine as "e-prescribing," others believe that transmitting a static image, picture or facsimile is of limited value to helping ensure information accuracy, quality control or data analysis. The benefit is maximized from e-prescribing only when prescriptions are transmitted in a manner so that a recipient may use and analyze the information without having to manually copy or enter the data received.

The end goal with e-prescribing should be full system connectivity between pharmacies and medical offices to allow for *two-way* communication. Such connectivity could better leverage pharmacy data and has the potential to notify prescribers of possible medication-related problems before they occur.

Another problematic aspect of the prescribing process is that it frequently does not engage the consumer to an appropriate degree. All too often patients leave the prescriber's office without having the adequate medication-related information effectively communicated to them. Of particular concern are the consumers who present to the pharmacy without knowing the most basic information such as the name of the medication or what it is for. Without this minimal knowledge, there is very little consumers can do on their own to identify errors – even the most obvious ones such as receiving the wrong medication.

Consumer Education Processes

At the center of the medication-use process is the consumer. In the community setting, successful medication use is heavily dependent upon consumer knowledge and motivation which can often be lacking. When a person is not well-informed and motivated to manage their therapy, they cannot be expected to take their medication correctly or be an active partner in screening for signs and symptoms of medication efficacy or toxicity. There are a variety of complex reasons why many consumers allow themselves to be passive participants in the medication use process but the most significant is that consumers are largely unaware of, or do not accept the personal risks associated with medication use.

In addition to the consumer education challenges that pertain to the prescribing process, the Panel identified other aspects of the medication use process that could be modified to provide patients with better information and tools to reduce medication errors.

Pharmacist Consultation

While pharmacists are widely known for their dispensing activities, they can also play an important role educating consumers to ensure that the patient or their caregiver knows what the medicine is for, how to take it correctly, and what signs/symptoms should be monitored to assess for efficacy and toxicity.

State regulation requires pharmacists to provide a verbal medication consultation to the patient or the patient's agent each time a new medication is dispensed, or whenever an existing medication therapy is dispensed with a change in dosage form, strength or instructions for use.[7] This consultation is to include "directions for use and storage and the importance of compliance with the directions." Also included should be a "discussion of the precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered."

In spite of these requirements, the Panel received testimony suggesting considerable variability in the quality of these consultations as well as the consistency to which they are offered by pharmacy staff and utilized by consumers. The reasons for this are not well defined but there appear to be contributing factors from both the pharmacist end (lack of time and incentives) and the consumer end (lack of awareness regarding availability and perceived value).

While there is not a lot of data about the effectiveness of this dispensing-related counseling, it is reasonable to assume that the significant number of consumer-related medication errors could be positively influenced by greater efforts in this arena, particularly with at risk populations including seniors and minority patients.

Prescription Labels and Labeling

The information that consumers need to know about their medication is often complex and may include unfamiliar language or concepts. Expecting a consumer to retain all the pertinent knowledge from a brief verbal encounter may not be reasonable in many instances. For this reason, it is important that consumers also receive written information regarding their prescription.

Often-times however, even this information can be forgotten and lost, and in those instances, the consumer may be left with nothing more than the prescription packaging and label to guide them. Testimony provided to the Panel identified many limitations related to the prescription label as an effective communication tool. These included the limited size of a prescription label (approximately 2 x 3 inches) which, due to established pharmacy systems, processes, and drug container variability would be functionally and financially difficult for the pharmacy industry to change.

Further complicating matters is the fact that there is already a significant amount of information required by California law to be printed on the label.[8] The most recent label requirement went into effect on January 1, 2006 and was created to help consumers identify erroneously filled prescriptions by mandating that pharmacies include the physical description of the dispensed medication, including its color, shape, and

[7] California Code of Regulations, Title 16, Section 1707.2

[8] California Business and Professions Code 4076

any identification code that appears on the tablets or capsules.

While this requirement is obviously directed at reducing errors, one might question the utility of some of the other label requirements which include the date of issue, the name of the pharmacy, the address of the pharmacy, the prescription number or other means of identifying the prescription, the name of the patient, the name of the prescriber, the name of the medication, the name of the medication's manufacturer, the strength of the drug, the quantity dispensed, the expiration date of the drug, and of course the directions for use. Given the limited space available, are all of these elements the most valuable pieces of information for the patient?

Regarding the directions of use, even when individuals are able to read and repeat back the directions, they may still not understand how to take the medication. This is particularly a problem for individuals with limited health literacy (the ability to read, understand and act on health information). A recent study by Davis, Wolf and others showed that even though 70.7% of patients with low literacy could correctly read and repeat the instructions, "Take two tablets by mouth twice daily," only 34.7% could accurately demonstrate the actual number of pills to be taken daily.[9] In this study the researchers found that it was common for consumers to make mistakes when dosing medicine for themselves, their elderly parents, and their children.

Tailoring and Targeting Consumer Education Efforts

To maximize the impact of consumer education activities, efforts will need to be tailored and targeted to individuals who are likely to achieve the greatest benefit. While the Panel did not come to consensus on the most important subset of consumers that are at "high risk" for medication errors, it did acknowledge that there are a variety of factors which may increase an individual's risk for experiencing a medication error.

In addition to 1) low health literacy, these can include; 2) limited English proficiency; 3) cultural incongruence with healthcare providers; 4) physical, cognitive and/or other impairments that make understanding and/or complying with medication instructions difficult; 5) age at either end of the age spectrum (the variability of a medication's response, metabolism and dose increases in children and seniors); 6) multiple medications; 7) multiple prescribers; 8) non-prescription medication use (including herbals, dietary supplements alcohol and tobacco); and 9) medication procurement from more than one pharmacy including mail-order. These factors must be taken into consideration in the development of any consumer education efforts.

Provider Payment/Incentive Processes

Incentives that directly or indirectly influence the behavior of prescribers and pharmacists are a key aspect of the medication use system. Testimony provided to the Panel indicated that prescriber incentives are frequently not aligned to promote spending time educating patients about medication use, or to closely follow patient compliance and medication monitoring parameters.

A fairly recent collaboration between healthcare purchasers, payers and medical groups provides incentives byway of "pay-for-performance" and shows promise for realigning prescriber incentives to reward behavior that results in positive outcomes. However, it is clear that there is still room for improvement in this area, particularly as it relates to safe and effective medication use.

Similarly, pharmacy incentives appear to do little to encourage pharmacist activity in areas related to patient education and the promotion of safe and effective medication use. Since pharmacies generally only receive compensation when a product is dispensed, financial pressures may, in fact, be driving pharmacy processes and personnel to minimize any activities not directly related to product distribution. Ironically, the structure of this financial model may possibly create disincentives for pharmacists to identify and prevent prescriptions with prescribing errors from leaving the pharmacy.

Fortunately, testimony provided to the Panel suggests that the healthcare system may be in the very early stages of what could be a paradigm shift. It appears that increasing numbers of healthcare purchasers and payers are beginning to understand that there is more to consider when it comes to medication than the simple cost of distribution, and the speed and convenience by which it can be put into the hands of consumers. There is a growing recognition that no matter how cheaply a drug can be purchased, the cost is too great if it does not elicit the desired effect, or worse, causes patient harm.

In response to this growing recognition, more and more healthcare purchasers and payers are developing

[9] Davis TC, Wolf MS, Bass PF 3rd, Thompson JA, Tilson HH, Neuberger M, et al. Literacy and misunderstanding prescription drug labels. Ann Intern Med. 2006;146:887-94.

specialized initiatives focused around improving medication use, particularly in target populations where safe, appropriate and effective medication use is critical. These "medication therapy management programs" have been developed for people with particular conditions such as diabetes[10], individuals who have multiple chronic conditions and/or take multiple medications, and those whose medication costs exceed a certain threshold.

Perhaps the most prominent example of this early trend is the requirement placed in the Medicare Modernization Act for sponsors of the Medicare Part D drug benefit to have in place a medication therapy management program designed to promote optimal therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions.

While medication therapy management programs may hold significant promise for reducing medication errors, many issues will need to be resolved before the full potential of such programs can be known and realized. As with any new healthcare initiative, there is uncertainty regarding how the quality and financial returns-on-investment can be maximized by adjusting program variables such as:

- The types of services that are provided (e.g. patient education, medication compliance packaging and comprehensive medication reviews);
- The patient populations that are targeted (e.g. those with a particular condition, medication, cost, or combination thereof);
- The types of providers who deliver various services (e.g. physicians, nurses and pharmacists);
- Service delivery models (e.g. face-to-face, telephone or mail); and
- Payment and documentation methodologies.

Until there is more information and standardization around issues such as these, the spread of medication therapy management programs will likely be slower than perhaps it should. Nonetheless, the fact that innovative purchasers and payers of healthcare are developing novel models to incentivize physicians, nurses, and/or pharmacists to pursue behaviors that will decrease medication errors is a positive step in the right direction.

Healthcare Provider Training and Licensure Processes

Obviously, simply aligning incentives to encourage safe medication practices among healthcare providers is not enough. Providers must also be cognizant of the seriousness of medication errors, know the behaviors to adopt that will reduce errors, and possess the knowledge and skills to effectively execute those behaviors.

Healthcare providers undergo extensive training to become licensed practitioners. Subsequent to licensure, providers must continue training to maintain their licenses. The vast majority of this training is clinical in nature. Most providers receive little education on subjects such as healthcare administration, error prevention, patient communication, and effective, systematic approaches to medication therapy management.

While testimony provided to the Panel indicates that some formal education on topics related to medication errors may be included in provider training programs, the very size of the medication errors problem suggests that the current amount may not be enough. More education in these areas would likely promote greater awareness among providers about what they can do to protect consumers. Informed providers can also be powerful advocates of change in a variety of healthcare settings.

Key Stakeholder Groups

In addition to the four key processes, the Panel identified three key stakeholder groups believed to play critical roles in the development and implementation of initiatives designed to address medication errors.

Consumer-Oriented Organizations

Since the consumer is at the center of the medication use process, it is imperative that all relevant consumer organizations be solicited to join the effort to prevent medication errors. These organizations can play critical roles in educating consumers about medication errors and advocating for healthcare policy and practice changes that have the potential to reduce errors. These groups may be government-related (e.g. the California Department of Consumer Affairs), private foundations, member-benefit organizations (e.g. AARP), or public-benefit organizations.

[10] Information was presented to the Panel on APhA Foundation's Asheville Project. Details can be found at www.aphafoundation.org/programs/Asheville_Project

Healthcare Provider Groups and Related Entities

Healthcare providers such as physicians, nurses and pharmacists are on the front lines of healthcare. In many respects, the burden of reducing medication errors will fall largely on their shoulders. A problem of this scope and size, however, cannot be solved by any single group of individuals, or even by a single sector of the healthcare system acting alone.

Any appreciable reduction in medication errors will require that the entities which support, direct, or influence provider behavior also be actively engaged in addressing this problem. These entities include the academic institutions and professional societies that train providers; the associations that advocate for them; the individuals that mange them; the companies that employ them; and the oversight boards that license and regulate them.

Healthcare Purchasers, Payers and Related Entities

The group that has perhaps greatest opportunity to influence the healthcare system consists of the entities that actually purchase and administer healthcare benefits – and to some extent, those which regulate and oversee the activities of these groups. Many of these entities have the power to decide which healthcare-related behaviors and outcomes are truly of value, and they can create payment structures, non-financial incentives and/or requirements to drive processes and behaviors that seek to deliver those results.

Stakeholders in this group include: the State of California which uses taxpayer monies to purchase, and through its Department of Health Services, administer healthcare benefits through programs such as Medi-Cal; private purchasers of health care such as employers which purchase healthcare for a majority of Californians under 65; commercial insurance companies which administer health benefits for both public and private sector purchasers; the California Departments of Insurance and Managed Health Care which regulate these insurance companies; pharmacy benefit managers which focus specifically on the administration of pharmacy benefits; and, of course, the Legislature and Administration of the State of California which possess the potential to influence and/or establish accountability for these groups.

Conclusion

Based upon the information provided to the Panel, and the identification of these key processes and stakeholders, the Panel developed 12 consensus recommendations in the following subject areas:

- **Communication Improvements** with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients;
- **Consumer Education** to increase consumer awareness regarding the proper use, and dangers of misuse, of prescription and over-the-counter medications;
- **Provider Standards and Incentives** with a focus on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety;
- **Training and Education for Healthcare Providers** on various medication safety practices;
- **Research** with a focus on obtaining information about the incidence, nature and frequency of medication errors in the community setting.
- **Other Topics to be Addressed** which were determined to be beyond the scope of the Panel but which the Panel recognizes must be addressed hand-in-hand with other practice enhancement efforts in order to assure success in the current and future marketplace and workforce environments.

The recommendations are provided in their entirety in the next section of the report.

SECTION II: RECOMMENDATIONS

A. Communication Improvements

Background:

Improving the quality of communication among prescribers, pharmacists and patients is critical to the success of any effort aimed at decreasing medication errors. The existing process for communication among health professionals and their patients leaves much room for improvement, according to testimony received by the Panel. Indeed, California health practitioners have been slow in their adoption of computer-based patient records and electronic prescribing.

Currently, pharmacist-patient consultation is often compromised by the pharmacist's lack of knowledge of the prescriber's treatment objectives, including such basic information as the condition being treated. Confirming prescriber intent with the patient at the time of dispensing is an additional means of confirming that the medication treatment is understood and properly implemented.

In addition, prescribers' lack of writing legibility has long compromised pharmacists in their efforts to correctly dispense the desired drug product and provide accurate instructions for use. Addressing these two problems of communication between prescribers and pharmacists has been shown to substantially decrease medication errors.

In regard to communication between consumers and their health care providers, an important step would be to adopt techniques that bridge the language and cultural diversity of the patient population in California. This would provide the prescriber and pharmacist with the means to confirm that the medication treatment is understood and will be properly implemented.

Another important improvement in communication between health care providers and their patients would result from improved readability of drug labels and user-friendly packaging.

Goal 1: Improve prescriber-pharmacist communication quality and accuracy regarding prescriptions.

Recommendation 1

Improve legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies (allowing for some exceptions) to use electronic prescribing.

Methods

1.1 Require each prescription to be legibly hand written or printed, computer generated or typed, and by 2010 that all prescriptions be computer generated or typed.

The California Board of Pharmacy and the California Medical Board shall review and seek modification of statutory and regulatory requirements as needed to implement adoption of computerized prescriber order entry (CPOE) systems and secure 2-way electronic communication between prescribers and pharmacies, with consideration for identified exceptions to the requirement.

1.2 Require the California Medical Board to collect and disseminate information in order to educate and assist physicians about the benefits of and ways to adopt electronic prescribing systems and supporting CPOE and secure 2-way transmission to pharmacies. Coordinate these efforts with related activities undertaken by the State. For example, Executive Order S-12-06 was issued by Governor Schwarzenegger on July 24, 2006 regarding efforts planned to make reforms regarding healthcare, especially regarding health information technology.

1.3 Require the California Medical Board to adopt regulations by January 1, 2008 that require

prescribers using electronic prescription systems to provide patients with a written "receipt" of the information that has been transmitted electronically to a pharmacy. The document should include at least the patient's name, the dosage and drug prescribed and the name of the pharmacy where the electronic prescription was sent, and should indicate that the receipt cannot be used as a duplicate order for the same prescription.

Goal 2: Improve prescriber-pharmacist and pharmacist-consumer communications to enhance understanding of the intended use of prescribed medication.

Recommendation 2

Require that the intended use of the medication be included on all prescriptions and require that the intended use of medication be included on medication label/labeling unless disapproved by the prescriber or the patient.

Methods

2.1. Require the California Board of Pharmacy and the California Medical Board to pursue necessary statutory and/or regulatory changes to require that by January 1, 2008 these entities coordinate efforts to develop plans to require prescribers to include the diagnosis, medical condition, symptoms or other indicators of the intended use of the medication on each prescription written, allowing for some exemptions.

2.2. Require the California Board of Pharmacy to pursue necessary statutory and/or regulation changes to require that the intended use of any prescribed medication be included on the medication label, unless the prescriber or consumer disapproves, and consumer disapproval is documented by the pharmacist.

Recommendation 3

Improve access to and awareness of language translation services by pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.

Methods

3.1 The California Board of Pharmacy, Department of Health Services and/or the Department of Consumer Affairs should develop and implement methods, when possible in coordination with other state entities, that are designed to reduce barriers for pharmacists at community pharmacies to access and utilize language translation services. These entities should report their respective related activities planned and undertaken annually on their respective websites and to the Assembly and Senate health committees, beginning January 1, 2008. They should, but not be limited to distributing information to pharmacies about the pharmacies' obligations to provide language translation services and resources for pharmacies to do so via the telephone.

Messages related to this method and goal should be included in the public awareness campaign (Recommendation #6) to inform consumers about their right to use language translation services and availability of these services at community pharmacies and other health care providers.

Recommendation 4

Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain a medication consultation from a pharmacist.

Methods

4.1 Require the California Board of Pharmacy to examine the existing requirements for prescription container labels, prescription containers, and supplementary consumer information, and to consider revising these requirements to encompass required, supplemental consumer information and California Board of Pharmacy contact information.

Require these finding be issued by January 1, 2009 and distributed to the Senate and Assembly Health committees, posted on the California Board of Pharmacy's website and that public notice be made by issuance of a press release.

4.2 Encourage prescription drug plans, health care service plans, and health insurance companies to develop strategies to provide incentives for pharmacies and drug manufacturers to package medications in a manner that increases medication compliance, safety and efficacy.

4.3 Require the California Board of Pharmacy to adopt regulations mandating all pharmacies, including non-resident pharmacies, provide written materials with all dispensed prescriptions that inform consumers of their right to receive a medication consultation from a pharmacist with any new or changed prescriptions. These regulations should include enforcement provisions and the California Board of Pharmacy should make enforcement a priority.

B. Consumer Education

Background:

There is a great need to increase consumer awareness of the proper use, and dangers of misuse, of prescription and over-the counter-medications. Consumers often do not appreciate the potency and risks involved in the use of drugs that are widely advertised and promoted on television, radio and print media.

The California Board of Pharmacy is in an excellent position to spearhead an educational effort directed toward the public concerning drug safety issues. In recent years, the Board has been recognized nationally for its consumer protection efforts. A Board program that capitalizes on their proven expertise in consumer safety and which takes into account health literacy and culturally appropriate communication could be very effective in alerting consumers to potential medication errors, and in motivating them to adhere to their drug treatment instructions. A commitment by the State of California to capitalize on this proven expertise will go far to aid consumers in understanding their role in recognizing potential medication errors and preventing injury from those that do occur.

Goal 3: Improve consumer awareness and knowledge about the risks of medication errors and about steps they can take to reduce their risk of medication errors.

Recommendation 5

Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.

Methods

5.1 Propose legislation allocating funds to and requiring the California Board of Pharmacy to:

a) Identify effective methods for educating consumers about ways to prevent and report medication errors. Include methods that are culturally and linguistically appropriate, especially addressing the needs of persons at high-risk for medication errors.

b) Develop guidelines and/or related regulations to define ways for effectively educating consumers to prevent medication errors. Include both verbal and written education strategies.

c) Disseminate information about the methods and guidelines/standards to specific relevant public and private sector entities, including mail-order (non-residential pharmacies) and pharmacies that dispense prescriptions to outpatients.

d) Improve public access to California Board of Pharmacy services (e.g., telephone, mail, and internet).

Recommendation 6

Establish an on-going public education campaign to prevent medication errors, targeting outpatients and persons in community settings.

Methods

6.1 Pass legislation allocating funds to and requiring the Department of Consumer Affairs and/or the California Board of Pharmacy to oversee development and implementation of a public education campaign to reduce medication errors. Public and/or private funds may be pursued.

The campaign shall be based on principles of public health practice and shall use methods that have been shown effective in educating consumers. The methods shall be culturally and linguistically appropriate and shall be developed in collaboration with other state entities.

The campaign shall develop messages that educate consumers about their medication use, risks, rights and responsibilities and shall include a consumer's right to basic consultation from a pharmacist with each new or changed prescription.

6.2 Require the California Board of Pharmacy and/or the Department of Consumer Affairs to collaborate with appropriate state entities and stakeholder groups, including but not limited to health plans, retail pharmacists, and consumer advocates representing persons at high risk for medication errors to:

a) Develop an evidence-based "safe medication use curriculum" that is designed to be used for educating consumers, and promote its availability to intermediaries, such as health care service plans, colleges, high schools, health insurers, Medi-Cal providers, and healthcare providers throughout the state who can educate consumers.

b) Post the curriculum on the websites of the relevant state departments and promote its availability through issuance of a press release and other public notice activities;

c) Develop and disseminate suggested strategies, possibly unique to each intermediary, to encourage consumers to attend presentations based on the curriculum.

d) Create a web-based interactive version of the curriculum that will be posted on websites of designated state entities and require those entities to promote the availability of the curriculum via no or low cost methods, such as press releases, faxes and email.

e) Coordinate this activity with the efforts to educate health care professionals about medication errors and prevention issues in Goal 5, Recommendation 10.

6.3 Recommend that the California Medical Board and the California Board of Pharmacy encourage physicians and other prescribers to post notice in their offices informing consumers of their right to know, and the benefits of understanding the name of any medication prescribed and the indication(s) and instructions for use, in addition to their right to consult with a pharmacist.

Recommendation 7

Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.

Methods

7.1 Require the California Board of Pharmacy and/or the Department of Consumer Affairs to collaborate with a cross-section of public and private sector entities, including prescription drug plans, health care service plans, health insurers, and/or mail-order pharmacies, to support and/or undertake efforts to educate consumers about safe medication use. Use legislative and regulatory means to ensure a joint effort is made by all agencies that regulate these entities to collaborate in these efforts.

C. Provider Standards and Incentives

Background:

The drug consultation given by a pharmacist to their patient, or the patient's agent, can be a powerful means for educating consumers about drug safety. However, current law regarding pharmacists' consultation contains only the minimal requirements that were established in the early 1990s. In light of the substantial changes the State's health care system has undergone since that time, a re-examination of the pharmacist's consultation requirement is in order.

The Panel recommends that the Board of Pharmacy establish new pharmacist consultation standards that would provide greater benefit and protections to the public. Consistency should be a key component of the new standards, and they should take into account the economic and workforce conditions that impact the ability of pharmacists to provide this essential service.

Medication therapy management programs (MTM) provide another important tool in avoiding medication errors. The purpose of these programs is to evaluate whether prescribed medications are yielding desired results and, if not, to recommend or implement adjustments to therapies to maximize outcomes. To properly protect consumers, MTM programs should meet minimum standards for provider qualifications and program design.

Goal 4: Improve the quality and availability of pharmacist-patient medication consultation.

Recommendation 8

Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.

Methods

8.1 Require the California Board of Pharmacy to review and, as needed, revise current regulations regarding patient consultation to focus on what would actually be useful to patients to help maximize their therapeutic outcomes and take their medications safely and effectively.

The California Board of Pharmacy shall invite stakeholders, including consumer representatives, to collaborate to develop minimal standards for required consultation. These deliberations should consider factors that reflect the current conditions of the business and healthcare environments, various types of pharmacy practices and practice settings (e.g. community, mail-order, extended care), and the "learning environment" available in those settings for providing consultation. The standards should be applied equally to all providers or entities dispensing medications to California consumers, including non-resident pharmacies.

Nothing in consideration of these standards shall preclude pharmacists from being paid for services that exceed these minimal standards.

These standards should address, at a minimum:

a) Encouraging or providing incentives to pharmacists for providing patient medication consultation with prescription renewals, when appropriate.

b) Re-examining the circumstances involved with patients' refusal of consultation, and what type of documentation is required, if any, for patients who refuse consultation. The Panel strongly emphasized that the following factors be considered as part of the re-examination process: (1) prohibiting any pharmacy employee from asking a patient or patient's agent if he/she wants pharmacist prescription consultation (i.e. no "screening" questions) and (2) requiring that the patient communicate the refusal of consultation directly to a pharmacist.

Recommendation 9

Establish standards for medication therapy management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers

Methods

9.1 Require the California Board of Pharmacy to identify best practices and to develop evidence-based standards of care for MTM programs, and to disseminate these to known MTM providers, the Department of Health Services, Department of Managed Health Care, Department of Insurance, the Managed Risk Medical Insurance Board, CalPERS, California Medical Board, and to applicable professional and healthcare associations (e.g. California Medical Association, California Pharmacists Association, California Association of Health Plans).

9.2 Require the Department of Health Services, Department of Managed Health Care, Department of Insurance, Managed Risk Medical Insurance Board, California Medical Board, Board of Registered Nursing, Board of Pharmacy, and appropriate private sector entities to develop and implement strategies to incentivize payers, pharmacists and other healthcare providers to implement and routinely use MTM standards of care. These public entities shall report their respective related activities to the Assembly and Senate Health Committees, and to notify the public by posting descriptions of their activities and/or any findings on their websites and notifying the public and media by issuing one or more press releases.

9.3 Consistent with the standards developed in this recommendation, require the Department of Managed Health Care, the Department of Health Services and the Department of Insurance to allow health plans, health insurers, and Pharmacy Benefit Managers flexibility in methods of implementing MTM programs, including via face-to-face interaction, call center advice lines, and secure e-mail communication.

9.4 Encourage state-funded programs (e.g., Medi-Cal and CalPERS) to establish financial and other incentives for healthcare providers and patients improving drug therapy compliance, including cases of over-use (including therapeutic duplication) and under-use of prescription medication.

D. Healthcare Provider Training and Education

Background:

Good communication skills are essential in the current health care environment, and are a key tool in reducing medication errors. Pharmacists and other health care professionals must take into account their patients' language skills and cultural characteristics in order to effectively convey essential information to them. There is therefore a need to educate prescribers and pharmacists concerning improved ways to help their patients understand the proper use of medications, the importance of complying with their treatment regimen, and the need to report any problems to their prescriber or pharmacist.

Considering the ever increasing numbers of patients who have conditions that can be managed with therapies that are frequently long-term and involve the use of multiple medications, healthcare providers are also likely to benefit from more training and education around the intricacies of medication therapy management (MTM). While much of this information is already an integral component of pharmacist training, many of the skills needed to apply it are distinct from a pharmacist's traditional dispensing role. Consequently some pharmacists may have a need to obtain other types of training as well.

Goal 5: Improve education and training of pharmacists and other health care professionals about medication errors and prevention methods.

Recommendation 10

Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.

Methods

10.1 Require that the licensing boards for relevant health care professionals (e.g., pharmacists, physicians, nurses, dentists and optometrists) establish specific requirements for training/education about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, and medication therapy management methods) as part of licensure, certification, and/or continuing education requirements. Further, require these boards to report their findings and plans for improving their requirements in this regard to the appropriate cabinet-level position, the Assembly and Senate Health Committees, and the public through posting of the report on their websites and issuing one or more press releases.

10.2 Encourage the colleges, universities, and schools that provide degree programs for health care professionals (e.g., pharmacists, physicians, nurses, dentists, optometrists, pharmacy technicians) to establish and maintain specific curricular requirements about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, medication therapy management methods).

10.3 Encourage employers of healthcare providers, as well as the healthcare professional associations (e.g., the California Medical Association, California Pharmacists Association, California Society of Health System Pharmacists, and California Nurses Association), to establish and maintain ongoing training and educational activities for their respective constituencies about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, medication therapy management methods).

10.4 Require that the licensing boards of relevant healthcare professions (e.g. pharmacists, physicians, nurses, dentists and optometrists) evaluate the effectiveness of their respective licensing requirements (e.g. board examinations) in determining a licentiate's ability to communicate medication-related information and instructions to consumers in a manner that reduces the risk of medication errors related to patient misunderstanding. Further, require these boards to report their findings and plans for improving their requirements in this regard to the appropriate cabinet-level position, the Assembly and Senate Health Committees, and the public through posting of the report on their websites and issuing one or more press releases.

E. Research about Prevalence & Occurrence of Medication Errors

Background:

Obtaining information about the incidence, nature and frequency of medication errors in the community setting is challenging. Most research on medication errors has been conducted in hospitals, even though the drugs administered in inpatient settings represent a very small proportion of medications dispensed. Indeed, there is comparatively little academic research available regarding medication errors occurring in the community setting. While it appears that this situation is beginning to improve, a greater emphasis on research related to medication errors in the community setting is definitely warranted.

Goal 6: Increase evidence-based information about the nature and prevalence of medication errors available to policy-makers, pharmacists, consumers, and other interested parties.

Recommendation 11

Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.

Methods

11.1 Require by legislation, regulation, joint legislative resolution, and/or issuance of a Governor's Executive Order that the California Board of Pharmacy establish an agreement with a private sector organization, such as the Institute of Safe Medication Practices (ISMP), to establish a pilot project to collect and analyze data about the nature and prevalence of medication errors at California community-based pharmacies.

Require that the cost of this project to the State be negligible.

Require the California Board of Pharmacy to share data about medication errors reported to it with the entity responsible for implementing this recommendation and that the Board collaborate with the entity responsible for implementing this recommendation to promote the project to consumers, pharmacies and providers. The project should ensure that:

a) Prescribers, pharmacists and consumers may voluntarily and confidentially report errors to the ISMP or other responsible entity.

b) The entity responsible for implementing this recommendation report annually to the California Board of Pharmacy, the California Medical Board and the Senate and Assembly health committees, and that these reports indicate if an error occurred either under the auspices of a health care facility or in a community setting (i.e., retail pharmacy or private residence) and the severity of the error (i.e., if it resulted, contributed or may have been associated with death, hospitalization or serious injury).

c) The information collected and reported by this project should not be used in any legal proceedings against prescribers and/or pharmacists.

d) The project be designed to minimize conflict with existing systems that are used to collect data from pharmacies as part of their current California Board of Pharmacy Quality program.

e) Efforts to inform consumers about this project include information handed out at pharmacies, on medication information sheets, and with related public education campaigns.

f) The California Board of Pharmacy and the Medical Board post the reports produced by this project on their respective websites.

g) Persons reporting errors to the entity responsible for implementing this recommendation be informed of their right to also report errors to the California Board of Pharmacy and the benefits of doing so.

F. Other Topics to be Addressed

Background:

The many obstacles that pharmacists face in providing drug consultation to their patients as required by law are exacerbated by the lack of a payment system that would compensate them for the time and expense associated with performing these mandated tasks. Before additional duties can be imposed on pharmacists practicing in the outpatient setting, changes to the health care financing/ reimbursement system must occur. This issue was beyond the charge of the Panel, but it was recognized to be an issue that must be addressed hand-in-hand with other practice enhancement efforts in order to assure success in the current and future marketplace and workforce environments.

Goal 7: Develop strategies designed to increase incentives for pharmacists to offer and provide medication consulting and medication therapy management services to consumers.

Recommendation 12

Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.

Methods

12.1 The Legislature should convene a panel of stakeholders representing California pharmacists, healthcare providers, consumer groups, payers, health plans and other perspectives to hold a series of public meetings and issue recommendations addressing the reimbursement of pharmacists for non-dispensing services.

Reimbursement for medication consultation should be based on standards of care (see recommendations and discussion under Goal 4). If such standards have not been adopted at the time that the panel is convened, then the panel should make recommendations to the California Board of Pharmacy about development of the standards.

In considering recommendations for reimbursing pharmacists for patient medication consultations, the panel should weigh factors based on patient-specific information, including, but not limited to time spent providing the consultation or complexity of the consultation (the number of medications taken by the consumer, the consumer's compliance challenges, language, literacy or translation needs, or patient diagnosis). Additionally, the panel should take into account the most current thinking on this subject from relevant regional or national entities such as the US Centers for Medicare and Medicaid Services, Quality Improvement Organizations, and pertinent payer and provider organizations.

SECTION III: APPENDICES

Appendix A: Panel Meeting Dates and Speakers

The Medication Errors Panel held 12 meetings in Sacramento, the first on May 5 and the last on November 16, 2006. Presentations were made to the panel by persons listed below on the dates indicated.

May 5
- Senator Jackie Speier, Panel Chair and Author of SCR 49
- Senator Sam Aanestad, Panel Member
- Lynn Rolston, CEO of CA Pharmacists Association
- Robert MacLaughlin, Aging and Long Term Care, Senate Health Subcommittee
- John Gilman, Assembly Health Committee
- Dawn Adler, Office of Assemblymember Betty Karnette
- Sang-ick Chang, M.D., San Mateo County Medical Center
- Michael J. Negrete, Pharm.D., Pharmacy Foundation of CA

May 19
- Eleanor M. Vogt, R.Ph., Ph.D., Health Sciences Clinical Professor and 2004 – 2005 Presidential Chair, UC San Francisco School of Pharmacy
- Patricia Harris, Executive Director, Board of Pharmacy
- John Gallapaga, SmartRx for Seniors
- Lisa Chan, Office of Assemblymember Wilma Chan

June 2
- Michael Cohen, R.Ph., MS, FASHP, founder of the Institute for Safe Medication Practices (ISMP)
- Patricia Harris, Executive Director, CA Board of Pharmacy
- Dave Thornton**,** Executive Director, CA Medical Board
- Dr. William Soller, PhD, Executive Director, Center for Consumer Self-Care, University of CA, San Francisco

June 16
- Bill G. Felkey, Professor, Pharmacy Care System, Auburn University, Alabama
- David Murphy, SureScripts
- Pam Bernadella, RPh, Manager, Pharmacy Professional Services, Target Corporation, Minnesota

June 30
- Victoria Bermudez, RN, CA Nurses Association
- Lori Hack, Interim CEO, CA Regional Health Information Organization
- Sharon Youmans, Pharm.D, MPH, Professor of Clinical Pharmacy, University of CA, San Francisco

August 11
- Dr. Robert E. Lee, Jr., Eli Lilly, and U.S. Food and Drug Administration Trademark Focus Group Member
- Tom Williams, CEO, Integrated Healthcare Association
- David Murphy, SureScripts and Get Connected CA
- Carmella Gutierrez, Lumetra
- Peter Boumenot, Lumetra, Electronic Health Records Implementation Consultant

August 25
- Paul Tang, MD, Vice President, Chief Medical Information Officer, Palo Alto Medical Foundation, Sutter Health

- Susan L. Ravnan, Pharm. D., Associate Professor, University of The Pacific Thomas J. Long School of Pharmacy and Health Sciences; CA Society of Health System Pharmacists representative

September 15
- Robert Friis, PhD, California State University Long Beach, Department of Health Sciences Chair, and American Public Health Association Southern California Chapter President
- Gurbinder Sadana, MD, FCCP - Director of Critical Care Services, Pomona Valley Hospital Medical Center; California Medical Association representative

September 29
- Panel committees begin work of drafting recommendations for final report

October 13
- J. Kevin Gorospe, Pharm. D., Chief, Medi-Cal Pharmacy Policy Unit
- Loriann De Martini, Pharm.D., Chief Pharmaceutical Consultant, Licensing and Certification Division, Department of Health Services

November 2
- Senator Jackie Speier, Panel Chair, met with the Panel to discuss major issues, and Panel's progress on developing final recommendations

November 16
- Final meeting of the Panel to discuss recommendations

Appendix B: Prior Legislative Efforts to Address Medication Safety

The following legislation relevant to the objectives of the Panel has been enacted:

- SB 1339 (Figueroa) became law in 2000 and requires pharmacies to establish quality assurance programs to reduce frequency of medication errors. Every pharmacy is required to have a system of tracking and assessing errors so that the proper steps can be taken to reduce the chance of a reoccurrence. It exempts any documents generated by the program from legal discovery proceedings.

- SB 1875 (Speier), 2000, requires hospitals and surgical centers to develop medication error reduction plans and submit the plans to the Department of Health Services. In order for a health facility or clinic to obtain a license it must complete a plan to eliminate or substantially reduce medication error by 2005.

- SB 292 (Speier) 2003, requires labels on pill bottles to include a written description of the drug that was prescribed, including its color, shape, and any identification code appearing on the tablets or capsules. (This bill initially sought to have a color image of the pill or tablet printed on the bottle label.)

- SB 151 (Burton), 2004, requires that tamper-resistant security forms be used for nearly all *written* prescriptions for controlled substances (Schedules II-V). This pre-printed and numbered form must contain at least ten security features and replaces the Schedule II triplicate prescription forms. Pharmacies must report Schedule III prescriptions to the CURES program.

There were six bills before the legislature during the 2005-2006 session that had objectives relevant to medication safety. They were the following:

- AB 71 (Chan) would have established the Office of the California Drug Safety Watch to administer a database of information about the safety and effectiveness of highly advertised prescription drugs. The database was to include reports of adverse drug reactions (ADRs) which would have been accessible to health professionals and the public. This bill is inactive.

- AB 657 (Karnette) would have required that the purpose or indication of a medication be listed on the prescription label if a prescriber had written it on the prescription. This bill is inactive.

- SB 1301 and SB 380 were both introduced by Senate Elaine Alquist in 2005. SB1301 was chaptered September 29, 2006 and requires acute care facilities to report ADRs to the Department of Health Services within five days of the occurrence. SB 380 originally contained a mandatory reporting requirement to the federal Food and Drug Administration for all serious ADRs, but was amended to address a non-related issue.

- SB 329 (Cedillo) 2005, would have established the California Prescription Drug Safety and Effectiveness Commission within the California Health and Human Services Agency. The Commission would request assistance from a unit of the University of California and be a repository of information about prescription drug safety and effectiveness. In February 2006, this bill was returned to Secretary of Senate pursuant to Joint Rule 56.

- AB 72 (Frommer) 2005, would have established the Patient Safety and Drug Review Transparency Act in order to ensure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. On January 31, 2006, this bill died on the inactive file.