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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: October 21 and 22, 2009

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

BOARD MEMBERS PRESENT:
Kenneth Schell, PharmD, President
Randy Kajioka, PharmD, Vice President
Stanley C. Weisser, RPh, Treasurer
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Greg Lippe, Public Member
Robert Swart, PharmD
Shirley Wheat, Public Member

BOARD MEMBERS NOT PRESENT: Ryan Brooks, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Schieldge, DCA Staff Counsel
Tessa Fraga, Staff Analyst

Call to Order

President Schell called the meeting to order at 9:03 a.m.

I. Ethical Decision Making for Regulators

Presentation – Kristy Schieldge, DCA Senior Staff Counsel

Kristy Schieldge, DCA Senior Staff Counsel, provided an overview of ethical decision making. She also reviewed major provisions of the Bagley–Keene Open Meeting Act. A series of hypothetical scenarios were highlighted and discussed.

Board Discussion

The board discussed the requirements of the Bagley-Keene Open Meeting Act as well as proper conduct for board members. Disqualification and abstention issues were addressed.

There was no additional board discussion. No public comment was provided.

Announcements

President Schell recognized former board members Bob Graul and Darlene Fujimoto who were attending the meeting and in the audience.

II. Approval of the Full Board Minutes of July 15 and 16, 2009

MOTION: Approve the minutes of the July 15 and July 16, 2009 Board Meeting.

M/S: Weisser/Swart

Approve: 8 Oppose: 0 Abstain: 0

III. Approval of the Full Board Minutes of August 19, 2009

MOTION: Approve the minutes of the August 19, 2009 Board Meeting.

M/S: Weisser/Wheat

Approve: 8 Oppose: 0 Abstain: 0

IV. Enforcement Committee Report and Action

Report of the Enforcement Committee Meeting Held September 16, 2009 and Recent Updates in Enforcement Activities

A. Overview of Proposals to Strengthen the Enforcement Programs of the Heath Care Boards of the Department of Consumer Affairs

1. Proposals of the Department of Consumer Affairs

   Dr. Robert Swart provided that over the prior 10 months, the Department of Consumer Affairs has initiated a number of initiatives aimed at strengthening the enforcement activities of the health care boards. He advised that the Board of Pharmacy is one of these agencies.

   Dr. Swart provided that these changes were initiated following problems identified at the Board of Registered Nursing (BRN) by the *Los Angeles Times*.

   Dr. Swart provided that the first major change was prioritization of fingerprinting of all licensees. He explained that fingerprinting allows a board to obtain federal and state background checks of applicants with respect to arrests and convictions entered into federal and state data bases by the courts and law enforcement agencies. Dr. Swart added that it also enables boards to obtain "subsequent" arrest and conviction information if a licensee is arrested or convicted in California.

   Dr. Swart provided that the second major problem reported in the *LA Times* was the time it was taking the BRN to investigate complaints and complete enforcement actions, which exceeded 3.5 years. He indicated that the BRN uses the department's Division of Investigation to investigate its complaints, and problems with recruitment and retention of investigators has been a problem. Dr. Swart advised that this delayed investigations. He stated that additionally the time it takes to secure complete work by the Attorney General's Office and Office of Administrative Hearings further added delays.

   Dr. Swart provided that DCA has responded with a series of proposals to strengthen the BRN's enforcement program as well as that of other health care boards. He added that board executive staff are working with the department on these changes.

   No public comment was provided.

2. Proposals of the California Business, Professions and Economic Development Committee

Dr. Swart stated that the Senate Business, Professions and Economic Development Committee developed a series of proposals. He stated that the overall goal is to complete formal investigations from the time a complaint is received, through investigation and through final action on the stipulation or proposed decision by the board within 18 months. Dr. Swart advised that this goal is a very aggressive standard, but one that the public deserves.

No public comment was provided.

3. SB 294 - 2009 Legislative Proposal of the Administration and Senate Business, Professions and Economic Development Committee

Dr. Swart stated that a joint legislative proposal, SB 294, was amended ("gutted and amended" in the parlance of the Legislature) on September 4, 2009 to carry some of the Administration's and Senate's proposals for improving DCA's enforcement programs. He stated that whereas initial hopes for the bill were to have it reach the Governor by the end of the legislative year on September 11, 2009, the bill has become a two-year bill.

No public comment was provided.

4. Enforcement Priorities of the Department of Consumer Affairs

Dr. Swart referenced members to the Department of Consumer Affairs (DCA) Guidelines for Complaint Prioritization contained within the board packet.

Presentation – Anne Sodergren, Assistant Executive Officer

Assistant Executive Officer Anne Sodergren provided an overview of the board's enforcement program. She stated that the Governor has established a goal for all investigation cases to be closed between 12 to 18 months. Ms. Sodergren explained that DCA has designed a new enforcement model to aid all boards with this timeline.

Joshua Room, Deputy Attorney General, provided an overview of preponderance of evidence, reasonable doubt (the criminal standard), and clear and convincing evidence. He explained that clear and convincing evidence is less than reasonable doubt.

Ms. Schieldge provided that the standard for license disciplinary action is clear and convincing evidence to a reasonable certainty.

Board Discussion

Dr. Swart sought clarification regarding the proposal that additional counsel would be assigned to the board under the DCA's proposal.

Ms. Sodergren provided that the administration is recommending that each board have its own in-house litigators.

Discussion continued regarding various aspects of the new enforcement model and the legislation required to implement it. It was clarified that there will be opportunity for public comment on the model in the future.

Presentation Continued

Ms. Sodergren provided an overview of the total processing times and closure statistics for categories of cases investigated by the board.

Ms. Sodergren stated that there has been significant growth in the number of licensees that the board regulates. She stated that there has also been growth in investigations, the number of complaints received, and application investigations. Ms. Sodergren reviewed the enforcement statistics for fiscal years 2004/2005, 2006/2007, and 2008/2009.

Mr. Room provided that, when compared to other boards, the board is very timely in its processing of investigations.

Ms. Sodergren provided that the board's performance statistics are publicly reported on a quarterly basis in the board packet.

Ms. Sodergren provided that the board is working to identify internal improvements. She stated that these improvements include a reduction in total case closure time by: routing of complaints on-line (instead of mailing), routing draft pleadings on-line for review, using on-line mail ballots by the board when voting on decisions, and the in-house preparation of default decisions (instead of the Attorney General's office preparing these).

Board Discussion

Dr. Swart discussed several occurrences where the respondent did not understand the accusation served upon them; and, consequently had a default decision rendered against them.

Mr. Room provided that this is a rare occurrence. He stated that it is at the discretion of the board to vacate the default.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided comments on the increased access to records proposal by the DCA and challenges for current pharmacy to provide records to all law enforcement without a subpoena.

There was no additional board discussion or public comment.

B. Enforcement Program of the Board of Pharmacy and Proposals to Strengthen Board Operations

Proposed Regulation for Pharmacists to Report on License Renewal Applications Prior Convictions and To Require Electronic Submission of Fingerprints for Pharmacists With No Prior History of Electronic Fingerprints On File

Dr. Swart provided that at the Enforcement Committee Meeting, the committee discussed the board's enforcement program. He stated that whereas the board has better timelines than the Board of Registered Nursing (BRN), they are not 12-18 months for most formal discipline, which is the average timeline targeted by the director and Administration. Dr. Swart advised that the board needs to strengthen its enforcement program, and provide faster resolution time. He indicated that the board will need additional staff. Dr. Swart provided that since August 2009, staff has been working on program changes and budget change proposals to augment staff so we can improve our program.

Dr. Swart stated that the Enforcement Committee recommends: Initiate a rulemaking on a regulation for pharmacists to: (1) report on license renewal applications prior convictions during the renewal period, and (2) to require electronic submission of fingerprints for pharmacists with no prior history of electronic fingerprints on file.

Dr. Swart provided that for years, the Board of Pharmacy has been fingerprinting applicants for individual licenses (pharmacists, pharmacist interns, technicians, designated representatives), and the officers and owners of board-licensed facilities (pharmacies, wholesalers, clinics, etc.).

Dr. Swart provided that pharmacists have been fingerprinted as a condition of licensure since September 1947 – only 150 individuals with active licenses do not have prints on file with the California Department of Justice. He advised that other boards only began fingerprinting applicants in the late 1980s and later.

Dr. Swart provided that the number of arrest and conviction reports (rap sheets) sent to the board on applicants and licensees is strongly dependent upon the speed with which local jurisdictions enter this information into the reporting system. He stated that in recent years, the number of these reports sent to the board has dramatically increased, and has exceeded the board's ability to

respond timely to these cases. As a result, the board submitted a budget change proposal early this year to ensure that it can timely review and investigate reports of criminal convictions and arrests. He advised that the board received 6.5 new positions effective July 1, 2009. Dr. Swart stated that the last two of these positions were filled in mid-September. He added that staff is now working to investigate a backlog of rap sheets awaiting review.

Dr. Swart provided that currently, the board's ability to ensure it has all information about the arrests and convictions of its licensees is not complete for two reasons:

1. Licensees who submitted fingerprints before 2001 submitted them on fingerprint cards, and the Department of Justice has not automated this process. Those who have been licensed since 2001 have submitted their fingerprints electronically through "LiveScan." Staff is concerned that it may not receive or receive timely rap sheets of those whose fingerprints are not electronically on file with the Department of Justice.
2. Licensees of the Board of Pharmacy are not required to certify at time of license renewal that they have not been convicted of anything. This is standard for other boards, and is a recommendation of the department for all health care boards.

Dr. Swart provided that in 2009, SB 389 was introduced to ensure all departmental agencies had fingerprints on file for all licensees, and that at each renewal, all licensees would certify that they had not been convicted of any crime during the renewal period. He advised that SB 389 was stalled in a policy committee of the Legislature.

Dr. Swart provided that staff recommend that the board move forward to secure these two elements for pharmacists, and then as this is completed for pharmacists, to move forward with technicians and designated representatives who were fingerprinted before 2001.

Dr. Swart provided that at the September Enforcement Committee Meeting, the committee recommended that the board move forward with this regulation.

Board Discussion

The board discussed the timeline and the inclusion of an implementation date for the regulation. Licensees were encouraged to renew in a timely manner to ensure efficient processing.

Stan Weisser expressed concern over the traffic infractions that are required to be reported. He suggested the $300 traffic fine standard may be to low, and result in a barrage of rap sheets.

The board discussed the workload impact with regards to the reporting of citations resulting in a $300 fine versus a $500 fine.

Executive Officer Virginia Herold provided that the fine standard is at the discretion of the board. She discussed the importance of the board's ability to review and investigate criminal convictions and arrests in order to protect the public. Ms. Herold indicated that the standard on the application is $500.

Dr. Swart provided that there should be consistency between fine standards on the application and the renewal forms.

There was no additional board discussion. No public comment was provided.

MOTION: Initiate rulemaking on proposed regulation for pharmacists to: (1) report on license renewal applications prior convictions during the renewal period, and (2) to require electronic submission of fingerprints for pharmacists with no prior history of electronic fingerprints on file. This rulemaking will go into effect 6 months after the approval of the Office of Administrative Law (OAL).

M/S: Schell/Wheat

Approve: 8 Oppose: 0 Abstain: 0

MOTION: Direct board staff to take all steps necessary to initiate the formal rulemaking process to adopt the proposed text at 16 CCR Section 1702 and to authorize the executive officer to make any non-substantive changes to the rulemaking package and to insert the effective date in subdivision (a).

M/S: Schell/Wheat

Approve: 8 Oppose: 0 Abstain: 0

MOTION: Change the renewal disclosure requirement in subdivision (b) from traffic infractions under $300 to traffic infractions under $500.

M/S: Swart/Weisser

Approve: 8 Oppose: 0 Abstain: 0

Proposed Language

To Add Section 1702 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Section 1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's renewal date that occurs on or after ([OAL insert effective date]).

(1) A pharmacists shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, omitting traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances.

(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1, 4005 Business and Professions Code. Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5, 4311, and 4400, Business and Professions Code; and Sections 11105(b)(10), and 11105(e), Penal Code.

C. Discussion of the Actions of the Department of Consumer Affairs Health Care Boards to Develop Regulations Required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for Practitioner Recovery/Monitoring Programs

Dr. Swart stated that at the June Enforcement Committee Meeting, the committee heard a presentation on SB 1441. He stated that Senate Bill1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program. Dr. Swart advised that this committee is subject to the Bagley-Keene Open Meeting Act and is comprised of executive officers and bureau chiefs from specified boards and bureaus. He indicated that the Board of Pharmacy is one of these participating boards.

Dr. Swart provided that given the timeline to develop these standards, the DCA created a workgroup consisting of staff from each of the healing arts boards. (The process is similar to process the board uses to promulgate a regulation.) He stated that the workgroup is responsible for developing recommended standards. Dr. Swart explained that the recommended standards will be vetted during a Uniform Standards Workshop, a public meeting akin to an informational hearing. He indicated that the draft standards will then be presented during a public meeting to the SACC for consideration and action. Dr. Swart announced that the last meeting is scheduled for November 16, 2009.

Dr. Swart provided that there have been public meetings to agree on the program standards for the monitoring programs; these have been held:

- May 6
- July 15
- September 22

Dr. Swart provided that the last meeting is proposed for November 10, 2009.

Dr. Swart provided that the SACC meetings were held:

- May 18
- September 2
- And the last meeting is set for November 16, 2009

The board suspended the Enforcement Report in order to recognize pharmacists in service for 50 years.

V. Recognition of Pharmacists Licensed with the Board for 50 Years

President Schell provided that the recognition of pharmacists in service for 50 years was a program initiated by former board member Stan Goldenberg several years ago. He noted that it is the board's honor to be able to continue the tradition.

President Schell recognized Katherine Owyoung. Ms. Owyoung was the only female in the first graduating class of the University of the Pacific in 1959. She served 40 years at St. Joseph Hospital where she served as the director of pharmacy. Ms. Owyoung highlighted some of the changes she has seen throughout her years as a pharmacist. President Schell presented Ms. Owyoung with a 50-year pin.

President Schell recognized Danny Chen. Mr. Chen graduated from the University of California, San Francisco in 1955. He served 34 years with Thrifty Drugstores. Ramón Castellblanch presented Mr. Chen with a 50-year pin.

President Schell recognized Jim Choi. Mr. Choi graduated from the University of Washington in 1954. He served two years in Korea and owned his own store for 23 years. Randy Kajioka presented Mr. Choi with a 50-year pin.

President Schell recognized Richard Mortensen. Mr. Mortensen discussed the enjoyment he has experienced throughout his practice as a pharmacist. He commended new pharmacists who are entering the practice. Greg Lippe presented Mr. Mortensen with a 50-year pin.

The board resumed the Enforcement Report.

D. Implementation of the Board of Pharmacy's Ethics Regulation, 16 CCR Sections 1773 and 1773.5

Dr. Swart provided that earlier this year, the board adopted a regulation to establish an ethics course as an enforcement option for those whose violations and resultant discipline involved at least an ethics issue. He stated that the ethics course is designed to be ethics counseling, done by individual introspection, working one-on-one with a consultant, and in a group setting.

Dr. Swart provided that the board will work with the Institute for Medical Quality to establish this course. He stated that the IMQ is a foundation of the California

Medical Association that operates a similar program for the Medical Board, and was the model the board used to develop the components for its ethics program.

Dr. Swart provided that when the board was considering options for ethics violations, it formed a subcommittee of Board Members Rob Swart and Susan Ravnan. He stated that now in implementing the program, as the parameters for the course are developed, President Schell has indicated that he would like to form a subcommittee to work with senior board staff in developing the program. Dr. Swart indicated that he has appointed Enforcement Chair Rob Swart to this subcommittee and will appoint one additional member.

Dr. Swart provided that the subcommittee will identify administrative discipline files where the violation, in part, had an ethical component (e.g., fraud, dispensing medicine without a prescription), and work with the course provider in establishing the parameters.

Dr. Swart provided that the goal is to have the course ready for administration at the end of the year.

President Schell added that Rosalyn Hackworth has been appointed to the subcommittee.

No public comment was provided.

E. Ongoing Discussion and Presentations About Prevention of Medication Errors

Dr. Swart provided that during this meeting, Dr. Michael Negrete of the Pharmacy Foundation of California will provide information on medication errors. He stated that this presentation is part of a CE presentation that Dr. Negrete has developed.

Dr. Swart stated that recently Consumers Union published an update of the 1999 Institute of Medicine (IOM) report of “To Error is Human – to Delay is Deadly.” The initial IOM report documented the large number of medication errors in hospitals, where as many as 98,000 people die annually, needlessly, due to preventable errors.

Dr. Swart provided that the conclusion of the 2009 Consumers Union report is that if anything, things have gotten worse in the last 10 years.

Dr. Swart provided that California regulators did initiate action based on the initial IOM report. He stated that since the 1999 report, the board secured legislation and underlying regulations to ensure that any medication error that reaches the patient must be subjected to a quality assurance review by the pharmacy to

prevent a reoccurrence. Dr. Swart advised that this is a standard component checked during all board inspections of pharmacies.

Dr. Swart provided that according to preliminary data from 2008-09, over 10 percent of the board's investigations involve medication errors. He stated that last fiscal year (as of June 1, 2009) the board closed 316 medication error complaints; 75 percent of these were substantiated.

Dr. Swart stated that the California Department of Public Health has implemented statutory requirements to improve the care in hospitals. He stated that a presentation is planned for the January 2010 Board Meeting on this subject. Dr. Swart explained that generally the law required hospitals to develop an error reduction plan by 2002 that was submitted to the Department of Public Health, hospitals then had until 2005 to implement the plan, and in 2009 the Department of Public Health began inspections of hospitals for compliance.

Presentation – Dr. Michael Negrete, Pharmacy Foundation of California

Dr. Michael Negrete, representing the Pharmacy Foundation of California, provided an overview on medication errors. He reviewed elements of medical care including adverse events, preventable adverse events, and medical errors.

Dr. Negrete addressed statistics and the increase in medication errors as well as factors contributing to this increase. He encouraged consumers to demand that their doctors and pharmacists be given the time and information they need to ensure the safety of their therapies.

Board Discussion

Dr. Swart provided comment regarding the education process for both the providers and the patients.

Dr. Kajioka discussed the importance for the patient to be proactive. He questioned if the medication error statistics include data on prescription drug abuse.

Dr. Negrete provided that the statistics do not differentiate between drug use and drug abuse.

Dr. Castellblanch asked if current research has addressed any correlation between medication errors and the adequacy of prescription drug labels.

Dr. Negrete discussed the importance of the consumer actually reading the information provided on the label.

Discussion continued regarding the information provided on a prescription label and information provided during a consultation. Concern was expressed regarding patient medical literacy and patient comprehension.

President Schell discussed the expansion of the term medication errors to medication therapy errors and the promotion of a partnership between prescribers, dispensers, and patients.

Ms. Herold provided that the board will be producing a brief video to demonstrate the importance of patient consultations. She stated that this video will be available on the board's Web site.

There was no additional board discussion. No public comment was provided.

F. Other Items from the September 16, 2009 Meeting

1. Discussion Regarding a Request to Use Pharmaceutical Manufacturer Patient Assistance Programs for Indigent Patients Receiving Care from County-Run Pharmacies

   Dr. Swart provided that the Enforcement Committee heard a request from LA County to permit it to better benefit from the use of patient assistance programs for indigent patients. He stated that LA County believes that they recoup $2 million in drug value from their current participation in these programs, but hope to find a means to more fully use these programs to save $8 million. Dr. Swart advised that they approached the Enforcement Committee hoping to find a way to replace the medication the County provides to medically indigent patients when receiving care in LA County facilities with the patient-specific medication later received from mail order pharmacies who distribute a manufacturer's drugs under a patient assistance program. He indicated that currently such returns to stock are not permitted, and it is difficult for patients to wait to receive the medication from mail order (some patients do not have addresses).

   Dr. Swart provided that at the end of the presentation, board staff agreed to work with attorneys to develop some proposals. He advised that there are no proposals to present at this time. Dr. Swart indicated that board staff will have some approaches available at the next committee meeting in December.

   No public comment was provided.

2. Presentation by Daichi Sankyo on Third Party Logistics Providers (Licensed Wholesalers) and Drug Manufacturers

   Dr. Swart provided that the Enforcement Committee heard a presentation by Daiichi Sankyo on the operations of third party logistics providers.

   No public comment was provided.

3. Presentation of the 2008 Report of the Research Advisory Panel of California

   Dr. Swart provided that the California Health and Safety Code establishes the Research Advisory Panel to oversee research involving use of controlled substances. He stated that section 11213 provides that:

   > Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purposes of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

   Dr. Swart provided that the Board of Pharmacy has one representative on this panel, Dr. Peter Koo of UCSF.

   Dr. Swart provided that the Enforcement Committee had no comment on this report.

   No public comment was provided.

G. Minutes of the September 16, 2009 Meeting

Dr. Swart provided that the minutes of the Enforcement Committee Meeting are contained within the board packet.

No public comment was provided.

H. Update on the Status of Drug and Sharps Take Back Programs in California Pharmacies

Ms. Herold provided that there are many take back programs operating throughout California. She advised that the majority of these programs do not follow the guidelines established by the California Integrated Waste Management Board (CIWMB). Ms. Herold provided that the next issue of *The Script* will promote and encourage the use of these guidelines.

Presentation – Bill Anderson, Curbside Inc.

Bill Anderson, representing Curbside Inc., provided an overview of a home generated non-controlled pharmaceutical collection program. He stated that the program consists of three main elements: (1) a secure drop-box container used for the collection of unwanted prescription drugs from patients, (2) witnessed on-site destruction of the drugs, and (3) final incineration of the materials.

Board Discussion

Dr. Swart asked if the container is leak proof.

Mr. Anderson provided that the container is completely sealed and consists of a heavy plastic liner to prevent leakage.

Mr. Room questioned if the containers are only installed in pharmacies.

Mr. Anderson provided that the containers are currently in a variety of public facilities including police stations, city halls, and senior centers.

Ms. Herold provided that in order to promote confidentiality and security, pharmacy staff should not assist patients with depositing drugs into the container.

Public Comment

Douglas Barcon sought clarification regarding the disposal of ointments and creams that are in full or partial tubes.

Ms. Herold provided that hazardous waste must be picked up by a licensed hazardous waste hauler.

Mr. Room provided that any aggregation of waste is classified as hazardous waste.

Discussion continued regarding the proper disposal and incineration of hazardous waste.

There was no additional board discussion or public comment.

I. Controlled Substances Utilization Review and Evaluation System (CURES) Implements Changes to Allow Pharmacies and Prescribers to Obtain Via the Internet Dispensing Histories of Patients

Dr. Swart stated that when the Board of Pharmacy first funded the CURES program back in the mid-1990s, the goal was to prevent patients with drug-seeking behavior from receiving controlled substances from pharmacies for drugs that should not have been prescribed. He stated that over the years, in part due to the costs of technology, it was not feasible to permit prescribers and pharmacies from reviewing the real-time dispensing of controlled substances to patients. Dr. Swart advised that pharmacies and prescribers who wanted such information on patients had to request written reports from the Department of Justice and to wait weeks for this information.

Dr. Swart provided that in September 2009, the Department of Justice announced that it could now provide online access to prescribers and pharmacies about the dispensing histories of controlled drugs to patients. He indicated that the data would be as old as three weeks.

Dr. Swart provided that at the next Board Meeting, staff from the DOJ's Bureau of Narcotic Enforcement will provide the board with a presentation on this system.

No public comment was provided.

J. Enforcement Statistics 2009-10

Dr. Swart referenced to the 2009-10 enforcement statistics contained within the board packet.

No public comment was provided.

K. First Quarterly Report on Enforcement Committee Goals for 2009/10

Dr. Swart referenced to the first quarterly report on the Enforcement's Committee's goals contained within the board packet.

No public comment was provided.

L. Public Comment

Dr. Douglas Hilblom, representing Prescription Solutions and the California Pharmacists Association (CPhA), provided comment on the guidelines established by the California Privacy and Security Advisory Board with regards to medication safety and the sharing of patient medical information. He encouraged the board to address this area at future meetings.

Steve Gray, representing Kaiser Permanente, encouraged the board to consider vendor owned inventory when considering 3PLs and Prescription Drug Discount Programs.

There was no additional public comment.

VI. Licensing Committee Report and Action

President Schell provided that there has been no Licensing Committee Meeting held since the July 2009 Board Meeting.

A. Subcommittee to Evaluate Drug Distribution within Hospitals

1. Summary of the Meeting Held September 17, 2009

Mr. Weisser provided that during the spring of 2008, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall. He stated that the board cited and fined the hospital pharmacies and pharmacists-in-charge of these pharmacies. Mr. Weisser indicated that because many of these hospitals and PICs have appealed the citations and fines, board members cannot discuss the specific parameters of any of these cases without recusing themselves from voting on the specific case in the future should they be appealed to the Office of Administrative Hearings.

Mr. Weisser provided that the recall system is not working. He stated that board staff worked closely with the California Department of Public Health and the California Society of Health-System Pharmacists to identify problems and we are hoping to develop California-specific solutions.

President Schell provided that he established a two-board member task force to work with these agencies on ways to improve recalls, and other changes needed to provide for improved drug distribution and control within a hospital. He stated that the first meeting of this subcommittee was March 2, 2009.

President Schell provided that the second meeting was held June 2, 2009, at University of California, San Francisco.

President Schell provided that the most recent meeting was held on September 17, 2009 in Sacramento. He stated that during this meeting presentations were given by Marjorie DePuy, Director, Industry Relations, HealthCare Distribution Management Association, Larry Hunley, Distribution Center Manager, McKesson Supply Solutions, Amy Gutierrez, PharmD, Director of Pharmacy Affairs, Los Angeles County Health Services and Elizabeth (Betty) Gregg, Manager, Recalls and Licensure, Cardinal Health. President Schell indicated each of the presenters provided information on the recall process from their perspective.

President Schell stated that also during the meeting, attendees discussed the draft best practices document and provided feedback. He provided the following summary of the main best practices in a recall process:

1. Pre-position the facility to receive early notice of recalls from multiple sources.
2. Identify if the facility has the product.
3. If so, quickly remove the product from all patient care areas.
4. Identify, assess, notify and treat patients who may have received the product.
5. Identify alternative products to maintain therapy.
6. Return the quarantined product.
7. Evaluate the process.

President Schell provided that attendees heard a presentation by Deputy Attorney General Joshua Room highlighting possible legislative and regulatory changes to improve drug distribution within a hospital. He stated that at the conclusion, attendees provided comments of the presentation and offered additional changes to be considered.

President Schell provided that the subcommittee will no longer be functioning in its current task force structure. He stated that the meetings were a tremendous success and provided a new avenue for reaching out to the public and the professional community.

No public comment was provided.

2. Draft Recall Procedures for Hospitals

President Schell referenced to the draft recall best practices for board member consideration. He stated that a finalized document will be presented during the next scheduled Licensing Committee Meeting, December 3, 2009 at LAX. President Schell advised that at the conclusion of this process, the best practices will be published on the board's Web site.

No public comment was provided.

3. Survey Results: Drug Distribution Within a Hospital

   President Schell provided that during the June 2009 Subcommittee Meeting, a survey was distributed to elicit responses to several questions surrounding the control of drugs within a hospital.

   President Schell provided an overview of the survey results.

   No public comment was provided.

4. Discussion of the Board on Possible Future Activities of this Subcommittee

   Mr. Weisser provided that all subcommittee meetings held were very outcome oriented and proved to be a valuable forum to take on such an important issue and ensure it was fully vetted. He advised that staff recommend that this separate subcommittee be dissolved and the matter referred back to the Licensing Committee for final approval.

   No public comment was provided.

B. Licensing Issues

1. Emergency and Disaster Response Planning: Presentation on the H1N1 Emergency Response Activities in California by the California Department of Public Health (CDPH)

   Mr. Weisser provided that when disasters strike California, people need emergency care, and those not injured in the event often are relocated from their homes without their medicines. He stated that in both cases, board licensees are called upon to aid these people in ways law may not specifically provide for. Mr. Weisser indicated that in the early to mid 2000s, the board sponsored legislation to ensure the public would not be deprived of necessary medicines when disasters occur and emergency response teams are making efforts to care for the public.

   Mr. Weisser provided that by late 2006 (following Hurricane Katrina), the board developed an emergency response policy to aid pharmacies with knowledge about what the board expected pharmacies, pharmacists, wholesalers and other licensees to do in the event of a declared disaster. He stated that the emergency response plan boils down to once an emergency is declared, use sound judgment, but “take care of patients.”

   Mr. Weisser provided that over the course of the last year, the Licensing Committee has heard presentations and discussed disaster response. He stated

that most recently, the committee and attendees heard a presentation from Dr. Dana Grau, the Department of Public Health (CDPH) Emergency Response Unit, who oversaw California's HINI response earlier this year. Mr. Weisser indicated that Dr. Grau shared the department's response as well as deficiencies identified in the disaster response plan that need correction before the next declared disaster.

Presentation – Dr. Dana Grau – Department of Public Health

Dr. Dana Grau, representing the Department of Public Health Emergency Response Unit (CDPH), provided an update on CDPH's response to the H1N1 emergency. He outlined CDPH's needs from pharmacies and pharmacists to respond to the emergency. Dr. Grau reviewed the needs of infants and young children that require a compounded version of Tamiflu and Relenza.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided comment on hospital bed availability for those affected by H1N1 and the validity of the information being provided by the media about the vaccine. He discussed the importance of the vaccine and proper dissemination of accurate information.

Discussion continued regarding H1N1 and the vaccine.

2. Proposed Delegation to the Board President to Act Pursuant to California Business and Professions Code Section 4062 to Waive Statutory Requirements to Benefit Public Safety in Response to a Declared Emergency or Disaster

   Mr. Weisser provided that during the October 2006 Board Meeting, the board voted to adopt a policy statement for pharmacies when providing emergency response. He indicated that a copy of this policy statement was published in the January 2007 issue of *The Script*.

   Mr. Weisser provided that Business and Professions Code section 4062 provides the board with broad waiver authority and was recently amended in SB 819 (Chapter 308, Statutes of 2009) to allow for the use of a mobile pharmacy in the event of a declared emergency as specified. He stated that the board intends to use this authority when warranted.

Board Discussion

Ms. Schieldge reviewed the board's options with respect to delegating authority collectively to the board or to an individual board member to waive statutory requirements to benefit public safety in response to a declared emergency or disaster. She recommended that the board limit this authority to situations wherein the board is unable to convene.

The board sought general clarification regarding its options and adherence to the Open Meetings Act. The board reached a consensus to allow any three members of the board to teleconference in the event that the board is unable to convene during a declared emergency.

Discussion continued with regards to both the authority of the board and of the Governor during a declared emergency.

Public Comment

President Schell sought clarification regarding what would be achieved during the emergency meeting.

Mr. Room provided that the members attending the emergency meeting would establish and issue guidelines regarding the laws that will be waived during the emergency.

There was no additional board discussion or public comment.

MOTION: In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, any three members of the board may convene a meeting by teleconference, by electronic communication (e.g., e-mail), or by other means of communication to exercise the powers delegated to full board pursuant to Business and Professions Code section 4062.

M/S: Weisser/Swart

Approve: 6 Oppose: 0 Abstain: 1

3. Update: Psychometric Assessment of the PTCB and ExCPT Pharmacy Technician Exams

   Mr. Weisser provided that during the April 2009 Board Meeting, the board voted to direct staff to take the necessary steps to secure a vendor to complete the necessary psychometric assessments of the Pharmacy Technician Certification Board (PTCB) and Exam for the Certification of Pharmacy Technicians (ExCPT). He stated that board staff initiated the process; however, because of an Executive Order signed by the Governor, staff were unable to proceed.

   Mr. Weisser provided that the psychometric assessment of the examination is needed to ensure for compliance with Section 139 of the Business and Professions Code and is the first step to allowing the use of the ExCPT exam as a qualifying method for licensure as a pharmacy technician.

   Mr. Weisser provided that board staff will resume this process and provide an update to the committee during its December 2009 meeting.

   No public comment was provided.

4. Reporting and Accounting of Intern Hours for California Pharmacy School Students

   Mr. Weisser provided that the Licensing Committee has discussed a major change to intern experience requirements established by the Accreditation Council for Pharmacy Education (ACPE) in the last few years. He stated that these new requirements added hours to the educational requirements students need as part of their intern training and are required as a condition for a school to maintain its accreditation status with the ACPE.

   Mr. Weisser provided that given the changes surrounding the intern hours requirements as well as the disparity in how the board accepts hours from various jurisdictions, board staff recommend that the intern hours requirements remain unchanged, but that the method by which staff confirm this information be contingent upon one of the following:

   - a candidate's PharmD graduation from an ACPE accredited school of pharmacy OR
   - licensure status in another state for one year OR
   - 1500 hours of experience for foreign educated pharmacist that satisfies all other requirements for licensure.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, sought clarification regarding the ACPE graduation requirement.

Ms. Herold provided that the board no longer receives license verification of intern hours from New York, Illinois, and Florida. She stated that a minimum of 1740 hours of intern experience is required in order to complete a PharmD degree at an ACPE accredited school of pharmacy. Ms. Herold indicated that the board will accept this standard as meeting the 1500 hours of intern experience requirement.

Dr. Gray expressed concern that new graduates are not adequately prepared.

There was no additional board discussion or public comment.

5. Impact of State Furloughs on Processing Timelines and Work Flow of the Board

Ms. Herold provided that in late June, the Governor issued an Executive Order imposing a third furlough day on each month on state employees. She stated that this order also closes state offices three Fridays each month through June 2010.

Ms. Herold provided that board and executive staff continue to evaluate the board's most mission-critical functions for the board's licensing unit staff. She stated that even with changes, processing times are extending well beyond the board's strategic objectives detailed in the strategic plan and may continue to grow. Ms. Herold indicated that the current processing times for pharmacy technician applications is about 90 days and is about 60 – 75 days for all other application types. She advised that while this is not where the board wants to be organizationally, it is reality for the near future.

Ms. Herold provided that to allow staff to focus on the most important functions of their jobs, processing applications and issuing licenses, executive staff twice previously authorized a temporary stop in responding to applicants calling on the status of a pending application. She stated that such a temporary stop allows staff to focus on reducing the backlog of new applications as well as complete a file inventory.

Ms. Herold encouraged all licensees to renew their licenses in a timely manner.

Ms. Herold stated that executive staff and managers continue to be available to address immediate or urgent applicant concerns.

President Schell recognized board staff for its efforts.

No public comment was provided.

6. Competency Committee Report

(a) Pharmacist Exam Performance Statistics for April 2009 – October 2009 CPJE and NAPLEX Exam Administrations

Mr. Weisser referenced to the breakdown of the passing rates for the CPJE and NAPLEX exams contained within the board packet. He stated that the overall passing rate during the specified time frame for the CPJE is 78.3 and 97.8 for the NAPLEX.

No public comment was provided.

(b) Job Analysis for the CPJE to Be Undertaken at the End of 2009

Mr. Weisser provided that pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the examination. He indicated that in order to complete this analysis, the committee recently developed a job analysis with the board's contracted psychometric firm. Mr. Weisser stated that the information learned from this survey will determine if changes are necessary to the content outline of the CPJE.

Mr. Weisser provided that the board anticipates releasing this survey to a random sample of pharmacists before the end of year. He stated that pharmacists that complete the survey will be awarded three hours of continuing education credit.

No public comment was provided.

C. First Quarterly Report on Licensing Committee Goals for 2009/10

Mr. Weisser referenced to the first quarterly report on the Licensing Committee's goals contained within the board packet.

VII. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

Dr. Doug Hillblom, representing Prescription Solutions, sought guidance from the board regarding participation in a distribution program for H1N1 therapy.

There was no additional public comment.

Recess for Day

The board meeting was recessed at 3:06 p.m.

The board reconvened at 9:07 a.m. on October 22, 2009.

VII. Legislation and Regulation Committee Report

Report of the Committee Meeting Held October 21, 2009

***Part 1: Regulation Report and Action* (Note: CCR as used below means California Code of Regulations)**

Mr. Lippe referred to the following regulations:

A. Board Approved Regulations -- Adopted

Amendment of 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course for Pharmacists

Background

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on the work of this subcommittee, the subcommittee recommended to the full the board that it vote to create a program similar to the program used by the Medical Board. This proposal would establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. The Office of Administrative Law approved the regulatory action on August 4, 2009, and the new regulations became effective on September 3, 2009.

B. Board Approved Regulations – Currently Undergoing Administrative Review
Pharmacies that Compound Medication – Repeal of Title 16 CCR §§1716.1 and 1716.2, Amend and Adopt §§1751 through 1751.8, and Adopt §§1735 through 1735.8

Background

Current pharmacy law authorizes a pharmacist to compound drug products as well as compound injectable sterile drug products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This regulation establishes guidelines to provide uniformity in compounding for California consumers.

Draft regulatory text was published at the end of August 2008, and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing.

At its January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt from some of the record keeping requirements detailed in Section 1735.3 those sterile products compounded on a one-time basis for administration within 2 hours, as specified. The modified text was noticed on February 26, 2009.

At the April 2009 Board Meeting, the board considered the comments received during the 45- and 15-day comment periods, along with a draft response to each. The board again considered modifications to proposed section 1735.3(a)(6) and subsequently voted to pursue a 2nd 15-day comment period to exempt from some of the record keeping requirements in proposed 1735.3(a)(6) those sterile products compounded on a one-time basis for administration within 24 hours, as specified. The 2nd 15-day comment period was noticed on May 4, 2009.

At the July 2009 Board Meeting the board considered the comments received during the 2nd 15-day comment period, as well as a draft response to each comment. The board then voted to adopt the regulation text as noticed on May 4, 2009, and to specify that the requirements would not go into effect for six months following approval by the Office of Administrative Law to allow for implementation. The board further moved that staff will exercise its enforcement discretion for an additional six months to allow for education and transition.

Staff compiled the final regulatory proposal, which is currently being reviewed by the department.

C. Board Approved Regulations – Currently Awaiting Notice

1. Title 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

Background

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

The Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. Board staff does not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

2. Title 16 CCR §§1721 and 1723.1 – Dishonest Conduct During a Pharmacist's Licensure Examination Confidentiality

Background

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §1721 and §1723.1 to strengthen the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of a qualifying licensing examination.

This recommendation was generated from the board's Competency Committee, which is responsible for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency and, if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

This regulation will be noticed in the future.

3. Title 16 CCR §1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Background

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

The proposed regulation specifies the criteria the board will utilize to consider approval of those accrediting agency requests.

This proposed regulation is still awaiting notice.

D. Regulations Under Development

1. Title 16 CCR §1780 – Update the USP Standards Reference Material

Background

CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

2. Title 16 CCR §1732.2 – Continuing Education for Competency Committee Members

Background

At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists. A committee member's term is generally about eight years.

The board also awards CE for:

- *Attending one board meeting annually (6 hours of CE),*
- *Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and*
- *Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).*

Board staff is drafting regulation language for consideration at a future Legislation and Regulation Committee meeting.

E. Proposed Regulations to Implement Recently Enrolled Legislation

1. Proposed changes to Title 16 CCR Section 1749 to conform with provisions contained in AB 1071 (Emmerson) Pharmacy Fees

Background

The board sponsored AB 1071, authored by Assembly Member Emmerson, to adjust application and renewal fees to ensure that the Board of Pharmacy has sufficient funds to fulfill all of its statutory obligations as a consumer protection agency. In most case, the measure established new minimum fees, and also capped future fees to increase no more than 30 percent.

AB 1071 was signed by the Governor on October 11, 2009, resulting in Chapter 270, Statutes of 2009. This mandate is effective January 1, 2010, which establishes these new fees.

At some point in the future, the board will need to amend its regulation requirements for fees so they are consistent with those in the new law. Those in the law take precedence over the fees in regulation if there is an inconsistency.

2. Proposed adoption of provisions to implement provisions contained in AB 931 (Fletcher) Emergency Supplies

Background

The Governor signed AB 931 on 10/11/09 to amend Health and Safety Code §1261.5 to increase the limit of oral dosage form and suppository dosage form drugs in a secure emergency pharmaceutical supplies container to 48 (from 24) in a health facility licensed under H&SC §1250. AB 931 places limitations on psychotherapeutic drugs, and also provides CDPH with authority to increase the number of those drugs in the e-kit, as specified. The measure is sponsored by the California Pharmacists Association. The board did not take a position on the bill.

Public Comment

Steve Gray, representing Kaiser Permanente, sought clarification regarding the timeframe for the compound regulation.

Ms. Herold provided that the compound regulation is not yet at the Office of Administrative Law (OAL). She advised that a 120-day extension has been granted to allow for the department's review.

There was no additional public comment.

Part 2. Legislative Report: Discussion and Action on Pending Legislation

The board reviewed the following pieces of legislation:

A. AB 931 (Fletcher, Chapter 491, Statutes of 2009) Emergency Supplies – Doses Stored in an Emergency Supplies Container

Committee Recommendation: To direct board staff to work on the provisions contained in AB 931.

Mr. Lippe provided an overview on AB 931 and indicated that it greatly expands the number of drugs and doses of drugs in emergency kits for skilled nursing facilities.

Board Discussion

Ms. Herold stated that board staff will generate some regulation requirements to ensure there is consistent accounting for the drugs in these kits. She stated that the draft language will be presented to the board at the January 2010 Board Meeting.

There was no additional board discussion. No public comment was provided.

MOTION: Direct board to staff to develop regulatory requirements for the emergency kits provided to skilled nursing facilities.

Approve: 8 Oppose: 0 Abstain: 0

B. §4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

Committee Recommendation: To direct staff to proceed with amending §4081 to specify a time period in which records shall be provided to the board when requested by an inspector or authorized representative of the board.

Mr. Lippe provided an overview on §4081.

Board Discussion

The board discussed an amendment to replace "an inspector or authorized representative of the board" with "authorized representative."

There was no additional board discussion. No public comment was provided.

MOTION: To approve the proposed amendment to the committee's recommendation.

Approve: 8 Oppose: 0 Abstain: 0

MOTION: To adopt the committee's recommendation as amended.

Approve: 8 Oppose: 0 Abstain: 0

Final Language

§ 4081. Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) When requested by an inspector or authorized representative of the board, the owner, corporate officers, or manager of any entity licensed by the board shall provide the board with records as requested within 72 hours of the request. The entity may request an extension of this timeframe for a period up to 14 days. Such a request must be made in writing and is subject to approval.

~~(b)~~ (c) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

~~(c)~~ (d) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

~~(d) This section shall become operative on January 1, 2006.~~

C. §4104 – Licensed Employee, Theft or Impairment: Pharmacy Procedures

Committee Recommendation: To amend §4101, subdivision (c) to require a pharmacy to provided the information specified in subparagraphs (1) through (6) within 14 days and to amend (c)(4) to include a provision that a pharmacy shall conduct an audit to determine the loss, if any, from the pharmacy, and that the audit results be provided to the board.

Mr. Lippe reviewed the amendments to §4104.

No public comment was provided.

MOTION: To adopt the committee's recommendation.

Approve: 8 Oppose: 0 Abstain: 0

Final Language

§ 4104. Licensed Employee, Theft or Impairment: Pharmacy Procedures

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report and provide to the board, within ~~30~~ 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual. As part of this evidence, the pharmacy shall conduct an audit to determine the loss, if any, from the pharmacy. A certified copy of the audit and results shall be provided to the board.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(d) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

D. §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

Committee Recommendation: To add a subsection to state that a nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the board to manufacture, compound, furnish, sell, dispense, or initiate, the prescription of any dangerous drug or dangerous device, or provide any pharmacy-related service to any patient in California.

Mr. Lippe provided an overview on §4112.

Board Discussion

Dr. Swart suggested that this requirement also be used in stipulations.

President Schell stated concern about the enforceability of this requirement and possible implementation issues.

Mr. Room provided some guidance on the possible implementation of this requirement.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, expressed concern with the provision and its implications. He encouraged the board to not move forward with this.

Rich Palombo, representing Medco Health, provided comment on the National Association of Boards of Pharmacy (NABP) clearinghouse.

Ms. Schieldge responded explaining some of the legal options to facilitate implementation of this issue. She stated that the board can provide licensure verification through the board's Web site as well as with a certification of licensure status.

Dr. Kajioka provided that it is the due diligence of the employer to verify that their employees are registered to service California. He discussed the importance of the board's ability to revoke a license.

Mr. Room offered a suggestion to amend the language to state "whose license has been revoked without subsequent reinstatement" and to add "or surrendered with disciplinary action pending."

Dr. Gray sought clarification on the frequency with which employers need to check on the license status of their employees.

Ms. Herold provided that license verification via the board's Web site is proof of licensure. She stated that license verifications can also be requested to the board for a minimal fee.

Discussion continued regarding license verification and the timeframe for which revocations are listed.

There was no additional board discussion or public comment.

MOTION: To adopt the committee's recommendation.

Approve: 6 Oppose: 2 Abstain: 0

Final Language

§ 4112. Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

§ 4112. (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the California State Board of Pharmacy to manufacture, compound, furnish, sell, dispense, initiate the prescription of any dangerous drug

California.

~~(d)~~ (e) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

~~(e)~~ (f) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

~~(f)~~ (g) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

~~(g)~~ (h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any

regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

~~(h)~~ (i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i)~~ (j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

~~(j)~~ (k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

E. §4120 – Nonresident Pharmacy; Registration Required

Committee Recommendation: The committee discussed the proposed repeal of §4120, and tabled this item to allow further research and consideration of the provisions that may be duplicative of other Pharmacy Law provisions.

Mr. Lippe provided that this section has been tabled by the committee.

No public comment was provided.

F. §4200.1 – Retaking Examinations; Limits; Requirements

Committee Discussion: To add §4200.1 as proposed to re-implement the provision in Pharmacy Law.

Mr. Lippe provided an overview on §4200.1. He stated that an amendment to remove the sunset date in this section was supported by the board but never made it into a 2009 bill. As such, the provision will sunset January 1, 2010.

Board Discussion

Mr. Room clarified this provision is needed to maintain curren requirements. He stated that the section will reauthorize a law that has been sunseted.

Ms. Herold stated that the board did support this provision last year.

There was no additional board discussion. No public comment was provided.

MOTION: Adopt the committee's recommendation.

Approve: 8 Oppose: 0 Abstain: 0

Final Language

§ 4200.1. Retaking Examinations; Limits; Requirements

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the California Practice Standards and Jurisprudence Examination for Pharmacists four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists.

G. §4301 – Unprofessional Conduct

Committee Recommendation: To amend §4301 (g), (q) and (t) as follows:

- *(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts or furnishing false, misleading, or incomplete information to the board, or the failure to furnish information requested by the board or required by this chapter.*
- *(q) Engaging in any conduct that subverts or attempts to ~~subvert~~ impede an investigation by the board.*
- *Strike subdivision (t) – the date the section becomes operative.*

Mr. Lippe provided an overview on §4301.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente and the California Pharmacists Association (CPhA), questioned if "knowingly" applies to both scenarios in subdivision (g).

The board discussed providing clarification to this section by adding a new subdivision. Clarification was provided that the burden is always on the agency to specify what it is requesting. It was the consensus of the board to refer this matter back to the committee.

MOTION: To refer this section back to the committee.

M/S: Schell/Kajioka

Approve: 8 Oppose: 0 Abstain: 0

Final Language

§ 4301. Obtaining License by Fraud, etc., Unprofessional Conduct: Incompetence or Gross Negligence, Furnishing False Information, etc.

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts or furnishing false,

information requested by the board or required by this chapter.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions,

and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, Information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to ~~subvert~~ impede an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

H. §4301.1 – Pharmacist License; Suspension; Felony Conviction

Committee Recommendation: The committee offered support for the proposal to add section 4301.1 and directed staff to work with counsel and others on language to bring back at a future committee meeting.

Mr. Lippe provided that this section was tabled by the committee.

No public comment was provided.

I. First Quarterly Report on Legislation/Regulation Committee Goals for 2009/10

President Schell referenced to the first quarterly report on the Legislation and Regulation Committee's goals contained within the board packet.

J. Public Comment

No public comment was provided.

IX. Communication and Public Education Committee Report and Action

President Schell provided that there has been no meeting of the Communication and Public Education Committee during this quarter.

A. Discussion and Possible Action to Initiate Rulemaking to Adopt Proposed Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Background

Senate Bill 472 (Chapter 470, Statutes of 2007) added Section 4076.5 to the Business and Professions Code, relating to development of patient-centered prescription drug labels. This statute requires the board to promulgate regulations for standardized, patient-centered, prescription drug labels on all prescription medication dispensed to patients in California by January 1, 2011. The board was also directed to hold special public forums statewide in order to seek input from the public on the issue of prescription labels. These forums and one-on-one surveys of consumers were conducted over a period of 17 months.

The timeline envisioned for this process was:
2008: conduct public hearings statewide
2009: develop regulations and adopt the requirements by the end of the year
2010: pharmacies implement requirements to be ready for 1/1/11 implementation
2011: requirements become effective and labels on prescription medicine are compliant

At the July and August 2009 Board Meetings, the board devoted time to development of the regulation requirements. In fact, the sole purpose of the August Board Meeting was to refine the regulation requirements.

At the October meeting, the board refined the regulation requirements and directed the release of the regulation language for the required 45 days of public comment. The board will hold a regulation hearing at the January 2010 Board Meeting, and if necessary, modify the language for 15 days of public comment,

and then adopt the regulation. This will allow pharmacies nearly 6- 9 months to implement the language, a bit less than the one year envisioned.

The board worked with a draft version of the language developed by the board during the August meeting.

President Schell read a letter provided by Senate Bill 472 author Senator Ellen Corbett in support of the draft regulations.

Board Discussion

Ms. Herold provided an overview of some of the issues involved with the regulation. Ms. Herold indicated that both draft versions of the regulation, the July 2009 "blue draft" and the August 2009 "pink draft," are generally consistent with the guidelines of the National Association of Boards of Pharmacy (NABP). She discussed where the US Pharmacopeia will be going with respect to the standardization. Ms. Herold highlighted the diversity of prescription labels already in use, some that are very patient centered.

Ms. Herold highlighted the timeline and encouraged the board to move the language at this meeting to initiate the rulemaking process.

Ms. Herold reviewed the research underway that is funded by the California Endowment to develop translations for the directions for use to aid California in developing these standards. She suggested that the board make these translations available for individual pharmacies to use at their own discretion.

Public Testimony

Steven Rosati provided support for the "pink draft." He presented sample labels exemplifying the ability to reformat a label easily based on the requirements from the "pink draft." Mr. Rosati highlighted recommended changes and provided justification for these changes.

Beth Abbott, representing Health Access Foundation, encouraged the board to move forward with the regulatory process. She provided that it is essential for labels to be workable and readable in order to reduce medical errors. Ms. Abbott provided that the board has done a comprehensive job to solicit information from consumers and researchers. She stated that she is convinced that any remaining concerns brought forward by industry can be addressed through the rulemaking process.

Diane Madoshi stated that seniors need a strong voice and deserve consideration. She urged the board to accept the standards of the "pink draft." Ms. Madoshi shared a story regarding a personal experience of a person who did not understand how to take her medication.

Dr. Swart discussed directions for use including “take at bedtime” and “take in the evening.”

Shirley Wheat sought clarification on pill box use that Ms. Madoshi provided during a previous meeting that contains a week’s supply of various drugs a patient takes.

Ms. Madoshi responded that, when a pill box is used, the label is still relied upon.

Hene Kelly, representing the California Alliance for Retired Americans (CARA), provided an overview of the CARA organization and urged the board to support CARA’s recommendations. She reviewed the current roll seniors play with regards to prescription drugs. Ms. Kelly explained her use of the pill box and highlighted how she uses the information on the prescription. She highlighted the problems with the current prescription bottle. Ms. Kelly spoke in support of the standardization of the directions for use as well as the font size and underscored the necessity of including the purpose or condition. She highlighted that the fastest growing population of seniors are those with English as a second language and underscored the need to translate labels in the dominant California languages. Ms. Kelly urged adoption of the regulation.

Alisha Tran, representing Asian Health Services, provided translation for Vilys Vuong. Ms. Vuong discussed her daily challenges with taking her medications and understanding the directions. She provided that she relies on her son-in-law’s interpretations to explain the directions, but she explained that she often forgets his explanation. Ms. Vuong stated that she hopes directions will be printed in Vietnamese and underscored the value of translated directions.

Jin Young, representing Asian Health Services, shared stories regarding patients who could not understand their prescription labels. She emphasized the need for directions that are understandable.

Ms. Wheat provided comment on a patient’s ability to understand the label and to understand how to take the medication. She provided that all patients are encouraged to speak to their physicians and pharmacists.

Ms. Young provided that patients who do not speak English cannot go back and check their label to verify the directions.

Dr. Swart indicated that he is concerned about providing a prescription with a label that is in a language that the pharmacist does not speak.

Dr. Castellblanch stated that the label is a vital piece of information.

Brett Kaufman, representing the pharmaceutical industry, stated that larger labels will impact container size, raise costs, and provide potential impact on the environment.

Mr. Lippe provided that many bottles may be thrown away as many people have indicated that they transfer their medications from the bottle to a pill box or other container.

Dr. Castellblanch highlighted the cost of human life with regards to people not understanding their prescription label.

Doreena Wong, representing the National Health Law Program, provided an overview of her organization. She stated that all of the organizations that have submitted letters are encouraging the board to initiate the rulemaking. Ms. Wong advised that the draft regulations are a good beginning point; but, would encourage the board to consider 12 languages consistent with Medi-Cal requirements. She provided an overview on the requirements in New York and highlighted a recent settlement agreement with Medco and the Office of Civil Rights which creates a language services program.

Ms. Wheat sought clarification of New York law and expressed concern that if the label only provides the translation, it will be difficult for the pharmacist to know if the provided information is correct.

Ms. Wong underscored the value of standardizing the directions for use.

Ms. Wheat asked how more complex directions would be translated.
Ms. Wong recommended that the prescription label be provided in both languages if possible.

Ms. Wheat expressed concern regarding liability and the quality control of translated prescriptions.

Discussion continued regarding liability and the responsibility for securing translations.

Cynthia Downs underscored the need for consistency. She encouraged the board to consider the needs of seniors and their caretakers.

Missy Johnson, representing the California Retailers Association (CRA), provided that the proposed regulations provide operational challenges. She highlighted the efforts of the CRA members. Ms. Johnson provided suggested changes to the board's draft regulation ("white draft").

Mary Staples, representing the National Association of Chain Drug Stores (NACDS), provided that the "pink draft" is overly prescriptive. She stated that the

“white draft” establishes general criteria instead of a specific format to provide a uniform label.

Jim Gross, representing the California Pharmacists Association (CPhA), asked if the proposed changes will improve or exacerbate the problem with medication errors. He expressed confusion with how the proposed regulation will help the patient and expressed concerned with the current construct. Mr. Gross stated support for the “white draft.”

Dr. Castellblanch expressed concern that the “white draft” does not meet the directives of SB 472.

Ms. Wheat spoke in support of the amendment offered in subdivision (h) of the “white draft” and sought clarification on the changes offered in (a).

Ms. Staples responded that there are other ways to highlight the information other than just the font size.

Dr. Swart referenced Mr. Rosati’s solution and asked for input regarding implementation.

Ms. Johnson expressed concern that the directions for use could be contrary to what the prescriber intends.

Don Gilbert, representing Rite Aid, expressed concern regarding translation and liability issues. He highlighted Rite Aid’s efforts including a brochure as well as phone interpretation.
Al Carter, representing Walgreens, detailed that the intent of the legislation was to reduce medication errors. He stated that pharmacists need to be freed up to talk to patients. Mr. Carter provided that Walgreens offers on-sight interpretative services and can also provide information in a large font at the request of the consumer.

Marty Martinez, representing the California Pan-Ethnic Health Network, provided that a lot of the concerns raised are all valid but have been vetted in other aspects of the health area. He strongly encouraged the board to move forward with the rulemaking.

The board discussed this issue with regards to the board’s liability and translations. It was clarified that the board could bear some potential for liability.

Wendy Ho provided that the regulations are a good starting point; but, there is room for improvement. She underscored the value of translations. Ms. Ho stated that the process needs to be moved forward and encouraged the board to initiate the rulemaking process.

Dan Wills, representing Grandpa's Compounding Pharmacies, expressed concern regarding standardized directions for compounding drugs and the diversity in fonts for other languages. He spoke in support of Rite Aid's efforts to provide oral translation services.

Dr. Steve Gray, representing Kaiser Permanente, provided support for the concept of a patient centered label. He stated that Kaiser is willing to work with the board. Dr. Gray expressed concern with the requirements in subdivision (h).

Vanessa Cajina requested action by the board and recognized the efforts by industry to provide oral translation services.

There was no additional public testimony.

Board Discussion

Ms. Herold advised the board of the regulatory process and strategically how the board should proceed. She summarized the challenges from the industry standpoint as well as from the consumer standpoint.

The board evaluated each subdivision of the "pink draft" while considering the public testimony and the proposed language within the submitted "white draft."

It was the consensus of the board to move ahead with subdivision (d) as drafted in the "pink draft."

It was the consensus of the board to move ahead with subdivision (e) as drafted in the "pink draft" and to change the deadline date to October 2011.

It was the consensus of the board to eliminate subdivision (g).

It was the consensus of the board to move ahead with subdivisions (b) and (c) as drafted in the "pink draft."

It was the consensus of the board to move ahead with subdivision (a) as drafted in the "pink draft" and to refine (a)(2) to combine the name of the drug and the strength of the drug.

The board discussed subdivision (h) with regards to available technology and whether translations are an option. It was the consensus of the board to move ahead with subdivision (h) from the "white draft" submitted by industry and to create a new subdivision (i) to direct the board to revisit the status of available technology in two years.

There was no additional board discussion.

MOTION: Initiate the rulemaking process with the proposed language developed by the board to Section 1707.5 relating to patient-centered prescription container labels.

M/S: Castellblanch/Hackworth

Approve: 6 Oppose: 0 Abstain: 1

Proposed Language

To Add Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1707.5 Patient Centered-Labels on Medication Containers

(a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point, sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.

(C) Directions for use

(D) Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is desired by the patient.

(2) For added emphasis, the label may also highlight in bold typeface or color, or use "white space" to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a)(1), and may appear in any style and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 tablet at bedtime

(B) Take 2 tablets at bedtime

(C) Take 3 tablets at bedtime

(D) Take 1 tablet in the morning

(E) Take 2 tablets in the morning

(F) Take 3 tablets in the morning

(G) Take 1 tablet in the morning, and Take 1 tablet at bedtime

(H) Take 2 tablets in the morning, and Take 2 tablets at bedtime

(I) Take 3 tablets in the morning, and Take 3 tablets at bedtime

(J) Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening

(K) Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening

(L) Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening

(M) Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime

(N) Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime

(O) Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime

(P) Take 1 tablet as needed for pain. You should not take more than __ tablets in one day

(Q) Take 2 tablets as needed for pain. You should not take more than __ tablets in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) For patients who have limited English proficiency, upon request by the patient, the pharmacy shall provide an oral language translation of the prescription container label's information specified in subdivision (a)(1) in the language of the patient.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

B. Update Report on *The Script*

President Schell provided that work on the next of *The Script* is nearly completed. He indicated that in order to save money, the board will be combing the July and January issues into one issue. President Schell stated that the issue will focus on new legislative requirements involving pharmacy law, interpretations of pharmacy law and the Integrated Waste Management Board's Model Guidelines for drug-take back programs.

President Schell provided that this is also the last issue that will be published and mailed to pharmacies and wholesalers. He stated that future issues will be e-version, released to licensees and the public electronically.

No public comment was provided.

C. Update on Public Outreach Activities

President Schell referenced to the following public and licensee outreach activities performed during the first quarter of Fiscal Year 09/10:

- July 3, 2009 – Executive Officer Herold spoke at a Board of Directors Meeting of the California Society Of Health-Systems Pharmacists.
- July 25, 2009 – President Schell volunteered in "Standdown" an event for homeless veterans in San Diego and dispensed prescriptions and counseled patient's regarding their medications.
- July 31, 2009 – Executive Officer Herold made a presentation on patient-centered medication labels during a "Women in Government Conference" in San Diego. The group was comprised of female legislators representing the western United States.

- September 12, 2009 – Board President Ken Schell made a presentation to the Indian Pharmacist Association about board activities.
- September 13, 2009 – Board Inspector Judi Nurse made a presentation to the California Pharmacist Association's Long-Term Care members regarding the DEA and CURES compliance issues.
- September 21, 2009 – Executive Officer Herold made a presentation on California e-pedigree requirements to Logipharma, a group of drug manufacturers and distributors.
- September 23, 2009 – Executive Officer Herold made a presentation on California e-pedigree requirements to Specialty Pharma, an association of contract drug manufacturers.
- September 24, 2009 – Executive Officer Herold provided an law update to the Sacramento Valley Chapter of the California Society of Health Systems Pharmacists.
- October 1, 2009 – Executive Officer Herold provided an update about board activities to the Board of Directors of California Society of Health-System Pharamcists.
- October 2 and 3, 2009 – Board of Pharmacy staffed a booth at CSHP's Annual Meeting, Seminar in San Diego.
- October 2, 2009 – Executive Officer Herold provided a presentation on 2009 pharmacy legislation at the CSHP Annual Meeting.
- October 3, 2009 – Board President Schell provided a presentation on Board of Pharmacy activities at the CSHP Annual Meeting.

No public comment was provided.

D. First Quarterly Report on Committee Goals for 2009/10

President Schell referenced to the first quarterly report on the Communication and Public Education Committee's goals contained within the board packet.

E. Public Comment

No public comment was provided.

X. Organizational Development Committee Report and Action

A. Budget Update/Report

1. Governor's Executive Order to Furlough State Employees

   Ms. Herold provided that the legislature and Governor debated necessary cuts and perhaps taxes to resolve the more than $25 billion shortfall in the 2009-10 budget.

   She stated that beginning February 2009 all board staff were furloughed two days per month. Ms. Herold indicated that in July 2009, the board's staff was furloughed one additional day each month, through June 2010. She added that the Governor also directed that state agencies close the first three Fridays per month.

   Ms. Herold provided that a byproduct of the furloughs is an increase in our timelines to review applications, issue licenses, investigate complaints and discipline licenses. She stated that the key business processes will be left intact and the focus of our activities will remain doing the most important activities first. Ms. Herold advised licensees to seek a status inquiry check via email in the event an application is pending more than 90 days.

   No public comment was provided.

2. Final Budget Report for 2008/09

   President Schell referenced to the Final Budget Report for 2008/09 contained within the board packet. He stated that in 2008/09, the board collected over $10 million in revenue, primarily from license fees and fines and had over $9 million in expenditure.

   No public comment was provided.

3. Budget Report and Constraints for 2009/10

   President Schell provided that the new fiscal year started July 1, 2009. He stated that the board received a budget augmentation of $650,000 this year to establish 6.5 new positions to review and investigate criminal convictions of board licensees – a unit necessary due to the exponential increase in the number of criminal conviction reports the board has received in recent years (from about 300 to nearly 3,000 annually). President Schell advised that the augmentation also includes enforcement expenses for anticipated added enforcement actions.

President Schell provided the following estimated budget figures (including a 15% reduction in operating expenses) for 2009-10:

- Revenue: $8,729,225
- Expenditures: $9,822,157

Board Discussion

Mr. Weisser sought clarification regarding the revenue figures.

Ms. Herold provided that the final budget report includes revenue collected for collected citation and fines and cost recovery.

There was no additional board discussion. No public comment was provided.

4. Fund Condition Report

President Schell provided that according to a fund condition report prepared by the department: the board will have the following fund conditions at the end of the identified fiscal years:

2008/09	$11,003,000	13.8 months in reserve (actual)
2009/10	$10,160,000	11.2 months in reserve
2010/11	$9,228,000	10.0 months in reserve
2011/12	$8,056,000	8.6 months in reserve

President Schell provided that the fund conditions represented above include the new fees (at their statutory minimums) as included in AB 1071(Chapter 270, Statutes of 2009).

Board Discussion

Dr. Castellblanch asked how long the current fees have been in effect.

Ms. Herold provided an overview of the current fees and history of fee increases and the newly enacted fee bill that increased the top range for most fees.

There was no additional board discussion. No public comment was provided.

5. Reimbursement to Board Members

President Schell referenced to the expenses and per diem payments to board members contained within the board packet provided.

No public comment was provided.

6. Board Meeting Dates for 2010

President Schell provided that the board still plans to hold 4 board meetings per year.

President Schell provided the following future board meeting dates for 2010:

- January 20-21: Sacramento
- April 21-22: Loma Linda
- July 28-29: Sacramento
- October 20-21: San Diego

President Schell provided that the department will host its second Professionals Achieving Consumer Trust Summit on July 27, 2010 in Sacramento. He stated that this is a new date and location. President Schell advised that this summit will be similar to the November 2008 Summit held in Los Angeles, where the boards and bureaus of the department host joint meetings and attend communal meetings on items of interest and will focus on "Going Green," Licensee Manpower Issues and Enforcement Enhancements.

No public comment was provided.

7. BreEZe (I-Licensing) Progress

President Schell provided that the Department of Consumer Affairs has been working for a number of years to replace and/or enhance the legacy licensing systems. He stated that a few years ago, the department initiated an I-Licensing project which would offer online application and renewal of licenses (a much needed relief from mail-in renewals). President Schell indicated that the feasibility study report was approved by the Department of Finance several years ago, and the board is in the first tier of new agencies that may be able to offer this service in the future.

President Schell provided that the board is about 2 years away from implementing an I-Licensing according to current estimates and timelines. He stated that the department hopes to award the contract for the system this year and is looking for an interim solution to allow for credit card payments.

President Schell provided that this priority project for the board means additional delays before the board can achieve on-line renewals of licenses. He stated that the executive officer has been an executive sponsor of this project, and periodic meetings have just been resumed due to staff changes in the Office of Information Services.

No public comment was provided.

B. Recognition Program of Pharmacists Who Have Been Licensed 50 Years

President Schell provided that since July 2005, the board has acknowledged 895 pharmacists with 50 or more years of licensure as pharmacists in California. Seventy-seven pharmacists reached this milestone between May and July 31, 2009. He stated that each was sent a certificate and invited to a future board meeting for public recognition.

No public comment was provided.

C. Personnel Update

1. Board Member Changes

Ms. Herold provided that there are currently nine board members, and four board member vacancies. She stated that the vacant positions are Governor appointments of one public member and three pharmacist members.

No public comment was provided.

2. Staff Changes

Ms. Herold provided that currently all staff positions are filled. She stated that there will be one inspector vacancy in December. Ms. Herold provided that the open exam for the inspector vacancy will be posted on-line.

Ms. Herold provided that the December staff meeting has been cancelled as a cost cutting measure.

President Schell provided that once a year, the board evaluates its executive officer. He stated that this evaluation process has been initiated. President Schell indicated that there is a form for this that will be sent to each board member in several weeks. President Schell explained that each member will have the opportunity to provide comments regarding the performance of the executive officer within the last year, and send these to President Schell. He stated that a final evaluation form will be prepared, which will be provided to the executive officer in closed session at the next board meeting.

No public comment was provided.

D. First Quarterly Report on the Committee's Goals for 2009/10

President Schell referenced to the first quarterly report on the Organizational Development Committee's goals contained within the board packet.

No public comment was provided.

E. Public Comment

Steve Gray, representing Kaiser Permanente, provided comment on the Troy and Alana Pack Foundation. He recommended that the board address this effort at a future meeting.

There was no additional public comment.

XI. Closed Session

The board moved into closed session to deliberate on disciplinary matters pursuant to Government Code section 11126(c)(3).

The meeting was adjourned at 2:48 p.m.

BAGLEY-KEENE OPEN MEETING ACT
TOP TEN RULES
(September 2009)

[NOTE: GC § = Government Code Section; AG = Opinions of the California Attorney General.]

1. All meetings are public. (GC §11123.)

2. Meetings must be noticed 10 calendar days in advance—including posting on the Internet. (GC §11125(a).)

3. Agenda required—must include a description of specific items to be discussed (GC §§ 11125 & 11125.1).

   a. No item may be added to the agenda unless it meets criteria for an emergency. (GC §11125(b).)

4. Meeting is "gathering" of a majority of the board or a majority of a committee of 3 or more persons where board business will be discussed. Includes telephone & e-mail communications. (GC § 11122.5; Stockton Newspapers Inc. v. Members of the Redevelopoment Agency of the City of Stockton (1985) 171 Cal.App.3d 95.)

5. Law applies to committees, subcommittees, and task forces that consist of 3 or more persons (includes all persons whether or not they are board members). (GC §11121)

6. Public comment must be allowed on agenda items before or during discussion of the items and before a vote, unless: (GC §11125.7.)

   a. The public was provided an opportunity to comment at a previous committee meeting of the board. If the item has been substantially changed, another opportunity for comment must be provided.

   b. The subject matter is appropriate for closed session.

7. Closed sessions (GC §11126.) At least one staff member must be present to record topics discussed and decisions made. (GC § 11126.1).

Closed session allowed:

   a. Discuss and vote on disciplinary matters under the Administrative Procedure Act (APA). (subd. (c)(3).)
   b. Prepare, approve or grade examinations. (subd. (c)(1).)

c. Pending litigation. (subd. (e)(1).)
d. Appointment, employment, or dismissal of executive officer (EO) unless EO requests such action to be held in public. (subd. (a), (b).)

No closed session allowed for:
a. Election of board officers. (68 AG 65.)
b. Discussion of controversial regulations or issues.

8. No secret ballots or votes except mail votes on APA enforcement matters. (68 AG 65; GC §11526.)

9. No proxy votes. (68 AG 65.)

10. Meetings by teleconferencing (GC §11123.)

a. Suitable audio or video must be audible to those present at designated location(s). (subd. (b)(1)(B).)
b. Notice and agenda required. (subd. (b)(1)(A).)
c. Every location open to the public and at least one member of board physically present at the specified location. All members must attend at a public location. (subds. (b)(1) (C), and (F).)
e. Rollcall vote required. (subd. (b)(1)(D).)
f. Emergency meeting closed sessions <u>not</u> allowed. (subd. (b)(1)(E).)

Reference: January 2009 "Public Meetings" Memorandum & Attached Guide to the Bagley-Keene Open Meeting Act
http://www.dca.ca.gov/publications/bagleykeene_meetingact.pdf

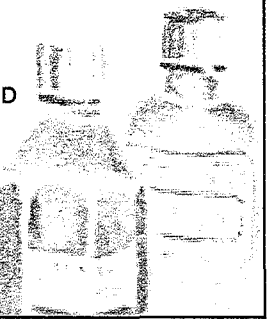
ETHICAL DECISION MAKING

Handout #2

Questions	Mandatory Disqualification	Need Further Discussion
Have you served as • investigator • prosecutor, or • advocate before or during the adjudicative proceeding?	**Yes**	
Are you biased or prejudiced for or against the person? or Do you have an interest (including a financial interest) in the proceeding?	**Yes** **Yes**	
Have you • engaged in a prohibited ex parte communication before or during adjudicative proceeding (may result in disqualification)? OR • complained to you about investigation currently in progress and said how great he or she is √ "Ex parte" communication: direct or indirect communication with you by one of the parties or its representative without notice and opportunity for all parties to participate in the communication (e.g. applicant or licensee (or someone acting on that person's behalf)		**Yes** **Yes**
Do you or your spouse or a close family member (such as an uncle or cousin) have personal knowledge of disputed evidentiary facts concerning the proceeding?		**Yes**
Do you doubt your capacity to be impartial?		**Yes**
Do you, for any reason, believe that your recusal would further the interests of justice?		**Yes**

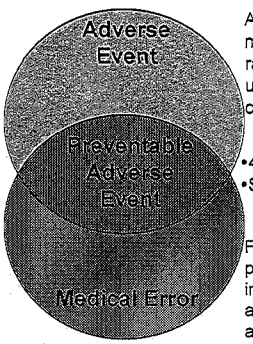
Medication Errors: Challenges & Opportunities

Michael J. Negrete, PharmD
Chief Executive Officer
Pharmacy Foundation of California



Definitions

Medical Care



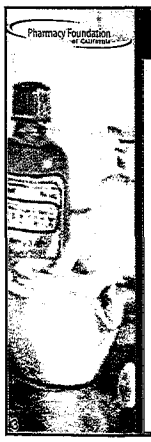
An injury caused by medical management rather than by the underlying disease or condition of the patient

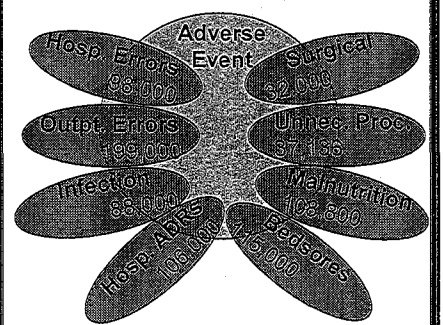
- 44,000-98,000 deaths
- $17-$29 billion/yr

Failure to complete a planned action as intended, or the use of a wrong plan to achieve an aim

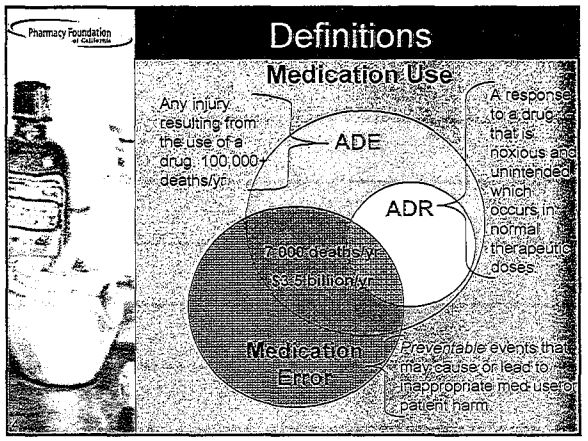
Definitions

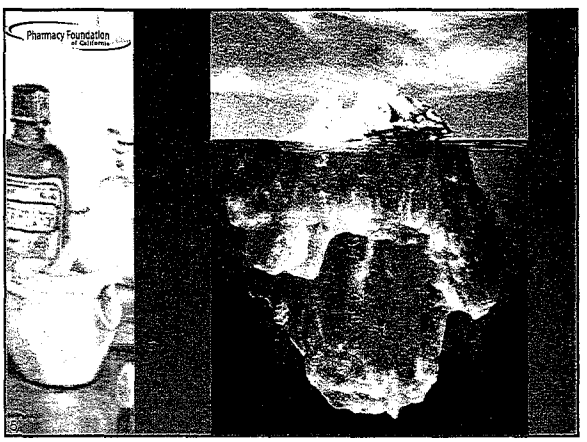
Medical Care

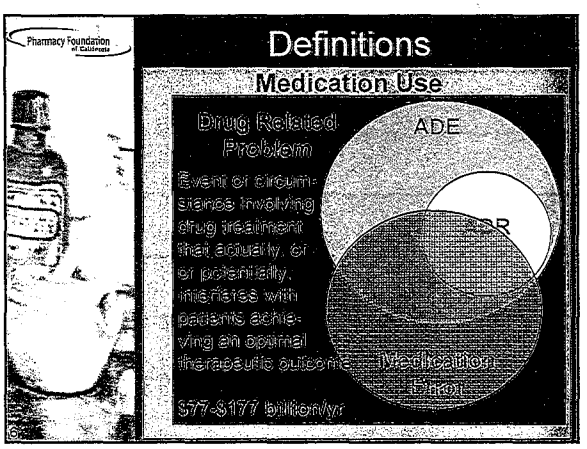




http://www.ourcivilisation.com/medicine/usamed/deaths.htm


Pharmacy Foundation of California
Definitions
Medication Use
Any injury resulting from the use of a drug. 100,000+ deaths/yr.
ADE
ADR
A response to a drug that is noxious and unintended which occurs in normal therapeutic doses.
7,000 deaths/yr
$3.5 billion/yr
Medication Error
Preventable events that may cause or lead to inappropriate med use or patient harm.


Pharmacy Foundation of California


Pharmacy Foundation of California
Definitions
Medication Use
Drug Related Problem
Event or circumstance involving drug treatment that actually, or potentially, interferes with patients achieving an optimal therapeutic outcome.
ADE
Medication Error
$77-$177 billion/yr

Fatal Medication Errors

(Philips, et al 2008)

- Analysis of CDC death certificates 1983-2004
- FME as cause of death

  "Accidental overdose of drug, wrong drug given or taken in error, and drug taken inadvertently [and] accidents in the use of drugs and biologicals in medical and surgical procedures."
- Excludes suicides & homicides due to poisoning, as well as etoh or "street drug" overdoses

Fatal Medication Errors

- 5 times more FME deaths occurred *in the home* than all other places combined (incl. hospitals)
- On average, more than 34 Americans die in their home *each day* because of a medication error

Skyrocketing Increases

- Between 1983 and 2004, these "domestic FMEs" increased by more than 1,000%
- Increase was 10 times greater than that observed among FMEs in all other non-domestic settings

Why Is This Happening?

Systems are perfectly designed to obtain the results that they achieve

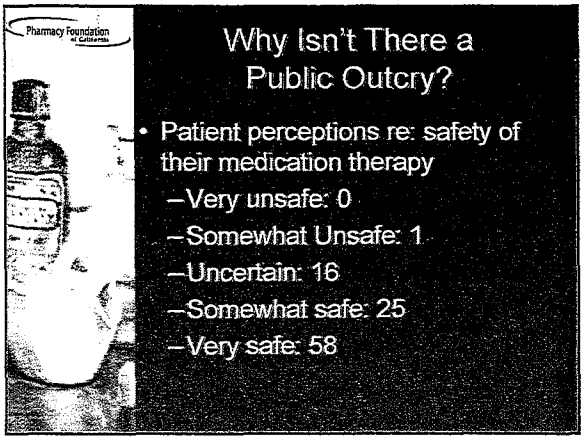
Why Is This Happening?

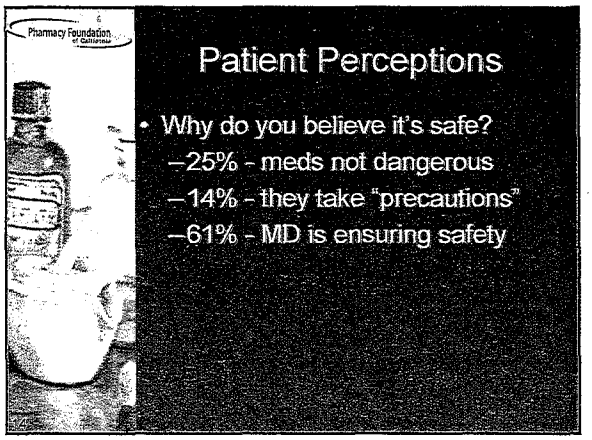
"External" Forces:
- Aging population
- Increases in chronic disease
- Medical advancements
- Resource constraints

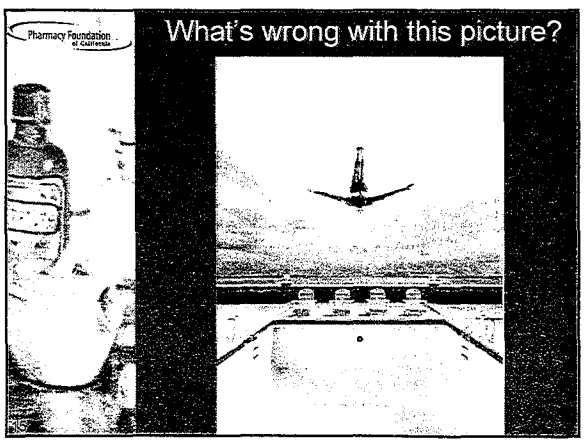
"Internal" Forces:
- Time & resource constraints
- Fragmentation of healthcare delivery
- Poor information technology

Why Is This Happening?

Consumers are increasingly being given more and more medications WITHOUT also being given the tools, support and information they need to safely use them.


Pharmacy Foundation
Why Isn't There a Public Outcry?
• Patient perceptions re: safety of their medication therapy
–Very unsafe: 0
–Somewhat Unsafe: 1
–Uncertain: 16
–Somewhat safe: 25
–Very safe: 58


Pharmacy Foundation
Patient Perceptions
• Why do you believe it's safe?
–25% - meds not dangerous
–14% - they take "precautions"
–61% - MD is ensuring safety


Pharmacy Foundation
What's wrong with this picture?

Consumers Must Understand:

No matter how smart or well-intentioned their doctors or pharmacists may be, they too often aren't given the information and time they need to ensure the safety of their therapies

Consumers Must Demand:

That their doctors and pharmacists be given the time and information they need to ensure the safety of their therapies.

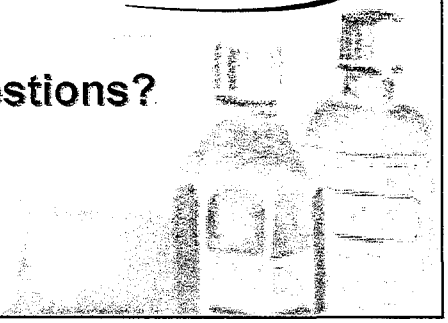
- Pharmacist consultations
- Medication Therapy Management
- Point-of-Care monitoring

Our Healthcare System is Driven by Chief Complaints

How do we get this to be a chief complaint of patients, caregivers, advocates and legislators?

Pharmacy Foundation
of California

Questions?



Home Generated Non-controlled Pharmaceutical Collection

CIWMB Model Program Implementation

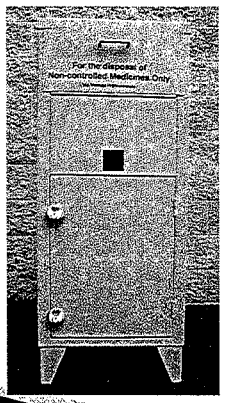
Curbside Inc.
500 South Jefferson St.
Placentia, CA 92870
714-223-3937 x 115
www.curbsideinc.com

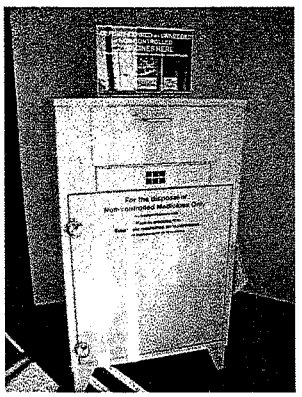
Program Design

- A drop-box will be placed at a participating pharmacy
- Current and new customers will visit the store to deposit their pharms with a high degree of possible incremental store purchases
- List of controlled substances attached to box
- One key held by the pharmacy, one by Curbside, it takes two keys to open the box
- Curbside visits periodically and removes drugs

The Drop-Box

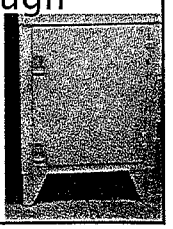
- Two sizes, 24 and 44 gallon, used for either pharms or sharps.





Security

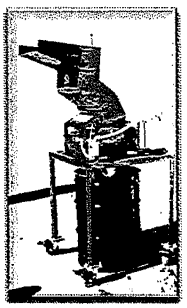
- Pharms are secured inside of 12 gauge steel box with two locks. Once deposited, only two keys can open
- When the Curbside employee arrives, the box is opened under the supervision of a pharmacy employee.
- No pharmacy or Curbside employee will physically touch a container or sort through them



Security

- The container in the drop-box is removed, a lid placed on top and both individuals walk to the parking lot with the container.
- The Curbside employee will power up the disposal machine and pour the contents of the larger container into the machine as the pharmacy employee watches. Entire process should take less than five minutes.

Security



- The materials poured into the machine are crushed and shredded into powder and plastic/glass pieces.
- The pharmacy employee signs a document indicating that they witnessed the destruction of the materials.
- The destroyed materials are transported to a facility where they will be destroyed by incineration.

Home Generated
{non-controlled}
Pharmaceutical
Destruction Verification Form

I certify that I opened the double locked Home Generated Pharmaceutical Program Drop-Box located at my store/facility jointly with an employee of Curbside Inc. The container inside the Drop-Box immediately had a lid placed over it and was taken to the Curbside Inc. vehicle located on the property without any inspection of the contents or physical handling of same.

I witnessed the Curbside Inc. employee, after weighing the collection container, pour the contents of the collection container into a machine that destroyed the materials by reducing them to small particles. When the process was complete, the empty collection container was placed into the unit and both locks were replaced.

I signed a shipping document which included the weight of the materials removed for destruction.

This location advertises that controlled substances are not accepted. A list of controlled substances is available in store for participants to review. I did not inspect the materials removed for destruction, to the best of my knowledge, all of the materials deposited and destroyed were non-controlled substances.

Authorized Witness Name _____ Title _____ Date _____

Signature _____

Store/Facility: _____ Store#_____

Address: _____ Doc#_____

City: _____ State: _____ Zip: _____

CSR: _____ %F: ___ Cond: G - NR Min: ____

Notes: _____

Regulatory Environment

- Non-controlled, non-hazardous substances are not controlled by any government entity
- Hazardous pharms generated by households are not federally regulated, however, we destroy them by incineration.
- This material is not a medical waste.

CA.GOV | _ *California Department of Toxic Substances Control*

The following was lifted from the web page of DTSC on 2-2-09

Pharmaceutical wastes that meet California's definition of hazardous waste but not RCRA's definition, as well as pharmaceutical wastes generated by people who are not regulated under RCRA, are subject to the Medical Waste Management Act (Division 104, Part 14 California Health and Safety Code). (However, pharmaceutical waste produced by a household is not regulated as hazardous waste or medical waste.)

Whether or not a specific generator or activity is regulated under the Medical Waste Management Act may depend on a number of factors. If you have questions about how a specific pharmaceutical waste is regulated, or about how to comply with the Medical Waste Management Act, you should contact the California Department of Health Services' Medical Waste Management Branch. More information on Pharmaceuticals as Medical Waste can be found at the California Department of Health Services web page.

What does this mean to a household?

Pharmaceutical waste produced by a household is exempt from classification as hazardous waste or medical waste. This means that a household may legally dispose of their waste pharmaceuticals and personal care products in the solid waste stream or into the sanitary sewer ("down the drain"). While these practices are legal, they may not be the environmentally preferred ways for a household to dispose of unwanted pharmaceuticals. Some local government agencies such as Household Hazardous Waste (HHW) Programs partner with pharmacies or hold their own pharmaceutical collection events. Call before taking the pharmaceuticals to an HHW facility.

Documentation

- Waste materials are weighed before they are destroyed on the vehicle
- A D.O.T. shipping document will list all details, a copy left at the store
- Curbside retains copies of manifests for all waste pharms shipped for final incineration

Orange County Pharmacists Association Program

- OCPhA launched a program in the Spring, four pharmacies have joined the program.
- All 4 accept non-controlled pharmaceuticals and sharps in separate boxes
- Estimated service interval at 6-8 weeks
- Estimated average collection weight 25 pounds

Jack Silberstein
Garden Grove CA
Grove Harbor Medical Center Pharmacy

Scott Parker – Orange CA
Watson's Drug Store

Program Cost

- Service fee consists of a stop charge and fee for disposal of waste on a per pound basis
- Drop-box loaned, no fee if there is one service each month, there is small per month fee for each month without a service.
- Three year agreement that fixes service fee, disposal price for two years.
- 90 day termination clause
- Never pay a service fee unless the box is serviced
- No set schedule, call center will work with pharmacy to set ideal service interval or call for service.

Bill Anderson will be available at Curbside's booth to demonstrate the drop boxes during the CIWMB/DTSC Building Bridges Conference. Also, please join Bill as he presents more program information at the Conference's Session 2 workshop on **Wednesday, November 4 from 10:30 am – 12:00 pm**

"Pink"

1707.5 Patient Centered-Labels on Medication Containers

Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

(a) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label, and shall be printed in at least a 12-point, san serif typeface, and listed in the following order:

1. Name of the patient
2. Name of the drug, brand and/or generic (Manufacturer's trade name, or the generic name and name of the manufacturer)
3. Strength of the drug
4. Directions for use
5. Purpose or condition, if entered onto the prescription [or otherwise known to the pharmacy and its inclusion on the label is desired by the patient]

(b) For added emphasis, the label may also highlight in bold typeface or color, or use "white space" to the set off the items listed in subdivision (a).

(c) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a), and may appear in any style and size typeface.

~~Or: Display of all other elements on the prescription drug label required by Business and Professions Code section 4076 may appear in any style or size type font, provided that the label can still meet the requirements of subdivision (a). The placement of these items on the drug label shall not obscure the emphasis on or placement of the items listed in (a).~~

(d) When applicable, directions for use shall use one of the following phrases:

1. Take 1 tablet at bedtime
2. Take 2 tablets at bedtime
3. Take 3 tablets at bedtime
4. Take 1 tablet in the morning
5. Take 2 tablets in the morning
6. Take 3 tablets in the morning
7. Take 1 tablet in the morning, and Take 1 tablet at bedtime
8. Take 2 tablets in the morning, and Take 2 tablets at bedtime
9. Take 3 tablets in the morning, and Take 3 tablets at bedtime
10. Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening

11. Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening
12. Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening
13. Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime
14. Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime
15. Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime
16. Take 1 tablet as needed for pain. You should not take more than ___ tablets in one day
17. Take 2 tablets as needed for pain. You should not take more than ___ tablets in one day

(e) By October 2010, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (d) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(f) Beginning in October 2010 and thereafter, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(g) ~~The board shall provide translations of the above-listed translations in at least the five most dominant non-English languages used in California.~~

When instructions for use specified by the prescriber do not conform to one of the items listed in subdivision (d) the pharmacy shall secure its own translation.

(h) For patients who cannot read English but can read in another language, upon request, the pharmacy shall provide a prescription container labeled with the components specified in subdivision (a) in the language of patient.

"Blue"

1707.5 Patient Centered-Labels on Medication Containers

Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

(a) Each of the following items shall be clustered into one area of the label, and shall be printed in at least 12-point, san serif typeface:

1. Name of the patient
2. Name of the drug, brand and/or generic (Manufacturer's trade name, or the generic name and name of the manufacturer)
3. Strength of the drug
4. Directions for use
5. Purpose or condition, if entered onto the prescription [or otherwise known to the pharmacy and its inclusion on the label is desired by the patient]

(b) For added emphasis, the label may also highlight in bold typeface or color items listed in subdivision (a).

(c) The remaining required elements for the label specified in Business and Professions Code section 4076 shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a), and may appear in any style and size typefont.

Or: Display of all other elements on the prescription drug label required by Business and Professions Code section 4076 may appear in any style or size type font, provided that the label can still meet the requirements of subdivision (a). The placement of these items on the drug label shall not obscure the emphasis on or placement of the items listed in (a).

(d) When applicable, directions for use shall use one of the following phrases:

1. Take 1 tablet at bedtime
2. Take 2 tablets at bedtime
3. Take 3 tablets at bedtime
4. Take 1 tablet in the morning
5. Take 2 tablets in the morning
6. Take 3 tablets in the morning
7. Take 1 tablet in the morning, and Take 1 tablet at bedtime
8. Take 2 tablets in the morning, and Take 2 tablets at bedtime
9. Take 3 tablets in the morning, and Take 3 tablets at bedtime
10. Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening
11. Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening
12. Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening
13. Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime
14. Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime

15. Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime
16. Take 1 tablet as needed for pain. You should not take more than ___ tablets in one day
17. Take 2 tablets as needed for pain. You should not take more than ___ tablets in one day

(e) By October 2010, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in (d) into at least five languages other than English, to facilitate use thereof by California pharmacies.

(f) Beginning in October 2010 and thereafter, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(g) The board shall provide translations of the above-listed translations in at least the five most dominant non-English languages used in California. When instructions for use specified by the prescriber do not conform to one of the items listed in subdivision (d) the pharmacy shall secure its own translation.

(h) For patients who cannot read English but can read in another language, upon request, the pharmacy shall provide a prescription container labeled with the components specified in subdivision (a) in the language of patient.

"White"

1707.5 Patient Centered Labels on Medication containers

Labels on drug containers dispensed to patients in California shall conform to the following ***criteria*** ~~format~~ to ensure patient-centeredness.

(a) ***The*** ~~Each of the~~ following items shall be clustered into one area of the label ~~that comprises at least 50 percent of the label, and shall be printed in at least a 12-point, san serif typeface, and listed in the following order~~:

1. Name of the patient
2. Name of the drug, brand and/or generic (Manufacturer's trade name, or the generic name and name of the manufacturer)
3. Strength of the drug
4. Directions for use
5. Purpose or condition, if entered onto the prescription ***by the prescriber*** ~~[or otherwise known to the pharmacy and its inclusion on the label is desired by the patient]~~

(b) For added emphasis, the label may also highlight in bold typeface or color, or use "white space" to the set off the items listed in subdivision (a).

(c) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a), and may appear in any style and size typeface.

~~Or: Display of all other elements on the prescription drug label required by Business and Professions Code section 4076 may appear in any style or size type font, provided that the label can still meet the requirements of subdivision (a). The placement of these items on the drug label shall not obscure the emphasis on or placement of the items listed in (a).~~

(d) ***Directions for use shall comply with the prescriber's instructions in a manner to aid patient understanding of how and when to use the medication.*** ~~When applicable, directions for use shall use on of the following phrases:~~

~~1. Take 1 tablet at bedtime~~
~~2. Take 2 tablets at bedtime~~
~~3. Take 3 tablets at bedtime~~
~~4. Take 1 tablet in the morning~~
~~5. Take 2 tablets in the morning~~
~~6. Take 3 tablets in the morning~~
~~7. Take 1 tablet in the morning, and Take 1 tablet at bedtime~~
~~8. Take 2 tablets in the morning, and Take 2 tablets at bedtime~~
~~9. Take 3 tablets in the morning, and Take 3 tablets at bedtime~~
~~10. Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening~~
~~11. Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening .~~
~~12. Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening~~
~~13. Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime~~
~~14. Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime~~
~~15. Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime~~
~~16. Take 1 tablet as needed for pain. You should not take more than _ tablets in one day~~
~~17. Take 2 tablets as needed for pain. You should not take more than _ tablets in one day~~

(e) By October 2010, ~~and updated as necessary, the board shall~~ ***the board may*** publish on its Web site ***examples for recommendations for prescription instructions that prescribers are recommended to use of prescribing relative to subsection (d).*** ~~translation of the directions for use listed in subdivision (d) into at least five languages other than English, to facilitate the use thereof by California pharmacies.~~

(f) Beginning in October 2010 and thereafter, the board ***may*** ~~shall collect and~~ publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(g) ~~The board shall provide translations of the above listed translations in at least the five most dominant non English languages used in California. When instructions for use specified by the prescriber do not conform to one of the items listed in subdivision (d) the pharmacy shall secure its own translation.~~

(h) For patients who ***have limited*** ~~cannot read~~ English ***proficiency*** ~~but can read in another language~~, upon request ***by the patient***, the pharmacy shall provide a ***oral language translation of the*** prescription container labeled ***information for*** ~~with~~ the components specified in subdivision (a) in the language of patient.

4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings *in* order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

(1) Medical literacy research that points to increased understandability of labels.

(2) Improved directions for use.

(3) Improved font types and sizes.

(4) Placement of information that is patient-centered.

(5) The needs of patients with limited English proficiency.

(6) The needs of senior citizens.

(7) Technology requirements necessary to implement the standards.

(d) (1) On or before January *1, 2011,* the board shall report to the Legislature on its progress under this section as of the time of the report.

(2) On or before January *1, 2013,* the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

CALIFORNIA NURSES ASSOCIATION
NATIONAL NURSES ORGANIZING COMMITTEE

A Voice for Nurses. A Vision for Healthcare.
www.calnurses.org / www.nnoc.net

October 9, 2009

Kenneth H. Schell, PharmD, President
California Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834
Via Fax (916) 574-8618

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Dr. Schell and Members of the California Board of Pharmacy:

The 86,000 registered nurses of the California Nurses Association/National Nurses Organizing Committee (CNA/NNOC) are writing to urge the Board of Pharmacy to discharge its duty under the law and adopt draft regulations implementing SB 472. Patients and consumers must not be kept needlessly waiting for draft regulations to be adopted. Any appropriate concerns about the draft regulations can be adequately addressed during the formal rulemaking process. Further delays are unnecessary and put the health of Californians at risk.

The staff of the Board of Pharmacy has done an excellent job for over a year researching the issues at hand, holding public hearings, conducting surveys, and reaching out to experts. The draft regulations that we have seen are a good start to begin the process of public review. CNA does have some suggestions to improve the proposed regulations (for example, translated standardized labels should be available in advance for all Medi-Cal Managed Care threshold languages), the public rulemaking process is the appropriate place to air our suggestions and discuss industry concerns. The draft regulations recommended by staff should be adopted at the next Board meeting to begin this formal rulemaking process.

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The Board had a chance to fulfill its obligation under the law at its August 2009 meeting by adopting the draft regulations recommended by staff. The Board instead opted for another, unwarranted, delay. We are concerned that if draft regulations are not adopted immediately by the Board, important deadlines will be missed. Even more important than the deadline in the statute, California's policymakers have determined that standardized, accessible, translated prescription labels are a vital element in appropriate health care delivery.

Without them we all risk injury, inappropriate care, or even death. Patients have a right to these labels and the Board must not be a barrier to that right.

If you have any questions or would like to follow up with us, please contact CNA's Sacramento office.

Sincerely,

Bonnie Castillo, RN
Director, Government Relations

Kenneth H. Schell, PharmD, President
California Board of Pharmacy
1625 N Market Blvd., N219
Sacramento, CA 95834
Fax: (916) 574-8618

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Dr. Schell and Members of the California Board of Pharmacy:

We are writing this letter on behalf of the several senior advocacy organizations to urge the Board of Pharmacy to discharge its duty under the law and adopt draft regulations implementing SB 472. Our organizations worked very hard to help pass SB 472, and participated in the public comment process to suggest improvements in the design and format of prescription drug labels. Seniors are the largest consumers of prescription drugs in California, and for years have expressed concerns about the difficulty reading and interpreting the information on their drug bottles. Now that there are draft regulations that take us one step closer to making what can be life saving changes to these drug labels, we urge you to proceed on adopting them. Any appropriate concerns about the draft regulations can be adequately addressed during the formal rulemaking process. Further delays are unnecessary and put the health of Californians at risk.

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The Board had a chance to fulfill its obligation under the law at its August 2009 meeting by adopting the draft regulations recommended by staff. The Board instead opted for another, unwarranted, delay. We are concerned that if draft regulations are not adopted immediately by the Board, important deadlines will be missed. Even more important than the deadline in the statute, California's policymakers have determined that standardized, accessible, translated prescription labels are a vital element in appropriate health care delivery. Without them we all risk injury, inappropriate care, or even death. Patients have a right to these labels and the Board must not be a barrier to that right.

If you have any questions or would like to follow up with any of us, you can call us at our number, listed below.

Sincerely,

Ernie Powell, AARP
Phone:

Betty Perry, OWL
Phone:

Margie Metzler, Gray Panthers of CA
Phone:

California School Employees Association
AFL-CIO

2045 Lundy Avenue
San Jose, CA 95131
(408) 473-1000
(800) 632-2128
Executive
FAX (408) 321-8227
First Floor
FAX (408) 954-0948
www.csea.com

Allan D. Clark
Association President

Josie Mooney
Executive Director

Member of the AFL-CIO

The nation's largest independent classified employee association

October 12, 2009

Kenneth H. Schell, PharmD, President
California Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834

Via Fax (916) 574-8618

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Dr. Schell and Members of the California Board of Pharmacy:

On behalf of the California School Employees Association, I am writing to urge the Board of Pharmacy to discharge its duty under the law and adopt draft regulations implementing SB 472. Our organization represents over 220,000 linguistically, racially, and ethnically diverse Californians, many of whom are seniors. Patients and consumers must not be kept needlessly waiting for draft regulations to be adopted. Any appropriate concerns about the draft regulations can be adequately addressed during the formal rulemaking process. Further delays are unnecessary and put the health of Californians at risk.

The staff of the Board of Pharmacy have done an excellent job for over a year researching the issues at hand, holding public hearings, conducting surveys, and reaching out to experts. The draft regulations that we have seen are a good start to begin the process of public review. Although we do have some suggestions to improve the proposed regulations that staff presented to the Board (for example, translated standardized labels should be available in advance for all Medi-Cal Managed Care threshold languages), the public rulemaking process is the appropriate place to air our suggestions and discuss industry concerns. The draft regulations recommended by staff should be adopted at the next Board meeting to begin this formal rulemaking process.

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The Board had a chance to fulfill its obligation under the law at its August 2009 meeting by adopting the draft regulations recommended by staff. The Board instead opted for another, unwarranted, delay. We are concerned that if draft regulations are not adopted immediately by the Board, important deadlines will be missed. Even more important than the deadline in the statute, California's policymakers have determined that standardized, accessible, translated prescription labels are a vital element in appropriate health care delivery. Without them we all risk injury, inappropriate care, or even death. Patients have a right to these labels and the Board must not be a barrier to that right.

If you have any questions or would like to follow up with us, please feel free to contact me at (530) 867-2591.

Sincerely,

California School Employees Association

Cindy Young

Cindy Young
Senior Health Policy Advisor

Cc: Barbara Howard, Director, CSEA Governmental Relations
Dolores Duran-Flores, CSEA Governmental Relations Manager

HEALTH ACCESS
CALIFORNIA

October 7, 2009

Kenneth H. Schell, PharmD, President
California Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834
Via Fax (916) 574-8618

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Dr. Schell and Members of the California Board of Pharmacy:

I am writing to you on behalf of the members of Health Access California, a statewide coalition representing consumers, seniors, people with disabilities, religious, labor, and multi-lingual/multi-cultural groups. We urge the Board of Pharmacy to adopt draft regulations implementing SB 472, California Patient Medication Safety Act (Corbett, D-San Leandro).

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a **standardized, patient-centered, prescription drug label** on all prescription medication dispensed to patients in California. This landmark legislation requires that the regulation outline requirements for drug labeling that take into account consumers' needs, particularly those of seniors and people with little medical literacy and/or limited English proficiency.

Over the last year we believe the staff of the Board of Pharmacy has done an excellent job researching the issues at hand, holding public hearings, conducting surveys, and incorporating research results into the draft regulation. We note that SB 472 underwent four revisions in the Senate and two in the Assembly before being signed into law. These revisions were largely to accommodate objections raised by the industry.

We believe the draft regulations presented to the Board in August represent a good start to begin the process of public review. We strongly believe that beginning the formal rule-making process is the appropriate venue to address any remaining concerns of the industry. Consequently, we urge the Board to undertake the public review process as soon as possible. The prevalence of medical prescription errors and the lack of public comprehension of prescription labels provide a compelling and urgent rationale for this legislation. We see no reason to introduce further unwarranted delays into

OAKLAND: 414 - 13th Street, Suite 450, Oakland, CA 94612-2608 PH: 510.873.8787, FAX: 510.873.8789
SACRAMENTO: 1127 11th Street, #234, Sacramento, CA 95814 PH: 916.497.0923, FAX: 916.497.0921
LOS ANGELES: 1930 Wilshire Blvd., Suite 1210, Los Angeles, CA 90057 PH: 213.413.3587, FAX: 213.413.8631
www.health-access.org

what California's policymakers have determined are needed "to increase consumer protection and improve the health, safety, and well-being of consumers."

We believe that standardized, readable, language-accessible, prescription labels are a vital element in appropriate health care delivery. Without them we all risk injury, inappropriate care, or even death. We strongly believe these draft regulations should be adopted at the next Board meeting in October to begin this formal rulemaking process.

If you have any questions or need more information, please contact Elizabeth Abbott, Project Director at Health Access, at (916) 497-0923, ext. 201 or at eabbott@health-access.org.

Sincerely,

Anthony Wright
Executive Director
Health Access
1127 11th Street, Suite 234
Sacramento, CA 95814

cc: Senator Ellen Corbett, author
Senator Elaine Alquist (D-Santa Clara), Chair, Senate Health
Senator Denise Ducheny (D-San Diego), Chair, Senate Budget
Senator Negrete-McLeod (D-Chino), Chair, Senate Business, Professions, & Economic Development
Assemblymember David Jones (D-Sacramento), Chair, Assembly Health
Assemblymember Noreen Evans (D-Santa Rosa), Chair, Assembly Budget
Assemblymember Mary Hayashi (D-Hayward), Chair, Assembly Business & Professions
Fred Aguiar, Secretary, State and Consumer Services Agency

CALPIRG
Standing Up To Powerful Interests

www.calpirg.org
1107 9th St., Ste. 601 • Sacramento, CA 95814
(916) 448-4516 (ph) • info@calpirg.org

October 12, 2009

Kenneth H. Schell, PharmD, President
California Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834
Via Fax (916) 574-8618

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Dr. Schell and Members of the California Board of Pharmacy:

On behalf of the California Public Interest Research Group (CALPIRG), I am writing to urge the Board of Pharmacy to discharge its duty under the law and adopt draft regulations implementing SB 472, creating patient-centered prescription drug labels. CALPIRG is a statewide membership-based public interest group that stands up to powerful interests, working to win concrete results for Californians' health and well-being. With researchers, advocates, organizers, and students, we advocate on behalf of consumers and all California's residents.

As strong supporters of the original legislation, which will help ensure that patients have access to comprehensive, understandable information about their prescriptions, we have been gratified to see the excellent job done by the staff of the Board of Pharmacy in researching the issues at hand, holding public hearings, conducting surveys, and reaching out to experts. The current draft regulations represent a strong starting point from which to begin the process of public review.

But we are concerned that the Board may be considering delaying action on these draft regulations. California Patients and consumers must not be kept needlessly waiting for rules implementing this important law to be adopted. Any appropriate concerns about the draft regulations can be adequately addressed during the formal rulemaking process. Further delays are unnecessary and put the health of Californians at risk.

Although we do have some suggestions to improve the proposed regulations that staff presented to the Board (for example, translated standardized labels should be available in advance for all Medi-Cal Managed Care threshold languages), the public rulemaking process is the appropriate place to air our suggestions and discuss industry concerns. The draft regulations recommended by staff should be adopted at the next Board meeting to begin this formal rulemaking process.

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The Board had a chance to fulfill its obligation under the law at its August 2009 meeting by adopting the draft regulations recommended by staff. The Board instead opted for another, unwarranted, delay.

We are concerned that if draft regulations are not adopted immediately by the Board, important deadlines will be missed. Even more important than the deadline in the statute, California's policymakers have determined that standardized, accessible, translated prescription labels are a vital element in appropriate health care delivery. Without them we all risk injury, inappropriate care, or even death. The need for action is clear.

If you have any questions about our position, please do not hesitate to contact me.

Sincerely,

Michael Russo
Health Care Advocate and Staff Attorney
California Public Interest Research Group (CALPIRG)
3435 Wilshire Blvd., # 385
Los Angeles, CA 90010
(213)251-3680 x332

SENIOR ACTION NETWORK

965 Mission Street, Suite 705 * San Francisco, CA 94103
Phone 546-1333 * Fax 546-1344 * www.SFSAN.ORG

October 6, 2009

Kenneth H. Schell, PharmD, President
California Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834
Via Fax (916) 574-8618

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Dr. Schell and Members of the California Board of Pharmacy:

On behalf Senior Action Network, I am writing to urge the Board of Pharmacy to discharge its duty under the law and adopt draft regulations implementing SB 472. Our organization represents seniors, persons with disabilities, patients, and linguistically, racially, and ethnically diverse Californians. Patients and consumers must not be kept needlessly waiting for draft regulations to be adopted. Any appropriate concerns about the draft regulations can be adequately addressed during the formal rulemaking process. Further delays are unnecessary and put the health of Californians at risk.

The staff of the Board of Pharmacy have done an excellent job for over a year researching the issues at hand, holding public hearings, conducting surveys, and reaching out to experts. The draft regulations that we have seen are a good start to begin the process of public review. Although we do have some suggestions to improve the proposed regulations that staff presented to the Board (for example, translated standardized labels should be available in advance for all Medi-Cal Managed Care threshold languages), the public rulemaking process is the appropriate place to air our suggestions and discuss industry concerns. The draft regulations recommended by staff should be adopted at the next Board meeting to begin this formal rulemaking process.

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The Board had a chance to fulfill its obligation under the law at its August 2009 meeting by adopting the draft regulations recommended by staff. The Board instead opted for another, unwarranted, delay. We are concerned that if draft regulations are not adopted immediately by the Board, important deadlines will be missed. Even more important than the deadline in the statute, California's policymakers have determined that standardized, accessible, translated prescription labels are a vital element in appropriate health care delivery. Without them we all risk injury, inappropriate care, or even death. Patients have a right to these labels and the Board must not be a barrier to that right.

If you have any questions or would like to follow up with us, please contact me.

Sincerely,

Barbara Blong

Barbara Blong
SAN Executive Director

California Alliance for Retired Americans

www.californiaalliance.org

Kenneth H. Schell, PharmD, President, California Board of Pharmacy
1625 N Market Blvd., N219
Sacramento, CA 95834 Fax: (916) 574-8618

October 1, 2009

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Dr. Schell and Members of the California Board of Pharmacy:

I am writing this letter on behalf of the California Alliance for Retired Americans (CARA) to urge the Board of Pharmacy to discharge its duty under the law and adopt draft regulations implementing SB 472. Our organization represents over 850,000 seniors and their families throughout California. We worked very hard to help pass SB 472, and participated in the public comment process to suggest improvements in the design and format of prescription drug labels. Seniors are the largest group of consumers of prescription drugs in California, and for years have expressed concerns about the difficulty reading and interpreting the information on their drug bottles. Now that there are draft regulations that take us one step closer to making what can be life saving changes to these drug labels, we urge you to proceed on adopting them. Any appropriate concerns about the draft regulations can be adequately addressed during the formal rulemaking process. Further delays are unnecessary and put the health of Californians at risk.

The Staff of the Board of Pharmacy have done an excellent job for over the last year researching the issues at hand, holding public hearings, conducting surveys, and reaching out to experts. The draft regulations that we have seen are a good start to begin the process of public review. Although we do have some suggestions to improve the proposed regulations that staff presented to the Board, the public rulemaking process is the appropriate place to air our suggestions and discuss industry concerns. The draft regulations recommended by staff should be adopted at the next Board meeting to begin this formal rulemaking process.

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The Board had a chance to fulfill its obligation under the law at its August 2009 meeting by adopting the draft regulations recommended by staff. Many of our members attended that meeting to hear the recommendations, and show our support for this step in the process. The Board instead opted for another, unwarranted, delay. We are concerned that if draft regulations are not adopted immediately by the Board, important deadlines will be missed. Even more important than the deadline in the statute, California's policymakers have determined that standardized, accessible, translated prescription labels are a vital element in appropriate health care delivery. Without them we all risk injury, inappropriate care, or even death. Patients have a right to these labels and the Board must not be a barrier to that right.

If you have any questions or would like to follow up with us, please contact us at 415-550-0828.

Sincerely,

Nan Brasmer

Nan Brasmer, CARA President

Main Office
600 Grand Avenue, Suite 410
Oakland, CA 94610
415.550.0828
877.223.6107 (toll free)
510.663.4099 (fax)

Southern California
309 N. Rampart Street, Suite A
Orange, CA 92868
714.244.7776
714.385.1544 (fax)

Kenneth H. Schell, PharmD, President
California Board of Pharmacy
1625 N Market Blvd., N219
Sacramento, CA 95834
Fax: (916) 574-8618

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Dr. Schell and Members of the California Board of Pharmacy:

We are writing this letter on behalf of the several senior advocacy organizations to urge the Board of Pharmacy to discharge its duty under the law and adopt draft regulations implementing SB 472. Our organizations worked very hard to help pass SB 472, and participated in the public comment process to suggest improvements in the design and format of prescription drug labels. Seniors are the largest consumers of prescription drugs in California, and for years have expressed concerns about the difficulty reading and interpreting the information on their drug bottles. Now that there are draft regulations that take us one step closer to making what can be life saving changes to these drug labels, we urge you to proceed on adopting them. Any appropriate concerns about the draft regulations can be adequately addressed during the formal rulemaking process. Further delays are unnecessary and put the health of Californians at risk.

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The Board had a chance to fulfill its obligation under the law at its August 2009 meeting by adopting the draft regulations recommended by staff. The Board instead opted for another, unwarranted, delay. We are concerned that if draft regulations are not adopted immediately by the Board, important deadlines will be missed. Even more important than the deadline in the statute, California's policymakers have determined that standardized, accessible, translated prescription labels are a vital element in appropriate health care delivery. Without them we all risk injury, inappropriate care, or even death. Patients have a right to these labels and the Board must not be a barrier to that right.

If you have any questions or would like to follow up with any of us, you can call us at our number, listed below.

Sincerely,

Ernie Powell, AARP
Phone:

Betty Perry, OWL
Phone:

Margie Metzler, Gray Panthers of CA
Phone:

CAPITOL OFFICE
STATE CAPITOL
SACRAMENTO, CA 95814
(916) 651-4010
(916) 327-2433 FAX

DISTRICT OFFICES
1057 MACARTHUR BLVD., STE 206
SAN LEANDRO, CA 94577
(510) 577-2310
(510) 577-2308 FAX

(408) 286-0329 SAN JOSE

39155 LIBERTY ST., STE F-610
FREMONT, CA 94538
(510) 794-3900
(510) 794-3940 FAX

Senate

California Legislature

ELLEN M. CORBETT

SENATOR

TENTH SENATE DISTRICT

STANDING COMMITTEES
CHAIR, JUDICIARY
APPROPRIATIONS
BUSINESS, PROFESSIONS & ECONOMIC DEVELOPMENT
ENERGY, UTILITIES & COMMUNICATIONS
ENVIRONMENTAL QUALITY
LEGISLATIVE ETHICS

SELECT COMMITTEES
CHAIR, BIOTECHNOLOGY
CHAIR, EARTHQUAKE & DISASTER PREPAREDNESS

October 20, 2009

Dr. Kenneth H. Schell, President
California Board of Pharmacy
1625 N. Market Boulevard, Ste. N219
Sacramento, CA 95834

Dear Dr. Schell:

I wish to take this opportunity to express my strong support of draft regulations, currently before the CA Board of Pharmacy, as it relates to the implementation of Senate Bill 472, which I authored.

As you may recall, this legislation was enacted with the intent to protect consumers by reducing the incidences of medication related errors. The legislation directs the Board to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy and other health care professionals to develop a standardized, patient-centered prescription drug label. It further directs the Board to consider all of the following factors when developing the new label:

- Medical literacy research that points to increased understandability of labels
- Improved directions for use
- Improved font types and sizes
- Placement of information that is patient-centered
- The needs of patients with limited English proficiency
- The needs of senior citizens
- Technology requirements necessary to implement the standards

It is my understanding that the Board was presented with draft regulations for consideration at its August 2009 meeting which met the above criteria, including the use of a 12 point sans serif font for specified items as well as standardization of directions for use and how those directions are to be translated. However, a

decision to adopt these draft regulations was delayed due to implementation concerns raised by industry representatives. I believe that these concerns are unwarranted and that any and all concerns about the draft regulations can be adequately addressed during the formal rulemaking process. I therefore respectfully request that the Board adopt these proposed draft regulations without delay and allow the process to move forward. Any further delays are unnecessary and risk the lives of millions of Californians.

Should you have any questions or if I may otherwise be of assistance, please do not hesitate to contact me.

Sincerely,

Ellen M. Corbett

ELLEN M. CORBETT
Senator, District 10

EMC:sm

CPEHN
California Pan-Ethnic Health Network

October 20, 2009

Kenneth H. Schell, PharmD
President
California Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834
Via Fax (916) 574-8618

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Dr. Schell and Members of the California Board of Pharmacy:

On behalf of the California Pan-Ethnic Health Network (CPEHN) and the organizations and individuals listed below, we are writing to urge the Board of Pharmacy to fulfill its duty under the law and adopt draft regulations implementing SB 472. Our organizations represent diverse patients and communities in Californians. Patients must not be kept needlessly waiting for draft regulations to be adopted. Any concerns about the draft regulations can be addressed during the formal rulemaking process. Further delays are unnecessary and put the health of Californians at risk.

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The Board had a chance to fulfill its obligation under the law at its August 2009 meeting by adopting the draft regulations recommended by staff. The Board instead opted for an unwarranted delay.

The Board of Pharmacy staff have done an excellent job over the past year researching the issue, holding public hearings, conducting surveys, and reaching out to experts. The draft regulations that we have seen are a good start to begin the process of public review. Although we do have some suggestions to improve the proposed regulations that staff presented to the Board (for example, translated standardized labels should be available on the Board website in all Medi-Cal Managed Care threshold languages), the public rulemaking process is the appropriate place to address stakeholder comments. The draft regulations recommended by staff should be adopted at the next Board meeting to begin this formal rulemaking process.

654 13TH Street • Oakland, CA 94612 • (510) 832-1160 • (510) 832-1175 FAX
www.cpehn.org • info@cpehn.org

We are concerned that if draft regulations are not adopted immediately by the Board, important deadlines will be missed. Even more important than the deadline in the statute, California's policymakers have determined that standardized, accessible, translated prescription labels are a vital element of quality health care. Without them we all risk injury, inappropriate care, or even death. The Board must begin the formal regulatory process now.

Sincerely,

Marty Martinez, MPP
Policy Director
California Pan-Ethnic Health Network

Organizational Signatories:

Lupe Rodriguez, ACCESS/Women's Health Rights Coalition

Guadalupe Morales, AltaMed Health Services Corporation

Sharen Muraoka, American Cancer Society, California Division, Inc.

Wendy Ho, Asian & Pacific Islander American Health Forum

Sedora Tantraphol, Asian Americans for Community Involvement

Dong Suh, Asian Health Services

Hala Masri, Asian Pacific American Legal Center

Rose Roach, CA School Employees Association

Eboni Gaytan, California Black Women's Health Project

Elizabeth Sholes, California Council of Churches/California Church IMPACT

Vanessa Cajina, California Immigrant Policy Center

Marisol Franco, California Latinas for Reproductive Justice

Cindy Young, California School Employees Association

Kinkini Banerjee, California WIC Association

Darlene March, Cal-Islanders Humanitarian Association

Joseph Villela, Coalition for Humane Immigrant Rights of Los Angeles

Lynette Jung Lee, East Bay Asian Local Development Corporation

Judith Baker, Federal Hemophilia Treatment Centers/Region IX

Jeff Xiong, Fresno Center for New Americans

Jeanette Anders, Language Line Services

Patrick Guillen, Libreria Del Pueblo, Inc.

Lynn Kersey, Maternal and Child Health Access

Anthony Maguadog, National Organization for the Advancement of Chamorro People

Kevin Prindiville, National Senior Citizens Law Center

Jessica Peters, Regional Asthma Management and Prevention (RAMP)

Anita Le, SSG/PALS for Health, and ALAS para tu Salud

Armando Valdez, Valdez & Associates

Individual Signatories:

Anneliese Wells

Darci Graves

Delia Rapolla

Diane Lesher

Fatima Rodriguez

Gloria Riese

Guadalupe Rodriguez

Idabelle Fosse

Jenna Carlsson

Jocelyn Nunez

Jose Antonio Gonzalez

Joseph Herzog

Maribet Rivera-Brute

Marisol Franco

Nora Goodfriend-Koven

Sharon Turner

Shoshana Silberman

Enforcement Program

Board of Pharmacy

Governor's Goal

- Close all cases between 12 to 18 months.
- Boards will be audited and Executive Officers held accountable.

New Enforcement Model

- Use of non-sworn investigators
- Use of in-house experts, paralegals and attorneys
- Improved access to records
- Automatic suspension for incarceration
- Delegated authority to issue investigational subpoenas

New Enforcement Model (con't)

- Policy for anonymous complaints
- Board member voting
- Default decisions and license surrenders
- Burden of proof
- Immediate cease practice order
- Suspension for positive drug test

New Enforcement Model (con't)

- Immediate stipulated settlement
- Mandatory revocation/license forfeiture

Total Time

- 2.5 years for disciplinary cases
- 330 days for citation and fine and letter of admonishment cases
- 330 days for all other investigations
- 70 days for non-jurisdictional cases

FY 08/09 Closures

90 days	593
180 days	384
1 year	668
2 years	379
3 years	82
Over 3 years	27
Total cases closed	2133

Complaints/Investigations

	FY 04/05	FY 06/07	FY 08/09
Initiated	**1480**	**2285**	**2515**
Closed	**1985**	**1657**	**2146**
Pending (at the end of FY)	**655**	**1484**	**2742**

Cases Pending by Team

	FY 04/05	FY 06/07	FY 08/09
Compliance Team	**87**	**94**	**194**
Drug Diversion/Fraud	**89**	**82**	**202**
Mediation/Enforcement Team	**108**	**322**	**126**
Probation/PRP	**40**	**61**	**98**
Criminal Conviction*			**1410**

* Unit Established Jan. 2009

Application Investigations

	FY 04/05	FY 06/07	FY 08/09
Initiated	**129**	**298**	**351**
Closed	**149**	**147**	**288**
Total	**149**	**147**	**288**
Pending (at the end of FY)	**39**	**186**	**338**

Citation and Fines

	FY 04/05	FY 06/07	FY 08/09
Issued	754	735	965
Closed	1004	657	1064
Total Fines Collected	$428,904.00	$436,711.70	$ 1,175,475.00

Administrative Cases

	FY 04/05	FY 06/07	FY 08/09
Referred to AG's Office	113	94	136
Pleadings Filed	73	88	72
Pending			
Pre-accusation	59	62	137
Post Accusation	77	56	99
Total	173	147	267
Closed	80	128	71

Internal Improvements

- Routing complaints on-line (approx. 30 day reduction in investigation time)
- Routing draft pleadings on-line (approx. 15 day reduction)
- On-line mail ballots (approx. 15 day reduction)
- Prepare default decisions (approx. 75 day reduction)

Medication Errors: Challenges & Opportunities

Michael J. Negrete, PharmD
Chief Executive Officer

Pharmacy Foundation of California

Pharmacy Foundation of California

Definitions

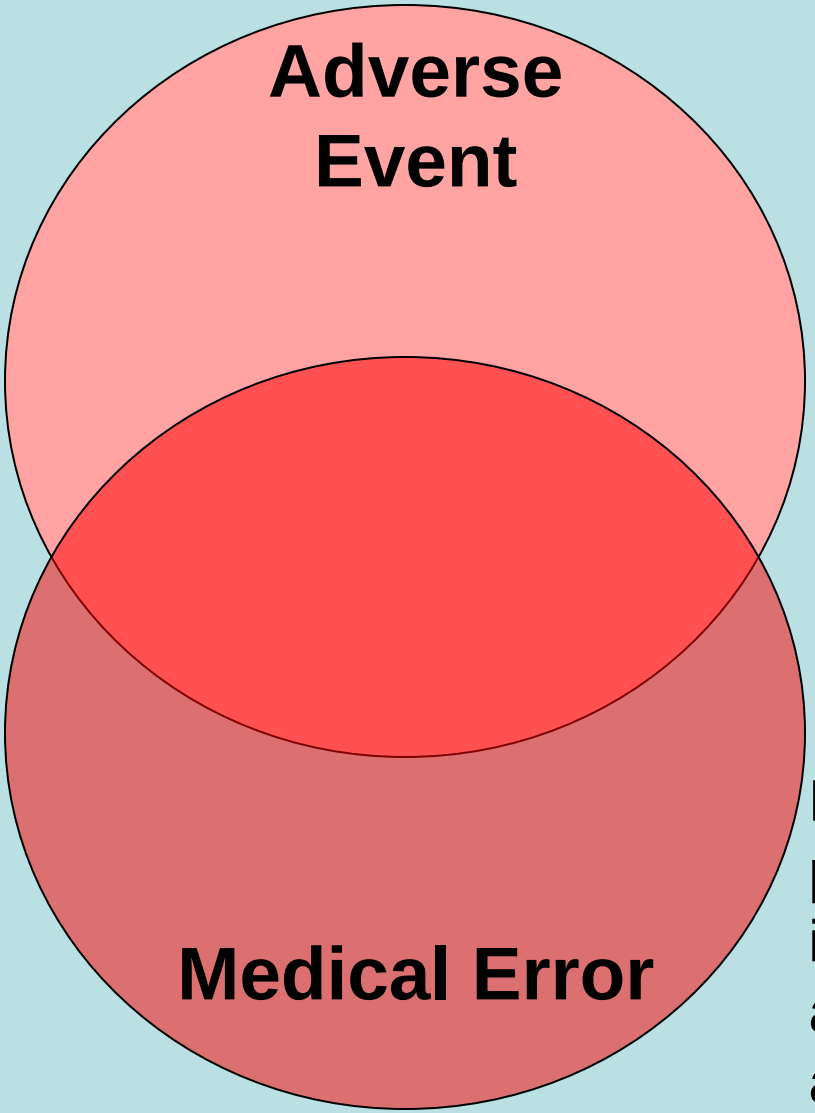
Definitions

Medical Care

Adverse Event

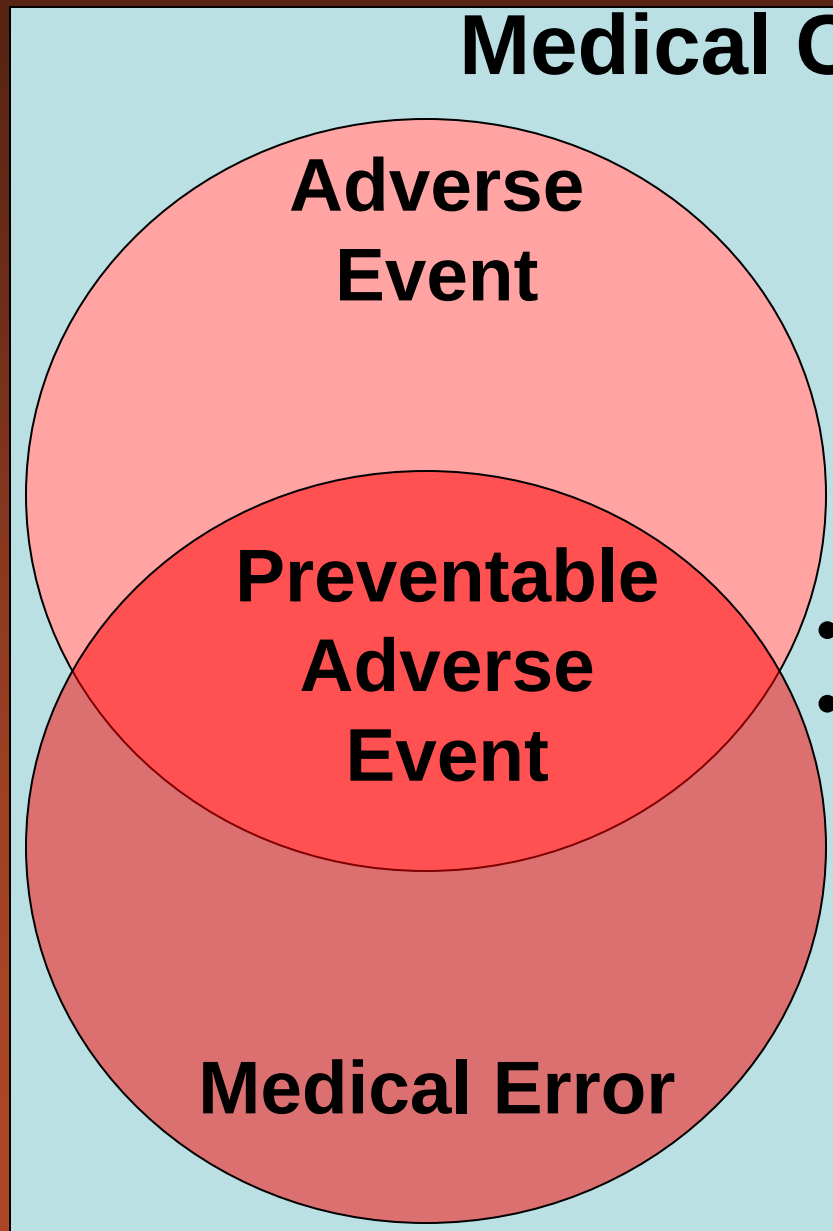
An injury caused by medical management rather than by the underlying disease or condition of the patient.

Definitions



Failure to complete a planned action as intended, or the use of a wrong plan to achieve an aim

Definitions



- 44,000-98,000 deaths
- $17-$29 billion/yr

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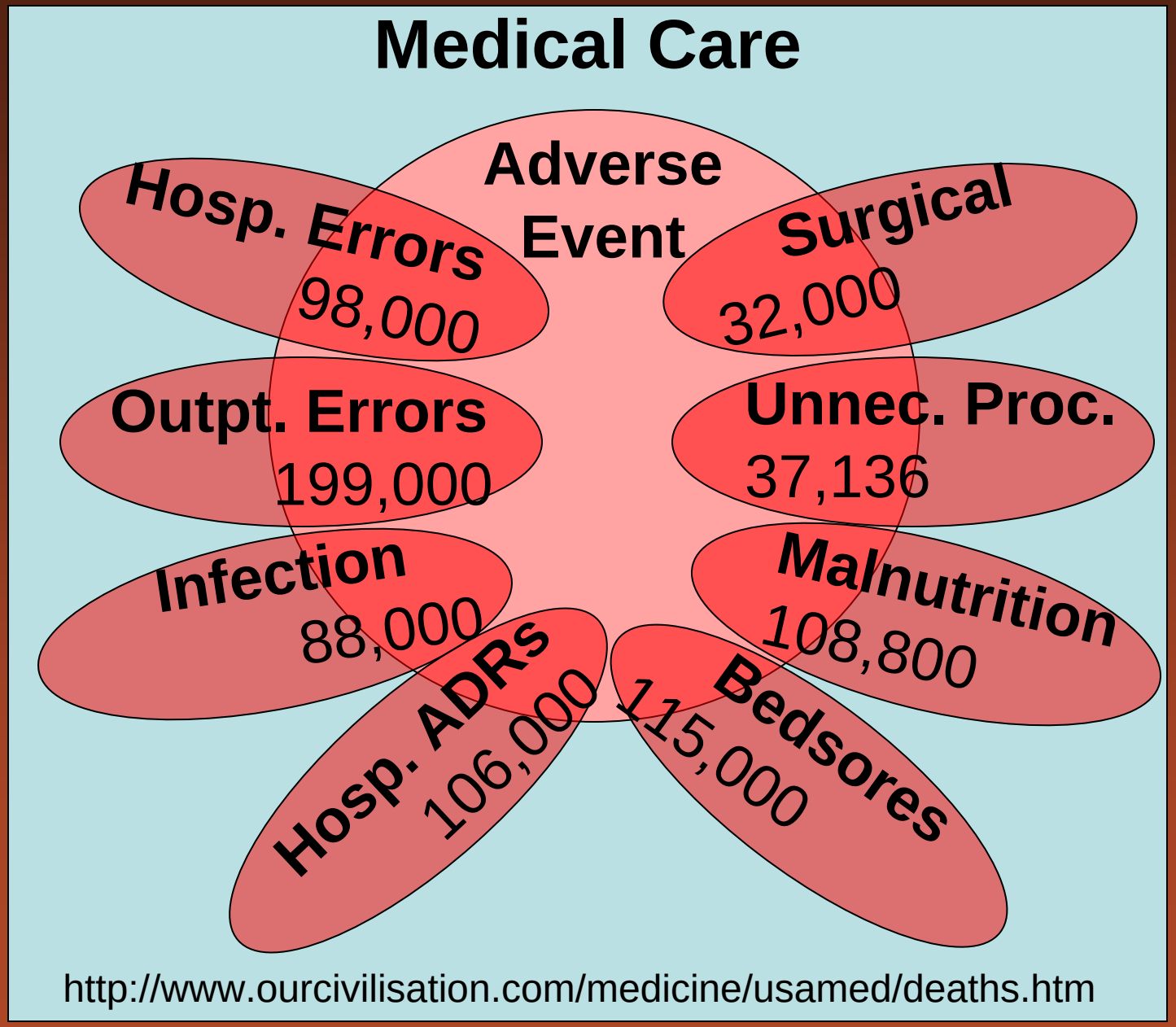
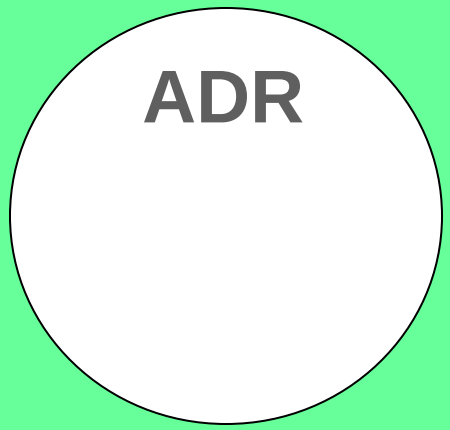
Definitions



Definitions

Medication Use

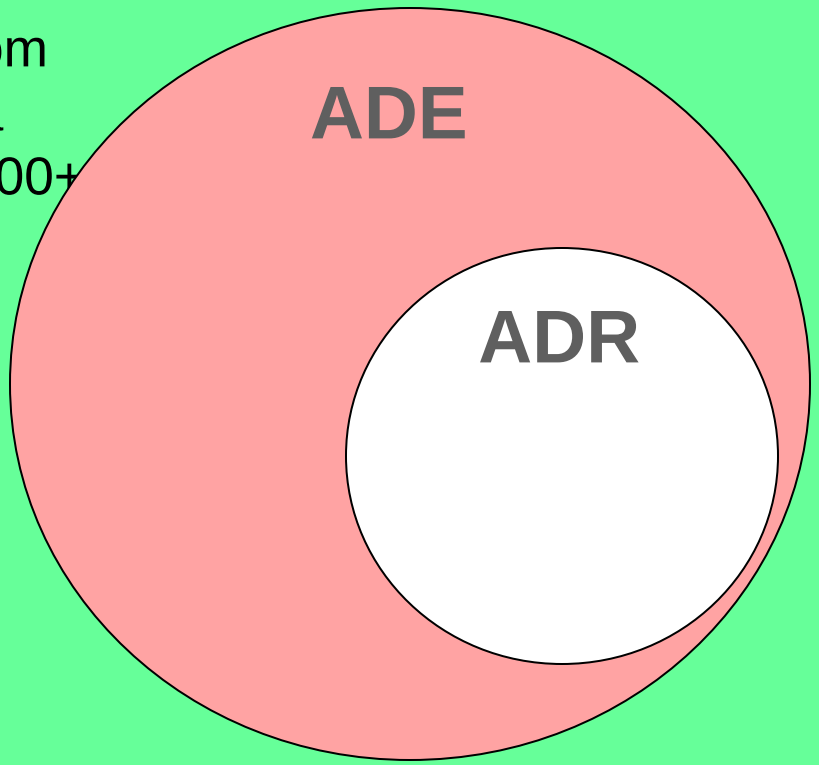


A response to a drug that is noxious and unintended, which occurs in normal therapeutic doses.

Definitions

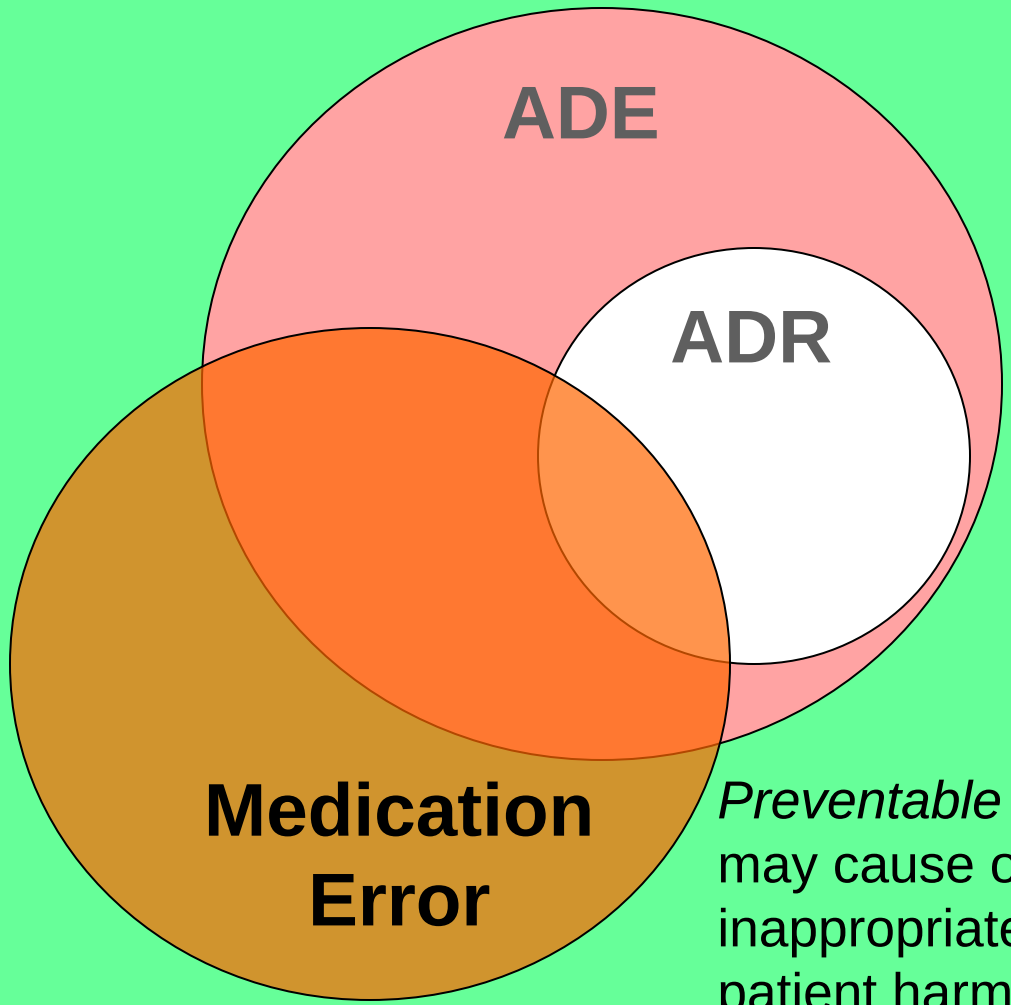
Medication Use

Any injury resulting from the use of a drug. 100,000+ deaths/yr



Definitions

Medication Use



Preventable events that may cause or lead to inappropriate med use or patient harm.

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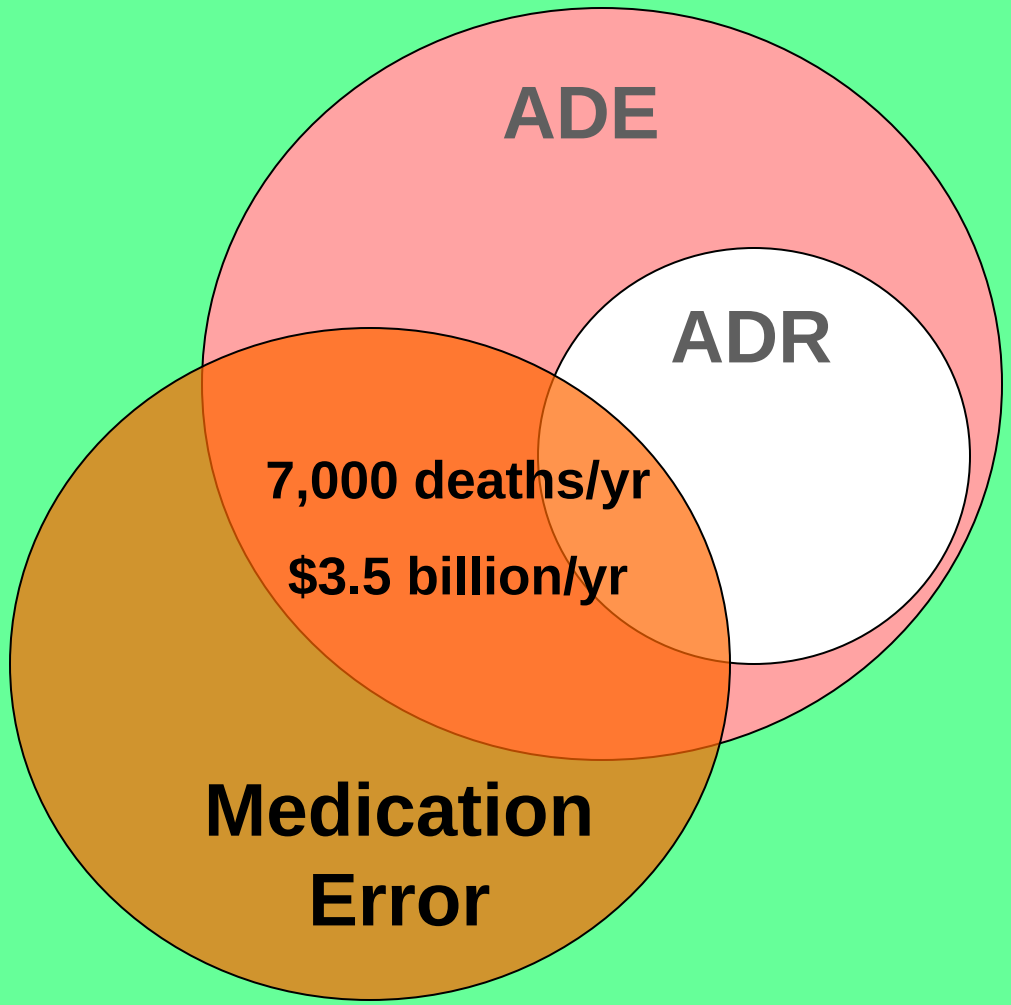
Definitions

Medication Use



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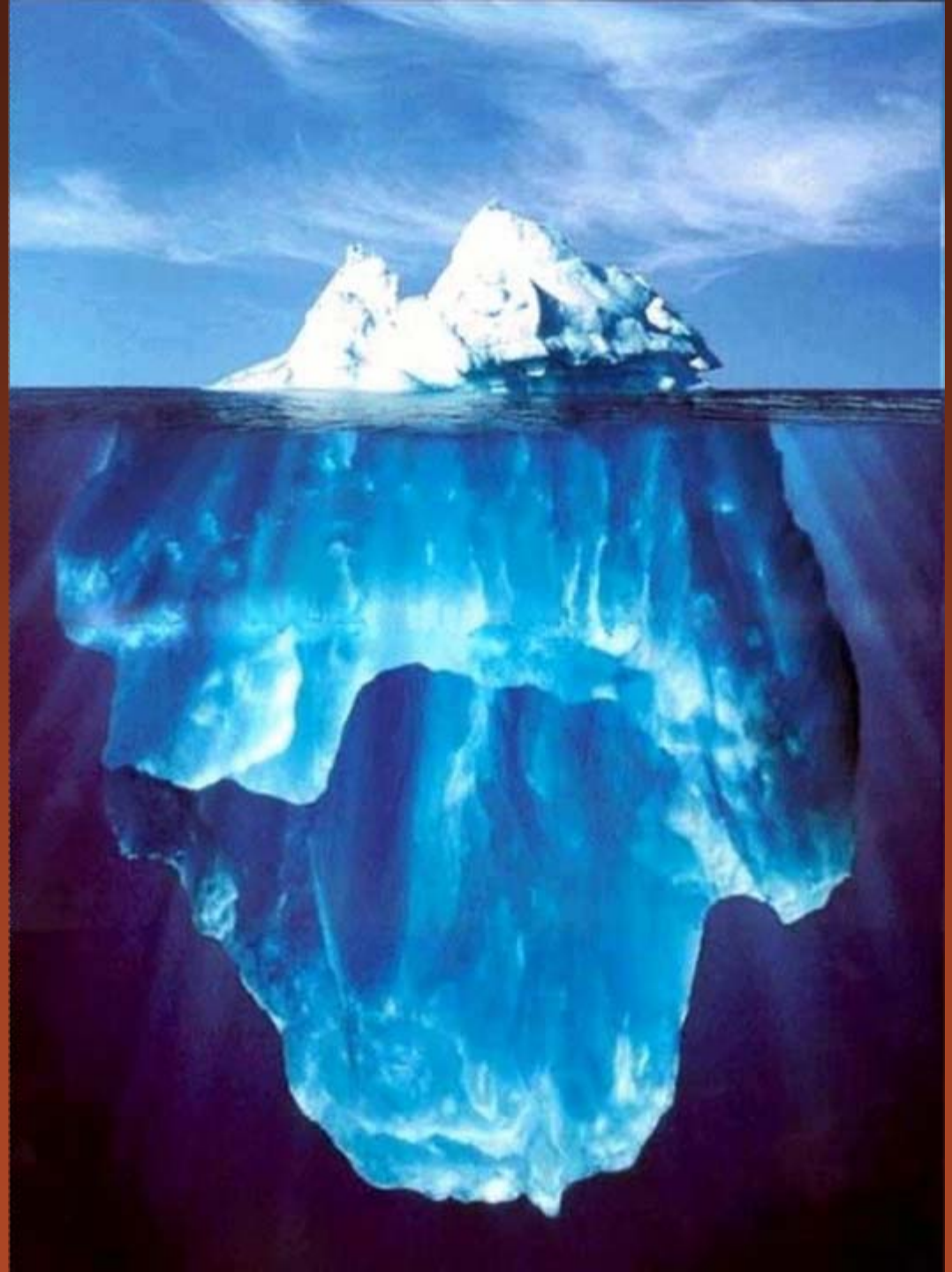
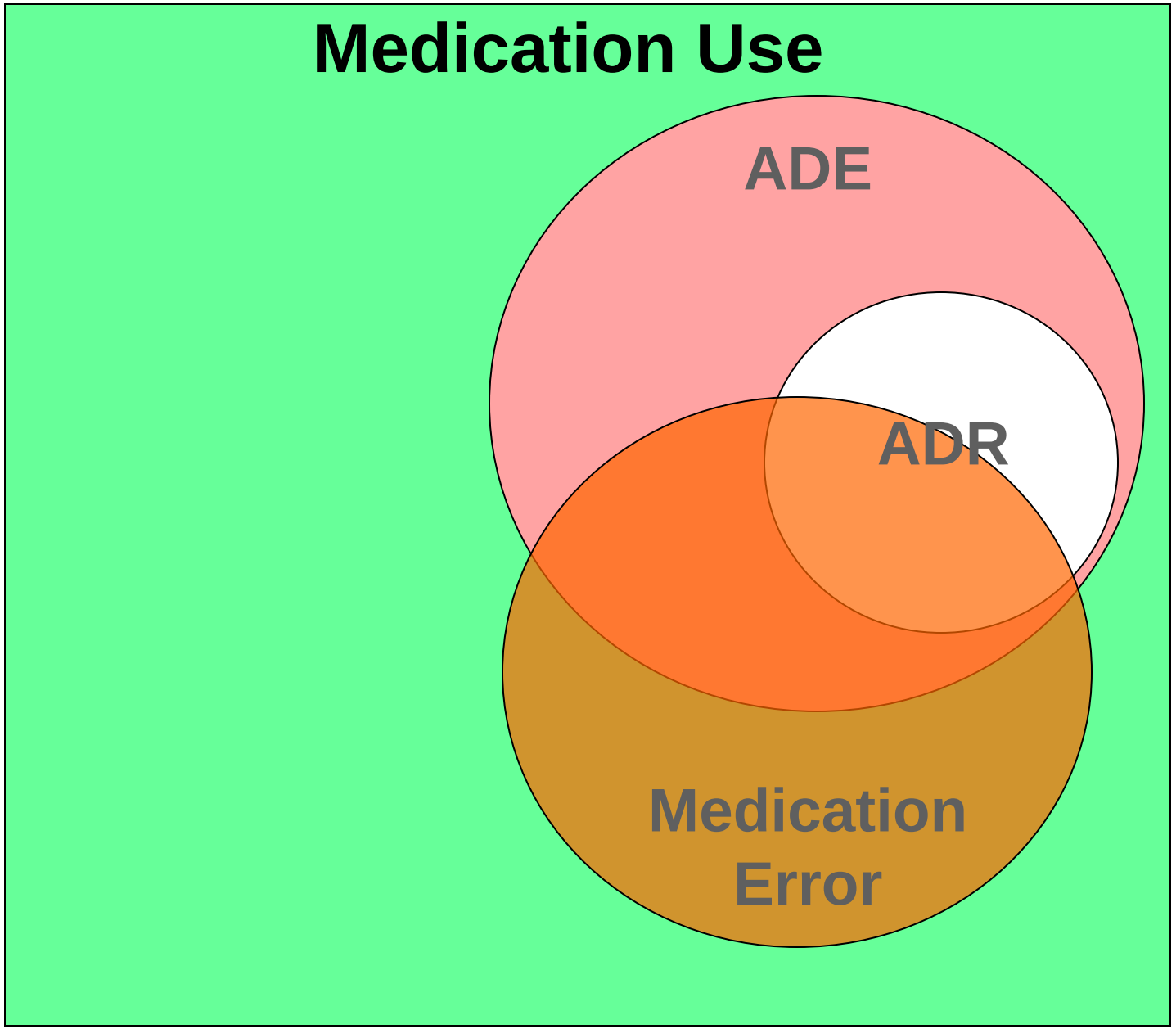


Definitions



Definitions

Medication Use

Drug Related Problem

Event or circum-stance involving drug treatment that actually, or or potentially, interferes with patients achie-ving an optimal therapeutic outcome

$77-$177 billion/yr

ADE

ADR

Medication Error

Fatal Medication Errors

(Philips, et al 2008)

- Analysis of CDC death certificates 1983-2004
- FME as cause of death

  "Accidental overdose of drug, wrong drug given or taken in error, and drug taken inadvertently [and] accidents in the use of drugs and biologicals in medical and surgical procedures."
- Excludes suicides & homicides due to poisoning, as well as etoh or "street drug" overdoses

Fatal Medication Errors

- 5 times more FME deaths occurred *in the home* than all other places combined (incl. hospitals)
- On average, more than 34 Americans die in their home *each day* because of a medication error

Skyrocketing Increases

- Between 1983 and 2004, these "domestic FMEs" increased by more than 1,000%
- Increase was 10 times greater than that observed among FMEs in all other non-domestic settings

Why Is This Happening?

Systems are perfectly designed to obtain the results that they achieve

Why Is This Happening?

"External" Forces:

- Aging population
- Increases in chronic disease
- Medical advancements
- Resource constraints

"Internal" Forces:

- Time & resource constraints
- Fragmentation of healthcare delivery
- Poor information technology

Why Is This Happening?

Consumers are increasingly being given more and more medications WITHOUT also being given the tools, support and information they need to safely use them.

Why Isn't There a Public Outcry?

- Patient perceptions re: safety of their medication therapy
  - Very unsafe:
  - Somewhat Unsafe:
  - Uncertain:
  - Somewhat safe:
  - Very safe:

Why Isn't There a Public Outcry?

- Patient perceptions re: safety of their medication therapy
  - Very unsafe: 0
  - Somewhat Unsafe:
  - Uncertain:
  - Somewhat safe:
  - Very safe:

Why Isn't There a Public Outcry?

- Patient perceptions re: safety of their medication therapy
  - Very unsafe: 0
  - Somewhat Unsafe: 1
  - Uncertain:
  - Somewhat safe:
  - Very safe:

Why Isn't There a Public Outcry?

- Patient perceptions re: safety of their medication therapy
  - Very unsafe: 0
  - Somewhat Unsafe: 1
  - Uncertain: 16
  - Somewhat safe:
  - Very safe:

Why Isn't There a Public Outcry?

- Patient perceptions re: safety of their medication therapy
  - Very unsafe: 0
  - Somewhat Unsafe: 1
  - Uncertain: 16
  - Somewhat safe: 25
  - Very safe:

Why Isn't There a Public Outcry?

- Patient perceptions re: safety of their medication therapy
  - Very unsafe: 0
  - Somewhat Unsafe: 1
  - Uncertain: 16
  - Somewhat safe: 25
  - Very safe: 58

Patient Perceptions

- Why do you believe it's safe?
  - 25% - meds not dangerous
  - 14% - they take "precautions"
  - 61% - MD is ensuring safety

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What's wrong with this picture?

Consumers Must Understand:

No matter how smart or well-intentioned their doctors or pharmacists may be, they too often aren't given the information and time they need to ensure the safety of their therapies

Consumers Must Demand:

That their doctors and pharmacists be given the time and information they need to ensure the safety of their therapies.

- Pharmacist consultations
- Medication Therapy Management
- Point-of-Care monitoring

Our Healthcare System is Driven by Chief Complaints

How do we get this to be a chief complaint of patients, caregivers, advocates and legislators?

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Questions?