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

Enforcement Committee Report

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The Enforcement Committee met on September 16, 2009, in Los Angeles. There was not a Work Group on E-Pedigree Meeting held in conjunction with this meeting. Minutes of this meeting are provided in **Attachment A**, at the back of this tab section.

A. FOR INFORMATION, DISCUSSION AND POSSIBLE ACTION: Overview of Proposals to Strengthen the Enforcement Programs of the Health Care Boards of the Department of Consumer Affairs

1. Proposals of the Department of Consumer Affairs

Attachment 1

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. The Board of Pharmacy is one of these agencies.

These changes were initiated following problems identified at the Board of Registered Nursing by the *Los Angeles Times*.

The first major change was prioritization of fingerprinting of all licensees. 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. It also enables boards to obtain "subsequent" arrest and conviction information if a licensee is arrested or convicted in California.

The second major problem reported in the *LA Times* was the time it was taking the Board of Registered Nursing to investigate complaints and complete enforcement actions, which exceeded 3.5 years. 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. This delayed investigations. Additionally the time it takes to secure complete work by the Attorney General's Office and Office of Administrative Hearings further added delays.

The DCA has responded with a series of proposals to strengthen the BRN's enforcement program as well as that of other health care boards. (**Attachment 1**)

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

Attachment 2

Concurrently, the Senate Business, Professions and Economic Development Committee developed a series of proposals. (**Attachment 2**) The overall goal is to complete formal investigations from the time a complete is received, through investigation and through final action on the stipulation or proposed decision by the board. The goal is 12-18 months – a very aggressive standard, but on that the public deserves.

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

Attachment 3

A joint legislative proposal, SB 294 was amended (“gutted and amended” in the parlance of the Legislature) on September 4 to carry some of the Administration’s and Senate’s proposals for improving DCA’s enforcement programs. (**Attachment 3**) Whereas initial hopes for the bill were to have it reach the Governor by the end of the legislative year on September 11, the bill has become a two year bill. A bill analysis of this bill is provided in **Attachment 3**.

4. Enforcement Priorities of the Department of Consumer Affairs

Attachment 4

For your information, **Attachment 4** contains the Department of Consumer Affairs Guidelines for complaint prioritization.

B. FOR INFORMATION, DISCUSSION AND ACTION: Enforcement Program of the Board of Pharmacy and Proposals to Strengthen Board Operations

At the Enforcement Committee Meeting, the committee discussed the board’s enforcement program. Whereas this board has better timelines than the BRNs, they are not 12-18 months for most formal discipline, which is the average timeline targeted by the director and Administration. The board needs to strengthen its enforcement program, and provide faster resolution time. The board will need additional staff. Since August staff has been working on program changes and budget change proposals to augment staff so we can improve our program.

1. **FOR INFORMATION:** During the Board Meeting, staff will provide an overview of the board’s enforcement program components.
2. **FOR ACTION:**

Enforcement Committee: 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.

Attachment 5

Background:

As mentioned above, the Board of Registered Nursing's failure to fully fingerprint its licensees, thereby preventing that board from learning about arrests and convictions of its licensees, resulted in several negative press articles at the beginning of the year.

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.).

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. But other boards only began fingerprinting applicants in the late 1980s and later. As a result, knowledge about serious criminal convictions involving licenses substantially related to their professional practices may not reach the licensing board and these individuals are allowed to remain in practice, risking patient safety.

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. 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 immediately review and investigate reports of criminal convictions and arrests. The board received 6.5 new positions effective July 1, 2009. The last two of these positions were filled in mid-September. These staff are now working to investigate a backlog of rap sheets awaiting review.

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 rapsheets 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.

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. However SB 389 was stalled in a policy committee of the Legislature.

As such, 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.

At the September Enforcement Committee Meeting, the committee recommended that the board move forward with this regulation. Draft language is provided in **Attachment 5**.

C. FOR INFORMATION: Discussion of the Actions of the Department of Consumer Affairs Health Care Boards to Develop Requirements Pursuant to SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for Practitioner Recovery Programs

Attachment 6

At the June Enforcement Committee Meeting, the committee heard a presentation on SB 1441. Senate Bill 1441 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. This committee is subject to Bagley-Keene Open Meeting Act and is comprised of executive officers and bureau chiefs from specified boards and bureaus. The Board of Pharmacy is one of these participating boards.

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.) The workgroup is responsible for developing recommended standards. The recommended standards will be vetted during a Uniform Standards Workshop, a public meeting akin to an informational hearing. The draft standards will then be presented during a public meeting to the SACC for consideration and action. The last meeting is scheduled for November 16.

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

And the last meeting is proposed for November 10, 2009

The SACC meetings were held:

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

Attachment 6 contains a copy of the draft of standards (through 12) developed to date.

D. FOR INFORMATION: Implementation of the Board of Pharmacy's Ethics Regulation, 16 CCR Section s 1773 and 11773.5

Earlier this year, the board adopted a regulation to establish an ethics course as an enforcement option for those whose violations and resultant discipline had an ethics issue. 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.

The board will work with the Institute for Medical Quality to establish this course. The IMQ is a foundation of the CMA that operates a similar program for the Medical Board, and was the model the board used to develop the components for its ethics program.

When the board was considering options for ethics violations, it formed a subcommittee of Board Members Rob Swart and Susan Ravnan. 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. He has appointed Enforcement Chair Rob Swart to this subcommittee and will appoint one additional member.

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 a course provider in establishing the parameters.

The goal is to have the course ready for administration at the end of the year.

E. FOR INFORMATION: Discussion and Presentations About Prevention of Medication Errors

Attachment 7

During this meeting, Dr. Michael Negrete of the Pharmacy Foundation of California will provide information on medication errors. This presentation is part of a CE presentation he has developed.

Additionally, recently Consumers Union published an update of the 1999 Institute of Medicine report of "To Error is Human," documenting the large number of medication errors in hospitals, where as many as 98,000 people die annually, needlessly, due to preventable errors. This report, titled "To Err is Human – to Delay is Deadly" is copied as **Attachment 7**.

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

California regulators did initiate action based on the initial IOM report. 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. This is a standard component checked during all board inspections of pharmacies.

According to preliminary data from 2008-09, over 10 percent of the board's investigations involve medication errors. Last fiscal year (as of June 1, 2009) we closed 316 medication error complaints; 75 percent of these were substantiated.

Additionally, the California Department of Public Health has implemented statutory requirements to improve the care in hospitals. A presentation is planned for the January 2010 Board Meeting on this subject. 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.

F. FOR INFORMATION: Other Items from the September 16, 2009 Enforcement Committee Meeting

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

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. 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 receive \$8 million. 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. 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).

At the end of the presentation, board staff agreed to work with attorneys to develop some proposals. At the time of this Board Meeting, there are no proposals to present. Board staff will have some approaches available at the next committee meeting in December.

2. Presentation by Daiichi Sankyo on Third Party Logistics Providers

The Enforcement Committee heard a presentation by Daiichi Sankyo on the operations of third party logistics providers. A copy of the presentation is attached to the meeting minutes in **Attachment A**.

3. Review of the Report of the 2008 Report of the Research Advisory Panel of California **Attachment 8**

The California Health and Safety Code establishes the Research Advisory Panel to oversee research involving use of controlled substances. 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.

In **Attachment 8** is a copy of the 2008 report of the panel that was recently received by the board. Pages 39 – 42 of this report provide the statutory mandate of the panel. The Board of Pharmacy has one representative on this panel – Dr. Peter Koo of UCSF.

The Enforcement Committee had no comment on this report.

G. FOR INFORMATION: Minutes of the September 16, 2009, Enforcement Committee Meeting

Attachment A

H. FOR INFORMATION AND POSSIBLE ACTION: Update on the Status of Drug and Sharps Take Back Programs in California Pharmacies

For nearly two years, the board has been working with other state and some local agencies to develop model guidelines for the take back of unwanted prescription drugs from patients. In February, the California Integrated Waste Management Board finalized these guidelines.

The guidelines were developed pursuant to SB 966 (Simitian, Statutes of 2007), and provide components for three primary types of take back programs: 1. in pharmacies or sometimes other locations, 2. at one-time or ongoing community events, and 3. return via mail back.

The board will publicize these guidelines in its next 2009 newsletter, *The Script*.

As reported at the last board meeting, according to data collected late in 2008 by the California Integrated Waste Management Board, fewer than 100 California pharmacies report they are participating in take back programs. This is probably lower than the actual number of pharmacies in California operating such programs, and anecdotally it seems that an increasing time number of pharmacies are establishing programs. However, staff is aware that many pharmacies will not participate in any take back program until the board supports the programs. (There are over 6,100 community pharmacies and over 500 hospital pharmacies in California.)

At this Board Meeting several licensed waste hauling companies that provide collection bins for drug and sharps take back will provide information to the board.

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

Attachment 9

When the Board of Pharmacy first funded the CURES program back in the mid-1990s, the goal was always to prevent patients with drug-seeking behavior from receiving controlled substances from pharmacies for drugs that should not have been prescribed. 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. 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.

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. The data would be as old as three weeks.

Attachment 9 contains access information and a press release from Attorney General Brown on the activation of this system.

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

J. FOR INFORMATION: Enforcement Statistics of the Board

Attachment 10

K. FOR INFORMATION: First Quarterly Report on Enforcement Committee Goals

Attachment 11

Attachment 1

Enforcement Program Changes of the DCA

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HEALTH BOARDS ENFORCEMENT MODEL

August 24, 2009

The Department of Consumer Affairs (DCA) is the umbrella agency for 18 healing arts boards whose core responsibilities are found in their examination, licensing, and enforcement programs. The examination of prospective licensees and implementation of strict licensing requirements ensure that those entering the profession demonstrate at least a minimum level of competence in their chosen field. Once licensed, the vast majority of practitioners serve consumers competently and professionally. However, when a person holding a license fails to uphold the established level of professionalism or ethics, swift and just enforcement must be taken in order to protect the integrity of the issued license.

Today, however, the boards' enforcement programs plagued with legal and procedural impediments that drastically delay the boards' ability to protect consumers and the integrity of their licensees.

Both licensees and consumers have an interest in quick resolution of complaints and discipline. Consumers need prompt disciplinary action against licensees who do not perform to professional standards. Professional licensees have an interest in timely review of consumer complaints to keep the trust of their patients.

The Medical Board and Dental Board are the only two health boards with staff investigators. And all boards use the Office of the Attorney General to prosecute cases through the Office of Administrative Hearings. However, the level of services provided varies from board to board. In addition, many boards are unaware of best practices or policies employed by other boards.

Numerous reports, audits, and reviews have recently noted the deficiencies of the professional enforcement process. Piecemeal recommendations for additional staff, streamlined operations, and better coordination among those involved have been implemented with minimal success.

A disciplinary process that takes three years or more to complete is simply not acceptable. Consumers and licensees deserve much better, and all stakeholders must work with DCA to quickly ensure improved consumer protection through effective enforcement.

The DCA recognizes that it does not operate in a vacuum. Consumer advocates, professional associations, and other government agencies must be involved in the development of a new enforcement system that produces swift and fair resolution of complaints.

The following suggestions for a new enforcement model are based on three elements. These are **Increased Accountability**, **Greater Efficiency**, and **Putting Consumers First**.

INCREASED ACCOUNTABILITY

Enforcement Staff

Most boards do not have investigators or prosecutors on their staff, rely on outside entities, including the DCA's Division of Investigation, the Office of the Attorney General, and the Office of Administrative Hearings. Housing investigators within the Division of Investigation does not allow investigators to specialize and can leave multiple boards vying for limited investigative staff. To the greatest extent possible, each board should retain and manage its own enforcement staff for maximum accountability. To achieve this, the following actions are recommended:

- Hire investigators directly within each board. Additionally, other staffing options, such as hiring paralegals to prepare less complex accusations, statements of issues, and stipulated settlements, should be considered.
- Hire expert consultants on staff and housed within each board. This would be similar to the Medical Board's vertical enforcement program, where on-staff experts would be utilized to review complaints or provide guidance to enforcement staff as necessary during the investigatory process.
- Seek statutory authority for the DCA to hire a staff of prosecuting attorneys that would be assigned to boards as necessary.
- Establish within DCA a small unit of sworn peace officers to provide services in those rare cases where the peace-officer training/status is needed. The DCA would also ensure that those requests for criminal background checks through CLETS are timely completed.
- Administrative changes should be made, in consultation with the Department of Finance, to enable boards to make budgetary changes more quickly to respond to changing conditions. Currently, budget cycles, restrictions on spending special funds, and other impediments often times force boards to be reactive rather than proactive when dealing with enforcement matters. Additionally, the DCA should work with the Department of Finance and State Personnel Board to look into ways of improving its recruitment and retention of enforcement personnel.

Administrative Hearings

Seek statutory authority for OAH to establish its own administrative hearings section and employ administrative law judges, to hear and decide cases specific to DCA healing arts boards and bureaus. This would maintain the existing "firewall" to ensure a separation of duties and the integrity of a neutral hearing by a third party. In addition,

accountability still resides, overall, with the State and Consumer Services Agency . Boards within DCA often experience significant delays in the prosecution of cases because of the long timeline for having a hearing set with an Administrative Law Judge. In order to improve prosecution timelines, a separate unit should be established within the Office of Administrative Hearings, with Administrative Law Judges dedicated to DCA cases.

Enforcement Compliance Officer

The DCA should establish an Enforcement and Compliance Officer. This position, which would report to the Director, would regularly examine each board's enforcement program to monitor enforcement performance and ensure compliance with all applicable requirements. Additionally, the Enforcement and Compliance Officer would conduct a complete audit of each board's enforcement program and prepare a full report, requiring board cooperation every 3-4 years. Findings would be shared with all boards and upon request, to any person. The enforcement monitor would also promote consistency and provide oversight.

Caseload/Timelines

Each board, with direction from DCA, should develop a policy for investigative caseload and timelines. Each board would be held accountable to those guidelines during regular audits by the DCA's Enforcement Compliance Officer. Assuming appropriate reforms are enacted, DCA expects investigations to take no more than 180 days (six months).

Performance Accountability

Seek statutory change that requires each board and their executive officer to meet the performance standards provided above in "Caseload/Timelines." Provide that failure to meet those standards after two consecutive audits is grounds for the Executive Officer to be dismissed by the DCA director and/or members to be dismissed by their respective appointing authorities.

Director/Ex-Officio Member

Seek statutory change to add the DCA director or his/her designee as an Ex-Officio member of each board. The addition will ensure accountability between the Board and the Department when coordination of enforcement and other efforts are needed.

Professional Development

Administrative action by the DCA to ensure continuing availability of training for enforcement staff. Training would be available to all boards' enforcement staff, and would include teaching best practices for record collection, performing investigations, and so forth. The training would be provided on a regular basis by DCA.

Special Fund Recognition

Each of DCA's Boards and Bureaus are funded by fees paid by licensees. There are occasions when statewide policies and budgetary process restrictions prevent them from utilizing all available resources. Consideration should be given to provide

additional flexibility to specially funded programs in order for them to more effectively respond to changing conditions.

Case Tracking System

Seek statutory mandate to require a new tracking database to be implemented within three years. DCA shall work with the Office of the Chief Information Officer to develop and implement the database. Boards currently use the DCA's CAS database system, as well as other self-created systems to monitor their enforcement workload. Several attempts have been made (over the last 10 years) to replace the existing CAS, though they have been quashed in the process. The CAS system is 17 years old, cumbersome, unreliable and inefficient. In order to hold board's accountable and measure outcomes, a new system must be put in place and exemptions to speed the development should be provided. The new system should be user-friendly, designed to track status and time frames of both internal and external processes. The system should allow cross license checking for every health board and should be linked to any other external system used in the enforcement process.

GREATER EFFICIENCY

Access to Records

Obtaining records is a key part of completing investigations. Investigators and prosecutors require personnel records, medical records, and criminal history records in the enforcement process.

- Statutory authority for each board to inspect and copy records and obtain certified records at any place where care, treatment or services are provided, without a subpoena. This includes, but is not limited to, personnel records, patient medical records, inspection of the facility, and, when probable cause exists, licensee medical records (including drug/alcohol test results, physical and psychological records, rehabilitation records). Require facility, employer and licensee to cooperate. Failure to provide records as requested may result in a citation and fine not to exceed \$25,000. With personal information, licensees and facilities would be able to obtain a court order preventing or limiting disclosure, with the burden of proof placed on the licensee or facility. Improper access to confidential records by employees of facility may be punished.
- Statutory requirement that each state agency *must* share all public and confidential records with DCA boards, upon request as part of an investigation. Improper access to confidential records by employees of facility may be punished.

Board Suspension

Seek statutory authority for each board's executive officer to suspend a license if the respondent or their legal representation fails to produce documents or participate in an interview, as requested by board staff. Time periods for failing to cooperate for egregious cases may be as little as 7-10 days, and 14-21 days for all other

investigations. The suspension may affect both individual licensees and facility licensees (i.e., pharmacies) and should remain in effect until the requests are met. It is incumbent upon the executive officer to provide notice to the licensee/facility as well as the licensee's employer (if applicable) of the suspension within 24 hours. The executive officer should be responsive within the same time frames if the licensee/facility is willing to cooperate and should lift the suspension within 24 hours of receipt of previously requested documentation/interviews. A suspension could be lifted or modified if the licensee files a petition for writ of mandate and obtains a court order. In this situation, the licensee has the burden of proof.

Automatic Suspension while Incarcerated for Felony or Serious Misdemeanor

Seek statutory mandate to automatically suspend the license and prohibit license renewal of any person who is incarcerated or being held in jail or prison for a felony listed in Penal Code section 1192.7, subdivision (c), or a serious misdemeanor. In addition, these same measures should be applied to any person incarcerated as a result of a felony conviction, regardless if the conviction is being appealed. However, in the latter, the suspension shall remain in effect until the administrative matter is heard.

Subpoenas

Administrative action by the DCA to provide training and grant authority to specific personnel to issue and enforce subpoenas. Even with authority to access records and the threat of a citation and fine, some facilities have still required a subpoena to access records.

Subject Matter Experts

Each board should develop a process to acquire new and qualified subject matter experts as needed to supplement the work of on-staff expert consultants. Subject matter experts would be utilized as needed for investigations requiring specialized expertise, to provide a final review of investigative materials, and provide expert testimony during hearings.

Citation and Fine Process

Seek statutory amendments to streamline and provide consistency for the citation and fine process for all boards. Under existing law, the option for an informal or formal hearing is given to licensees. New procedures would allow the executive officer and two board members to hear the appeal and render a decision, which may be appealed to the full board. Allow hearings to be held in person or telephonically.

Egregious Complaints

Most boards currently have established guidelines that advise when to seek an Interim Suspension Order. Each board should similarly develop a policy to identify cases that may qualify as egregious, warranting expedited handling and immediate suspension.

Intake Process/Complaint Handling

Administrative action by each board, with DCA's assistance, to establish core guidelines to address how complaints should be received, reviewed and assigned. The guidelines should also address the best practices employed by several boards on how to process

each complaint, including appropriate resources to retrieve and review records, and acceptable timeframes. In addition, the guidelines would address when the focus of an administrative investigation should also be referred criminally to the local district attorney.

Development of Complaint Forms and Handling of Anonymous Complaints

Often times, consumer complaints lack sufficient detail to investigate. In cases where a consumer is willing to identify himself or herself, a standardize form may be developed to ensure appropriate information is provided by the consumer so that an effective investigation can be initiated. Further, each board should adopt a policy to identify how it wishes to handle anonymous complaints.

Fees for Records

Only a small number of external governmental agencies charge boards for producing records. However, under current practices, completing the payment can delay delivery of the requested records. A statutory mandate should be sought to compel any law enforcement agency, court, other government entity, health facility or employer who charges a fee for copies of any records, produce and deliver those copies prior to receiving payment from a board.

Board Member Voting

In order to accelerate the timeframe by which Board's render final disciplinary decision, each Board should establish a process for board member to vote through mail, delivery services and/or electronic means.

Default License Surrenders/Revocations

In many cases, the licensee does not contest the disciplinary action and/or voluntarily surrenders his/her license. In these cases, legislative authority should be secured to allow the executive officer to sign all default decisions with an order for license surrender or revocation.

PUTTING CONSUMERS FIRST

After a license is issued, the law grants the licensee a property right to his/her license. As such, a board cannot take action against a licensee without cause, and when a board seeks to take action, the licensee is entitled to certain due process protections, including a hearing. While due process cannot be taken away, the state has discretion in regards to the amount of due process afforded. Over time, due process protections have grown to favor licensees at the expense of consumers. The DCA believes that it is time to put consumers ahead of licensees when disciplinary actions are at issue.

Burden of Proof

A significant contributor to the lengthy enforcement process centers around the burden of proof required of revoking a license. The standard is currently a "clear and convincing" standard of proof that requires a significant burden before a license might be revoked. If an appropriate standard for burden of proof were established, such as a

“preponderance” standard, investigations and hearings could be streamlined considerably. Statutory changes should be pursued to establish an appropriate burden of proof to discipline or suspend a license.

Immediate Suspension Order

Legislative authority to allow the DCA Director (or his/her designee), at the request of an Executive Officer, to immediately suspend any license based on probable cause that the licensee has engaged in conduct that poses an imminent risk of serious harm to the public health, safety and welfare. Such conduct may include, but is not limited to, involvement in serious crimes (e.g. murder, kidnapping, serious bodily harm, sexual assault, etc...), acts occurring at work (e.g. under the influence of drugs or alcohol, serious patient neglect, etc...) or any other act that rises to the level of “imminent risk of serious harm.” The licensee and his/her legal representation and employer (if known) shall be provided notice within 24 hours. The suspension should have a 180 day cap, but must be reviewed by the Director (or his/her designee) at least monthly. In addition, the executive officer should be responsible for reviewing the case upon receipt of any new information to determine if the suspensions should remain in place. The executive officer should notify the Director immediately if he/she believes the suspension order should be lifted. In extremely rare instances, for reasons outside the board’s control, an extension may be granted by the Director, not to exceed 90 days. An immediate suspension order could be lifted or modified if the licensee files a petition for writ of mandate and obtains a court order. In this situation, the licensee has the burden of proof.

Ability to Refuse to Renew a License

Provide that a board may refuse to renew a license on the ground that the licensee has been convicted of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

Diversion Programs

A number of healing arts boards administer diversion programs for licensees with substance abuse or mental health problems. Diversion programs are intended to remove licensees from practice as quickly as possible, and to provide licensees with substance abuse and mental health problems an opportunity to rehabilitate. Diversion programs generally provide a licensee the option of entering into an ongoing monitoring program of some sort, in exchange for the board ceasing an investigation. However, there have been a number of problems with diversion programs, ranging from policy concerns with the general premise of such programs, to practical concerns regarding the efficacy of such programs.

Despite the intent of diversion programs, these programs allow licensees who are violating the law to escape enforcement. Many diversion programs allow licensees with substance abuse or mental health problems to enter into the program confidentially, leaving consumers in the dark.

The DCA proposes to eliminate all diversion programs, and to make it the policy of the healing arts boards to place licensees who have substance abuse or mental health problems on probation, where restrictions can be placed on their practice and where they can be monitored. Additionally, placing these licensees on probation does not allow them to escape enforcement or keep their illegal actions confidential from consumers.

In addition to eliminating diversion programs, the DCA should establish a department-wide contract with a vendor to perform random drug testing for licensees who are on probation for substance abuse problems. The DCA's Enforcement and Compliance Officer should also audit the vendor on a regular basis.

Lastly, the DCA should seek authority to compel any licensee to submit to a drug/alcohol screening, without a subpoena, upon receipt of a complaint or any information where the board has probable cause to believe the licensee is under the influence of drugs or alcohol while at work. If the licensee refuses to submit a sample, or if the test results indicate the licensee was under the influence, the license would be suspended through the "Immediate Suspension Order" process, as described above.

Immediate Suspension for Positive Drug/Alcohol Test

If a disciplinary decision was stayed pending substance abuse treatment, the board should seek authority to automatically suspend the license upon a respondent testing positive for alcohol or drugs.

Immediate Stipulated Settlement

Existing law should be clarified to ensure that a board can enter into a legally binding stipulated settlement prior to filing a formal accusation or drafting a statement of issues. This could reduce workload on enforcement staff. The stipulated settlement may include revocation, surrender, probation, citation and fine, or any other form of discipline. Must also provide that if the stipulation includes probation, that the terms and conditions may not be modified, nor can the respondent petition for early termination of probation.

Statutory changes should also include explicit authority for a board to enter into a stipulated settlement with an applicant for licensure who is on probation or a similar form of discipline from another state licensing entity or an out-of-state licensing entity.

Mandatory Revocation

Seek a statutory mandate requiring any Administrative Law Judge presiding over a disciplinary hearing to order revocation of a license if it is found that the licensee committed unlawful sexual contact with a patient or any other act of sexual misconduct, or was convicted of a felony sex offense or an inherently dangerous felony.

Additionally, current law requires some boards to deny an application or revoke the license of an individual who is required to register as a sex offender as a result of a felony conviction. This provision should be replicated in the practice acts of all or most healing arts boards.

Mandatory Reporting

In order to take action against licensees who violate the law, boards must be aware of the wrongdoing. Boards rely on consumers and other parties to file complaints against those licensees so that they may begin an investigation. The following statutory changes should be sought to improve reporting of violations by licensees:

- Require court clerks to notify *all* health boards of convictions. Also require boards with knowledge that a licensee holds a license by another board, to report to that board any discipline taken.
- Prohibit "regulatory gag clause," where civil settlement prohibits consumer or consumer's legal counsel from filing complaint with board.
- Require employers of licensees and certain other licensees to report known violations made by another licensee. Authorize the issuance of a citation and fine for failure to report.
- Require all licensees to self report any arrest, conviction, or violation of their specific licensing act immediately, and upon application for license renewal. Also require licensees to notify the arresting agency of all professional licenses held.

National Database Search

Seek statutory authority for each board to charge an applicant for licensure for the actual costs to check bona fide databases for disciplinary information. Each board should develop a policy to perform a search on any known bona fide national or other bona fide database as appropriate. The costs to perform searches on current licensees should be paid by the board.

Fingerprinting

While all new fingerprints are performed electronically, not all records at the Department of Justice are kept electronically for licensees who were fingerprinted in the past. Retrieving non-electronic records adds unnecessary time to investigations. The DCA recommends requiring the Department of Justice to place all fingerprint records in its electronic system within four years.

Transparency

Seek statutory requirement that all boards post all disciplinary actions on their web sites, including public reprimands, citations and fines, accusations, statements of issues, stipulated settlements, etc.

Patient Notification

Business and Professions Code Section 138 require all licensees to notify consumers that they are a licensee of their respective board. However, compliance with this requirement has been slow. The DCA should take administrative action to ensure that all boards are enforcing this requirement.

Fiscal Resources

In order to ensure that enforcement changes can be successfully implemented, boards should seek to increase their licensing fees by regulation, or increase the statutory maximum, as necessary.

In addition to, or in lieu of, pursuing fee increases, all boards should consider the following changes relating to cost recovery for enforcement workload:

- Pursue statutory changes as necessary to make cost recovery statutes for all boards authorize the collection of the actual cost.
- Administrative action by DCA to procure one department-wide contract with a collection agency

Attachment 2

Enforcement Program Changes Recommended by the California Senate

INFORMATIONAL HEARING

CREATING A SEAMLESS ENFORCEMENT PROGRAM FOR CONSUMER BOARDS

Monday, August 17, 2009

9:00 A.M. – 12:00 P.M.

Room 3191, State Capitol

BACKGROUND PAPER

Problems with the Board of Registered Nursing Enforcement and Diversion Programs

Since its inception in 1913 as the Bureau of Registration of Nurses, charged with administering nursing examinations, registering qualified registered nurses, accrediting nursing schools, and revoking licenses of nurses found to be unsafe to practice, the protection of the public has been the core function of the Board of Registered Nursing (BRN). The importance of this function is further emphasized in Business and Professions Code Section 2708.1 which states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Lately, the public protection function of the BRN has been confronted by revelations of lengthy enforcement timeframes against problem nurses who continue to practice and provide care to the detriment of patients.

On July 11, 2009, the *Los Angeles Times*, in conjunction with *Pro-Publica*, a non-profit investigative news agency, published an article entitled "*When Caregivers Harm: Problem Nurses Stay on the Job as Patients Suffer*"¹ charging that the BRN, which oversees California's more than 350,000 nurses, often takes years to act on complaints of egregious misconduct. Nurses with histories of drug abuse, negligence, violence, and incompetence continue to provide care, and the BRN often took more than three years, on average, to investigate and discipline errant nurses. The other findings and issues raised by the article include the following:

- 1) **Delays.** Complaints often take a circuitous route through several clogged bureaucracies: from the nursing board for initial assessment to the Department of Consumer Affairs (DCA) for investigation, to the California Attorney General's Office (AG's Office) for case filing and the state Office of Administrative Hearings (OAH) for trial. Lastly, the case goes back to the BRN for a final decision. The biggest bottleneck occurs at the investigation stage, as DCA staffers struggle to handle complaints against nurses as well as those against cosmetologists, acupuncturists and others. Another reason given for the delay is that the nursing

¹ See Charles Ornstein, Tracy Weber & Maloy Moore, *When Caregivers Harm: Problem Nurses Stay on the Job as Patients Suffer*, L.A. Times, July 11, 2009, available at <http://www.latimes.com/news/local/la-me-nurse12-2009jul12,0,2185588.story>.

board must share a pool of fewer than 40 field investigators with up to 25 other licensing boards and bureaus, and some investigators handle up to 100 cases at a time.

- 2) **Sanctions by Other Agencies or Boards.** The BRN failed to act against nurses whose misconduct already had been thoroughly documented and sanctioned by others. There were 120 nurses that were identified by the reporters who were suspended or fired by employers, disciplined by another California licensing board or restricted from practice by other states, yet have blemish-free records with the BRN.
- 3) **Probation and Grounds for Revocation.** The BRN gave probation to hundreds of nurses, ordering monitoring and work restrictions, then failed to crack down as many landed in trouble again and again. One nurse given probation in 2005 missed 38 drug screens, tested positive for alcohol five times and was fired from a job before the BRN revoked his probation three years later. More than half the nurses who respond to allegations from the BRN are handed a second chance. Each year, California places at least 110 nurses on probation, warning that if they get in trouble again, their licenses may be yanked. In reality, such action seldom happens quickly, if at all, according to a review of hundreds of nurse disciplinary records. Just five board staff monitors 470 nurses on probation. Often nurses must undergo physical and mental exams, take drug tests, submit to workplace monitoring and attend rehabilitation or support groups. But when they don't meet some or any of those requirements, years often pass before the BRN tries to revoke their probation. At times, the punishment for violating probation is more probation.
- 4) **Emergency Suspensions.** The BRN failed to use its authority to immediately stop potentially dangerous nurses from practicing. It obtained emergency suspensions of nursing licenses just 29 times from 2002-2007. In contrast, Florida's nursing regulators, who oversee 40% fewer nurses, take such action more than 70 times each year.
- 5) **Funding.** Current and former state attorneys indicate that at times they have been asked to suspend work on nursing board cases to save money. The BRN has not raised its fees in 18 years.
- 6) **Statute of Limitations.** There is no legal pressure for the BRN to act faster. Unlike with disciplinary cases against doctors, there is no statute of limitations on nurses. The delays make the pursuit of cases more difficult: witnesses die, records are purged and former co-workers cannot be found.
- 7) **Hospital Reporting.** Most states require hospitals to report nurses who have been fired or suspended for harming a patient or other serious misconduct. The Board of Vocational Nursing and Psychiatric Technicians (BVNPT) also has this requirement.² However, the BRN does not have a similar requirement for nurses.

² See Business and Professions Code § 2878.1. Any employer of a licensed vocational nurse is required to report to the BVNPT the suspension or termination for cause of any licensed vocational nurse in its employ. This Section also defines suspension or termination for cause for purposes of reporting.

- 8) **Disclosure and Tracking of Cases.** The BRN also largely shuts itself off from information about nurses licensed in California who get in trouble. It is not part of a national compact of 23 state nursing boards that share information about nurses who are under investigation or have been disciplined. And unlike 35 states, California does not put the names of all its registered nurses into an industry database. So if a California-licensed nurse gets in trouble in another state, the state may not know to notify California. Perhaps the most telling instances of dysfunction is when other states act against nurses for crimes and misdeeds committed in California before California's own board does.
- 9) **Fingerprinting and Criminal or Disciplinary Disclosure Requirements.** In a separate article published by the *LA Times*, and in collaboration with *ProPublica* on October 4, 2008,³ it was revealed that nurses convicted of crimes, including sex offenses and attempted murder continue to be licensed by the BRN. As a result of these findings, emergency measures were adopted to require all nurses licensed by the BRN to be fingerprinted and to disclose in their license renewal forms criminal convictions or any discipline imposed by another jurisdiction. The fingerprinting and criminal or disciplinary disclosure requirements were later implemented for other consumer health-boards. SB 389, legislation introduced by Senator Gloria Negrete McLeod in this Session, would have codified and expanded the fingerprinting and criminal or disciplinary disclosure requirements. However, SB 389 initially failed passage in the Assembly Public Safety Committee because of concerns that requiring existing licensees to be fingerprinted might delay the license renewal process. SB 389 is now a two year bill.

In response to the *LA Times* revelations, Governor Schwarzenegger on July 16, 2009, replaced four current members of the BRN and appointed two long-time vacancies. In addition, the former Executive Director Officer of the BRN and the Chief of the Division of Investigation (DOI) at DCA also resigned.

On July 25, 2009, the *LA Times* published another article on the BRN,⁴ this time on the failures of its drug diversion program. This article pointed out that participants in the program continue to practice while intoxicated, stole drugs from the bedridden and falsified records to cover their tracks. Moreover, more than half of those participating in drug diversion did not complete the program, and even those who were labeled as "public risk" or are considered dangerous to continue to treat patients did not trigger immediate action or public disclosure by the BRN. The article further pointed out that because the program is confidential, it is impossible to know how many enrollees relapse or harm patients. But the article points out that a review of court and regulatory records filed since 2002, as well as interviews with diversion participants, regulators and experts suggests that dozens of nurses have not upheld their end of the bargain and oversight is lacking.

On July 27, 2009, the DCA convened a meeting for the purpose of taking testimony and evidence relevant to the BRN enforcement program. This meeting included

³ See Charles Ornstein & Tracy Weber, *Criminal Past Is No Bar to Nursing in California*, L.A. Times, October 4, 2008, available at <http://www.latimes.com/news/local/la-na-nursing5-2008oct05,0,3509040.story>.

⁴ See Tracy Weber & Charles Ornstein, *Loose Reins on Nurses in Drug Abuse Program*, L.A. Times, July 25, 2009, available at <http://www.latimes.com/news/local/la-me-nurse-diversion25-2009jul25,0,128964.story>.

presentations by the DOI and the AG's Office. The BRN's discussion focused on its proposals that were contained in the "*Enforcement Report On the Board of Registered Nursing.*" The report pointed out the following barriers to the enforcement process:

- 1) **Understaffing.** For a number of years, BRN's enforcement unit has been understaffed. For example, five case analysts are assigned 400 – 600 cases.
- 2) **Delays at DOI.** DOI investigators (who provide investigative services to BRN) carry a caseload of 100 cases per investigator.
- 3) **Delays at the AG's Office.** On average, it takes the AG's Office 7.5 months to prepare an accusation, petition to revoke probation or statement of issues. Moreover, AG staff often allows respondents to file a notice of defense long after the 15-day time limit, which lengthens the time a case is processed by the AG's Office. The practice of the AG of not requesting a hearing date when notice of defense is received is also contributing to the delays. The AG's Office often waits for settlement negotiations to break down before requesting a hearing date with OAH.
- 4) **Lack of Information Sharing.** Information sharing between the BRN and BVNPT could be improved. For example, BRN cannot access the licensing or disciplinary records of the BVNPT. In addition, there is no cross-reporting requirement for other agencies to report to the BRN nurses who violate the Nursing Practice Act.
- 5) **Tracking of cases.** BRN relies upon an outdated, limited and cumbersome tracking system that is managed by DCA. Due to limitations of the automated system, BRN has created duplicative systems that do not interact with the DCA's system, therefore staff are required to make multiple entries.
- 6) **Storage.** BRN does not have sufficient space to store case files on-site. Many files are stored off-site and must be transferred to the board office as needed.
- 7) **Waiting for Licensee Decision to Participate in a Diversion Program.** When a substance abuse case is referred to the diversion program, the investigation is placed on hold *while the licensee decides* if he/she wants to enter diversion. This practice allows the licensee to delay final disposition of the case.
- 8) **Lack of Communication in the Diversion Program.** There is limited communication between the diversion program and the enforcement program which can delay investigation of licensees who are unsuccessfully diverted and are terminated from the program.
- 9) **Procurement of Health Records.** Investigators often have difficulties acquiring health records because there is no penalty for a licensee or healthcare facility that does not provide health records that assist investigators in investigating complaints.

10) **Automatic Suspensions.** BRN lacks a number of enforcement tools, including the ability to automatically suspend licensees pending a hearing.

11) **Mandatory Reporting.** There is no mandatory reporting requirement for employers of potential violations of the Nursing Practice Act.

The Center for Public Interest Law submitted a list of suggestions to improve the enforcement programs of the BRN and other healthcare licensing boards of the DCA. Further discussion of those suggestions can be found later in this paper.

Problems with the Department's Division of Investigation

According to DCA's 2007- 2008 Annual Report, "The Division of Investigation (DOI) serves as DCA's law enforcement and investigative branch. Its mission is to protect the public health, safety and welfare of consumers. DOI does this by providing timely, objective, courteous, and cost-effective investigations of alleged misconduct by licensees of client agencies, which often involves illegal use and theft of drugs, sexual misconduct, quality of care issues, and unlicensed activity. DOI and collects and assemble the necessary information needed to file criminal, administrative and civil actions by or on behalf of these agencies . . . In addition, DOI's Special Operations Unit leads DCA programs and investigations on workplace violence prevention and threat assessments, criminal offender record information program and clearances, infraction citation program and clearances, and internal affairs investigations. The Unit also oversees DOI internal programs and investigations which involve firearms, defensive tactics, computer forensics, background investigations, and internal affairs investigations."

DOI employs sworn peace officers to provide the investigative services described above. The division has seven field offices throughout the state from which field staff investigate complaints for DOI client agencies. As indicated above, DOI handles investigations for BRN. However, DOI also serves as the investigative arm of 20 other regulatory boards/bureaus within DCA, including:

Healthcare Licensing Boards	Non-Healthcare Licensing Boards
Acupuncture Board	Architects Board
Board of Behavioral Sciences	Athletic Commission
Hearing Aid Dispensers Bureau	Barbering & Cosmetology Board
Board of Occupational Therapy	Cemetery & Funeral Bureau
Board of Optometry	Court Reporters Board
Physical Therapy Board	Bureau of Electronic & Appliance Repair
Respiratory Care Board	Board for Professional Engineers & Land Surveyors
Speech Language and Audiology Board	Board for Geologists & Geophysicists
Veterinary Medical Board	Bureau of Security & Investigative Services
BVNPT	Structural Pest Control Board

This diversity of clientele means that investigators must be familiar with at least 21 different sets of laws and regulations, and DOI investigators are given limited opportunity to specialize on cases.

The following are several critical problems which have been identified in the administration and management of DOI and in the investigation of cases.

1) **Lack of Investigators and Increased Caseloads.** According to testimony offered by the Acting DOI Chief at DCA's July 27, 2009 hearing, DOI staffing levels have decreased from 55 authorized investigator positions in 2000-2001 to 42 authorized in 2008-2009. He further testified that the division currently has 38 field investigator positions, with only 31 filled. DOI management reports that the staff turnover and loss of authorized positions has exacerbated the backlogs at DOI. However, in 2006-2007, DOI augmented its Special Operations Unit (SOU) with two additional investigators. SOU now has five investigators dedicated to internal investigations. Additionally, there are 12 supervising investigators at DOI. The workload in SOU is not documented in this report.

DOI reports that, in addition to reduced staff, the DOI workload has increased by 27%. In December 2001, DOI had 1313 open investigations. As of December 2008, there were 1778 open cases at DOI.

Recruiting, hiring and training new investigators are lengthy processes. According to DOI, it typically takes over seven months to hire a new investigator; approximately three months to conduct the mandatory background check and four months of peace officer training at a formal training academy. After the academy, it can take a year for a new investigator to have developed the knowledge and skills necessary to independently conduct investigations in the field.

According to DOI, prior to January 2009, some investigators were assigned more than 100 cases. The average caseload per investigator fluctuated monthly as new cases were assigned and others closed. Since January 1, 2009, investigators are assigned no more than 25-30 cases at a time. The unassigned cases (approximately 500 at present) remain at the queue at each field office awaiting assignment.

In contrast, the Medical Board of California (MBC), which oversees over 160,000 licensees, employs its own investigators. The table on the next page represents the difference in authorized investigative staff between DOI and MBC.

FY 2008-2009	Staff Classification	Authorized Positions⁵	Licensees Served
Medical Board Regional Offices	Investigator	19	160,000
	Sr. Investigator	47	
	<i>Total</i>	66	
DOI SOU and Field Offices	Investigator	8	Over 700,000 (health boards only)
	Sr. Investigator	36.5	
	<i>Total</i>	44.5	

⁵ See 2009/10 Wages and Salaries

2) Retention of DOI Staff.

Retention of DOI staff is also long-standing problem, and staff turnover at DOI has affected its ability to provide timely services to its clients. In the past nine years, DOI has had three different division Chiefs. According to the current Acting Chief of DOI, 80% of DOI staff have left the division since 2000. This high turnover has been attributed to retirement, change in management, pay disparity, heavy caseloads, and the broad subject matter of investigations.

The disparity in pay for sworn peace officers working as investigators for state agencies has been cited as a reason it is difficult to recruit and retain DOI investigators. The chart below shows a sampling of investigator classifications employed at state agencies. As shown, the entry level salary for DCA investigators is \$271 less than at least six other state departments. Similarly, DCA investigators top salary is \$536 a month less than investigators working at three other departments.

Department	Investigator Monthly Salary Range
Consumer Affairs	3,631 - 5,631
Corporations	3,631- 5,631
Toxic Substances Control	3,902 - 5,631
Employment Development	3,902 - 5,631
Alcoholic Beverage Control	3,902 - 5,631
Motor Vehicles	3,902 - 6,194
Mental Health	3,902 - 6,194
Insurance	3,902 - 6,194

It should be noted that these salaries are based on scope and complexity of work performed by the investigator and they are set by the Department of Personnel Administration after negotiations with unions.

3) No Uniformity in the Use of DOI to Investigate Cases.

While all of the DCA boards and bureaus are mandated to follow the Administrative Procedures Act, there is no uniformity in the use of DOI to investigate cases. For example, the Dental, Medical and Pharmacy boards use their own staff to investigate complaints and monitor their probationers. The Psychology, Podiatric Medicine, Physician Assistants and Osteopathic Boards contract with the Medical Board for investigative services. In contrast, the Board of Behavioral Sciences employs non-sworn in-house investigative analysts, and uses DOI on a very limited basis, such as for undercover work and to obtain information that is only accessible to sworn peace officers.

4) Lack of Management and Prioritization of Cases and Severe Delays in Investigating Cases.

A survey of health boards highlighted in this report revealed that, regardless of who conducts the investigation, the average time it took to complete an investigation in the past three years was well over one year for health boards. The shortest average

time for DOI to investigate a complaint was 285 days for BVNPT in 2002/03. The longest average investigation time was 665 days for BRN in 2008/09.

Average Time to Investigate Complaints									
	Type of Investigator	2001/02	2002/03	2003/04	2004/05	2005/06	2006/07	2007/08	2008/09
BVNPT	In-house staff	314	130	183	122	119	334	154	176
	DOI	509	285	352	388	536	539	475	665
BRN	DOI	436	482	441	503	545	646	637	403
Behavioral Sciences*	DOI and In-house staff	214	308	305	324	223	313	396	547
Dental Board	In-house staff	No data	315	225	256	248	249	210	304
Podiatric Medicine	MBC	337	199	271	257	307	260	338	419
Medical Board	MBC	198	208	220	259	277	307	324	350
Pharmacy**	In-house staff	238	229	230	180	166	197	238	285
Chiropractic Examiners***	Private contractors and in-house staff	164	222	256	327	337	437	415	418

*Complaints were referred to DOI from 2000/01 – 2007/08. In 2008/09, investigations were completed by both in-house investigative analysts and DOI.

**Average days for both mediated cases (informal investigations) and cases referred to a board inspector for formal investigation.

*** The board contracted with private investigators and used internal board staff to conduct investigations through June 2008. Board staff currently conducts investigations.

In September 2006, DOI issued a memorandum to all DOI clients explaining that, due to DOI's high caseload and low staffing levels, the division was going to limit the types of cases it would accept. DOI asked clients to follow its new "Request for Services (RFS) Guidelines" when considering if the board should refer a case for investigation. DOI stated that criminal cases, sexual misconduct, drug diversion and serious injury should continue to be referred for investigation. However, the memorandum advised that the following types of cases should not be referred to DOI:

- Licensee probation checks
- Complaints filed by anonymous victims regarding unprofessional conduct and negligence/incompetence
- Complaints of unlicensed activity made by anonymous persons
- Cases in which the incident occurred a year or more prior to the current date (depending on the severity of the allegations).

The memo stated that DOI supervisors would review incoming RFS for compliance with the guidelines, and assess available resources to determine if the case should be assigned. DOI also instructed boards that prior to referring cases to DOI, boards should obtain patient records and have them reviewed by an expert to determine the need for further investigation. However, no formal training was offered to the boards on how to perform the document retrieval or probation monitoring.

According to DOI, this was the second attempt by DOI since 2000 to reduce the number of RFS sent to DOI that had the potential to be resolved through the clients' own resources. Both attempts were met with mixed reaction from its clients and, in many circumstances; concessions were made to accommodate the client's request on a case by case basis. DOI points out that there is no data to verify the number of RFS that were returned to clients or to verify how many RFS were not sent to DOI based upon the guidelines.

In January 2009, DOI announced the creation of a complaint intake unit, which was intended to provide faster closure of cases that do not require a formal investigation conducted by a peace officer. The complaint intake unit evaluates the RFS to see if non-sworn DOI staff can perform the requested service. If the intake unit is able to, it performs the service. Often, the services provided by the intake unit are the document collection that DOI previously instructed boards to do themselves.

According to the new procedures, once a case reaches the field office, a supervisor will evaluate it to determine if it is a high priority (see below for discussion of priority cases). High priority cases are assigned to investigators. If the case is not a high priority, it is not assigned to an investigator and placed in a queue. Investigators now are assigned 25–30 cases to work at any given time. Once a case is complete, the investigator is given another new case. DOI states that this new case management system allows supervisors to manage, monitor and prioritize cases in the queue and gives management the opportunity to hold the supervisors accountable. However, as stated above, the unassigned cases remain at the queue, awaiting referral. DOI estimates that only 50% of pending cases in the queue require work by its field investigators. It is assumed that these cases were assigned to the field offices prior to creation of the complaint intake unit.

Additionally, DOI points out that as of December 31, 2008, DOI had 1778 open cases with 693 of those cases over 365 days old. As of July 1, 2009, DOI had 1512 open cases with 670 of those cases being more than 365 days old. DOI indicated that this figure has dropped steadily since it peaked at 753 in March 2009.

In an effort to address the BRN cases that are over a year old, DOI initiated its "365 Project" in late 2008 in which DOI and BRN staff review cases that are one year or older to determine whether the case should go forward, and if so, what action should be taken. At that time, 470 BRN cases were over a year old, as of March 2009, 100 of those had been closed. DOI has proposed creating a similar intake task force which will consist of representatives from DOI and its clients for the purpose of setting criteria for review of cases that are over one year old.

There are no formal standards for prioritizing cases. Early in 2006, DOI created a working group to formulate guidelines for prioritizing complaints. The working group

included representatives from DOI clients, DCA legal counsel and DOI staff. A draft document was developed but was never formally adopted. However, the draft document was used to justify the return of cases to clients in November of 2006. Additionally, as noted above, DOI continues to work cases that do not meet DOI's own RFS guidelines.

It is the Committee's understanding that in the past DOI was given direction to give higher priority to cases involving the underground economy rather than those involving cases of consumer harm. In DCA's 2007/08 annual report, DCA made unlicensed activity a priority by creating a new Unlicensed Activity Unit to provide education and services to consumers, businesses, and students on the importance of licensure. As part of this priority, DCA created a toll-free number to report unlicensed activity, and conducted multiple statewide enforcement stings or sweeps to combat unlicensed activity. The level of involvement by DOI investigators during these stings is unclear. According to DCA data, in 2007/08, 259 cases alleging unlicensed activity that were investigated by sworn peace officers were closed, 103 of which were DOI client cases.

5) Lack of Coordination and Communication with Client Board.

DOI has also been criticized for lack of coordination and communication with the boards in its handling of cases. DOI's monthly case reports only show billable hours. The reports do not provide information on what type of work has been performed or the status of the case. Additionally, DOI does not hold regular meetings with clients regarding performance expectations and service. Some boards state that they do not receive regular communication regarding their cases from DOI. For example, when clients complete an RFS, the RFS contains instructions from the client to DOI. Clients are also given the option of requesting the case be expedited. Until recently, the Committee is advised that DOI did not typically confirm or deny the request to expedite. It is unclear when or how clients are notified that their case have been assigned or placed in the "queue." Prior to 2009, DOI did not provide formal training to its client agencies on how to complete the RFS or how to prepare a case for transmittal to DOI. Nor has DOI provided formal training on how boards should handle cases that DOI will not work.

6) Lack of Accountability.

If performance measures or expectation exists for DOI, clients are not advised of those expectations. In contrast, the boards and bureaus within DCA are required to publish an annual report that includes a myriad of licensing and enforcement statistics, including the length time it takes to complete investigations. Although DOI clients must report the length of investigations, DOI does not publicly report any performance data at all. This means that the clients are held responsible for the lengthy investigations, not the DOI.

Moreover, the budgeting mechanism for DOI services is very complicated and creates a lack of accountability. Clients' annual budgets are estimated based on anticipated usage of investigative hours. If the client goes under or over the estimated usage, the difference is "rolled forward" as a debit or a credit into the client's budget two years later. Furthermore, the annual "amount charged" for

service is often different from the "actual cost." Clients do not know how much they will be charged by the hour for investigative service until the end of the fiscal year when DCA budget staff calculates it by dividing the entire DOI operating expenses (which includes rent, weapons, vehicles, gas, training, and support staff and management salaries) among DOI clients based on usage of DOI service. The attached table shows how BRN budget for DOI has been calculated from Fiscal Year 2005/06 to 2010/11.

Additionally, there are multiple hourly rates within a fiscal year, such as 1) estimate for cost recovery charged to probationers, 2) actual cost recovery charged to probationers, and 3) hourly rate charged to DOI clients. For example, in the beginning of Fiscal Year 2008/09, clients were provided an estimated cost of \$152 per hour. At the end of the Fiscal Year, the actual rate for cost recovery was \$190 per hour.

In 2008, DOI began issuing client satisfaction surveys with every completed case file when it is returned to the client for review and possible action. The survey questions are divided into five categories: thoroughness, grammar/spelling, timeliness, effectiveness, and overall rating. The survey results are listed below:

Category	# Responses Received	Rating
Thoroughness	279	96% rated good or excellent
Grammar/Spelling	286	98% rated good or excellent
Timeliness	139	48% rated good or excellent
Effectiveness	179	62% rated very effective
Overall Rating	280	96% rated good or excellent

In 2007/08, DOI closed approximately, 1,100 cases but only 286 survey responses have been received to date and only 139 responded to the timeliness question. DOI reports that 48% of the responses rated timeliness as "good" or "excellent," which means 52% rated timeliness "fair" or "poor." Therefore, DOI clients have positive rating for timeliness for only 70 of approximately 1,100 cases.

AG and OAH Processes too Lengthy and Boards Not Kept Informed About Cases

Attorney General's Office

All of the regulatory boards and bureaus within DCA rely upon the AG's Office for prosecution of their cases. The AG's Office has two separate sections providing legal services to DCA clients: the Licensing Litigation Section and the Health Quality Enforcement (HQE) Section. Each section has its own leadership and process.

The Licensing Section represents state regulatory agencies created to protect Californians from physical or economic harm in their dealings with over a million licensed businesses and professionals. Licensing Section represents licensing boards, bureaus and commissions in both administrative and trial court proceedings to deny, revoke or suspend licenses in cases brought against state-licensed professionals such as contractors, accountants, dentists, chiropractors, nurses, engineers, physical

therapists, auto repair and pest control firms. The Licensing Section has 85 attorneys and its clients include the following DCA boards/bureaus:

- | | |
|---------------------------------------------------|-------------------------------------------------------|
| 1. Board of Behavioral Sciences | 16. Board of Engineers and Land Surveyors |
| 2. Board of Accountancy | 17. Board for Geologists and Geophysicists |
| 3. Cemetery and Funeral Bureau | 18. Guide Dogs for the Blind |
| 4. Board of Architects | 19. Landscape Architects Technical Committee |
| 5. Dental Board of California | 20. Bureau of Home Furnishings and Thermal Insulation |
| 6. Dental Hygiene Committee | 21. Bureau of Electronic and Appliance Repair |
| 7. Athletic Commission | 22. Board of Registered Nursing |
| 8. Bureau of Automotive Repair | 23. Structural Pest Control Board |
| 9. Board of Barbering and Cosmetology | 24. Professional Fiduciaries Bureau |
| 10. Court Reporters Board | 25. Veterinary Medical Board |
| 11. Board of Optometry | |
| 12. Board of Chiropractic Examiners | |
| 13. Board of Pharmacy | |
| 14. Bureau of Security and Investigative Services | |
| 15. Contractors State License Board | |

Note: Bold text indicates health care licensing boards.

In contrast, the HQE Section is primarily responsible for prosecuting disciplinary proceedings against physicians, psychologists, doctors of podiatric medicine, acupuncturists, physical therapists, and other healthcare licensees and applicants. According to the AG's Office, HQE Section was created in 1991 by the Legislature to represent and assist the Medical Board of California, Acupuncture Board, Board of Podiatric Medicine, Board of Psychology, Hearing Aid Dispensers Bureau, Physician Assistant Committee, Physical Therapy Board, Respiratory Care Board, and other boards and committees in the intake and investigation of consumer complaints, medical malpractice settlements and judgments, and other matters that could constitute unprofessional conduct. The HQE Section is involved in handling all phases of administrative litigation, including the prosecution of disciplinary proceedings and seeking interim suspensions or other injunctive relief when emergency relief is necessary to prevent imminent harm to the public. The section also handles the enforcement of subpoenas, writs and appeals, civil matters or lawsuits filed against its client agencies or their staff, and other types of civil litigation in state and federal courts.

HQE has 49 attorneys representing and assisting the following DCA boards/bureaus:

- | | |
|--------------------------------|----------------------------------|
| 1. Medical Board of California | 5. Board of Psychology |
| 2. Osteopathic Medical Board | 6. Hearing Aid Dispensers Bureau |
| 3. Acupuncture Board | 7. Physical Therapy Board |
| 4. Board of Podiatric Medicine | 8. Respiratory Care Board |

The following are several critical problems which have been identified in the prosecution of cases by the AG's Office.

Once investigated, meritorious cases are referred to the AG's Office for prosecution, which can be an extremely lengthy process. In 2008/09, the average case referred to

the AG's Office by the boards highlighted in this report took over 400 days to complete. These delays can be attributed to inadequate case work prior to referral for prosecution, limitations of administrative proceedings, inadequate case tracking system that does not interface with clients, lack of communication with clients and investigators, and lack of specialization by prosecuting attorneys.

1. **Lengthy Delays in the Handling of Cases.** As indicated above, there are delays in the prosecution of cases at the AG's Office that is contributing to the lengthy enforcement and disciplinary process. According to statistics provided by the AG's Office at the July 27, 2009 DCA hearing, the average time for the AG to close BRN cases peaked at 502 days in 2006-2007. This timeline was reduced to 295 days in 2008-2009. In 2007-2008, Licensing Section was referred 2,289 cases by its client boards, 698 of which came from health boards. The chart below represents the average time for the Licensing and HQE Sections to process complaints for boards.

Average Time for to Process Complaints at Attorney General's Office										
	AG Section		2001 /02	2002 /03	2003 /04	2004 /05	2005 /06	2006 /07	2007 /08	2008 /09
BVNPT	Licensing	Pre-accusation	233	389	285	285	324	309	182	150
		Post-accusation	280	575	566	542	362	475	336	423
BRN	Licensing	Pre-accusation	223	249	189	239	183	335	224	159
		Post-accusation	355	310	277	334	267	247	273	265
Behavioral Sciences	Licensing	Pre-accusation	148	133	129	137	94	153	117	278
		Post-accusation	330	330	297	369	324	362	364	370
Dental Board	Licensing	Pre- and Post-accusation	No data	413	591	619	414	518	524	489
Podiatric Medicine	HQE	Pre-accusation	51	154	138	175	118	76	137	152
		Post-accusation	585	475	337	495	349	337	298	373
Medical Board	HQE	Pre-accusation	103	91	107	116	132	127	121	103
		Post-accusation	437	471	513	473	515	446	471	381
Board of Pharmacy	Licensing	Pre-accusation	373	240	269	228	199	252	200	291
		Post-accusation	462	288	332	327	266	284	285	411
Chiropractic Examiners	Licensing	Pre-accusation	413	358	207	445	294	568	560	232
		Post-accusation	483	565	559	652	508	566	823	191

It should be noted that the time specified above excludes the length of time between pleading and proposed default decision, the length of time between receipt of notice of defense to request to set a case, length of time between opening of matter and proposed settlement, and length of time between receipt of notice of defense and proposed settlement.

2. Lack of Communication and Coordination with Clients.

It is unclear how the Licensing Section communicates with the boards to apprise them of developments in cases it is prosecuting on boards' behalf. For example, at the July 27, 2009 DCA hearing, the AG's Office indicated that the AG usually holds off requesting a hearing with the OAH because the request generates the opening of a case at OAH and billable activity to boards, and to prevent costs. The AG's Office points out that if boards prefer to not hold off on requesting hearing dates, the boards need to notify the AG of their intents. It is also unclear of what kind of updates boards get on cases handled by the AG's Office.

3. Lack of Specialized AGs for Healthcare Licensing Boards.

As indicated above, the Licensing Section handles cases for a number of boards and bureaus. In contrast, the HQE Section is focused solely on healthcare licensing boards. Dedicating specific AGs to prosecute healthcare licensing boards' cases may reduce delays, as attorney become experts in their fields.

4. Lack of a Training Program for DAGs and other Employees Handling Healthcare Licensing Boards.

It appears that there is no training program for DAGs in the Licensing Section to ensure that there is a common and consistent knowledge base, especially for prosecuting cases related to healthcare licensing boards. According to the Medical Board of California's July 2009 Report to the Legislature on the Vertical Enforcement Model,⁶ one of the recommendations made was for a mandated joint statewide training for all DAGs and investigators, regardless of their level, experience or past training, to achieve a common foundation and understanding, as well as to foster team building between staffs.

Moreover, at the July 27, 2009 DCA hearing, the AG's Office pointed out that Legal Assistant Teams (LAT) plead cases on behalf of the AG's Office. Additionally, it was pointed out that LATs spend an average of 8-12 hours for diversion cases, mostly to review medical records. Again, it is unclear what type of training exists for LATs in pleading healthcare board cases, and reviewing medical records.

⁶ See Medical Board Of California, *Report To The Legislature Vertical Enforcement Model*, June 2009.

Office of Administrative Hearings (OAH)

The OAH is a quasi-judicial tribunal charged with hearing administrative law cases of over 150 State and 800 local government agencies, including all of the cases brought by the AG's Office on behalf of DCA boards and bureaus.

According to OAH, the following chart represents the average number of days a case is open for specified healthcare licensing boards:

Office of Administrative Hearings 1/1/06 to 7/21/2009		
Board Name	# Cases Opened	Average # Days Case is Opened
Behavioral Sciences	112	134
Dental Board	295	140
Medical Board	958	161
Board of Pharmacy	236	128
Podiatric Medicine	27	136
Registered Nursing	900	127
Vocational Nursing & Psychiatric Technicians	402	118

OAH assigns Administrative Law Judges (ALJs) to oversee proceedings that require formal administrative hearings. As noted above, OAH provides these services to over 950 different governmental agencies. DCA boards and bureaus have over 40 different laws and regulations with which the judges must be familiar. However, only ALJs assigned to work on cases referred by the allied health boards receive specialized medical training. The lack of specialization and training for the types of cases referred by the remaining boards and bureaus creates a situation in which judges may issue inconsistent decisions.

1) Lack of Specialized ALJs for Healthcare Licensing Boards.

There is no specialized section within OAH to hear cases only for healthcare licensing boards. In contrast, Government Code Section 11371 establishes within the OAH a Medical Quality Hearing Panel, consisting of no fewer than five full-time administrative law judges. The Code requires the ALJs to have a medical training as recommended by the MBC and approved by the Director of OAH. Unlike the ALJs for the MBC, which hear cases specifically for physicians, surgeons and other allied health professionals that the MBC regulates, the ALJs for the other healthcare licensing boards also hear cases for non-healthcare boards.

2) Lack of Training for ALJs Handling Healthcare Licensing Boards Cases.

As specified above, ALJs in the Medical Quality Hearing Panel are required to have a medical training, it is unclear if ALJs that hear other healthcare licensing boards' cases receive appropriate training.

Impact of Budgetary Cuts and Loans to General Fund

1) Employee Furloughs.

On December 19, 2008, the Governor issued Executive Order S-16-08 which ordered all represented and non-represented state employees under his authority to begin taking two furloughs day a month beginning February 1, 2009 through June 30, 2010. On July 1, 2009, the Governor issued Executive Order S-13-09 which ordered an additional furlough day for all represented and non-represented state employees. Both of the furlough orders applied to all state agencies regardless of funding source, but provided for "limited" exemptions.

The furlough orders only affect employees of the executive branch. The orders do not apply to about 15,000 people working for independently elected officers in constitutional offices. These offices include:

- Attorney General's Office
- Bureau of State Audits
- Insurance Commissioner
- Judicial system
- Legislative Counsel Bureau
- Legislative offices
- Lieutenant Governor's office
- Public Utilities Commission
- Secretary of State
- State Board of Equalization
- State Controller's Office
- State Treasurer's Office
- Superintendent of Public Instruction

Additionally, some workers within the executive branch are exempt from furloughs including:

- California Highway Patrol officers (but not other CHP staff)
- California Department of Forestry and Fire Protection workers (but only during fire season)
- 500 attorneys working for the State Compensation Insurance Fund (but not other state fund workers).

A survey of DCA boards reveals that the services provided to the public is dropping significantly. The BRN estimates they have lost over 3,100 staff hours through July 2009, and that in total it will loose over 11,040 staff hours. This is equivalent to more than five full time staff positions. The MBC has suffered a reduction of 15,800 enforcement hours through July 2009 and will loose 48,000 hours by June 2010, the equivalent of 25 full time personnel. Pharmacy Board reports that the number of pending cases has increased by almost 800 since the furloughs began. This loss of staff will lengthen the time it is taking to process and close complaints and investigations.

Boards report that attempts to work cases are frustrated by the furloughs. Staff is impeded from interacting with non-furloughed individuals and entities, thus delaying enforcement response times. Examples of non-furloughed constituents

include expert witnesses, case witnesses, licensees, health facilities, other non-furloughed state agencies, and the public in general. Also, the three day furlough slows down production in other program areas, like licensing, mail delivery, and cashiering. This slows down overall work flow throughout the office and has added a negative effect on enforcement programs which rely upon these other services.

On July 23, 2009, SR 25 was introduced by Senator Gloria Negrete McLeod to urge the Governor to exempt from the furloughs enforcement officers of the DCA and various healthcare licensing boards that are directly involved in pursuing consumer complaints. SR 25 states that requiring employee furloughs of special fund boards that oversee the health and safety of the public and requiring the closure of these regulatory boards inhibits the consumer protection activities of the boards and further slows the enforcement process down, and is completely unnecessary to resolving any of the state's budget problems.

2) Loans to the General Fund.

Recently, there have been multiple loans from DCA's special fund programs to augment the General Fund in order to balance the General Fund budget. For instance, in 2002-2003, \$164.6 million was loaned, \$41.4 million was loaned in 2003-2004 and \$96.5 million was loaned in 2008-2009. Overall, \$302.5 million was borrowed from DCA's special fund programs from 2003-2004 to 2008-2009. To date, \$46.6 million has been repaid, leaving a balance of \$237.8 million. BRN alone funded a \$14 million loan to the General Fund. This money, which is paid by licensees for the specific purpose of funding the regulatory programs, could have been used to augment the enforcement programs.

3) Denial of Budget Change Proposals (BCP's) for Enforcement Positions.

Committee staff has learned that in the past, BCPs for additional positions, including positions for enforcement, have not been authorized for various boards. Although there is no estimate on the actual number of BCPs that were not authorized, the delays in the enforcement process could be attributed to the lack of additional enforcement positions.

Additionally, the Department of Finance's 2009-2010 Budget Preparation Guidelines include the following:

Requests for New Positions – The Administration's policy is to continue to contain the growth in authorized positions. Requests for new positions generally will be limited to redirections of existing positions. When requesting new positions, departments are required to clearly establish the long and short-term benefits to be gained by increasing personnel as opposed to other possible alternatives (e.g., automation, workload readjustments). Other alternatives that have been considered must also

be identified and analyzed. BCPs requesting new positions must effectively justify why a redirection is not possible. If new positions are approved, positions will be budgeted at the mid-step, unless evidence is provided justifying a higher level for hard-to-fill classifications or based on the department's hiring practices. Finance must approve the establishment of any position above mid-step of the respective salary range.

The Administration has maintained a policy designed to contain the growth of state government and has encouraged state agencies to avoid requesting additional staff. The Administration suggests state agencies seek alternatives, such as redirection of existing positions or automation. These instructions do not take into account the fact that DCA programs are funded by fees collected for the sole purpose of funding the regulatory operations.

Recommended Changes

The following is an initial list of recommended changes and options for the boards, State and Consumer Services Agency (CSA), the DCA, the AG's Office, and the OAH to consider for reforming and improving the enforcement process not only for the BRN, but other consumer boards under the DCA. Also included are recommendations for changes and reforms to the diversion programs of the BRN and healthcare boards under the DCA. These recommendations have been provided by the Center for Public Interest Law (CPIL), the DCA's Division of Investigation (DOI), the AG's Office (AG), the BRN and pursuant to discussions which Committee staff has had with many of the boards. Committee staff has provided its own recommendations to be considered in this context. Consideration will also be given to other recommendations made during the August 17th hearing and will be implemented as deemed necessary.

Auditing of Enforcement and Diversion Programs

According to the CPIL, the DCA and the BRN should seek appointment of an "Enforcement Monitor" to thoroughly audit the BRN's enforcement and diversion programs. (In fact, an audit of the private vendor that administers the BRN's diversion program is already required by SB 1441 (Ridley-Thomas), passed in 2008.) In recent years, enforcement monitors have been appointed for several DCA agencies, including the Contractors State License Board, the Dental Board, and the Medical Board of California (the MBC's enforcement monitor statute, now-repealed Business and Professions Code section 2220.1, was enacted in SB 1950 (Figueroa) in 2002 and is attached as Exhibit A). The CPIL participated in both the CSLB (2001–2003) and the MBC (2003–2005) enforcement monitor projects; additionally, the CPIL's Executive Director was the State Bar Discipline Monitor in a much earlier enforcement monitor project during 1987–1992.

Ideally, the Monitor would study and evaluate both programs, gathering and analyzing data and interviewing board staff and stakeholders; and release a report including findings and recommendations on all aspects of both programs. Some recommendations will require legislation; the Monitor and the Board would draft that legislation and advocate its approval. Other recommendations may require rulemaking or policy decisions by the Board. The Monitor should remain in place to ensure that all recommendations are properly implemented.

Staff Recommends: Legislation should be immediately pursued which would require the appointment of an "Enforcement Monitor" to thoroughly audit the BRN's enforcement and diversion programs.

Increased Resources for Enforcement Programs

According to the CPIL, the BRN needs to secure and devote additional resources to support both its enforcement and diversion programs. Those resources must come from nurse licensing fees, specifically renewal fees. The current statutory ceiling on biennial renewal fees is \$150 (Business and Professions Code Section 2815). The BRN regulation (Section 1417, Title 16 of the California Code of Regulations) sets actual biennial renewal fees at \$80 — meaning nurses pay \$40 per year in licensing fees. The BRN renewal fees have not increased in 18 years, while the number of licensed nurses has increased substantially during that time period.

By way of comparison, physicians, podiatrists, and attorneys pay approximately \$400 per year in licensing fees. The CPIL is not saying nurses should pay \$400 per year, but argues that they should clearly pay much more than they currently do to support a vigorous and aggressive program that protects patients from dangerous nurses.

The BRN recommends increasing enforcement staff by approximately 60 positions to augment existing operations in the complaint unit, enhance probation and diversion participant monitoring, and manage disciplinary cases.

Staff Comments: Another major resource which the BRN and other boards lack is an updated and integrated information/computer system for purposes of licensing and tracking enforcement cases. For over a decade the DCA has struggled to update its licensing and enforcement information system. The DCA's current Consumer Affairs System (CAS), which was created in the early 1980s, is the mainframe database used department-wide to track licensing and enforcement activities. CAS is typically used in conjunction with the Applicant Tracking System (ATS), a separate database of the same vintage, that electronically tracks licensing applicants, processes payments, tracks applicant examination eligibility, and examination scheduling. Together, these two outdated proprietary database applications, track and document the boards' and bureaus' regulatory operations.

In the mid-1990s, DCA began a process to replace CAS/ATS with a new proprietary computer system, Integrated Consumer Protection System (ICPS). This system was to

be developed by a contracted vendor to meet the specified terms and needs identified by the DCA's licensing agencies. A great deal of time, staffing and financial resources were dedicated to establishing the criteria and standards for ICPS; the cost of the project was shared by the DCA's licensing agencies relative to their projected fund conditions, and full development and implementation of the new system was expected to be in excess of \$6 million. The costs and workability of the ICPS system was a crosscutting issue in its 1998 sunset review the Joint Committee. Ultimately, DCA later abandoned ICPS.

In 2001, DCA again began moving ahead with the possible purchase of another computer system to replace the existing licensing, enforcement and applicant tracking systems. It was called the Professional Licensing and Enforcement Management System (PLEMS) and implementation was targeted for 2003/2004.

In 2003, the Department of Finance suspended financing for the work on implementation of PLEMS. Finance was not convinced that the proposed project was an essential information technology activity and had other issues with implementation of the information system and required DCA to conduct additional research. The DCA consequently suspended work on the PLEMS system.

Over the years, the lack of a viable alternative to the CAS system has severely limited DCA's licensing agencies. Requests by the Structural Pest Control Board to allow the use of the ATS for tracking applicant fingerprints was denied citing the data base was too fragile to allow the board to use the system. However other agencies (Bureau of Automotive Repair, Hearing Aid Dispensers Bureau, Cemetery and Funeral Bureau) have been transitioned into using the ATS and CAS systems.

In 2004, in the *Initial Report of MBC Enforcement Program Monitor*, the Monitor noted that CAS is so antiquated that the Department is reluctant to support further upgrades to it. Because CAS fails to meet its needs, the MBC is forced to track some information manually or with additional small database programs.

In recent years DCA has established an iLicensing system, and the system is available to several licensing boards such as Barbering and Cosmetology, Dental Board, Nursing Board, Board of Psychology, and Bureau of Security and Investigative Services. iLicensing allows online license renewals and applications. iLicensing has been renamed BREEZE, and was anticipated to expand the licensing system to the entire department.

In recent developments, earlier this summer, the BREEZE request for proposal (RFP) was cancelled due to on-going bidder deficiencies. After consulting with Agency and the Department of General Services, the DCA has decided to prepare a new RPF for release. The project does not include an enforcement or disciplinary element, but rather includes the ability to receive applications, renewals, duplicate/replacement request, address changes and associated electronic fee payments using a credit card. It is now anticipated that the BREEZE vendor contract will be awarded in early 2010.

Staff Recommends: *Increasing the annual licensing fee for nurses to cover increased costs for the BRN's enforcement program and to also provide for the increase in staffing levels necessary for BRN's enforcement program.*

The DCA should immediately move forward with providing an information/ computer system that would allow for the BRN and other boards, DOI, DCA and DOJ to be more integrated in handling all aspects of licensing and enforcement; especially allowing for the tracking of complaints and disciplinary cases. This system should be fully integrated with DOI's Case Assignment Tracking System (CATS).

Authorization to Spend Licensing Fees on Enforcement

According to the CPIL, the BRN and other DCA occupational licensing agencies are "special fund" agencies in that they are funded not by the state's General Fund (the account that was \$26 billion in deficit) but by their own "special funds" consisting of fees paid by licensees. These licensing fees flow steadily in to each board and are statutorily required to fund the regulatory programs of each board.

In recent years, when the General Fund has experienced problems, Governors (of both parties) have instituted hiring freezes, mandatory budget cuts, and — most recently — "furloughs" of state employees at all state agencies. While the application of these measures to programs and employees of General Fund agencies does in fact save the General Fund money, the application of these measures to "special fund" agencies like the BRN saves no money for the General Fund and simply deprives the BRN of the ability to spend money on hand for enforcement and other purposes. It is not fair to the BRN and other special fund agencies to excoriate them for slow case processing and demand that they improve their enforcement programs while depriving them of the ability to use money paid by their licensees for that very purpose. Indeed, at the Medical Board's July 24, 2009 meeting, its enforcement chief noted that the current "furlough" requirement is costing the MBC almost 4,300 investigative hours per month — the equivalent of losing 28 or 29 of the MBC's 70 investigative positions.

The Administration should consider exempting special fund agencies from furloughs and other requirements intended to save General Fund expenditures. At the very least, those requirements on law enforcement agencies that regulate healthcare professionals in order to protect the public should be significantly relaxed.

Staff Comments: Over the years, the Administration has subjected special-fund boards to the same hiring freezes, elimination of vacant positions, budget cuts and now furloughs that applies to general fund agencies in times of a budget crisis. This Administration has also taken the unique step of "borrowing" from several of the boards reserve funds to place into the general fund to be paid back at some unspecified date. This Committee along with the Assembly Business and Professions Committee has over the years reviewed all boards (through the process of sunset review) and any anticipated problems in the appropriate funding of their programs has been considered and efforts have been made to either reduce their budget or program requirements, or

increase their level of funding through license fee increases. The Legislature and the Administration have now placed boards in a position of not being able to spend the revenue which has been made available to them for purposes of properly running their enforcement programs. They have either been denied spending authority for their increased revenue by denial of BCPs or by other directives, which has had the effect of increasing their reserve funds, and then find that rather than having any chance of using these funds in the future to deal with increased enforcement costs, the money reverts back to the general fund by way of a "loan." Unless there is strong mandate that licensing fees should only be used for purposes of properly operating the boards this vicious cycle will continue.

One of the outcomes of budget changes and cutbacks to boards has been the slow down of cases or actual holding off on pursuing cases by DOI and the AG's Office because the board(s) ran out of money at some point later in the fiscal year. For example, it appears as if the BRN had to tell the AG to slow down or stop working on its cases for a certain amount of months for fiscal years 2003-2004, 2004-2005, 2006-2007, 2007-2008 and 2008-2009.

Staff Recommends: *Exempt from the furloughs enforcement officers of the DCA and various special-fund healthcare licensing boards who are directly involved in pursuing consumer complaints.* (The Chair of this Committee has introduced SR 25 urging the Governor to implement this recommendation.)

Rather than reserve funds being loaned to the general fund, all reserve funds should be placed in an "emergency reserve enforcement fund" to be used only for purposes related to the board's enforcement programs. These funds should be immediately available, without the need to receive spending authority, if for some reason enforcement costs exceed budgetary allocations. This will ensure that boards are not placed in the position of having to either "slow down" their cases or ask either DOI or the AG to stop work on their cases and that boards are sufficiently funded for other purposes related to enforcement.

Enhanced Detection and Reporting of Problem Licensees

According to the CPIL, over the past two decades, the Medical Board's enforcement program has been the subject of significant media attention and at least seven full-scale bills have been passed by the Legislature overhauling many aspects of its enforcement and diversion programs. Those bills have enacted several "mandatory reporting mechanisms" that have significantly enhanced the MBC's ability to detect problem physicians. Thus, the MBC is not solely dependent on patient complaints in detecting physicians who warrant investigative attention.

Regrettably, as the CPIL argues, very few of those detection provisions have been replicated at other healthcare licensing boards. The BRN [and other health related boards] should seek the following detection mechanisms:

1. When a hospital, health facility, or HMO revokes a physician's admitting privileges for "medical disciplinary cause or reason" (or suspends or restricts those privileges for more than 30 days in a 12-month period), Business and Professions Code section 805 requires that hospital, health facility, or HMO to file a report with the Medical Board, informing the Board of its action. This enables MBC to detect a potential problem and permits it to initiate, at its discretion, an investigation into the matter.

Nurses who are fired or terminated by hospitals are not reported to the BRN under section 805. Nor does the BRN's statute contain any sort of employer reporting mandate. Other healthcare licensing boards have sought such a mandate, including the Respiratory Care Board (Business and Professions Code Sections 3758 and 3758.6) and the Board for Licensed Vocational Nurses and Psychiatric Technicians (BVNPT) (Business and Professions Code Sections 2878.1 and 4521.2). The BRN should seek an employer reporting mandate.

2. Business and Professions Code Section 802.1 requires physicians to self-report to their board(s), in writing, criminal indictments charging a felony and any ~~criminal~~ conviction (felony or misdemeanor). This section does not apply to nurses. It should be expanded to apply to them. A self-report on their license renewal form every two years is not soon enough for effective detection.
3. Business and Professions Code Section 803 requires courtroom clerks to notify some healthcare boards of the criminal convictions of their licensees. This provision has never required courtroom clerks to notify the BRN of the criminal convictions of nurses. Section 803.5 requires prosecutors to notify courtroom clerks when a defendant is a licensee of some healthcare boards — so as to prompt the Section 803 notice to the licensee's board if the licensee is convicted of a crime. Section 803.5 has never been applied to nurses. Both sections should be expanded to require notice to the BRN of criminal convictions of its licensees.
4. It is unclear whether any state law requires a state licensee to notify his/her regulator of a disciplinary action taken by another state (or even a different agency in California). State law should require a nurse who is cross-licensed by the BRN and the BVNPT to notify one board when he/she has been disciplined by the other board. Obviously, the BRN should notify the BVNPT when it disciplines a person who is licensed by the BVNPT (and vice versa), but apparently, neither board is promptly informing the other of its discipline of a cross-licensed individual, and the Consumer Affairs System (CAS) computer system utilized by the DCA boards does not automatically forward such a notice to all boards regarding persons licensed by more than one board.
5. For over a decade, Business and Professions Code Section 138 has required all the DCA boards to require their licensees to provide notice to patients, clients, and customers that they are licensed by the State of California, to inform

consumers that regulated people are licensed by the State (as opposed to federal or local authorities). Legislative analyses of the bill enacting Section 138 indicate that its purposes are to inform consumers where they may file a complaint against a state licensee, thereby enhancing each board's detection capabilities, and to enable consumers to avail themselves of board Web sites and the information posted thereon.

However, most the DCA healthcare boards, including the BRN, have never implemented Section 138. The Medical Board very recently (July 24, 2009) adopted a regulation requiring physicians to notify patients that "Medical doctors are licensed and regulated by the Medical Board of California. (800) 633-2232. www.mbc.ca.gov." The regulation offers a number of options that permit physicians in all sorts of practice settings to comply with the disclosure requirement. The BRN should adopt regulations in compliance with Section 138.

6. Business and Professions Code Section 2220.7 prohibits a physician from including, in an agreement that settles a civil malpractice lawsuit, a "regulatory gag clause" that prohibits the plaintiff/victim from filing a complaint with the Medical Board, and/or prevents the plaintiff/victim from cooperating with the Medical Board if it investigates the incident that led to the civil settlement, and/or requires the plaintiff/victim to withdraw a pending complaint that he/she has already filed with the Medical Board.

Section 2220.7 is a critically important detection provision. It is patterned after a provision in the State Bar Act (Business and Professions Code Section 6090.5), a 20-year-old provision that prohibits lawyers who are being sued for legal malpractice from requiring their client, in a civil settlement agreement, from filing a complaint with the State Bar. Similarly, licensed healthcare providers should not be able to manipulate civil settlement agreements in order to conceal information of their own misconduct from their own state regulator. This important provision, which now applies to physicians, has not been extended to nurses and other healthcare professionals, and it should be.

Staff Recommends: *This Committee should conduct a hearing during the interim recess to determine which of the mandatory reporting requirements and notice provisions for physicians and surgeons should be applicable to nurses and other healthcare professionals. The prohibition on a "regulatory gag clause" in a civil malpractice lawsuit settlement involving other healthcare practitioners should be immediately implemented.*

Faster Screening of Complaints and Prioritization of Cases

CPIL states that an enforcement monitor should determine why it takes the BRN staff an average of 105 days to screen complaints in order to determine whether they should be referred for formal investigation, when it takes MBC an average of 61 days to accomplish the same task. Clearly, as CPIL argues, the BRN is not protecting the

public if a complaint about a substance-abusing nurse sits in its complaint screening unit for three months before it is referred for investigation. CPIL indicates that the possible reasons may be inadequate staffing of the BRN's complaint screening unit, inadequate training of those who staff the unit, and the lack of mandatory priorities that would require expedited handling of certain kinds of egregious complaints. MBC is subject to Business and Professions Code Section 2220.05, which sets forth certain kinds of cases for "priority" handling by MBC's complaint screening unit and its investigators and prosecutors.

Staff Recommends: *This Committee should work with the BRN to establish priorities for the handling of complaints and those which should be immediately sent for investigation and these priorities should be immediately implemented. The BRN should also utilize, similar to the MBC, nurse consultants to assist in the screening and prioritization of complaints for investigation or possible referral to the District Attorney's Office for criminal violations.*

Faster and More Efficient Investigations by DOI and Boards

According to the CPIL, when the BRN receives a complaint, screens it, and determines that it should be referred for formal investigation, the BRN uses sworn peace officer investigators from the DCA's DOI. While these individuals are professional investigators, they are generalists who do not specialize in any particular kind of complaint. They have extraordinarily high caseloads — estimated by the *LA Times* at 100 cases per investigator. They may not have experience or expertise in gathering medical records that are (a) privileged, and (b) needed in order to prove the elements of a quality of care violation by a nurse or other healthcare professional. Lack of experience in this area, and inadequate access to experts who can assist in the analysis or interpretation of medical records substantially slows the investigation of a quality of care case.

The CPIL recommends that the BRN should seek its own investigators — either a subset of DOI investigators who are devoted primarily to the BRN cases, or its own investigative employees. Alternatively, the BRN should contract with the MBC for the use of its peace officer investigators to work quality of care cases. The MBC investigators are stationed at approximately twelve district offices throughout the State. Their caseloads average fewer than 25 cases per investigator — and that includes 16 ongoing investigations plus 7 completed investigations which have been referred for the filing of an investigation and for which they remain responsible for investigative follow-up. The MBC investigators have substantial training and experience in obtaining medical records for use at administrative evidentiary hearings; additionally, they have access to medical consultants (physician employees) who are available at each district office and assist in the analysis and interpretation of medical records.

Staff Recommends: *The BRN and the DCA should consider either consolidating all sworn investigators under DOI and creating two sections similar to the AG's office, one which deals with health quality cases from the various healthcare boards and the other*

section which would deal with general licensing board cases, or as recommended by CPIL, allow the BRN to both seek and have its own investigators or use investigators of the MBC. (Another alternative is indicated below under discussion of the AG's Office and would either eliminate DOI and move all sworn investigators to the AG's Office or at least allow investigators who specialize in health related cases to be under the AG's Office.)

Other recommendations include:

1. DOI should immediately prioritize existing cases and work with boards to assist them in prioritizing cases which could be handled by the individual boards or referred immediately to DOI.
2. Allow boards to hire non-sworn investigators to investigate cases which may or may not be referred to DOI and allow boards to continue with their own specialized investigators, but working more in conjunction with the AG's Office when necessary.
3. Assure that all sworn and non-sworn investigators receive appropriate training.
4. Create within DCA a position of Deputy Director of Enforcement with major oversight responsibility for DCA's enforcement programs and act as liaison with the boards, the DOI, the AG, the OAH and local law enforcement agencies to ensure timely filing of disciplinary actions and prosecution and hearing of cases. However, the day to day responsibilities of the DOI should continue to be the responsibility of the Chief of DOI.
5. Change the process of payment for DOI services to that more closely aligned with the AG's office.

Faster and More Efficient Prosecution of Cases by the AG's Office

According to the CPIL, after a complaint has been investigated and the BRN staff determines that the investigatory file contains sufficient evidence to justify disciplinary action, the BRN uses an attorney from the Licensing Section of the Attorney General's Office to file and prosecute the disciplinary action against its licensee. Similar to the DOI investigators, the Licensing Section attorneys are generalists who do not usually specialize in any particular type of disciplinary action. They prosecute all sorts of the DCA licensees, from barbers to landscape architects to nurses. They have high caseloads and are not necessarily familiar with the Nursing Practice Act or the BRN's regulations.

In contrast, the MBC uses attorneys from the Health Quality Enforcement (HQE) Section of the Attorney General's Office to file and prosecute disciplinary actions against physicians. The HQE is created in Government Code Section 12529 *et seq.*; it handles the MBC cases against physicians and also cases against the licensees of

several "allied health licensing programs" such as the Board of Podiatric Medicine, the Board of Psychology and the Physician Assistant Committee.

Under Government Code section 12529.6, the HQE investigators and the MBC prosecutors work together from the time a complaint is referred for investigation in a format called "vertical enforcement" (VE). VE increases the efficiency of the MBC investigations, because the prosecutor is involved in the design of the investigation, reviews the evidence as it comes in, and is able to direct the closure of cases in which proof of a violation by clear and convincing evidence is not surfacing. This is beneficial for both the accused licensee and the public: nonmeritorious cases are closed more quickly (benefiting the licensee), thus allowing the investigator/prosecutor team to move on to attack meritorious cases more quickly (benefiting the public).

The DOI investigators do not work in VE format with HQE or the Licensing Section prosecutors. A generalist investigator completes an investigation with little or no legal guidance on the elements of the offense, and then hands off a "completed investigation" to a generalist prosecutor who has had no role in the design of the investigation and who thereafter has no investigative assistance. The CPIL argues that this creates enormous inefficiencies.

The CPIL further indicates that the MBC's specialized investigators and prosecutors have had a positive effect on the MBC case cycle times vs. the BRN case cycle times. The average BRN investigation takes 634 days, while the average MBC investigation of a physician case takes 324 days. After an investigation is completed, it takes a Licensing prosecutor an average of 265 days to file the formal accusation (which turns a confidential investigation into a matter of public record), while it takes an HQE prosecutor 121 days to file an accusation. The CPIL is not implying that MBC's case processing times are acceptable. However, they do indicate that they are much better than the BRN's.

The CPIL argues that there is no good reason why the BRN should not use the HQE as opposed to the Licensing Section. The division of work between the HQE and Licensing was based on the structure of the Medical Board when the HQE was created in 1991. However, that structure has changed significantly since then, and a 2001 audit of the structure of the Attorney General's Office by PricewaterhouseCoopers suggested a more efficient and subject-matter-based split of work between the HQE and the Licensing Section.

As further argued by the CPIL, the use of the HQE attorneys could substantially enhance the quality and speed of the BRN prosecutions – especially quality of care cases. The HQE attorneys are familiar with medical records, medical experts, and other issues inherent in quality of care disciplinary matters in which nurses may be involved. The CPIL believes that the HQE should be restructured so that it serves not only MBC and some of its former allied health programs but also the BRN, the Dental Board, the Board of Pharmacy, and perhaps the Board of Optometry.

The CPIL has long advocated (since 1989) that even greater efficiencies could be achieved if the MBC's investigators were removed from MBC and transferred to the Department of Justice to work in VE fashion with HQE prosecutors — under the same roof, employed by the same shop, and stationed in the same offices throughout the state. The CPIL recommends that this is clearly an option that should be considered now: A revamped HQE that serves all the major healthcare licensing boards, staffed with both specialist prosecutors and specialist investigators working together in VE teams.

The CPIL also recommends that the newly revamped HQE should also have a special "strike force" of investigators and prosecutors that can immediately handle: (a) those who fail diversion, (b) criminal convictions, (c) those that violate probation conditions, and (d) any other high-profile type cases that need immediate attention.

The Licensing Section of the AG's Office, Senior Assistant Attorney General Alfredo Terrazas, identified several areas in which improvements could be made for the BRN. They are as follows:

1. Streamline Conviction Cases. As indicated by Mr. Terrazas, the BRN could cut down its turn around time on conviction cases by obtaining only rap sheets or computer print outs of the convictions. It is not necessary for the BRN to seek certified court documents since the AG is already required to do so. Also, there is not need for boards to send any warning letters to licensees to explain their criminal conviction.
2. Triage Complaints with Liaison DAGs. As indicated earlier, the AG instituted a Liaison DAG at BRN on a once of month basis to initiate a screening function of cases. (This was called the DIDO program.) It is recommended that this program be reinstated. According to Mr. Terrazas, this recommendation involves much less entanglement and structural changes than a VE model and has proven to be an effective way tying together investigative/prosecutorial services.
3. Plead Statutory Violations without Expert Reports. For cases that involve factual allegations that, standing alone, themselves constitute gross negligence of incompetence, the AG should be allowed to plead and file the cases immediately, rather than waiting for expert reports. Since 70% to 80% of these cases end up settling, a substantial number of these matters could be filed quickly and could avoid the need for securing expert reports, which delay the process.
4. Delegate Authority to the Executive Officer (EO) Re Stipulated Settlements and Default Decisions. Mr. Terrazas indicates that a majority of filed cases settle and the receipt of a Notice of Defense can trigger either settlement discussions or the taking of a Default Decision. Stipulated settlements are a more expeditious and less costly method of case resolution. The EO can provide summary reports of all settlements to the Board and it can provide constant review and feedback to the EO so that policies can be established and adjusted as necessary. Also,

there have been instances of undue delays between when a fully-signed settlement has been forwarded to the Board's headquarters and when it has been placed on the Board's agenda for a vote. Delegating this authority to the EO, as asserted by Mr. Terrazas, will result in a final disposition of these matters much quicker. The fact that the BRN has reduced the number of its annual meetings has only increased the need for this.

5. Implement a "Real Time" Case Information System. Mr. Terrazas indicates that everyone would be better served if an accurate "real time" case management system were established to enable case managers to proactively track cases at any stage of the process rather than a reactive tracking. The system could also be designed to interact with whatever tracking mechanisms or case management systems exist at DOI and/or the AG's Office. In this way, everyone will be on the same page and comparing "apples with apples" so that when someone either at agency, the Governor's Office, a reporter, a public records act request, an Enforcement Monitor, whoever the requestor may be, the data can be retrieved quickly and accurately. (This issue and recommendation is addressed under the discussion of the need for a new information system for DCA and the boards under the need for additional "resources" in this paper.)

Staff Comments: Another issue that CPIL is concerned about, is the time it takes the AG to prepare a proposed default decision. The filing of a default decision is made once a licensee has failed to file a "notice of defense" when an accusation has been served on him or her. If the licensee fails to file a notice of defense within a specified timeframe, he or she is subject to a default judgment because of a failure to appear or make a defense of their disciplinary case. In 2004-2005 it was taking the AG almost 6 months to file a proposed default decision. In 2008-2009 it was down to about 2.5 months. As argued by CPIL, filing of a proposed default decision is "not rocket science," and should only take a matter of hours.

Staff Recommends: *If maintaining and reforming DOI is not considered as a viable option, or if it is decided that DOI should only be responsible for investigating non-health related cases, then the DCA, MBC and the AG should consider moving all of the MBC and DOI investigators involved with health-related cases to the AG's Office so they can work in teams with HQE prosecutors in a VE format, as recommended by the CPIL.*

The AG's Office attorneys should also be realigned into two units: (1) the HQE which would do all healthcare cases (MBC, BRN, Pharmacy, Dentists, etc.) and (2) the Licensing Section which would handle disciplinary matters for all other non-health DCA boards (e.g., Architects, Engineers, Accountants, etc.). More evidence of the success of the DIDO program as a proven effective model of investigative/prosecutorial services would need to be provided before consideration should be given to rejecting the implementation of the VE format for investigations and prosecution of cases. Initial reports seem to indicate some success of the VE format in both the investigation and prosecution of health-related disciplinary cases.

Except for the reinstatement of the DIDO program, all recommendations of the AG's Licensing Section should be given strong consideration, some of which could be implemented immediately.

Consideration should also be given to setting certain timeframes for the AG in the filing of accusations, proposed default decisions, the setting of a hearing date once a notice of defense is received, etc.

Use of Specialist Administrative Law Judges

In addition to specialist investigators and specialist prosecutors, the MBC uses administrative law judges (ALJs) from the Office of Administrative Hearings (OAH) who are appointed to a special panel called the "Medical Quality Hearing Panel" under Government Code Section 11371. These judges specialize in medical discipline cases and are trained in medical terminology and records issues. CPIL recommends that the DCA, the BRN, and the OAH should consider whether the BRN and the other major healthcare boards could utilize the Medical Quality Hearing Panel in order to achieve higher-quality ALJ decisions.

Staff Recommends: *The OAH should consider whether the BRN and other major healthcare boards could utilize the Medical Quality Hearing Panel so as to have more specialize ALJ's dealing with the more complicated healthcare quality cases.*

More Effective Probation Monitoring

According to the CPIL, in many of the BRN's disciplinary decisions, the BRN places a licensee on probation subject to multiple terms and conditions. In this situation, the BRN has expended an average of 3.5 years (and has spent a minimum of six figures) to take a formal, public disciplinary action against a licensee. That action has resulted in a license revocation but the revocation has been stayed, the licensee has possibly been required to take some time off on suspension, and then spends years on probation subject to terms and conditions. This entire process, as the CPIL argues, is meaningless unless the BRN vigorously monitors compliance with those terms and conditions of probation; noncompliance with any of them should prompt an immediate petition for revocation of probation and revocation of the license.

Regrettably, as the CPIL states, the *LA Times* series has exposed serious probation violations which have gone unaddressed by the BRN for years. This is inexcusable. The *Times* describes the BRN's probation unit as "five board monitors oversee[ing] about 470 nurses on probation." This is grossly inadequate. Probationers, by definition, are individuals who have violated the law but are being given a second chance. Probation orders often require compliance with 10-15 conditions each. Probation monitors are not meaningfully capable of monitoring more than 50-60 cases each. As the CPIL argues, probation violations should not be tolerated; in other words, they should be dealt with on a "zero tolerance" basis. One violation should yield an immediate petition to revoke probation and revoke the license. That does not happen at

the BRN. "That must happen at the BRN; that is the only action that is consistent with the Board's "paramount" public protection mandate."

The CPIL recommends that probation monitoring could occur either at the revamped HQE in the Department of Justice discussed above, or via staff at the BRN. However, those staff must not handle excessive caseloads and they must have easy access to peace officer investigators and prosecutors who will act in a "strike force" fashion to obtain evidence of any probation violation and file an immediate petition to revoke probation and to revoke the license. "Nothing less should be tolerated," as stated by the CPIL.

Staff Recommends: *There should be created within the revamped DOI or HQE a special "strike force" to handle cases involving failed diversion, criminal convictions, violations of probation, and other cases needing immediate attention such as an interim suspension order (ISO) or temporary restraining order (TRO). The BRN staff and other boards which lack sufficient staff should have staffing levels immediately increased to deal with probation monitoring of cases.*

Enhanced Disclosure of Information About Licensees

According to the CPIL, the *LA Times* series revealed that, in addition to patients, nurse employers rely heavily on the BRN's Web site for information about California-licensed nurses. However, the BRN is subject only to Business and Professions Code Section 27, which requires the BRN to disclose only its own disciplinary decisions concerning nurses. Although the BRN collects other information about its licensees, it is not required to post any of that information on its Web site.

For almost ten years, the MBC has been subject to Business and Professions Code Sections 803.1 and 2027. These sections require the MBC to disclose considerably more information about its physician licensees than the BRN must disclose about its nurse licensees. These provisions also require that disclosure to occur via the most efficient means possible: the Internet.

CPIL recommends that consistent with the MBC's public disclosure statutes, the BRN should be required to disclose, on its Internet Web site, the following information about its licensees and former licensees:

1. Information regarding any enforcement actions taken by the BRN or by another state or jurisdiction, including temporary restraining orders issued; interim suspension orders issued; revocations, suspensions, probations, or limitations on practice ordered by the board, including those made part of a probationary order or stipulated agreement; public letters of reprimand issued; and infractions, citations or fines imposed.

2. All current accusations filed by the AG, including those accusations that are on appeal.
3. Civil judgments or arbitration awards in any amount; and civil settlement agreements where there are three or more in the past ten years that are in excess of \$10,000.
4. All felony convictions reported to the Board, and all misdemeanor criminal convictions that result in a disciplinary action or an accusation that is not subsequently withdrawn or dismissed.

Staff Recommends: This Committee should include as part of its hearing during the interim recess what public disclosure requirements for physicians and surgeons should be applicable to nurses and other healthcare professionals.

Diversion Programs Should be Substantially Improved or be Abolished

According to the CPIL, diversion programs purport to monitor substance-abusing licensees, and most programs, including the BRN's, afford confidential participation to those licensees, such that patients are not able to know whether their provider is in such a program and/or is afflicted with substance abuse. As such, these programs operate in an area of significant sensitivity and grave public risk. A substance-abusing healthcare professional poses a strong risk of irreparable harm to the many patients that he/she may treat on any day that he/she uses drugs/alcohol or suffers from the effects of long-term substance abuse.

The BRN's diversion program, created in 1985, is modeled after the state's first diversion program for physicians created at the Medical Board in 1981. The MBC's program was audited four times between 1982 and 2004; it failed all four audits miserably, the CPIL asserts. After the fourth failed audit (which was conducted by the Medical Board Enforcement Monitor in 2004), the Legislature enacted 2005 legislation imposing a June 30, 2008 sunset date on the diversion program, effectively giving the MBC two more years and one more chance to address all of the deficiencies identified by the Enforcement Monitor and other auditors. Despite the fact that the MBC pumped \$500,000 in additional resources into the program between 2004 and 2006, the program failed a fifth audit in 2007, conducted by the Bureau of State Audits. Confronted with the BSA's audit results and with the testimony of patients who had been injured by physicians while they were participating in the diversion program, the MBC voted unanimously to abolish its program as of June 30, 2008.

The BRN's program operates somewhat differently from the MBC's program in at least two respects: (1) the BRN uses a private vendor to administer the program — a vendor that has never been audited, and (2) the BRN requires a "cease practice" period of all nurses entering the program — a period that may last from three to twelve months during which the nurse must agree not to work. During this time, the nurse has an opportunity to focus on recovery and demonstrate to the program that he/she is capable

of safe practice. However, as was documented in the July 25, 2009 *LA Times* article, the BRN has no way to enforce its "cease practice" mandate. It performs no investigations and has no way to know whether a nurse who has agreed to cease practice has in fact stopped practicing. Further, because the "cease practice" agreement is not public information or available in any way to nurse employers, nurses subject to a "cease practice" order can and do return to work (or find work with a different employer or employers), and can and do divert drugs from their workplace and use while on duty. "This is unacceptable," as stated by the CPIL.

As the CPIL notes above, the BRN's diversion program has never been audited in its 24-year existence. The private vendor of the BRN's diversion program is currently subject to audit by DCA pursuant to SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008); but that audit has not yet commenced. Clearly, as argued by CPIL, "that audit must be expedited and its results used to fashion comprehensive reforms to the BRN's diversion program."

As further argued by CPIL, the absence of an independent, external audit of the BRN's diversion program casts doubt on any of the Board's rosy claims about the program and the way the vendor runs it. For example, the BRN can argue that nurses in the diversion program are drug-tested X times per month, but the BRN has no idea whether the vendor is actually testing participants X times per month, and/or whether those tests are truly random or they are administered on days the participant anticipated (as happened at the MBC). The absence of an external audit renders the "success rate" claimed by the BRN moot. That rate is simply the number of nurses who enter the program and eventually complete it. If its monitoring mechanisms are so lax that anybody could complete it (including alcoholics and addicts who are manipulative and desirous of maintaining both their licenses and their addictions), a "success rate" is meaningless.

But the *LA Times* series focused not only on the program as run by the private vendor based on standards set by the BRN (which standards apparently allow five relapses while in the program before a nurse's participation is terminated), but also on the BRN's performance after a nurse has been kicked out of the diversion program. The findings according to the CPIL are inexcusable. As stated by the CPIL, it is incomprehensible that BRN could possibly take an average of 15 months after its own diversion program has terminated a nurse's participation because of repeated relapses and noncompliance and labeled that nurse a "public safety threat" just to file an accusation against that nurse. It is positively mind-boggling that it could take an additional ten months for the Board to take disciplinary action against that nurse.

The CPIL argues that these programs should operate on a zero tolerance basis. One relapse should result in public license suspension to protect patients and future employers. Terminations from the diversion program should march to the front of the complaint screening/investigation hierarchy and should be dealt with by a properly-resourced strike force of investigators and prosecutors.

In fact, as further pointed out by the CPIL, the MBC Enforcement Monitor recommended that the MBC consider a mechanism similar to that in Penal Code Section 1000, to ensure that those who do not and cannot comply with the terms and conditions of a diversion program are promptly removed from practice. As a condition of entering the diversion program, and especially for nurses who are on license probation, a nurse should be required to stipulate that he/she has violated the Nursing Practice Act and surrender his/her license. That stipulation would be deferred pending the nurse's entry into the program. If the nurse successfully completes the program, the stipulation is destroyed. If the nurse relapses while in the program, the stipulation is activated and the suspension takes effect immediately. This would ensure that a nurse who has been given one last chance, and who has blown that chance, is publicly removed from practice and cannot provide healthcare. (The BRN has also indicated that they want this "automatic suspension" provision for nurses who flunk out of their Diversion program.)

Staff Comments: SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) established within the Department of Consumer Affairs the Substance Abuse Coordination Committee (SACC) to formulate by January 1, 2010, uniform standards that will be used by healing arts boards in dealing with substance-abusing licensees, whether or not a healthcare board operates a diversion program. These standards, at a minimum, include: requirements for clinical diagnostic evaluation of licensees; requirements for the temporary removal of the licensee from practice for clinical diagnostic evaluation and any treatment, and criteria before being permitted to return to practice on a full-time or part-time basis; all aspects of drug testing; whether inpatient, outpatient, or other type of treatment is necessary; worksite monitoring requirements and standards; consequences for major and minor violations; and criteria for a licensee to return to practice and petition for reinstatement of a full and unrestricted license.

On March 3, 2009, the SACC conducted its first public hearing and the discussion included an overview of diversion programs, the importance of addressing substance abuse issues for healthcare professionals and the impact of allowing healthcare professionals who are impaired to continue to practice. During this meeting, the SACC members agreed to draft uniform guidelines for each of the standards. During subsequent meetings, roundtable discussions were held on the draft uniform standards, including public comments.

Staff Recommends: *As recommended earlier, the Enforcement Monitor appointed to the BRN should audit the diversion program and recommend either substantial changes to the program to assure that substance-abusing nurses are properly monitored or the elimination of the program operated by the BRN. In the meantime, a sunset date of January 1, 2011, should be placed immediately on this program and other diversion programs provided by the boards. The DCA shall also immediately proceed with the audit on the effectiveness, efficiency, and overall performance of the vendor chosen by the department to manage diversion programs for substance-abusing licensees of healthcare licensing boards. Based on this audit, the DCA shall immediately make recommendations to the Legislature regarding the continuation of these programs by*

the boards, and if continued, any changes or reforms necessary to ensure that individuals participating in these programs are properly monitored, and that the public is protected from healthcare practitioners who are impaired due to alcohol or drug abuse or mental or physical illness.

The DCA shall also immediately provide to the Legislature an update on the work of the Substance Abuse Coordination Committee and at what time the Committee will have completed its work and provide uniform standards that will be used by all health licensing boards which provide diversion programs.

As recommended by CPIL and the BRN, provide for the automatic suspension of a nurse's license similar to that in Penal Code Section 1000, to ensure that those who do not and cannot comply with the terms and conditions of a diversion program are promptly removed from practice.

Other Changes and Recommendations for the BRN and Other Health Related Boards

Staff Recommendations: The following are other changes and recommendations which should be made to the BRN and possibly other health related boards under the DCA:

- 1. Immediately provide for the BRN a medical records request statute (similar to Business and Professions Code Section 2225 which applies to the MBC and its investigators) and a penalty on doctors/hospitals/facilities for failure to comply with a lawful request for medical records (similar to Business and Professions Code Section 2225.5).*
- 2. Immediately require the BRN as well as other health related boards to provide an annual report (similar to the MBC under Business and Professions Code Section 2313) on its enforcement program statistics, including the timeframes for every step in the enforcement process.*

Attachment 3

Senate Bill 294



BILL NUMBER: SB 294

VERSION: September 4, 2009 (Amended)
AUTHOR: Negrete McLeod
SPONSOR:
BOARD POSITION: None
SUBJECT: Healing Arts Boards; Enforcement Programs

EXISTING LAW:

- Establishes within the Department of Consumer Affairs various consumer-protection boards bureaus and commissions.
- Requires that information on suspensions and revocations of licenses and other related enforcement actions be made available on specified boards' internet sites, in compliance with DCA's "Guidelines for Access to Public Records."
- Authorizes the Director/DCA to audit and review the disciplinary proceedings of specified boards and allows the director to make recommendations for changes to the disciplinary system.
- Requires the Director/DCA to report to the Senate and Assembly annually regarding any findings from any audit, review, or monitoring and evaluation conducted.
- Grants all investigators of DCA's Division of Investigation, the Medical Board and the Board of Dental Examiners "peace officer authority" when conducting investigations
- Requires a Clerk of the Court to transmit to the appropriate board specified information related to convictions of or judgments against those licensed (Medical Board, Osteopathic Medical Board, Board of Podiatric Medicine, etc.; 803.5, 803.6)
- Provides for requirements of Diversion Programs for various boards (Dental Board, Osteopathic physicians and surgeons, physical therapists, nurses, physician assistants, pharmacists, veterinarians)

As amended 9/4/09, THIS BILL WOULD:

1. Require the DCA to establish an information technology system, no later than December 31, 2012, that will integrate all of the DCA's licensing and enforcement functions as specified.
2. Require all healing arts boards to post enforcement-related licensee information online.
3. Require all healing arts boards to submit an annual report regarding their enforcement program to the DCA and to the Legislature no later than October 1 of each year.
4. Prohibit a licensee of a health care board permission to be included in any provision arising from his or her practice to settle a civil dispute as specified.
5. Authorize the Executive Officer of healing Arts boards to adopt a default decision or a proposed settlement agreement as a result of an administrative action against a licensee.
6. Allow the Attorney General's Office (AG), investigative agents and a health care license board and its investigators access to confidential medical records for the purpose of an investigation and would authorize fines for a failure to produce required records as specified (Pharmacy is not included in the list of boards with expanded peace officer authority).
7. Provide for the automatic suspension of a license of a health care licensee while that licensee is incarcerated.

8. Authorizes a health care board to order a mandatory revocation of a license for a crime involving sexual misconduct or a sexual offense.
9. Require all healing arts licensees to self-report any indictment or disciplinary action taken against the licensee directly to the entity (Board) that issued his or her license.
10. Require a report of a crime or personal injury judgment against a licensee to be sent by the licensee or the Clerk of the Court to the respective healing arts board within 10 days of judgment, as specified.
11. Require a report of charges for a crime committed by a licensee to be sent by the District Attorney, City Attorney, or Clerk of the Court to the respective healing arts board within 48 hours of conviction.
12. Require the Clerk of the Court to transmit any felony preliminary hearing transcripts to the appropriate healing arts board in which the licensee is licensed.
13. Sunsets all healing arts boards' Diversion Programs on January 1, 2012.
14. Requires a licensee terminated from a diversion program to be placed on suspension until the licensee successfully petitions for reinstatement.
15. Requires a diversion contractor to report (within 5 days) any act of substantial noncompliance with a diversion agreement to the respective board. Failure to report as specified is grounds for termination of a Diversion contract with a provider.
16. Defines reasons that a participant may be terminated from a diversion program.

DISCUSSION:

Following widely publicized allegations of discipline problems at one of DCA's boards, Senator Negrete McLeod convened a meeting on in August 2009 of the Senate Committee on Business Professions and Economic Development to look into the current enforcement processes of many of the boards within DCA and the lengthy disciplinary process that boards utilize prior to taking final action on a licensee's privileged license.

As amended 9/4/09, staff estimates that SB 294 may impact on the board's current operations as identified below.

Annual Report – IT Solution. This bill requires the board to prepare and submit an annual report regarding its enforcement program to the DCA and to the Legislature each year. The legislation also requires the Department to implement and make available an IT system to integrate all of the licensing and enforcement functions specified in this measure, with an implementation of that system by December 31, 2012. Should the reporting required by this measure be required before such a system is made available, the board will require additional staff resources to comply with the mandate. (One half-time, associate-level staff).

E.O. Adoption of Decision or Settlement. This bill authorizes the Executive Officer to adopt a default decision or a proposed settlement agreement as a result of an administrative action. The board anticipates that a minor savings in Board Member time may be realized, and that minor costs related to the board's current mail-vote process (for such decisions) may be absorbable.

Peace Officer Authority. The Board of Pharmacy's investigators (pharmacy inspectors) are not identified within the provisions of expanded peace officer authority related to access to confidential medical records for purposes of its investigations.

Self-Reporting / Indictment, Disciplinary Actions. This bill requires that the board's licensees self-report to the board any indictment or disciplinary action taken against them. Likewise, this bill requires that a report of a crime or personal injury judgment against a licensee be sent by the Clerk of the Court to the board within 10 days of such judgment. Staff estimates that these provisions may speed up the time that the board initiates an investigation and that any additional workload would be minor and absorbed within existing resources. However, upon close monitoring, any spike in investigation numbers may result in a BCP for additional staff.

Diversion Program Sunset. This measure sunsets the board's Diversion Program on January 1, 2012. Until that time, this bill makes changes to the diversion programs in DCA to define reasons that a licensee may be terminated from the program as well as time frames that a diversion contractor is to notify a board of substantial noncompliance.

FISCAL IMPACT:

The following staff augmentation will be required to comply with provisions related to the monitoring of licensees on a diversion program.

- 1 Full-time Licensed Clinician (MFT, LCSW, Psychologist) –Dedicated case manager; clinical intake; clinical call-in
- 1 Full-time Associate Governmental Program Analyst – Treatment referrals and follow up
- 1 Half-time Associate Governmental Program Analyst – Collect and report data
- 1 Full-time Management Services Technician – Compliance monitor

BILL HISTORY:

2009

- Sept. 8 Re-referred to Com. on B&P pursuant to Assembly Rule 77.2.
- Sept. 4 Read third time. Amended. To third reading. (*Gut & Amend*)
- Sept. 2 From inactive file to third reading file.
- Sept. 1 Notice of motion to remove from inactive file given by Assembly Member Krekorian.
- Aug. 17 Placed on inactive file on request of Assembly Member Krekorian.
- July 16 Read second time. To Consent Calendar.
- July 15 From committee: Do pass. To Consent Calendar. (Ayes 16. Noes 0.) (Heard in committee on July 15.)
- July 1 Read second time. Amended. Re-referred to Com. on APPR.
- June 30 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 10. Noes 0.) (Heard in committee on June 30.)
- June 8 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B. & P.
- May 21 To Com. on B. & P.
- May 11 In Assembly. Read first time. Held at Desk.
- May 11 Read third time. Passed. (Ayes 25. Noes 11. Page 825.) To Assembly.
- Apr. 28 Read second time. To third reading.
- Apr. 27 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
- Apr. 17 Set for hearing April 27.
- Apr. 14 From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 6. Noes 1. Page 806.) Re-referred to Com. on APPR.
- Mar. 31 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B., P. & E.D.
- Mar. 25 Set for hearing April 13.
- Mar. 9 To Com. on B., P. & E.D.
- Feb. 26 From print. May be acted upon on or after March 28.
- Feb. 25 Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN ASSEMBLY SEPTEMBER 4, 2009

AMENDED IN ASSEMBLY JULY 1, 2009

AMENDED IN ASSEMBLY JUNE 8, 2009

AMENDED IN SENATE MARCH 31, 2009

SENATE BILL

No. 294

Introduced by Senator Negrete McLeod

February 25, 2009

~~An act to add Section 2835.7 to the Business and Professions Code, relating to nurse practitioners. An act to amend Sections 27, 116, 160, 726, 802.1, 803, 803.5, 803.6, 1695.5, 2365, 2663, 2666, 2715, 2770.7, 3534.1, 3534.5, 4365, 4369, and 4870 of, to add Sections 1695.7, 1699.2, 2365.5, 2372, 2669.2, 2770.16, 2770.18, 2835.7, 3534.12, 4375, 4870.5, and 4873.2 to, to add Article 10.1 (commencing with Section 720) to Chapter 1 of Division 2 of, to add and repeal Section 2719 of, and to repeal Article 4.7 (commencing with Section 1695) of Chapter 4 of, Article 15 (commencing with Section 2360) of Chapter 5 of, Article 5.5 (commencing with Section 2662) of Chapter 5.7 of, Article 3.1 (commencing with Section 2770) of Chapter 6 of, Article 6.5 (commencing with Section 3534) of Chapter 7.7 of, Article 21 (commencing with Section 4360) of Chapter 9 of, and Article 3.5 (commencing with Section 4860) of Chapter 11 of, Division 2 of, the Business and Professions Code, relating to healing arts.~~

LEGISLATIVE COUNSEL'S DIGEST

SB 294, as amended, Negrete McLeod. ~~Nurse practitioners. Healing arts.~~

SB 294

— 2 —

Existing law provides for the regulation of healing arts licensees by various boards within the Department of Consumer Affairs. The department is under the control of the Director of Consumer Affairs.

(1) Existing law requires certain boards within the department to disclose on the Internet information on their respective licensees.

This bill would additionally require specified healing arts boards to disclose on the Internet information on their respective licensees.

Existing law authorizes the director to audit and review, among other things, inquiries and complaints regarding licensees, dismissals of disciplinary cases, and discipline short of formal accusation by the Medical Board of California and the California Board of Podiatric Medicine.

This bill would additionally authorize the director to audit and review the aforementioned activities by any of the healing arts boards. The bill would also declare the intent of the Legislature that the department establish an information technology system to create and update healing arts license information and track enforcement cases pertaining to these licensees.

Existing law requires a physician and surgeon, osteopathic physician and surgeon, and a doctor of podiatric medicine to report to his or her respective board when there is an indictment or information charging a felony against the licensee or he or she been convicted of a felony or misdemeanor:

This bill would expand that requirement to any licensee of a healing arts board, as specified, would require these licensees to submit a written report, and would require a report when disciplinary action is taken against a licensee by another healing arts board or by a healing arts board of another state.

Existing law requires the district attorney, city attorney, and other prosecuting agencies to notify the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, the State Board of Chiropractic Examiners, and other allied health boards and the court clerk if felony charges have been filed against one of the board's licensees.

This bill would instead require that notice to be provided to any healing arts board and the court clerk if felony charges are filed against a licensee. By imposing additional duties on these local agencies, the bill would impose a state-mandated local program.

Existing law requires, within 10 days after a court judgment, the clerk of the court to report to the appropriate board when a licentiate has

committed a crime or is liable for any death or personal injury resulting in a specified judgment. Existing law also requires the clerk of the court to transmit to certain boards specified felony preliminary transcript hearings concerning a defendant licensee.

This bill would instead require the clerk of the court to report that information and to transmit those transcripts to any described healing arts board.

(2) Under existing law, healing arts licensees are regulated by various boards and these boards are authorized to issue, deny, suspend, and revoke licenses based on various grounds and these boards are also authorized to take disciplinary action against their licensees for the failure to comply with its laws and regulations. Existing law requires or authorizes the board to appoint an executive officer or an executive director to, among other things, perform duties delegated by the board.

This bill would authorize the executive officer or the executive director of specified healing arts licensing boards, where an administrative action has been filed by the board to revoke the license of a licensee and the licensee has failed to file a notice of defense, appear at the hearing, or has agreed to surrender his or her license, to adopt a proposed default decision or a proposed settlement agreement. The bill would also provide that the license of a licensee shall be suspended if the licensee is incarcerated after the conviction of a felony and would require the board to notify the licensee of the suspension and of his or her right to a specified hearing. The bill would also specify the timeframes for suspending a license under certain circumstances if the conviction was substantially related to the qualifications, functions, or duties of the licensee's respective board.

The bill would also prohibit a licensee of specified healing arts boards from including certain provisions in an agreement to settle a civil dispute arising from his or her practice, as specified. The bill would make a licensee or a health care facility that fails to comply with a patient's medical record request, as specified, within 15 days, or who fails or refuses to comply with a court order mandating release of records, subject to civil and criminal penalties, as specified. By creating a new crime, the bill would impose a state-mandated local program.

The bill would authorize the Attorney General and his or her investigative agents, and these healing arts boards to inquire into any alleged violation of the laws under the board's jurisdiction and to inspect documents subject to specified procedures.

The bill would require these healing arts boards to report annually, by October 1, to the department and the Legislature certain information, including, but not limited to, the total number of consumer calls received by the board, the total number of complaint forms received by the board, the total number of convictions reported to the board, and the total number of licensees in diversion or on probation for alcohol or drug abuse.

(3) Existing law establishes diversion and recovery programs to identify and rehabilitate dentists, osteopathic physicians and surgeons, physical therapists and physical therapy assistants, registered nurses, physician assistants, pharmacists and intern pharmacists, and veterinarians and registered veterinary technicians whose competency may be impaired due to, among other things, alcohol and drug abuse.

The bill would make the provisions establishing these diversion programs inoperative on January 1, 2012.

Existing law makes a licensee terminated from a diversion program for failing to comply with the program's requirements subject to disciplinary action by his or her respective board.

This bill would instead provide that the participant's license shall be suspended until the participant petitions the board for reinstatement of his or her license, certificate, or board approval and is granted a probationary or unrestricted license, certificate, or board approval. The bill would also require a third party or state agency or private organization administering the diversion program to report, as specified, to the program manager or chairperson any act of substantial noncompliance, as defined, by the participant with the program.

(4) Existing law, the Nursing Practice Act, provides for the licensure and regulation of nurses by the Board of Registered Nursing. Existing law authorizes the board to employ personnel as it deems necessary to carry out the act's provisions, except that the employment of personnel to provide investigative services shall be in the Division of Investigations within the Department of Consumer Affairs.

This bill would remove that limitation and would authorize the board to employ investigators, nurse consultants, and other personnel as it deems necessary. The bill would also specify that these investigators have the authority of peace officers while carrying out their board duties.

The bill would require the Director of Consumer Affairs, by March 1, 2010, to appoint an enforcement program monitor to serve until October 1, 2011, who would be required to, among other things, monitor

and evaluate the board's disciplinary system and procedures. The bill would prohibit the enforcement program monitor from exercising authority over the board's disciplinary operations or staff. The bill would require the enforcement program monitor, by December 1, 2010, to submit a specified initial written report to the board, the department, and the Legislature and to issue a final written report by October 1, 2011.

Existing law, the Nursing Practice Act, provides for the certification and regulation of nurse practitioners and nurse-midwives by the Board of Registered Nursing and specifies requirements for qualification or certification as a nurse practitioner. Under the act, the practice of nursing is defined, in part, as providing direct and indirect patient care services, as specified, including the dispensing of drugs or devices under specified circumstances. The practice of nursing is also described as the implementation, based on observed abnormalities, of standardized procedures, defined as policies and protocols developed by specified facilities in collaboration with administrators and health professionals, including physicians and surgeons and nurses.

This bill would authorize the implementation of standardized procedures that would expand the duties of a nurse practitioner in the scope of his or her practice, as enumerated. The bill would make specified findings and declarations in that regard.

(5) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no-yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 27 of the Business and Professions Code
2 is amended to read:

1 27. (a) Every entity specified in subdivision (b), on or after
2 July 1, 2001, shall provide on the Internet information regarding
3 the status of every license issued by that entity in accordance with
4 the California Public Records Act (Chapter 3.5 (commencing with
5 Section 6250) of Division 7 of Title 1 of the Government Code
6 and the Information Practices Act of 1977 (Chapter 1 (commencing
7 with Section 1798) of Title 1.8 of Part 4 of Division 3 of the Civil
8 Code). The public information to be provided on the Internet shall
9 include information on suspensions and revocations of licenses
10 issued by the entity and other related enforcement action taken by
11 the entity relative to persons, businesses, or facilities subject to
12 licensure or regulation by the entity. In providing information on
13 the Internet, each entity shall comply with the Department of
14 Consumer Affairs Guidelines for Access to Public Records. The
15 information may not include personal information, including home
16 telephone number, date of birth, or social security number. Each
17 entity shall disclose a licensee's address of record. However, each
18 entity shall allow a licensee to provide a post office box number
19 or other alternate address, instead of his or her home address, as
20 the address of record. This section shall not preclude an entity
21 from also requiring a licensee, who has provided a post office box
22 number or other alternative mailing address as his or her address
23 of record, to provide a physical business address or residence
24 address only for the entity's internal administrative use and not
25 for disclosure as the licensee's address of record or disclosure on
26 the Internet.

27 (b) Each of the following entities within the Department of
28 Consumer Affairs shall comply with the requirements of this
29 section:

30 (1) The Acupuncture Board shall disclose information on its
31 licensees.

32 (2) The Board of Behavioral Sciences shall disclose information
33 on its licensees, including marriage and family therapists, licensed
34 clinical social workers, and licensed educational psychologists.

35 (3) The Dental Board of California shall disclose information
36 on its licensees.

37 (4) The State Board of Optometry shall disclose information
38 regarding certificates of registration to practice optometry,
39 statements of licensure, optometric corporation registrations, branch
40 office licenses, and fictitious name permits of their licensees.

1 (5) The Board for Professional Engineers and Land Surveyors
2 shall disclose information on its registrants and licensees.

3 (6) The Structural Pest Control Board shall disclose information
4 on its licensees, including applicators, field representatives, and
5 operators in the areas of fumigation, general pest and wood
6 destroying pests and organisms, and wood roof cleaning and
7 treatment.

8 (7) The Bureau of Automotive Repair shall disclose information
9 on its licensees, including auto repair dealers, smog stations, lamp
10 and brake stations, smog check technicians, and smog inspection
11 certification stations.

12 (8) The Bureau of Electronic and Appliance Repair shall disclose
13 information on its licensees, including major appliance repair
14 dealers, combination dealers (electronic and appliance), electronic
15 repair dealers, service contract sellers, and service contract
16 administrators.

17 (9) The Cemetery Program and Funeral Bureau shall disclose
18 information on its licensees, including cemetery brokers, cemetery
19 salespersons, crematories, and cremated remains disposers.

20 (10) The Funeral Directors and Embalmers Program Cemetery
21 and Funeral Bureau shall disclose information on its licensees,
22 including embalmers, funeral establishments, and funeral directors.

23 (11) The Contractors' State License Board shall disclose
24 information on its licensees in accordance with Chapter 9
25 (commencing with Section 7000) of Division 3. In addition to
26 information related to licenses as specified in subdivision (a), the
27 board shall also disclose information provided to the board by the
28 Labor Commissioner pursuant to Section 98.9 of the Labor Code.

29 (12) The Board of Psychology shall disclose information on its
30 licensees, including psychologists, psychological assistants, and
31 registered psychologists.

32 (13) The State Board of Chiropractic Examiners shall disclose
33 information on its licensees.

34 (14) The Board of Registered Nursing shall disclose information
35 on its licensees.

36 (15) The Board of Vocational Nursing and Psychiatric
37 Technicians of the State of California shall disclose information
38 on its licensees.

39 (16) The Veterinary Medical Board shall disclose information
40 on its licensees and registrants.

1 (17) The Physical Therapy Board of California shall disclose
2 information on its licensees.

3 (18) The California State Board of Pharmacy shall disclose
4 information on its licensees.

5 (19) The Speech-Language Pathology and Audiology Board
6 shall disclose information on its licensees.

7 (20) The Respiratory Care Board of California shall disclose
8 information on its licensees.

9 (21) The California Board of Occupational Therapy shall
10 disclose information on its licensees.

11 (22) The Naturopathic Medicine Committee, the Osteopathic
12 Medical Board of California shall disclose information on its
13 licensees.

14 (23) The Physician Assistant Committee of the Medical Board
15 of California shall disclose information on its licensees.

16 (24) The Dental Hygiene Committee of California shall disclose
17 information on its licensees.

18 (c) "Internet" for the purposes of this section has the meaning
19 set forth in paragraph (6) of subdivision (e) of Section 17538.

20 SEC. 2. Section 116 of the Business and Professions Code is
21 amended to read:

22 116. (a) The director may audit and review, upon his or her
23 own initiative, or upon the request of a consumer or licensee,
24 inquiries and complaints regarding licensees, dismissals of
25 disciplinary cases, the opening, conduct, or closure of
26 investigations, informal conferences, and discipline short of formal
27 accusation by the Medical Board of California, the allied health
28 professional boards, and the California Board of Podiatric Medicine
29 any of the healing arts boards established under Division 2
30 (commencing with Section 500) or under any initiative act referred
31 to in that division. The director may make recommendations for
32 changes to the disciplinary system to the appropriate board, the
33 Legislature, or both.

34 (b) The director shall report to the Chairpersons of the Senate
35 Business and Professions Committee and the Assembly Health
36 Committee annually, commencing March 1, 1995, regarding his
37 or her findings from any audit, review, or monitoring and
38 evaluation conducted pursuant to this section.

39 SEC. 3. Section 160 of the Business and Professions Code is
40 amended to read:

1 160. The Chief and all investigators of the Division of
 2 Investigation of the department and all investigators of the Medical
 3 Board of California and the Board of Dental Examiners Dental
 4 Board of California, and the designated investigators of the Board
 5 of Registered Nursing have the authority of peace officers while
 6 engaged in exercising the powers granted or performing the duties
 7 imposed upon them or the division in investigating the laws
 8 administered by the various boards comprising the department or
 9 commencing directly or indirectly any criminal prosecution arising
 10 from any investigation conducted under these laws. All persons
 11 herein referred to shall be deemed to be acting within the scope
 12 of employment with respect to all acts and matters in this section
 13 set forth.

14 SEC. 4. Article 10.1 (commencing with Section 720) is added
 15 to Chapter 1 of Division 2 of the Business and Professions Code,
 16 to read:

17 Article 10.1. Healing Arts Licensing Enforcement

18
 19
 20 720. (a) Unless otherwise provided, as used in this article, the
 21 term "board" shall include all of the following:

- 22 (1) The Dental Board of California.
- 23 (2) The Medical Board of California.
- 24 (3) The State Board of Optometry.
- 25 (4) The California State Board of Pharmacy.
- 26 (5) The Board of Registered Nursing.
- 27 (6) The Board of Behavioral Sciences.
- 28 (7) The Board of Vocational Nursing and Psychiatric
 29 Technicians of the State of California.
- 30 (8) The Respiratory Care Board of California.
- 31 (9) The Acupuncture Board.
- 32 (10) The Board of Psychology.
- 33 (11) The California Board of Podiatric Medicine.
- 34 (12) The Physical Therapy Board of California.
- 35 (13) The Hearing Aid Dispensers Bureau.
- 36 (14) The Physician Assistant Committee of the Medical Board
 37 of California.
- 38 (15) The Speech-Language Pathology and Audiology Board.
- 39 (16) The California Board of Occupational Therapy.
- 40 (17) The Osteopathic Medical Board of California.

1 (18) The Naturopathic Medicine Committee, the Osteopathic
 2 Medical Board of California.

3 (19) The Dental Hygiene Committee of California.

4 (20) The State Board of Chiropractic Examiners.

5 (21) The Veterinary Medical Board.

6 (b) Unless otherwise provided, as used in this article, "licensee"
 7 means a licensee of a board described in subdivision (a).

8 720.2. (a) The executive officer or executive director of a
 9 board may adopt a proposed default decision where an
 10 administrative action to revoke a license has been filed by the
 11 board and the licensee has failed to file a notice of defense or to
 12 appear at the hearing and a proposed default decision revoking
 13 the license has been issued.

14 (b) The executive officer or executive director of a board may
 15 adopt a proposed settlement agreement where an administrative
 16 action to revoke a license has been filed by the board and the
 17 licensee has agreed to surrender his or her license.

18 720.4. (a) The license of a licensee of a board shall be
 19 suspended automatically during any time that the licensee is
 20 incarcerated after conviction of a felony, regardless of whether
 21 the conviction has been appealed. The board shall, immediately
 22 upon receipt of the certified copy of the record of conviction from
 23 the court clerk, determine whether the license of the licensee has
 24 been automatically suspended by virtue of his or her incarceration,
 25 and if so, the duration of that suspension. The board shall notify
 26 the licensee of the license suspension and of his or her right to
 27 elect to have the issue of penalty heard as provided in subdivision
 28 (d).

29 (b) Upon receipt of the certified copy of the record of conviction,
 30 if after a hearing before an administrative law judge from the
 31 Office of Administrative Law it is determined that the felony for
 32 which the licensee was convicted was substantially related to the
 33 qualifications, functions, or duties of the licensee, the board shall
 34 suspend the license until the time for appeal has elapsed, if no
 35 appeal has been taken, or until the judgment of conviction has
 36 been affirmed on appeal or has otherwise become final, and until
 37 further order of the board.

38 (c) Notwithstanding subdivision (b), conviction of a charge of
 39 violating any federal statutes or regulations or any statute or
 40 regulation of this state regulating dangerous drugs or controlled

1 substances, or a conviction pursuant to Section 187, 261, 262, or
2 288 of the Penal Code, shall be conclusively presumed to be
3 substantially related to the qualifications, functions, or duties of
4 a licensee and no hearing shall be held on this issue. However,
5 upon its own motion or for good cause shown, the board may
6 decline to impose or may set aside the suspension when it appears
7 to be in the interest of justice to do so, with due regard to
8 maintaining the integrity of and confidence in the practice
9 regulated by the board.

10 (d) (1) Discipline may be ordered against a license in
11 accordance with the laws and regulations of the board when the
12 time for appeal has elapsed, the judgment of conviction has been
13 affirmed on appeal, or an order granting probation is made
14 suspending the imposition of the sentence, irrespective of a
15 subsequent order under Section 1203.4 of the Penal Code allowing
16 the person to withdraw his or her plea of guilty and to enter a plea
17 of not guilty, setting aside the verdict of guilty, or dismissing the
18 accusation, complaint, information, or indictment.

19 (2) The issue of penalty shall be heard by an administrative law
20 judge from the Office of Administrative Law. The hearing shall
21 not be held until the judgment of conviction has become final or,
22 irrespective of a subsequent order under Section 1203.4 of the
23 Penal Code, an order granting probation has been made
24 suspending the imposition of sentence, except that a licensee may,
25 at his or her option, elect to have the issue of penalty decided
26 before those time periods have elapsed. Where the licensee so
27 elects, the issue of penalty shall be heard in the manner described
28 in subdivision (b) at the hearing to determine whether the
29 conviction was substantially related to the qualifications, functions,
30 or duties of a licensee. If the conviction of a licensee who has made
31 this election is overturned on appeal, any discipline ordered
32 pursuant to this section shall automatically cease. Nothing in this
33 subdivision shall prohibit the board from pursuing disciplinary
34 action based on any cause other than the overturned conviction.

35 (e) The record of the proceedings resulting in the conviction,
36 including a transcript of the testimony therein, may be received
37 in evidence.

38 (f) Any other provision of law setting forth a procedure for the
39 suspension or revocation of a license issued by a board shall not
40 apply to proceedings conducted pursuant to this section.

1 (g) This section shall not apply to a physician and surgeon's
2 certificate subject to Section 2236.1.

3 720.6. Except as otherwise provided, any proposed decision
4 or decision issued under this article in accordance with the
5 procedures set forth in Chapter 5 (commencing with Section 11500)
6 of Part 1 of Division 3 of Title 2 of the Government Code, that
7 contains any finding of fact that the licensee or registrant engaged
8 in any act of sexual contact, as defined in Section 729, with a
9 patient, or has committed an act or has been convicted of a sex
10 offense as defined in Section 44010 of the Education Code, shall
11 contain an order of revocation. The revocation shall not be stayed
12 by the administrative law judge. Unless otherwise provided in the
13 laws and regulations of the board, the patient shall no longer be
14 considered a patient of the licensee when the order for services
15 and procedures provided by the licensee is terminated,
16 discontinued, or not renewed by the licensee.

17 720.8. (a) A licensee of a board shall not include or permit to
18 be included any of the following provisions in an agreement to
19 settle a civil dispute arising from his or her practice, whether the
20 agreement is made before or after the filing of an action:

21 (1) A provision that prohibits another party to the dispute from
22 contacting or cooperating with the board.

23 (2) A provision that prohibits another party to the dispute from
24 filing a complaint with the board.

25 (3) A provision that requires another party to the dispute to
26 withdraw a complaint he or she has filed with the board.

27 (b) A provision described in subdivision (a) is void as against
28 public policy.

29 (c) A violation of this section constitutes unprofessional conduct
30 and may subject the licensee to disciplinary action.

31 (d) If a board complies with Section 2220.7, that board shall
32 not be subject to the requirements of this section.

33 720.10. (a) Notwithstanding any other provision of law making
34 a communication between a licensee of a board and his or her
35 patients a privileged communication, those provisions shall not
36 apply to investigations or proceedings conducted by a board.
37 Members of a board, deputies, employees, agents, the Attorney
38 General's Office, and representatives of the board shall keep in
39 confidence during the course of investigations the names of any
40 patients whose records are reviewed and may not disclose or reveal

1 those names, except as is necessary during the course of an
2 investigation, unless and until proceedings are instituted. The
3 authority under this subdivision to examine records of patients in
4 the office of a licensee is limited to records of patients who have
5 complained to the board about that licensee.

6 (b) Notwithstanding any other provision of law, the Attorney
7 General and his or her investigative agents, and a board and its
8 investigators and representatives may inquire into any alleged
9 violation of the laws under the jurisdiction of the board or any
10 other federal or state law, regulation, or rule relevant to the
11 practice regulated by the board, whichever is applicable, and may
12 inspect documents relevant to those investigations in accordance
13 with the following procedures:

14 (1) Any document relevant to an investigation may be inspected,
15 and copies may be obtained, where patient consent is given.

16 (2) Any document relevant to the business operations of a
17 licensee, and not involving medical records attributable to
18 identifiable patients, may be inspected and copied where relevant
19 to an investigation of a licensee.

20 (c) In all cases where documents are inspected or copies of
21 those documents are received, their acquisition or review shall be
22 arranged so as not to unnecessarily disrupt the medical and
23 business operations of the licensee or of the facility where the
24 records are kept or used.

25 (d) Where documents are lawfully requested from licensees in
26 accordance with this section by the Attorney General or his or her
27 agents or deputies, or investigators of any board, they shall be
28 provided within 15 business days of receipt of the request, unless
29 the licensee is unable to provide the documents within this time
30 period for good cause, including, but not limited to, physical
31 inability to access the records in the time allowed due to illness
32 or travel. Failure to produce requested documents or copies
33 thereof, after being informed of the required deadline, shall
34 constitute unprofessional conduct. A board may use its authority
35 to cite and fine a licensee for any violation of this section. This
36 remedy is in addition to any other authority of the board to sanction
37 a licensee for a delay in producing requested records.

38 (e) Searches conducted of the office or medical facility of any
39 licensee shall not interfere with the recordkeeping format or

1 preservation needs of any licensee necessary for the lawful care
2 of patients.

3 (f) If a board complies with Section 2225, that board shall not
4 be subject to the requirements of this section.

5 720.12. (a) A board, and the Attorney General, shall return
6 any original documents received pursuant to Section 720.12 to the
7 licensee from whom they were obtained within seven calendar
8 days.

9 (b) If a board complies with Section 2225.3, that board shall
10 not be subject to the requirements of this section.

11 720.14. (a) (1) A licensee who fails or refuses to comply with
12 a request for the certified medical records of a patient, that is
13 accompanied by that patient's written authorization for release
14 of records to a board, within 15 days of receiving the request and
15 authorization, shall pay to the board a civil penalty of one thousand
16 dollars (\$1,000) per day for each day that the documents have not
17 been produced after the 15th day, up to ten thousand dollars
18 (\$10,000), unless the licensee is unable to provide the documents
19 within this time period for good cause.

20 (2) A health care facility shall comply with a request for the
21 certified medical records of a patient that is accompanied by that
22 patient's written authorization for release of records to a board
23 together with a notice citing this section and describing the
24 penalties for failure to comply with this section. Failure to provide
25 the authorizing patient's certified medical records to the board
26 within 30 days of receiving the request, authorization, and notice
27 shall subject the health care facility to a civil penalty, payable to
28 the board, of up to one thousand dollars (\$1,000) per day for each
29 day that the documents have not been produced after the 20th day,
30 up to ten thousand dollars (\$10,000), unless the health care facility
31 is unable to provide the documents within this time period for good
32 cause. This paragraph shall not require health care facilities to
33 assist the boards in obtaining the patient's authorization. A board
34 shall pay the reasonable costs of copying the certified medical
35 records, but shall not be required to pay such cost prior to the
36 production of the medical records.

37 (b) (1) A licensee who fails or refuses to comply with a court
38 order, issued in the enforcement of a subpoena, mandating the
39 release of records to a board, shall pay to the board a civil penalty
40 of one thousand dollars (\$1,000) per day for each day that the

1 documents have not been produced after the date by which the
2 court order requires the documents to be produced, unless it is
3 determined that the order is unlawful or invalid. Any statute of
4 limitations applicable to the filing of an accusation by the board
5 shall be tolled during the period the licensee is out of compliance
6 with the court order and during any related appeals.

7 (2) Any licensee who fails or refuses to comply with a court
8 order, issued in the enforcement of a subpoena, mandating the
9 release of records to a board is guilty of a misdemeanor punishable
10 by a fine payable to the board not to exceed five thousand dollars
11 (\$5,000). The fine shall be added to the licensee's renewal fee if
12 it is not paid by the next succeeding renewal date. Any statute of
13 limitations applicable to the filing of an accusation by a board
14 shall be tolled during the period the licensee is out of compliance
15 with the court order and during any related appeals.

16 (3) A health care facility that fails or refuses to comply with a
17 court order, issued in the enforcement of a subpoena, mandating
18 the release of patient records to a board, that is accompanied by
19 a notice citing this section and describing the penalties for failure
20 to comply with this section, shall pay to the board a civil penalty
21 of up to one thousand dollars (\$1,000) per day for each day that
22 the documents have not been produced, up to ten thousand dollars
23 (\$10,000), after the date by which the court order requires the
24 documents to be produced, unless it is determined that the order
25 is unlawful or invalid. Any statute of limitations applicable to the
26 filing of an accusation by the board against a licensee shall be
27 tolled during the period the health care facility is out of compliance
28 with the court order and during any related appeals.

29 (4) Any health care facility that fails or refuses to comply with
30 a court order, issued in the enforcement of a subpoena, mandating
31 the release of records to a health care license board is guilty of a
32 misdemeanor punishable by a fine payable to the board not to
33 exceed five thousand dollars (\$5,000). Any statute of limitations
34 applicable to the filing of an accusation by the board against a
35 licensee shall be tolled during the period the health care facility
36 is out of compliance with the court order and during any related
37 appeals.

38 (c) Multiple acts by a licensee in violation of subdivision (b)
39 shall be punishable by a fine not to exceed five thousand dollars
40 (\$5,000) or by imprisonment in a county jail not exceeding six

1 months, or by both that fine and imprisonment. Multiple acts by
2 a health care facility in violation of subdivision (b) shall be
3 punishable by a fine not to exceed five thousand dollars (\$5,000)
4 and shall be reported to the State Department of Public Health
5 and shall be considered as grounds for disciplinary action with
6 respect to licensure, including suspension or revocation of the
7 license or certificate.

8 (d) A failure or refusal of a licensee to comply with a court
9 order, issued in the enforcement of a subpoena, mandating the
10 release of records to the board constitutes unprofessional conduct
11 and is grounds for suspension or revocation of his or her license.

12 (e) Imposition of the civil penalties authorized by this section
13 shall be in accordance with the Administrative Procedure Act
14 (Chapter 5 (commencing with Section 11500) of Division 3 of Title
15 2 of the Government Code). Any civil penalties paid to or received
16 by a board pursuant to this section shall be deposited into the fund
17 administered by the board.

18 (f) For purposes of this section, "certified medical records"
19 means a copy of the patient's medical records authenticated by
20 the licensee or health care facility, as appropriate, on a form
21 prescribed by the licensee's board.

22 (g) For purposes of this section, a "health care facility" means
23 a clinic or health facility licensed or exempt from licensure
24 pursuant to Division 2 (commencing with Section 1200) of the
25 Health and Safety Code.

26 (h) If a board complies with Section 2225.5, that board shall
27 not be subject to the requirements of this section.

28 (i) This section shall not apply to a licensee who does not have
29 access to, or control over, certified medical records.

30 720.16. (a) Each board shall report annually to the department
31 and the Legislature, not later than October 1 of each year, the
32 following information:

33 (1) The total number of consumer calls received by the board
34 and the number of consumer calls or letters designated as
35 discipline-related complaints.

36 (2) The total number of complaint forms received by the board.

37 (3) The total number of reports received by the board pursuant
38 to Section 801, 801.01, and 803, as applicable.

39 (4) The total number of coroner reports received by the board.

40 (5) The total number of convictions reported to the board.

- 1 (6) *The total number of criminal filings reported to the board.*
- 2 (7) *If the board is authorized to receive reports pursuant to*
- 3 *Section 805, the total number of Section 805 reports received by*
- 4 *the board, by the type of peer review body reporting and, where*
- 5 *applicable, the type of health care facility involved, and the total*
- 6 *number and type of administrative or disciplinary actions taken*
- 7 *by the board with respect to the reports, and their disposition.*
- 8 (8) *The total number of complaints closed or resolved without*
- 9 *discipline, prior to accusation.*
- 10 (9) *The total number of complaints and reports referred for*
- 11 *formal investigation.*
- 12 (10) *The total number of accusations filed and the final*
- 13 *disposition of accusations through the board and court review,*
- 14 *respectively.*
- 15 (11) *The total number of citations issued, with fines and without*
- 16 *fines, and the number of public letters of reprimand, letters of*
- 17 *admonishment, or other similar action issued, if applicable.*
- 18 (12) *The total number of final licensee disciplinary actions*
- 19 *taken, by category.*
- 20 (13) *The total number of cases in process for more than six*
- 21 *months, more than 12 months, more than 18 months, and more*
- 22 *than 24 months, from receipt of a complaint by the board.*
- 23 (14) *The average and median time in processing complaints,*
- 24 *from original receipt of the complaint by the board, for all cases,*
- 25 *at each stage of the disciplinary process and court review,*
- 26 *respectively.*
- 27 (15) *The total number of licensees in diversion or on probation*
- 28 *for alcohol or drug abuse or mental disorder, and the number of*
- 29 *licensees successfully completing diversion programs or probation,*
- 30 *and failing to do so, respectively.*
- 31 (16) *The total number of probation violation reports and*
- 32 *probation revocation filings, and their dispositions.*
- 33 (17) *The total number of petitions for reinstatement, and their*
- 34 *dispositions.*
- 35 (18) *The total number of caseloads of investigators for original*
- 36 *cases and for probation cases, respectively.*
- 37 (b) *"Action," for purposes of this section, includes proceedings*
- 38 *brought by, or on behalf of, the board against licensees for*
- 39 *unprofessional conduct that have not been finally adjudicated, as*
- 40 *well as disciplinary actions taken against licensees.*

- 1 (c) *If a board complies with Section 2313, that board shall not*
- 2 *be subject to the requirements of this section.*
- 3 SEC. 5. *Section 726 of the Business and Professions Code is*
- 4 *amended to read:*
- 5 726. (a) *The commission of any act of sexual abuse,*
- 6 *misconduct, or relations with a patient, client, or customer*
- 7 *constitutes unprofessional conduct and grounds for disciplinary*
- 8 *action for any person licensed under this division, and under any*
- 9 *initiative act referred to in this division and under Chapter 17*
- 10 *(commencing with Section 9000) of Division 3.*
- 11 (b) *The commission of, and conviction for, any act of sexual*
- 12 *abuse, misconduct or attempted sexual misconduct, whether or*
- 13 *not with a patient, or conviction of a felony requiring registration*
- 14 *pursuant to Section 290 of the Penal Code shall be considered a*
- 15 *crime substantially related to the qualifications, functions, or duties*
- 16 *of a healing arts board licensee.*
- 17 ~~This~~
- 18 (c) *This section shall not apply to sexual contact between a*
- 19 *physician and surgeon and his or her spouse or person in an*
- 20 *equivalent domestic relationship when that physician and surgeon*
- 21 *provides medical treatment, other than psychotherapeutic treatment,*
- 22 *to his or her spouse or person in an equivalent domestic*
- 23 *relationship.*
- 24 SEC. 6. *Section 802.1 of the Business and Professions Code*
- 25 *is amended to read:*
- 26 802.1. (a) (1) ~~A physician and surgeon, osteopathic physician~~
- 27 ~~and surgeon, and a doctor of podiatric medicine. Any licensee of a~~
- 28 ~~healing arts board established under this division or under any~~
- 29 ~~initiative act referred to in this division shall submit a written~~
- 30 ~~report either of any of the following to the entity that issued his or~~
- 31 ~~her license:~~
- 32 (A) *The bringing of an indictment or information charging a*
- 33 *felony against the licensee.*
- 34 (B) *The conviction of the licensee, including any verdict of*
- 35 *guilty, or plea of guilty or no contest, of any felony or*
- 36 *misdemeanor.*
- 37 (C) *Any disciplinary action ever taken by another healing arts*
- 38 *board of this state or a healing arts board of another state.*

1 (2) The report required by this subdivision shall be made in
2 writing within 30 days of the date of the bringing of the indictment
3 or information or of the conviction or disciplinary action.

4 (b) Failure to make a report required by this section shall be a
5 public offense punishable by a fine not to exceed five thousand
6 dollars (\$5,000).

7 SEC. 7. Section 803 of the Business and Professions Code is
8 amended to read:

9 803. (a) Except as provided in subdivision (b), within 10 days
10 after a judgment by a court of this state that a person who holds a
11 license, certificate, or other similar authority from the Board of
12 Behavioral Science Examiners or from an agency mentioned in
13 subdivision (a) of Section 800 (except a person licensed pursuant
14 to Chapter 3 (commencing with Section 1200)) any of the healing
15 arts boards established under this division or under any initiative
16 act referred to in this division has committed a crime, or is liable
17 for any death or personal injury resulting in a judgment for an
18 amount in excess of thirty thousand dollars (\$30,000) caused by
19 his or her negligence, error or omission in practice, or his or her
20 rendering unauthorized professional services, the clerk of the court
21 that rendered the judgment shall report that fact to the agency that
22 issued the license, certificate, or other similar authority.

23 (b) For purposes of a physician and surgeon, osteopathic
24 physician and surgeon, or doctor of podiatric medicine, who is
25 liable for any death or personal injury resulting in a judgment of
26 any amount caused by his or her negligence, error or omission in
27 practice, or his or her rendering unauthorized professional services,
28 the clerk of the court that rendered the judgment shall report that
29 fact to the agency that issued the license.

30 SEC. 8. Section 803.5 of the Business and Professions Code
31 is amended to read:

32 803.5. (a) The district attorney, city attorney, or other
33 prosecuting agency shall notify the Medical Board of California,
34 the Osteopathic Medical Board of California, the California Board
35 of Podiatric Medicine, the State Board of Chiropractic Examiners,
36 or other appropriate allied health board, the appropriate healing
37 arts board established under this division or under any initiative
38 act referred to in this division and the clerk of the court in which
39 the charges have been filed, of any filings against a licensee of
40 that board charging a felony immediately upon obtaining

1 information that the defendant is a licensee of the board. The notice
2 shall identify the licensee and describe the crimes charged and the
3 facts alleged. The prosecuting agency shall also notify the clerk
4 of the court in which the action is pending that the defendant is a
5 licensee, and the clerk shall record prominently in the file that the
6 defendant holds a license from one of the boards described above.

7 (b) The clerk of the court in which a licensee of one of the
8 boards is convicted of a crime shall, within 48 hours after the
9 conviction, transmit a certified copy of the record of conviction
10 to the applicable board.

11 SEC. 9. Section 803.6 of the Business and Professions Code
12 is amended to read:

13 803.6. (a) The clerk of the court shall transmit any felony
14 preliminary hearing transcript concerning a defendant licensee to
15 the Medical Board of California, the Osteopathic Medical Board
16 of California, the California Board of Podiatric Medicine, or other
17 appropriate allied health board, as applicable; any of the healing
18 arts boards established under this division or under any initiative
19 act referred to in this division where the total length of the
20 transcript is under 800 pages and shall notify the appropriate board
21 of any proceeding where the transcript exceeds that length.

22 (b) In any case where a probation report on a licensee is prepared
23 for a court pursuant to Section 1203 of the Penal Code, a copy of
24 that report shall be transmitted by the probation officer to the
25 appropriate board.

26 SEC. 10. Section 1695.5 of the Business and Professions Code
27 is amended to read:

28 1695.5. (a) The board shall establish criteria for the acceptance,
29 denial, or termination of licentiates in a diversion program. Unless
30 ordered by the board as a condition of licentiate disciplinary
31 probation, only those licentiates who have voluntarily requested
32 diversion treatment and supervision by a committee shall
33 participate in a diversion program.

34 (b) A licentiate who is not the subject of a current investigation
35 may self-refer to the diversion program on a confidential basis,
36 except as provided in subdivision (f).

37 (c) A licentiate under current investigation by the board may
38 also request entry into the diversion program by contacting the
39 board's Diversion Program Manager. The Diversion Program
40 Manager may refer the licentiate requesting participation in the

1 program to a diversion evaluation committee for evaluation of
 2 eligibility. Prior to authorizing a licentiate to enter into the
 3 diversion program, the Diversion Program Manager may require
 4 the licentiate, while under current investigation for any violations
 5 of the Dental Practice Act or other violations, to execute a
 6 statement of understanding that states that the licentiate understands
 7 that his or her violations of the Dental Practice Act or other statutes
 8 that would otherwise be the basis for discipline, may still be
 9 investigated and the subject of disciplinary action.

10 (d) If the reasons for a current investigation of a licentiate are
 11 based primarily on the self-administration of any controlled
 12 substance or dangerous drugs or alcohol under Section 1681 of
 13 the Business and Professions Code, or the illegal possession,
 14 prescription, or nonviolent procurement of any controlled substance
 15 or dangerous drugs for self-administration that does not involve
 16 actual, direct harm to the public, the board shall close the
 17 investigation without further action if the licentiate is accepted
 18 into the board's diversion program and successfully completes the
 19 requirements of the program. If the licentiate withdraws or is
 20 terminated from the program by a diversion evaluation committee,
 21 and the termination is approved by the program manager, the
 22 investigation shall be reopened and disciplinary action imposed,
 23 if warranted, as determined by the board.

24 (e) Neither acceptance nor participation in the diversion program
 25 shall preclude the board from investigating or continuing to
 26 investigate, or taking disciplinary action or continuing to take
 27 disciplinary action against, any licentiate for any unprofessional
 28 conduct committed before, during, or after participation in the
 29 diversion program.

30 (f) All licentiates shall sign an agreement of understanding that
 31 the withdrawal or termination from the diversion program at a time
 32 when a diversion evaluation committee determines the licentiate
 33 presents a threat to the public's health and safety shall result in the
 34 utilization by the board of diversion treatment records in
 35 disciplinary or criminal proceedings.

36 (g) ~~Any~~ *The license of a licentiate who is* terminated from the
 37 diversion program for failure to comply with program requirements
 38 ~~is subject to disciplinary action by the board for acts committed~~
 39 ~~before, during, and after participation in the diversion program. A~~
 40 ~~licentiate who has been under investigation by the board and has~~

1 ~~been terminated from the diversion program by a diversion~~
 2 ~~evaluation committee shall be reported by the diversion evaluation~~
 3 ~~committee to the board. shall be placed on suspension until the~~
 4 ~~licentiate petitions the board for reinstatement of his or her license~~
 5 ~~and is granted a probationary or unrestricted license.~~

6 SEC. 11. Section 1695.7 is added to the Business and
 7 Professions Code, to read:

8 1695.7. (a) Any third-party vendor under contract with the
 9 board for the administration of the diversion program shall report
 10 to the program manager within five days any act, by a licentiate,
 11 of substantial noncompliance with the program. For purposes of
 12 this section, "substantial noncompliance" includes, but is not
 13 limited to, a failed drug test, a relapse, refusal to submit to a drug
 14 test, failure to comply with any practice limitations, repeated or
 15 material failure to comply with other requirements of the program,
 16 or termination from the program.

17 (b) Failure by a third-party vendor to comply with this section
 18 is grounds for termination of a contract for the administration of
 19 the diversion program.

20 SEC. 12. Section 1699.2 is added to the Business and
 21 Professions Code, to read:

22 1699.2. This article shall remain in effect only until January
 23 1, 2012, and as of that date is repealed, unless a later enacted
 24 statute, that is enacted before January 1, 2012, deletes or extends
 25 that date.

26 SEC. 13. Section 2365 of the Business and Professions Code
 27 is amended to read:

28 2365. (a) The board shall establish criteria for the acceptance,
 29 denial, or termination of participants in the diversion program.
 30 Unless ordered by the board as a condition of disciplinary
 31 probation, only those participants who have voluntarily requested
 32 diversion treatment and supervision by a committee shall
 33 participate in the diversion program.

34 (b) A participant who is not the subject of a current investigation
 35 may self-refer to the diversion program on a confidential basis,
 36 except as provided in subdivision (f).

37 (c) A participant under current investigation by the board may
 38 also request entry into the diversion program by contacting the
 39 board's Diversion Program Manager. The Diversion Program
 40 Manager may refer the participant requesting participation in the

1 program to a diversion evaluation committee for evaluation of
 2 eligibility. Prior to authorizing a licentiate to enter into the
 3 diversion program, the Diversion Program Manager may require
 4 the licentiate, while under current investigation for any violations
 5 of the Medical Practice Act or other violations, to execute a
 6 statement of understanding that states that the licentiate understands
 7 that his or her violations of the Medical Practice Act or other
 8 statutes that would otherwise be the basis for discipline may still
 9 be investigated and the subject of disciplinary action.

10 (d) If the reasons for a current investigation of a participant are
 11 based primarily on the self-administration of any controlled
 12 substance or dangerous drugs or alcohol under Section 2239, or
 13 the illegal possession, prescription, or nonviolent procurement of
 14 any controlled substance or dangerous drugs for self-administration
 15 that does not involve actual, direct harm to the public, the board
 16 may close the investigation without further action if the licentiate
 17 is accepted into the board's diversion program and successfully
 18 completes the requirements of the program. If the participant
 19 withdraws or is terminated from the program by a diversion
 20 evaluation committee, and the termination is approved by the
 21 program manager, the investigation may be reopened and
 22 disciplinary action imposed, if warranted, as determined by the
 23 board.

24 (e) Neither acceptance nor participation in the diversion program
 25 shall preclude the board from investigating or continuing to
 26 investigate, or taking disciplinary action or continuing to take
 27 disciplinary action against, any participant for any unprofessional
 28 conduct committed before, during, or after participation in the
 29 diversion program.

30 (f) All participants shall sign an agreement of understanding
 31 that the withdrawal or termination from the diversion program at
 32 a time when a diversion evaluation committee determines the
 33 licentiate presents a threat to the public's health and safety shall
 34 result in the utilization by the board of diversion treatment records
 35 in disciplinary or criminal proceedings.

36 (g) ~~Any~~ *The license of a participant who is terminated from the*
 37 *diversion program for failure to comply with program requirements*
 38 *is subject to disciplinary action by the board for acts committed*
 39 *before, during, and after participation in the diversion program. A*
 40 *participant who has been under investigation by the board and has*

1 ~~been terminated from the diversion program by a diversion~~
 2 ~~evaluation committee shall be reported by the diversion evaluation~~
 3 ~~committee to the board. shall be placed on suspension until the~~
 4 ~~participant petitions the board for reinstatement of his or her~~
 5 ~~certificate and is granted a probationary or unrestricted certificate.~~

6 SEC. 14. Section 2365.5 is added to the Business and
 7 Professions Code, to read:

8 2365.5. (a) Any third-party vendor under contract with the
 9 board for the administration of the diversion program shall report
 10 to the program manager within five days any act, by a participant,
 11 of substantial noncompliance with the program. For purposes of
 12 this section, "substantial noncompliance" includes, but is not
 13 limited to, a failed drug test, a relapse, refusal to submit to a drug
 14 test, failure to comply with any practice limitations, repeated or
 15 material failure to comply with other requirements of the program,
 16 or termination from the program.

17 (b) Failure by a third-party vendor to comply with this section
 18 is grounds for termination of a contract for the administration of
 19 the diversion program.

20 SEC. 15. Section 2372 is added to the Business and Professions
 21 Code, to read:

22 2372. This article shall remain in effect only until January 1,
 23 2012, and as of that date is repealed, unless a later enacted statute,
 24 that is enacted before January 1, 2012, deletes or extends that
 25 date.

26 SEC. 16. Section 2663 of the Business and Professions Code
 27 is amended to read:

28 2663. (a) The board shall establish and administer a diversion
 29 program for the rehabilitation of physical therapists and physical
 30 therapist assistants whose competency is impaired due to the abuse
 31 of drugs or alcohol. The board may contract with any other state
 32 agency or a private organization or third-party vendor to perform
 33 its duties under this article. The board may establish one or more
 34 diversion evaluation committees to assist it in carrying out its
 35 duties under this article. Any diversion evaluation committee
 36 established by the board shall operate under the direction of the
 37 diversion program manager, as designated by the executive officer
 38 of the board. The program manager has the primary responsibility
 39 to review and evaluate recommendations of the committee.

1 (b) (1) Any state agency or private organization or third-party
2 vendor under contract with the board for the administration of the
3 diversion program shall report within five days to the program
4 manager any act, by a participant, of substantial noncompliance
5 with the program. For purposes of this section, "substantial
6 noncompliance" includes, but is not limited to, a failed drug test,
7 a relapse, refusal to submit to a drug test, failure to comply with
8 any practice limitations, repeated or material failure to comply
9 with other requirements of the program, or termination from the
10 program.

11 (2) Failure by a state agency or private organization or
12 third-party vendor to comply with this subdivision is grounds for
13 termination of a contract for the administration of the diversion
14 program.

15 SEC. 17. Section 2666 of the Business and Professions Code
16 is amended to read:

17 2666. (a) Criteria for acceptance into the diversion program
18 shall include all of the following:

19 (1) The applicant shall be licensed as a physical therapist or
20 approved as a physical therapist assistant by the board and shall
21 be a resident of California.

22 (2) The applicant shall be found to abuse dangerous drugs or
23 alcoholic beverages in a manner which may affect his or her ability
24 to practice physical therapy safely or competently.

25 (3) The applicant shall have voluntarily requested admission to
26 the program or shall be accepted into the program in accordance
27 with terms and conditions resulting from a disciplinary action.

28 (4) The applicant shall agree to undertake any medical or
29 psychiatric examination ordered to evaluate the applicant for
30 participation in the program.

31 (5) The applicant shall cooperate with the program by providing
32 medical information, disclosure authorizations, and releases of
33 liability as may be necessary for participation in the program.

34 (6) The applicant shall agree in writing to cooperate with all
35 elements of the treatment program designed for him or her.

36 Any applicant may be denied participation in the program if the
37 board, the program manager, or a diversion evaluation committee
38 determines that the applicant will not substantially benefit from
39 participation in the program or that the applicant's participation

1 in the program creates too great a risk to the public health, safety,
2 or welfare.

3 (b) A participant may be terminated from the program for any
4 of the following reasons:

5 (1) The participant has successfully completed the treatment
6 program.

7 (2) The participant has failed to comply with the treatment
8 program designated for him or her.

9 (3) The participant fails to meet any of the criteria set forth in
10 subdivision (a) or (c).

11 (4) It is determined that the participant has not substantially
12 benefited from participation in the program or that his or her
13 continued participation in the program creates too great a risk to
14 the public health, safety, or welfare. Whenever an applicant is
15 denied participation in the program or a participant is terminated
16 from the program for any reason other than the successful
17 completion of the program, and it is determined that the continued
18 practice of physical therapy by that individual creates too great a
19 risk to the public health, safety, and welfare, that fact shall be
20 reported to the executive officer of the board and all documents
21 and information pertaining to and supporting that conclusion shall
22 be provided to the executive officer. The matter may be referred
23 for investigation and disciplinary action by the board. Each physical
24 therapist or physical therapy assistant who requests participation
25 in a diversion program shall agree to cooperate with the recovery
26 program designed for him or her. Any failure to comply with that
27 program may result in termination of participation in the program.

28 The diversion evaluation committee shall inform each participant
29 in the program of the procedures followed in the program, of the
30 rights and responsibilities of a physical therapist or physical
31 therapist assistant in the program, and the possible results of
32 noncompliance with the program.

33 (c) In addition to the criteria and causes set forth in subdivision
34 (a), the board may set forth in its regulations additional criteria for
35 admission to the program or causes for termination from the
36 program.

37 (d) The license of a physical therapist or the approval of a
38 physical therapy assistant who is terminated from the diversion
39 program for failure to comply with program requirements shall
40 be placed on suspension until the physical therapist or physical

1 *therapy assistant petitions the board for reinstatement of his or*
2 *her license or board approval and is granted a probationary or*
3 *unrestricted license or board approval.*

4 *SEC. 18. Section 2669.2 is added to the Business and*
5 *Professions Code, to read:*

6 *2669.2. This article shall remain in effect only until January*
7 *1, 2012, and as of that date is repealed, unless a later enacted*
8 *statute, that is enacted before January 1, 2012, deletes or extends*
9 *that date.*

10 *SEC. 19. Section 2715 of the Business and Professions Code*
11 *is amended to read:*

12 *2715. The board shall prosecute all persons guilty of violating*
13 *the provisions of this chapter.*

14 ~~*Except as provided by Section 159.5, the*~~

15 *The board, in accordance with the provisions of the Civil Service*
16 *Law, may employ such investigators, nurse consultants, and other*
17 *personnel as it deems necessary to carry into effect the provisions*
18 *of this chapter. Investigators employed by the board shall be*
19 *provided special training in investigating nursing practice*
20 *activities.*

21 *The board shall have and use a seal bearing the name "Board of*
22 *Registered Nursing." The board may adopt, amend, or repeal, in*
23 *accordance with the provisions of Chapter 4.5 (commencing with*
24 *Section 11371); of Part 1; of Division 3; of Title 2 of the*
25 *Government Code, such rules and regulations as may be reasonably*
26 *necessary to enable it to carry into effect the provisions of this*
27 *chapter.*

28 *SEC. 20. Section 2719 is added to the Business and Professions*
29 *Code, to read:*

30 *2719. (a) (1) On or before March 1, 2010, the director shall*
31 *appoint an enforcement program monitor. The director may retain*
32 *a person for this position through a personal services contract,*
33 *the Legislature finding, pursuant to Section 19130 of the*
34 *Government Code, that this is a new state function.*

35 *(2) The director shall supervise the enforcement program*
36 *monitor and may terminate or dismiss him or her from this position.*

37 *(b) The director shall advertise the availability of the*
38 *enforcement program monitor position. The requirements for this*
39 *position shall include, but not be limited to, experience in*
40 *conducting investigations and familiarity with state laws,*

1 *regulations and rules, procedures pertaining to the board, and*
2 *relevant administrative procedures.*

3 *(c) (1) The enforcement program monitor shall monitor and*
4 *evaluate the disciplinary system and procedures of the board,*
5 *making his or her highest priority the reform and reengineering*
6 *of the board's enforcement program and operations and the*
7 *improvement of the overall efficiency of the board's disciplinary*
8 *system.*

9 *(2) The enforcement program monitor's duties shall be*
10 *performed on a continuing basis for a period of 19 months from*
11 *the date of the enforcement program monitor's appointment. These*
12 *duties shall include, but not be limited to, reviewing and making*
13 *recommendations with respect to the following: improving the*
14 *quality and consistency of complaint processing and investigation,*
15 *reducing the timeframes for completing complaint processing and*
16 *investigation, reducing any complaint backlog, assessing the*
17 *relative value to the board of various sources of complaints or*
18 *information available to the board about licensees in identifying*
19 *licensees who practice substandard care causing serious patient*
20 *harm, and assuring consistency in the application of sanctions or*
21 *discipline imposed on licensees. These duties shall also include*
22 *reviewing and making recommendations in the following areas:*
23 *the accurate and consistent implementation of the laws and rules*
24 *affecting discipline; appropriate application of investigation and*
25 *prosecution priorities; an assessment of the concerns of the board,*
26 *the department's Division of Investigation, the Attorney General's*
27 *Office, the defense bar, licensees, and patients regarding*
28 *disciplinary matters or procedures; and the board's cooperation*
29 *with other governmental entities charged with enforcing related*
30 *laws and regulations regarding nurses.*

31 *(3) The enforcement program monitor shall also evaluate the*
32 *effectiveness and efficiency of the board's diversion program and*
33 *make recommendations regarding the continuation of the program*
34 *and any changes or reforms required to assure that nurses*
35 *participating in the program are appropriately monitored and the*
36 *public is protected from nurses who are impaired due to alcohol*
37 *or drug abuse or mental or physical illness.*

38 *(4) (A) The enforcement program monitor shall exercise no*
39 *authority over the board's disciplinary operations or staff;*
40 *however, the board, its staff, the department's Division of*

1 Investigation, and the Attorney General's Office shall cooperate
2 with him or her with respect to his or her duties.

3 (B) The board, its staff, the department's Division of
4 Investigation, and the Attorney General's Office shall provide
5 data, information, and case files as requested by the enforcement
6 program monitor to perform all of his or her duties. The provision
7 of confidential data, information, and case files by the board to
8 the enforcement program monitor at any time after the appointment
9 of the monitor shall not constitute a waiver of any exemption from
10 disclosure or discovery or of any confidentiality protection or
11 privilege otherwise provided by law that is applicable to the data,
12 information, or case files.

13 (5) The director shall assist the enforcement program monitor
14 in the performance of his or her duties, and the enforcement
15 program monitor shall have the same investigative authority as
16 the director.

17 (d) On or before December 1, 2010, the enforcement program
18 monitor shall submit an initial written report of his or her findings
19 and conclusions to the board, the department, and the Legislature,
20 and be available to make oral reports to each, if requested to do
21 so. The enforcement program monitor may also provide additional
22 information to either the department or the Legislature at his or
23 her discretion and at the request of either the department or the
24 Legislature. The enforcement program monitor shall make his or
25 her reports available to the public and the media. The enforcement
26 program monitor shall make every effort to provide the board with
27 an opportunity to reply to any facts, findings, issues, or conclusions
28 in his or her reports with which the board may disagree.

29 (e) The board shall reimburse the department for all of the costs
30 associated with the employment of an enforcement program
31 monitor.

32 (f) On or before October 1, 2011, the enforcement program
33 monitor shall issue a final written report. The final report shall
34 include final findings and conclusions on the topics addressed in
35 the reports submitted by the monitor pursuant to subdivision (d).

36 (g) This section shall become inoperative on October 1, 2011,
37 and, as of January 1, 2012, is repealed, unless a later enacted
38 statute, that becomes operative on or before January 1, 2012,
39 deletes or extends the dates on which it becomes inoperative and
40 is repealed.

1 SEC. 21. Section 2770.7 of the Business and Professions Code
2 is amended to read:

3 2770.7. (a) The board shall establish criteria for the acceptance,
4 denial, or termination of registered nurses in the diversion program.
5 Only those registered nurses who have voluntarily requested to
6 participate in the diversion program shall participate in the
7 program.

8 (b) A registered nurse under current investigation by the board
9 may request entry into the diversion program by contacting the
10 board. Prior to authorizing a registered nurse to enter into the
11 diversion program, the board may require the registered nurse
12 under current investigation for any violations of this chapter or
13 any other provision of this code to execute a statement of
14 understanding that states that the registered nurse understands that
15 his or her violations that would otherwise be the basis for discipline
16 may still be investigated and may be the subject of disciplinary
17 action.

18 (c) If the reasons for a current investigation of a registered nurse
19 are based primarily on the self-administration of any controlled
20 substance or dangerous drug or alcohol under Section 2762, or the
21 illegal possession, prescription, or nonviolent procurement of any
22 controlled substance or dangerous drug for self-administration that
23 does not involve actual, direct harm to the public, the board shall
24 close the investigation without further action if the registered nurse
25 is accepted into the board's diversion program and successfully
26 completes the requirements of the program. If the registered nurse
27 withdraws or is terminated from the program by a diversion
28 evaluation committee, and the termination is approved by the
29 program manager, the investigation shall be reopened and
30 disciplinary action imposed, if warranted, as determined by the
31 board.

32 (d) Neither acceptance nor participation in the diversion program
33 shall preclude the board from investigating or continuing to
34 investigate, or taking disciplinary action or continuing to take
35 disciplinary action against, any registered nurse for any
36 unprofessional conduct committed before, during, or after
37 participation in the diversion program.

38 (e) All registered nurses shall sign an agreement of
39 understanding that the withdrawal or termination from the diversion
40 program at a time when the program manager or diversion

1 evaluation committee determines the licentiate presents a threat
2 to the public's health and safety shall result in the utilization by
3 the board of diversion treatment records in disciplinary or criminal
4 proceedings.

5 (f) ~~Any~~The license of a registered nurse who is terminated from
6 the diversion program for failure to comply with program
7 requirements is subject to disciplinary action by the board for acts
8 committed before, during, and after participation in the diversion
9 program. A registered nurse who has been under investigation by
10 the board and has been terminated from the diversion program by
11 a diversion evaluation committee shall be reported by the diversion
12 evaluation committee to the board. shall be placed on suspension
13 until the licentiate petitions the board for reinstatement of his or
14 her license and is granted a probationary or unrestricted license.

15 SEC. 22. Section 2770.16 is added to the Business and
16 Professions Code, to read:

17 2770.16. (a) Any third-party vendor under contract with the
18 board for the administration of the diversion program shall report
19 within five days to the program manager any act, by a registered
20 nurse, of substantial noncompliance with the program. For
21 purposes of this section, "substantial noncompliance" includes,
22 but is not limited to, a failed drug test, a relapse, refusal to submit
23 to a drug test, failure to comply with any practice limitations,
24 repeated or material failure to comply with other requirements of
25 the program, or termination from the program.

26 (b) Failure by a third-party vendor to comply with this section
27 is grounds for termination of a contract for the administration of
28 the diversion program.

29 SEC. 23. Section 2770.18 is added to the Business and
30 Professions Code, to read:

31 2770.18. This article shall remain in effect only until January
32 1, 2012, and as of that date is repealed, unless a later enacted
33 statute, that is enacted before January 1, 2012, deletes or extends
34 that date.

35 SECTION 1. The Legislature finds and declares all of the
36 following:

37 (a) Nurse practitioners are registered nurses who have a graduate
38 education and clinical training, and who provide a wide range of
39 services and care.

1 (b) Under current law, nurse practitioners have the same
2 statutory authority to provide services and care as do registered
3 nurses. However, the law allows those registered nurses who the
4 Board of Registered Nursing has determined meet the standards
5 for a nurse practitioner to provide care and services beyond those
6 specified in statute for registered nurses where those services are
7 performed pursuant to standardized procedures and protocols
8 developed through collaboration among administrators and health
9 professionals, including physicians and surgeons, in the organized
10 health care system in which a nurse practitioner practices.

11 (c) The Legislature reiterates its intention to allow each
12 organized health care system in which a nurse practitioner practices
13 to define those services nurse practitioners may perform in
14 standardized procedures developed pursuant to Section 2725 of
15 the Business and Professions Code.

16 (d) Notwithstanding the foregoing, the Legislature finds that
17 there may be some ambiguity in current law regarding what
18 services and functions to be performed by nurse practitioners may
19 be included in standardized procedures and protocols.

20 (e) Therefore, to remove this ambiguity, the Legislature hereby
21 clarifies that standardized procedures and protocols may include
22 the specified services and functions set forth in this act so that
23 health care entities may allow nurse practitioners to engage in
24 those activities if the entities choose to do so, and that third-party
25 payors understand that those services and functions can be
26 performed by nurse practitioners if they are included in an entity's
27 standardized procedures and protocols.

28 SEC. 2.

29 SEC. 24. Section 2835.7 is added to the Business and
30 Professions Code, to read:

31 2835.7. (a) In addition to any other practices that meet the
32 general criteria set forth in statute or regulation for inclusion in
33 standardized procedures developed through collaboration among
34 administrators and health professionals, including physicians and
35 surgeons and nurses, pursuant to Section 2725, standardized
36 procedures may be implemented that authorize a nurse practitioner
37 to do any of the following:

38 (1) Order durable medical equipment, subject to any limitations
39 set forth in the standardized procedures. Notwithstanding that

1 authority, nothing in this paragraph shall operate to limit the ability
2 of a third-party payor to require prior approval.

3 (2) After performance of a physical examination by the nurse
4 practitioner and collaboration with a physician and surgeon, certify
5 disability pursuant to Section 2708 of the Unemployment Insurance
6 Code.

7 (3) For individuals receiving home health services or personal
8 care services, after consultation with the treating physician and
9 surgeon, approve, sign, modify, or add to a plan of treatment or
10 plan of care.

11 (b) Nothing in this section shall be construed to affect the
12 validity of any standardized procedures in effect prior to the
13 enactment of this section or those adopted subsequent to enactment.

14 *SEC. 25. Section 3534.1 of the Business and Professions Code*
15 *is amended to read:*

16 3534.1. (a) The examining committee shall establish and
17 administer a diversion program for the rehabilitation of physician
18 assistants whose competency is impaired due to the abuse of drugs
19 or alcohol. The examining committee may contract with any other
20 state agency or a private organization or a third-party vendor to
21 perform its duties under this article. The examining committee
22 may establish one or more diversion evaluation committees to
23 assist it in carrying out its duties under this article. As used in this
24 article, "committee" means a diversion evaluation committee. A
25 committee created under this article operates under the direction
26 of the diversion program manager, as designated by the executive
27 officer of the examining committee. The program manager has the
28 primary responsibility to review and evaluate recommendations
29 of the committee.

30 (b) (1) Any state agency or private organization or third-party
31 vendor under contract with the examining committee for the
32 administration of the diversion program shall report within five
33 days to the program manager any act, by a participant, of
34 substantial noncompliance with the program. For purposes of this
35 section, "substantial noncompliance" includes, but is not limited
36 to, a failed drug test, a relapse, refusal to submit to a drug test,
37 failure to comply with any practice limitations, repeated or
38 material failure to comply with other requirements of the program,
39 or termination from the program.

1 (2) Failure by a state agency or private organization or
2 third-party vendor to comply with this subdivision is grounds for
3 termination of a contract for the administration of the diversion
4 program.

5 *SEC. 26. Section 3534.5 of the Business and Professions Code*
6 *is amended to read:*

7 3534.5. (a) A participant may be terminated from the program
8 for any of the following reasons: ~~(a) the participant has successfully~~
9 ~~completed the treatment program; (b) the participant has failed to~~
10 ~~comply with the treatment program designated for him or her; (c)~~
11 ~~the participant fails to meet any of the criteria set forth in~~
12 ~~subdivision (d); or (d) it is determined that the participant has not~~
13 ~~substantially benefited from participation in the program or that~~
14 ~~his or her continued participation in the program creates too great~~
15 ~~a risk to the public health, safety, or welfare. Whenever~~

16 (1) The participant has successfully completed the treatment
17 program.

18 (2) The participant has failed to comply with the treatment
19 program designated for him or her.

20 (3) The participant fails to meet any of the criteria set forth in
21 Section 3534.4.

22 (4) It is determined that the participant has not substantially
23 benefited from participation in the program or that his or her
24 continued participation in the program creates too great a risk to
25 the public health, safety, or welfare.

26 (b) Whenever an applicant is denied participation in the program
27 or a participant is terminated from the program for any reason
28 other than the successful completion of the program, and it is
29 determined that the continued practice of medicine by that
30 individual creates too great a risk to the public health and safety,
31 that fact shall be reported to the executive officer of the examining
32 committee and all documents and information pertaining to and
33 supporting that conclusion shall be provided to the executive
34 officer. The matter may be referred for investigation and
35 disciplinary action by the examining committee. Each

36 (c) The license of a physician assistant who is terminated from
37 the diversion program for failure to comply with program
38 requirements shall be placed on suspension until the licentiate
39 petitions the board for reinstatement of his or her license and is
40 granted a probationary or unrestricted license.

1 (d) Each physician assistant who requests participation in a
2 diversion program shall agree to cooperate with the recovery
3 program designed for him or her. Any failure to comply with that
4 program may result in termination of participation in the program.

5 The
6 (e) The examination committee shall inform each participant in
7 the program of the procedures followed in the program, of the
8 rights and responsibilities of a physician assistant in the program,
9 and the possible results of noncompliance with the program.

10 SEC. 27. Section 3534.12 is added to the Business and
11 Professions Code, to read:

12 3534.12. This article shall remain in effect only until January
13 1, 2012, and as of that date is repealed, unless a later enacted
14 statute, that is enacted before January 1, 2012, deletes or extends
15 that date.

16 SEC. 28. Section 4365 of the Business and Professions Code
17 is amended to read:

18 4365. (a) The board shall contract with one or more qualified
19 contractors to administer the pharmacists recovery program.

20 (b) (1) Any third-party vendor under contract with the board
21 for the administration of the pharmacists recovery program shall
22 report within five days to the program manager any act, by a
23 participant, of substantial noncompliance with the program. For
24 purposes of this section, "substantial noncompliance" includes,
25 but is not limited to, a failed drug test, a relapse, refusal to submit
26 to a drug test, failure to comply with any practice limitations,
27 repeated or material failure to comply with other requirements of
28 the program, or termination from the program.

29 (2) Failure by a third-party vendor to comply with this
30 subdivision is grounds for termination of a contract for the
31 administration of the pharmacists recovery program.

32 SEC. 29. Section 4369 of the Business and Professions Code
33 is amended to read:

34 4369. (a) Any failure to comply with the treatment contract,
35 determination that the participant is failing to derive benefit from
36 the program, or other requirements of the pharmacists recovery
37 program may result in the termination of the pharmacist's or intern
38 pharmacist's participation in the pharmacists recovery program.
39 The name and license number of a pharmacist or intern pharmacist

1 who is terminated from the pharmacists recovery program and the
2 basis for the termination shall be reported to the board.

3 (b) The license of a pharmacist or intern pharmacist terminated
4 from the pharmacists recovery program for failure to comply with
5 program requirements shall be placed on suspension until the
6 licensee petitions the board for reinstatement of his or her license
7 and is granted a probationary or unrestricted license.

8 (b)
9 (c) Participation in the pharmacists recovery program shall not
10 be a defense to any disciplinary action that may be taken by the
11 board.

12 (e)
13 (d) No provision of this article shall preclude the board from
14 commencing disciplinary action against a licensee who is
15 terminated from the pharmacists recovery program.

16 SEC. 30. Section 4375 is added to the Business and Professions
17 Code, to read:

18 4375. This article shall remain in effect only until January 1,
19 2012, and as of that date is repealed, unless a later enacted statute,
20 that is enacted before January 1, 2012, deletes or extends that
21 date.

22 SEC. 31. Section 4870 of the Business and Professions Code
23 is amended to read:

24 4870. (a) Each veterinarian and registered veterinary technician
25 who requests participation in a diversion program shall agree to
26 cooperate with the treatment program designed by a diversion
27 evaluation committee. Any failure to comply with the provisions
28 of a treatment program may result in termination of the
29 veterinarian's or registered veterinary technician's participation
30 in a program.

31 (b) The license of a veterinarian or registration of a registered
32 veterinary technician who is terminated from the diversion program
33 for failure to comply with program requirements shall be placed
34 on suspension until the veterinarian or registered veterinary
35 technician petitions the board for reinstatement of his or her license
36 or registration.

37 SEC. 32. Section 4870.5 is added to the Business and
38 Professions Code, to read:

39 4870.5. (a) Any third-party vendor under contract with the
40 board for the administration of the diversion program shall report

1 within five days to the appropriate chairperson any act, by a
2 veterinarian or registered veterinary technician, of substantial
3 noncompliance with the program. For purposes of this section,
4 "substantial noncompliance" includes, but is not limited to, a
5 failed drug test, a relapse, refusal to submit to a drug test, failure
6 to comply with any practice limitations, repeated or material
7 failure to comply with other requirements of the program, or
8 termination from the program.

9 (b) Failure by a third-party vendor to comply with this section
10 is grounds for termination of a contract for the administration of
11 the diversion program.

12 SEC. 33. Section 4873.2 is added to the Business and
13 Professions Code, to read:

14 4873.2. This article shall remain in effect only until January
15 1, 2012, and as of that date is repealed, unless a later enacted
16 statute, that is enacted before January 1, 2012, deletes or extends
17 that date.

18 SEC. 34. (a) It is the intent of the Legislature that the
19 Department of Consumer Affairs shall, on or before December
20 31, 2012, establish an enterprise information technology system
21 necessary to electronically create and update healing arts license
22 information, track enforcement cases, and allocate enforcement
23 efforts pertaining to healing arts licensees. The Legislature intends
24 the system to be designed as an integrated system to support all
25 business automation requirements of the department's licensing
26 and enforcement functions.

27 (b) The Legislature also intends the department to enter into
28 contracts for telecommunication, programming, data analysis,
29 data processing, and other services necessary to develop, operate,
30 and maintain the enterprise information technology system.

31 SEC. 35. The Legislature finds and declares all of the following
32 with respect to Section 2835.7 of the Business and Professions
33 Code, as added by Section 24 of this act:

34 (a) Nurse practitioners are registered nurses who have a
35 graduate education and clinical training, and who provide a wide
36 range of services and care.

37 (b) Under current law, nurse practitioners have the same
38 statutory authority to provide services and care as do registered
39 nurses. However, the law allows those registered nurses who the
40 Board of Registered Nursing has determined meet the standards

1 for a nurse practitioner to provide care and services beyond those
2 specified in statute for registered nurses where those services are
3 performed pursuant to standardized procedures and protocols
4 developed through collaboration among administrators and health
5 professionals, including physicians and surgeons, in the organized
6 health care system in which a nurse practitioner practices.

7 (c) The Legislature reiterates its intention to allow each
8 organized health care system in which a nurse practitioner
9 practices to define those services nurse practitioners may perform
10 in standardized procedures developed pursuant to Section 2725
11 of the Business and Professions Code.

12 (d) Notwithstanding the foregoing, the Legislature finds that
13 there may be some ambiguity in current law regarding what
14 services and functions to be performed by nurse practitioners may
15 be included in standardized procedures and protocols.

16 (e) Therefore, to remove this ambiguity, the Legislature hereby
17 clarifies that standardized procedures and protocols may include
18 the specified services and functions set forth in this act so that
19 health care entities may allow nurse practitioners to engage in
20 those activities if the entities choose to do so, and that third-party
21 payors understand that those services and functions can be
22 performed by nurse practitioners if they are included in an entity's
23 standardized procedures and protocols.

24 SEC. 36. No reimbursement is required by this act pursuant
25 to Section 6 of Article XIII B of the California Constitution for
26 certain costs that may be incurred by a local agency or school
27 district because, in that regard, this act creates a new crime or
28 infraction, eliminates a crime or infraction, or changes the penalty
29 for a crime or infraction, within the meaning of Section 17556 of
30 the Government Code, or changes the definition of a crime within
31 the meaning of Section 6 of Article XIII B of the California
32 Constitution.

33 However, if the Commission on State Mandates determines that
34 this act contains other costs mandated by the state, reimbursement
35 to local agencies and school districts for those costs shall be made
36 pursuant to Part 7 (commencing with Section 17500) of Division
37 4 of Title 2 of the Government Code.

O

Attachment 4

Enforcement Program Priorities of the DCA



MEMORANDUM

DATE: October 6, 2009

TO: Executive Officers, Executive Directors, and Bureau Chiefs for
DCA Health Care Agencies

FROM: 
BRIAN J. STIGER, Director
Department of Consumer Affairs

SUBJECT: UPDATED - Complaint Prioritization Guidelines for Health Care
Agencies

On August 31, 2009, I issued a memorandum encouraging each health care agency to consider using recommended complaint prioritization guidelines. Since then, the department has received some feedback on the guidelines and made slight changes to them. A copy of the revised guidelines is attached.

As with the prior version, each category of complaint is given a priority of "urgent" (requiring the most immediate resources), "high" (the next highest priority) or "routine" (handled in the ordinary course of business). I encourage you to apply these guidelines to complaints received by your agency.

Thank you for your assistance.

Attachment

cc: Doreathea Johnson, Deputy Director for Legal Affairs

Complaint Prioritization Guidelines for DCA Health Care Agencies

As complaints are received, a staff person should immediately review each complaint to determine the appropriate course of action based on the complaint prioritization guidelines. The table below represents true guidelines - depending on the facts, a different level of priority may be warranted. For example, a complaint based on a report from a health care practitioner data bank (normally routine) may be re-prioritized to a higher level of response based on the nature of the underlying acts.

Agencies should continue to review complaints warranting urgent or high attention to determine whether to seek an Interim Suspension Order, a Penal Code section 23 request or other interim action as described in Deputy Director for Legal Affairs Doreatha Johnson's memorandum dated December 15, 2008.

Priority Level	Complaint Category
Urgent (Highest Priority)	(In general, any act resulting in death or serious injury) Gross negligence, incompetence or repeated negligent acts that involve death or serious bodily injury Drug or alcohol abuse by the licensee resulting in death or serious bodily injury Repeated acts of clearly excessive prescribing, furnishing or administering of controlled substances, or repeated acts of prescribing w/o a good faith exam Sexual misconduct with patient during course of treatment or examination Practicing while under the influence of drugs or alcohol Physical or mental abuse with injury Unlicensed activity alleged to have resulted in patient injuries Aiding and abetting unlicensed activity alleged to have resulted in patient injuries Arrests or convictions substantially related to the area of practice (Note: may be re-categorized based on the nature of the underlying acts) Impairments (mental, physical or as a result of alcohol or drug abuse including termination from a diversion program) Theft of prescription drugs Furnishing prescription drugs without a prescription

10/6/09

High	<p>Negligence or incompetence without serious bodily injury</p> <p>Physical or mental abuse (without injury)</p> <p>Reports pursuant to Bus. & Prof. Code § 800 et seq. (Note: may be re-categorized based on the nature of the underlying acts)</p> <p>Bus. & Prof. Code § 805 Health facility reports or other employer generated reports (Note: may be re-categorized based on the nature of the underlying acts)</p> <p>Complaints about licensees on probation (whether or not injury)</p> <p>Prescribing drugs without a "good faith" exam (where authority to prescribe exists)</p> <p>Prescribing or dispensing drugs without authority</p> <p>Multiple complaints of the same violation</p> <p>Complaints with multiple prior complaints</p> <p>Unlicensed activities (with no apparent harm)</p> <p>Aiding and abetting unlicensed activity (with no apparent harm)</p> <p>Exam subversion (where exam may be compromised)</p> <p>When evidence will likely be destroyed or unavailable</p>
Routine	<p>False/misleading advertising</p> <p>Patient abandonment</p> <p>Fraud</p> <p>Failure to release medical records</p> <p>Record keeping violations</p> <p>Applicant misconduct</p> <p>National practitioner data bank reports or other reports of out-of-state discipline (Note: may be re-categorized based on the nature of the underlying acts)</p> <p>Workers compensation complaints (Note: may be re-categorized based on the nature of the underlying acts)</p> <p>Non-jurisdictional complaints (fee disputes, billing)</p> <p>Exam subversion (exam not compromised)</p> <p>Continuing education</p> <p>Breach of confidentiality</p>

Attachment 5

Proposed Fingerprint Regulation for the Board of Pharmacy

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 or registrant's renewal date that occurs on or after (JOAL insert effective date), or as directed by the board.

(1) A pharmacist 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, as directed by the Board, 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 \$300 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, and 4400, Business and Professions Code; and Sections 11105(b)(10), and 11105(e), Penal Code.

Attachment 6

SB 1441 Implementation

SB 1441 REQUIREMENT

- (1) Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

Draft Uniform Standard #1

If a board has determined that a clinical diagnostic evaluation is necessary in order to evaluate whether practice restrictions or other actions are warranted, the following minimum standards shall apply.

1. The clinical diagnostic evaluation shall be conducted by a licensed practitioner who:

- holds a valid, unrestricted license to do so;
- has three (3) years experience in providing evaluations of health professionals with substance abuse disorders;
- is approved by the board;

2. The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.

3. The clinical diagnostic evaluation report shall:

- set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem;
- set forth, in the evaluator's opinion, whether the licensee is a threat to himself/herself or others; and,
- set forth, in the evaluator's opinion, recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice.

The evaluator may not have a financial relationship, personal relationship, or business relationship with the licensee. The evaluator shall provide an objective, unbiased, and independent evaluation.

If the evaluator determines during the evaluation process that a licensee is a threat to himself/herself or others, the evaluator shall notify the board within 24 hours of such a determination.

For all evaluations, a final written report shall be provided to the board no later than 30 days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed ninety (90) days.

SB 1441 REQUIREMENT

(2) Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in subdivision (a) and any treatment recommended by the evaluator described in subdivision (a) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

Draft Uniform Standard # 2

1. The board shall determine on a case-by-case basis whether a licensee shall be temporarily removed from practice to undergo the clinical diagnostic evaluation and any treatment recommended by the evaluator. The board may utilize any statutory provisions or other authority for temporary removal of the licensee.
2. Specific requirements for the temporary removal of the licensee from practice shall be determined on a case-by-case basis by the board using the following criteria:
 - license type;
 - licensee's history;
 - documented length of sobriety/time that has elapsed since substance use;
 - scope and pattern of use;
 - treatment history;
 - licensee's medical history and current medical condition;
 - nature, duration and severity of substance abuse, and
 - threat to himself/herself or the public.
3. These same criteria shall be used by the board to determine whether to permit a licensee to return to practice on a part- or full-time basis.

SB 1441 REQUIREMENT

(3) Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status or condition.

Draft Uniform Standard #3

If the licensee has an employer, he/she shall provide the name, physical address, and telephone number of all employers and shall give specific, written consent that the licensee authorizes the board and the employers to communicate regarding the licensee's work status, performance, and monitoring.

SB 1441 REQUIREMENT

(4) Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomness, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

DRAFT UNIFORM STANDARD #4

The following minimum standards apply to a licensee subject to drug testing:

1. Licensees shall be tested no less than eighteen (18) times per year for the first three (3) years of continual abstinence. After the first three (3) years, licensees shall be tested no less than twelve (12) times per year.
2. The scheduling of tests shall be done on a random basis, preferably by a computer program, or as directed by the board.
3. Licensees shall be required to make daily contact to determine if testing is required.
4. Licensees shall be required to test on the date of notification as directed by the board.
5. Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation.
6. Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines.
7. Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered.
8. Collection of specimens shall be observed.
9. Prior to vacation or absence, alternative testing location(s) must be approved by the board.
10. Laboratories shall be certified by the National Laboratory Certification Program or the equivalent in other countries.
11. A collection site must submit a specimen to the laboratory within one business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The appropriate board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

SB 1441 REQUIREMENT

(5) Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

Draft Uniform Standard # 5

If the board determines a licensee must attend group meetings or support groups, the following standards shall apply:

1. When determining the frequency of required group meeting attendance, consideration shall be given to the following:
 - the licensee's history;
 - the documented length of sobriety/time that has elapsed since substance use;
 - the recommendation of the clinical evaluator;
 - the scope and pattern of use;
 - the licensee's treatment history; and,
 - the nature, duration, and severity of substance abuse.
2. The licensee shall be required to submit to the board, at least once a month, documentation of attendance at the group meeting signed or initialed by a representative of the meeting's organizer.

If the board determines a licensee must attend a group meeting facilitated by an individual who reports directly or indirectly to the board, in addition to the requirements above, the following standards shall also apply:

3. The meeting facilitator must have a minimum of three years experience in the treatment and rehabilitation of substance abuse.
4. The meeting facilitator must not have a financial relationship, personal relationship, or business relationship with the licensee.
5. The document showing attendance must be signed by the group meeting facilitator and must include the licensee's name, the group name, the date and location of the meeting, and the licensee's level of participation and progress in treatment.
6. The facilitator shall report any unexcused absence within two (2) business days.

SB 1441 REQUIREMENT

(6) Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

Draft Uniform Standard #6

In determining whether inpatient, outpatient, or other type of treatment is necessary, the Board shall consider the following criteria:

- recommendation of the clinical diagnostic evaluation pursuant to Uniform Standard #1;
- license type;
- licensee's history;
- documented length of sobriety/time that has elapsed since substance abuse;
- scope and pattern of substance use;
- licensee's treatment history;
- licensee's medical history and current medical condition;
- nature, duration, and severity of substance abuse, and
- threat to himself/herself or the public.



ISSUE MEMORANDUM	
DATE	August 10, 2009
TO	SB 1441 Substance Abuse Coordination Committee
FROM	SB 1441 Uniform Standards Staff Working Group Debi Mitchell Physical Therapy Board of California
SUBJECT	SB 1441 Uniform Standard # 7

SB 1441 REQUIREMENT

(7) Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

DRAFT UNIFORM STANDARD #7

If the Board determines a worksite monitor is necessary, the worksite monitor shall meet the following requirements to be considered for approval by the Board.

The worksite monitor must meet the following qualifications:

1. Shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the Board. This provision may be waived by the Board on a case-by-case basis.
2. The monitor's licensure scope of practice shall include the scope of practice of the licensee that is being monitored or be another health care professional approved by the board.
3. Shall have an active unrestricted license, with no disciplinary action within the last five years.
4. Shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the Board.

5. The worksite monitor must adhere to the required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the Board.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.

6. Reporting by the worksite monitor to the Board shall be as follows:
 - a) Any suspected substance abuse must be verbally reported to the Board and the licensee's employer within one hour of occurrence. If occurrence is not during the Board's normal business hours the report must be within one hour of the next business day. A written report shall be submitted to the Board within 48 hours of occurrence.

 - b) The worksite monitor shall complete and submit a written report monthly or as directed by the Board. The report shall include:
 - the licensee's name;
 - license number;
 - worksite monitor's name and signature;
 - worksite monitor's license number;
 - worksite location(s);
 - dates licensee had face-to-face contact with monitor;
 - staff interviewed, if applicable;
 - attendance report;
 - any change in behavior and/or personal habits;
 - any indicators that can lead to suspected substance abuse.

7. The licensee shall complete the required consent forms and sign an agreement with the worksite monitor and the Board to allow the Board to communicate with the worksite monitor.

DISCUSSION

As directed in SB1441, the boards are required to establish worksite monitor requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors. The worksite monitor's role is to monitor a licensee who is chemically impaired and to ensure that the licensee is not abusing drugs and/or alcohol. The monitor is also responsible for reporting to the board whether patient safety may be at risk and any change in the licensee's behavior that may be cause for suspected substance abuse.

In considering the standards used to determine the qualifications, methods, and reporting requirements for the worksite monitor, members of the working group believe that the requirements should be able to encompass all the various types of practice settings and at the same time protect patients.

It was agreed by all members when developing the worksite monitor's qualifications that the worksite monitor should not have any financial or personal relationship with the licensee. This will ensure that the worksite monitor is providing impartial evaluations. The provision that allows boards to waive this requirement is due to the fact that some licensees may only have available to them a worksite monitor who is their employer. The boards will review these types of situations on a case-by-case basis. Discussion of the work group included; should the worksite monitor be of the same profession or can it be another health care professional. It was agreed that it was important that the worksite monitor be a health care professional but that he or she did not have to be of the same profession as this may not be manageable in a hospital setting if the manager of the department is of a different profession.

In developing the criteria for the methods of monitoring the licensee, members of the working group agreed that the standard must require the worksite monitor to have frequent face-to-face contact with the licensee in order to assess the licensee's appearance, eye contact, and behavior. It was determined that as part of monitoring the licensee, the worksite monitor needs to interview the staff in the office on the licensee's behavior and review the attendance records in order to adequately report to the board the licensee's overall performance.

The reporting criteria was developed by the members to identify a timeline for reporting to the board possible substance abuse by the licensee, what information must be included in the worksite monitor report, and the timeline the report shall be submitted to the board.

Also, included in the standard is language to require the licensee and worksite monitor sign and submit the required consent forms and affirmations in order for the board to communicate with the worksite monitor(s).

The members acknowledged that many practitioners have solo-practices and that the standard needed to identify a means for those practitioners to have a worksite monitor.

The work group recommends that DCA develop and offer a webcast training course on how to be an effective worksite monitor for all worksite monitors to review prior to being approved by the Boards.

PROS

- Implementing Uniform Standard #7 will provide ongoing documentation of the licensee's behavior and will ensure the public's safety.
- In establishing the licensee have a worksite monitor, the boards will be immediately notified if a licensee is suspected of working under the influence of drugs and/or alcohol.

CONS

- Due to statutory conflict, some boards will need to make statute changes to coincide with uniform standard #7.

PUBLIC COMMENT

Public comment received included:

- It may be cumbersome to the worksite monitor to document each date he or she had face-to-face contact with the licensee.
- A recommendation to change "or" to "and/or" under section 1(d) for the worksite monitor to review the licensee's disciplinary order and/or contract
- To consider changing the word "regular" to "frequent" under section 2(a).
- To consider allowing a worksite monitor to be a non-licensed individual.

The workgroup took into consideration the comment that it may be too cumbersome for the worksite monitor to document all dates the worksite monitor had face-to-face contact with the licensee. It was agreed that in order to have proper documentation to ensure public protection the workgroup agreed to require the worksite monitor to document each date he or she had face-to-face contact with the licensee. The workgroup also changed the reporting time from "quarterly" to "monthly" in section 3(b).

In response to the public comment, the workgroup made the recommended changes to section 1(d) and 2(a).

The workgroup agreed not to add a non-licensed individual as an option as a worksite monitor.



ISSUE MEMORANDUM

DATE	August 4, 2009
TO	SB 1441 Substance Abuse Coordination Committee
FROM	SB 1441 Uniform Standards Staff Working Group Kim Madsen, BBS and Anne Sodergren, Pharmacy
SUBJECT	SB 1441 Uniform Standard #8

SB 1441 REQUIREMENT

(8) Procedures to be followed when a licensee tests positive for a banned substance.

DRAFT UNIFORM STANDARD #8

The procedures below shall be followed when a licensee tests positive for a banned substance:

1. Communication with the board probation coordinator or recovery program if applicable;
2. Confrontation of the licensee;
3. Communication with the employer and worksite monitor, if applicable;
4. Communication with any treatment provider including support group facilitator.

Based on information gathered, at least one of the procedures below shall be followed in response to a positive test for a banned substance:

1. Pursue administrative options include revocation and/or suspension
2. Require participation in inpatient and/or outpatient treatment
3. Increase frequency of testing
4. Practice restrictions e.g. increased level of supervised practice, limit the scope of duties.
5. Removal from practice for the purpose of assessment.

DISCUSSION

The workgroup considered the circumstances in which a licensee would be subjected to testing either through the terms/conditions set forth in a disciplinary order or in a recovery program contract. The workgroup was cognizant that in either of these circumstances specific consequences for a positive may already be specified.

Written comment was received from Kaiser Permanente Northern California Division Physician David Pating and Kaiser Permanente Southern California Division Physician Stephanie Shaner. Both Dr. Pating and Dr. Shaner requested that the option of removing the licensee from practice for the purpose of assessment be added to the standard.

Public comments received during the public hearing indicated support for inclusion of this option.

The workgroup determined that adding the option of removing a licensee from practice for assessment was appropriate.

Elinore McCance-Katz M.D., PhD provided written comments regarding the use of a Medical Review Officer (MRO) to interpret the results of the test, if necessary. Dr. McCance-Katz stated that it was extremely important that the boards understand what a MRO does. Dr. McCance-Katz explained that if a urine test is positive for a prohibited substance (e.g. Oxycodone in a licensee who is opioid-addicted); a MRO would look into this and if the MRO found that the licensee had a valid prescription; it would be called a negative screen.

Further, Dr. McCance-Katz stated that a health care professional with addiction is not to use prohibited substances, prescribed or not, if they are working in their profession. Dr. McCance-Katz suggested a better approach would be to have a medical director for these monitoring programs who have MRO experience, but understands the nature of addiction in healthcare professionals and can attend to public safety.

Dr. McCance-Katz also suggested adding the option of immediate cessation from practice if a licensee was practicing their healthcare profession. The cessation of practice would remain in place until an assessment is completed and recommendations were reviewed and considered by the Board.

The workgroup considered the comments of Dr. McCance-Katz relating to the use of a MRO. The Use of an MRO is to determine if a positive drug test can be attributed to another cause other than ingestion of a prohibited substance.

PROS

The procedures recommended by the workgroup are ones that can be followed in cases which a disciplinary order or recovery program contract exist. Moreover, the procedures provide boards with consistent options when responding to a positive test; ensuring consumer protection.

CONS

Due to statutory conflict, some boards will need to make statute changes to coincide with uniform standard #8.

Legislative and Policy Review Division

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ISSUE MEMORANDUM

DATE	August 6, 2009
TO	SB 1441 Substance Abuse Coordination Committee
FROM	SB 1441 Uniform Standards Staff Working Group April Alameda, Chiropractic Board
SUBJECT	SB 1441 Uniform Standard # 9

SB 1441 REQUIREMENT

(9) Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

DRAFT UNIFORM STANDARD #9

The procedures below shall be followed when a licensee is confirmed to have ingested a banned substance:

1. Communication with the board probation coordinator or recovery program if applicable;
2. Confrontation of the licensee;
3. Communication with the employer and worksite monitor, if applicable;
4. Communication with any treatment provider including support group facilitator.

Based on information gathered, at least one of the procedures below shall be followed in response to confirmation of an ingested banned substance:

1. Pursue administrative options including revocation and/or suspension;
2. Required participation in inpatient and/or outpatient treatment;
3. Increased frequency of testing;
4. Practice restriction e.g. increased level of supervised practice; limit the scope of duties;
5. Removal from practice for the purpose of assessment.

DISCUSSION

There was minimal discussion regarding uniform standard #9 and it was agreed upon that the procedures followed in uniform standard #8 also be followed in #9.

Upon conclusion of the July 15, 2009, public meeting, it was determined the first section was unnecessary and appeared to be procedures that would be followed prior to a confirmation of having ingested a banned substance. As a result, it was deleted from the standard.

PROS/CONS

No strong arguments, either for or against the standard as drafted, were identified in the group's discussion.

PUBLIC COMMENT

Written comment was received from Kaiser Permanente Northern California Division Physician David Pating and Kaiser Permanente Southern California Division Physician Stephanie Shaner. Both Dr. Pating and Dr. Shaner requested that the option of removing the licensee from practice for the purpose of assessment be added to the standard. Further, both expressed support for the process currently undertaken by DCA noting that health professionals with drug or alcohol addiction can be safely rehabilitated when they are provided supervised monitoring with clear standards.

Public comments received during the public hearing indicated support for inclusion of this option. The workgroup determined that adding the option of removing a licensee from practice for assessment was appropriate.

Elinore McCance-Katz M.D., PhD provided written comments regarding the use of a Medical Review Officer (MRO) to interpret the results of the test, if necessary. Dr. McCance-Katz stated that it was extremely important that the boards understand what a MRO does. Dr. McCance-Katz explained that if a urine test is positive for a prohibited substance (e.g. Oxycodone in a licensee who is opioid-addicted); a MRO would look into this and if the MRO found that the licensee had a valid prescription; it would be called a negative screen.

Further, Dr. McCance-Katz stated that a health care professional with addiction is not to use prohibited substances, prescribed or not, if they are working in their profession. Dr. McCance-Katz suggested a better approach would be to have a medical director for these monitoring programs who have MRO experience, but understands the nature of addiction in healthcare professionals and can attend to public safety.

Dr. McCance-Katz also suggested adding the option of immediate cessation from practice if a licensee was practicing their healthcare profession. The cessation of practice would remain in place until an assessment is completed and recommendations were reviewed and considered by the Board.

The workgroup considered the comments of Dr. McCance-Katz relating to the use of a MRO. Following the discussion, the workgroup decided to remove this procedure from the standard. The workgroup determined that this procedure neither improved nor weakened the standard so long as the other procedures were in effect.



ISSUE MEMORANDUM

DATE	August 10, 2009
TO	SB 1441 Substance Abuse Coordination Committee
FROM	SB 1441 Uniform Standards Staff Working Group Richard De Cuir and Kimberly Kirchmeyer
SUBJECT	SB 1441

SB 1441 REQUIREMENT

(10) Specific consequences for major and minor violations. In particular, the committee shall consider the use of a "deferred prosecution" stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency until or unless licensee commits a major violation, in which case it is revived and license is surrendered.

DRAFT UNIFORM STANDARD #10

The Board shall review each violation of a contract, disciplinary order or probationary order on a case-by-case basis and determine the consequences based upon the following guidelines:

Major Violations may include, but may not be limited to:

1. Failure to complete a board-ordered program;
2. Failure to undergo a required clinical diagnostic evaluation;
3. Multiple minor violations;
4. Treating patients while under the influence of drugs/alcohol;
5. Any drug/alcohol related act which would constitute a violation of the practice act or state/federal laws;
6. Refusing to obtain biological testing for substance abuse.

Consequences for major violations may include, but may not be limited to:

1. Termination of a contract/agreement
2. Referral for disciplinary action such as:
 - Suspension
 - Revocation
 - Other action as determined by the Board

Minor Violations may include, but may not be limited to:

1. Untimely receipt of required documentation;
2. Missed biological testing for substance abuse;
3. Non-attendance at group meetings;
4. Failure to contact a monitor when required;
5. Any other violations that do not present an immediate threat to the violator or to the public.

Consequences for minor violations may include, but may not be limited to:

1. Removal from practice;
2. Practice limitations;
3. Required supervision;
4. Increased documentation
5. Issuance of citation and fine or a warning notice;
6. Required reevaluation/testing.

DISCUSSION

Specific Consequences for Minor and Major Violations

In looking at the first segment of this uniform standard, the work group found itself having to engage in extensive discussions surrounding what constitutes a major vs. minor violation. The work group initially separated the violations (major vs. minor) to determine what would

be considered patient harm by the respective boards. The work group agreed this standard does not require **any** delineation on the major or minor violations themselves. However, in trying to write specific consequences, the work group had to identify specific types of violations. There was also considerable discussion surrounding whether to prioritize the violations for each category (major and minor). The work group agreed on several types of violations and prioritized them accordingly. Prioritization of the violations (both major and minor), as well as the consequences as delineated above evolved into two categories.

The first category of consequences resulting from major violations resulted in consequences that were usually the maximum allowed by current law under each board's respective statutes (i.e. termination from board ordered program, license revocation, ISO, PC23, etc.). The second category of consequences resulted from minor violations which might be more technical in nature and only necessitated the respective board to tighten the previously determined board disciplinary or diversion related actions.

Consider use of "Deferred Prosecution"

The initial research completed by the work group considered the potential use of a variation to the criminal use of deferred prosecution authorized under Section 1000 of the Penal Code. Due to the other options available to the boards that in effect accomplish the same goal as deferred prosecution such as closing an investigation while licensees are in the diversion program, the group did not feel it was necessary to add this enforcement tool at this time.

Workgroup Discussion Items

While draft Uniform Standard may appear rather succinct, there was much discussion at the workgroup level on a number of issues including:

- 1) Whether or not the Uniform Standard #10 even required defining a major vs. a minor violation since the standard itself only directed defining consequences;
- 2) How Uniform Standard #10 applied to a licensee in a diversion or rehabilitation program, as well as a board disciplinary action in determining appropriate action;
- 3) The workgroup also thought that some violations might be included in both major and minor violation categories depending on the severity of the violation;

Public Comment

Public comment received included:

- Under the consequences section of Uniform Standard #10, for both major and minor violations, it was recommended that the sentence be added "At least one of the following consequences shall be taken";
- For major violation #6, the word "Refusing" should be replaced with the word "Failure";
- Under minor violations bullet #2-"Missed biological testing" should be eliminated;

- Under Consequences, a bullet needed to be added which stated "Or other violations as determined by the board."



ISSUE MEMORANDUM

DATE	August 6, 2009
TO	SB 1441 Substance Abuse Coordination Committee
FROM	SB 1441 Uniform Standards Staff Working Group Kim Madsen, BBS
SUBJECT	SB 1441 Uniform Standard #11

SB 1441 REQUIREMENT

(11) Criteria that a licensee must meet in order to petition for return to practice on a full time basis.

DRAFT UNIFORM STANDARD #11

“Petition” as used in this standard is an informal request as opposed to a “Petition for Modification” under the Administrative Procedure Act.

The licensee shall meet the following criteria before submitting a request (petition) to return to full time practice:

1. Demonstrated sustained compliance with current recovery program.
2. Demonstrated the ability to practice safely as evidenced by current work site reports, evaluations, and any other information relating to the licensee’s substance abuse.

DISCUSSION

The workgroup approached this standard by first defining the term “petition” as this term represents several different meanings depending on the circumstances and settings in which the term is used. For example, an individual whose license is restricted through a disciplinary order is afforded the opportunity under the Administrative Procedures Act (Government Code Section 11522) and individual board statues to petition for modification of the terms and conditions imposed on the license after a specified time

period has passed. Therefore, the workgroup determined for the purposes of this standard, that the

term "petition" is an informal request by a licensee whose license has been restricted through another process.

The workgroup did not receive any written comment regarding this standard.

Several comments received during the public meeting indicated a desire for establishing a specific time period before the licensee may submit a petition.

The workgroup considered establishing a specific time period, however, each licensee's situation is unique. Establishing a specific time period for all licensees to meet is problematic in that it in some circumstances it would be far too restrictive and in others far too lenient. The workgroup determined that demonstration of sustained compliance by licensee and the use of various reports, evaluations, and other information was a better measurement of a licensee's ability to resume full time practice. Further, the procedures will allow a board the flexibility necessary in assessing a licensee's ability to return to full time practice safely.

CONS

Adopting the recommended criteria for this standard pose no risk to public safety and is in accordance with DCA's mandate to ensure consumer protection.

PROS

The criteria recommended by the workgroup are ones that can be followed in all cases. The criteria allow the licensee and board the flexibility in determining the licensee's ability to safely resume full time practice while ensuring consumer protection.



ISSUE MEMORANDUM

DATE	August 6, 2009
TO	SB 1441 Substance Abuse Coordination Committee
FROM	SB 1441 Uniform Standards Staff Working Group Kim Madsen, BBS
SUBJECT	SB 1441 Uniform Standard #12

SB 1441 REQUIREMENT

(12) Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

DRAFT UNIFORM STANDARD #12

“Petition for Reinstatement” as used in this standard is an informal request (petition) as opposed to a “Petition for Reinstatement” under the Administrative Procedure Act.

The licensee must meet the following criteria to request (petition) for a full and unrestricted license.

1. Demonstrated sustained compliance with the terms of the disciplinary order, if applicable.
2. Demonstrated successful completion of recovery program, if required.
3. Demonstrated a consistent and sustained participation in activities that promote and support their recovery including, but not limited to, ongoing support meetings, therapy, counseling, relapse prevention plan, and community activities.
4. Demonstrated that he or she is able to practice safely.

DISCUSSION

The workgroup approached this standard by first defining the term "petition for reinstatement" as this term represents several different meanings depending on the circumstances and setting in which it is used. For an example, an individual whose license is revoked through a disciplinary order is afforded the opportunity under the Administrative Procedures Act (Government Code Section 11522) and individual board statues to petition for reinstatement of the license after a specified time period has passed. Therefore, the workgroup determined for the purposes of this standard, that the term "petition for reinstatement" is an informal request by a licensee whose license has been restricted through another process.

The workgroup considered that a licensee would benefit from established criteria to be met prior to petitioning for reinstatement of his/her license. However, the workgroup recognized that it while it was important to establish criteria; it was equally important to provide the individual board the flexibility to determine if a licensee could return to unrestricted practice without compromising consumer protection. Therefore, the criterion was established with these considerations.

The workgroup did not receive any written or public comment on this standard.

CONS

Adopting the recommended criteria for this standard pose no risk to public safety and is in accordance with DCA's mandate to ensure consumer protection.

PROS

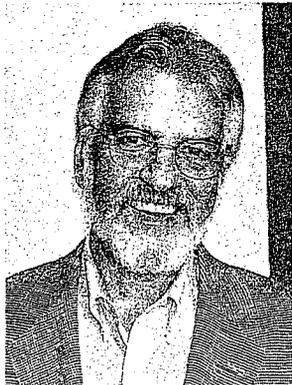
The criteria recommended by the workgroup are ones that can be followed in all cases. The criterion allows the licensee and the individual board the flexibility in determining the licensee's suitability to resume a full time practice without restrictions and ensures a high level of consumer protection.

Attachment 7

Medication Errors

Revisiting 'To Err Is Human'

Preventable medical and medication errors should figure more prominently in the current debate on healthcare reform



Over this summer, the leading news headlines have routinely focused on the intense debate in Washington over healthcare reform. Fairly intricate discussions over population demographics, reimbursement rates and the like tend to get boiled down to slogans: "universal healthcare" or "healthcare rationing" and the like. It's the nature of politically driven debates to reduce a complex topic like healthcare this way; it's almost as if a sports championship was decided by how well the cheerleaders perform than the athletes on the field. For all its faults, the debate is moving forward, although the final destination cannot yet be identified.

One topic, though, that we wish got bigger play in the debates is the cost and harm of preventable medical errors. This year also happens to be the 10th anniversary of the Institute of Medicine's *To Err is Human* report, which put the quality-control problems of the healthcare system in stark terms: some 98,000 lives lost per year due to preventable medical errors (which, it turns out, is likely to be a significant underestimate). Preventable medication errors—which involve pharmaceuticals specifically—take several thousand lives per year.

The costs of these problems was put at \$17-29 billion per year then; given inflation (and the inflation in the cost of healthcare specifically), it's not unreasonable to assume that medical errors cost the American public \$50 billion annually today—or, to put it in the 10-year time frames that legislators love to bandy about in Washington, some \$500 billion. That's a sum that should figure prominently in the healthcare reform debate.

The Institute of Medicine followed up the 1999 report with a 2006 study specifically on medication errors. The problems were then, and are now, well known: unclear labeling, too-similar-sounding drug names, and all the problems associated with handwritten prescriptions and instructions. Which shines a light on one of our feature stories this month, "Labels & Package Content" (p. 1). We're impressed with the range of products and packaging innovations that these suppliers have developed, but our sense is that they are underutilized by the biopharma industry.

The Consumer Reports organization (consumerreports.com), noted the 10th anniversary of *To Err is Human* earlier this year, and came out with an assessment entitled *To Err is Human—To Delay is Deadly*, noting that very little progress has been made on improving the medical errors situation.

In August, Public Citizen, reviving much of the data published in the IOM reports, estimated that basic patient safety reforms (including reducing medication errors by greater use of computerized physician order entry) could save 85,000 lives and \$35 billion annually.

It's both a blessing and a curse that the biopharma industry is something of a bystander when it comes to how drugs are administered to patients. Healthcare providers have been busy in excluding biopharma industry representatives from their facilities, but then they turn around and blunder—sometimes grotesquely—how drugs are used. Still, the industry can help itself by doing all it can to make its products more error-proof.

Nicholas Basta
Editor in Chief

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TO ERR IS HUMAN – TO DELAY IS DEADLY

Ten years later, a million lives lost, billions of dollars wasted

May 2009

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TO ERR IS HUMAN – TO DELAY IS DEADLY

Ten years later, a million lives lost, billions of dollars wasted

Executive Summary

Ten years ago the Institute of Medicine (IOM) declared that as many as 98,000 people die each year needlessly because of preventable medical harm, including health care-acquired infections (See sidebar: Preventable medical harm). Ten years later, we don't know if we've made any real progress, and efforts to reduce the harm caused by our medical care system are few and fragmented. With little transparency and no public reporting (except where hard fought state laws now require public reporting of hospital infections), scarce data does not paint a picture of real progress.

Based on our review of the scant evidence, we believe that preventable medical harm still accounts for more than 100,000 deaths each year – a million lives over the past decade. This statistic by all logic is conservative. For example, the Centers for Disease Control and Prevention (CDC) estimates that hospital-acquired infections alone kill 99,000 people each year. This needless death is unacceptable, and we must demand action from our health-care system.

In this report we give the country a **fail-ing grade** on progress on select recommendations we believe necessary to create a health-care system free of preventable medical harm.

Few hospitals have adopted well-known systems to prevent medication errors and the FDA rarely intervenes.

While the FDA reviews new drug names for potential confusion, it rarely requires name changes of existing drugs despite high levels of documented confusion among drugs, which can result in dangerous medication errors. Computerized prescribing and dispensing systems have not been widely adopted by hospitals or doctors, despite evidence that they make patients safer.

A national system of accountability through transparency as recommended by the IOM has not been created.

While 26 states now require public reporting of some hospital-acquired infections, the medical error reporting currently in place fails to create external pressure for change. In most cases hospital-specific information is confidential and under-reporting of errors is not curbed by systematic validation of the reported data.

No national entity has been empowered to coordinate and track patient safety improvements.

Ten years after *To Err is Human*, we have no national entity comprehensively tracking patient safety events or progress in reducing medical harm and we are unable to tell if we are any better off than we were a decade ago. While the federal Agency for Healthcare Research and Quality attempts to monitor progress on patient safety, its efforts fall short of what is needed.

Doctors and other health professionals are not expected to demonstrate competency.

There has been some piecemeal action on patient safety by peers and purchasers, but there is no evidence that physicians, nurses, and other health care providers are any more competent in patient safety practices than they were ten years ago.

The U.S. health-care system needs nationwide mandatory, validated and public (MVP) reporting of preventable health care-acquired infections and medical errors. Medication errors—cited as a major problem by the IOM ten years ago—remain a serious problem today. The FDA, doctors, hospitals, and drug manufacturers must establish better practices at every stage of the treatment process to track

and prevent harm from medication errors. Professional standards regarding patient safety should ensure competent care. While some progress has been made by private initiatives and through purchasing policies, regulators have not demanded universal competency testing for doctors and nurses.

Doctors and hospitals raise concerns that public reporting of medical harm will lead to frivolous lawsuits. But the best way to prevent claims is to put systems in place to prevent harm. Experience with public reporting in the states demonstrates the tort concerns about such disclosures is overstated. With a civil justice system weakened by limited compensation to harmed patients and inadequate oversight of health care, public reporting of preventable medical harm is today perhaps the only effective accountability measure we have.

The current health reform debate presents a remarkable opportunity for improving access to health care in America – but that health care should be safe. Patient safety needs to be a major part of these reforms.

“How much of a problem is patient safety? The unsettling fact is that no one knows.”

- Dr. Lucian Leape, March 2008

Introduction

In November 1999 the Institute of Medicine (IOM) issued the report *To Err is Human*, detailing a problem the public knew of only anecdotally: doctors and other health care professionals can make mistakes. The report also revealed something that most people didn't know: the U.S. health-care system wasn't doing enough to prevent these mistakes, and preventable medical errors were killing as many as 98,000 people a year.¹ (See Sidebar: Behind the Statistics: Real Lives).

"Medical mistakes 8th top killer" screamed the headline in USA Today.² "Medical Errors Blamed for Many Deaths; As Many as 98,000 a Year in U.S. Linked to Mistakes" reported the front page of the Washington Post.³ IOM report co-author Dr. Lucian Leape compared deaths from medical care to three fully loaded jumbo jets crashing every-other day, a sound-bite repeated by the New York Times editorial board.⁴

"Experts Say Better Quality Controls Might Save Countless Lives. Washington, Are You Listening?" asked the LA Times Editorial Board.⁵ The country certainly was. The story was featured on three major network news shows the next morning, and carried in three major news magazines the next week.⁶ A Kaiser Family Foundation survey over the following weeks found that more than half of Americans had heard of the IOM report and Kaiser called the report the "most closely followed health policy story of 1999."⁷

The IOM report estimated that medical errors cost the U.S. \$17-\$29 billion a year, and called for sweeping changes to the health-care system to improve patient safety (defined by the IOM as "freedom from accidental injury"⁸). The "combined goal of the recommendations" said the IOM, is to "... make errors costly to health-care organizations and providers, so they are compelled to take action

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to improve safety." The IOM also called for a measurable improvement in patient safety, stating "it would be irresponsible to expect anything less than a 50% reduction in errors over five years."⁹

Within days, the Clinton administration asked a federal task force to examine the IOM's recommendations.¹⁰ The task force quickly agreed with the majority of the IOM's findings.¹¹ The IOM report spurred seven hearings on Capitol Hill over the following three months, and soon at least five federal bills were filed regarding medical errors.¹² Congress allocated \$50 million to the Agency for Healthcare Research and Quality (AHRQ) for patient safety research grants in the 2001 budget, citing the IOM report as evidence of the need for work on the problem.¹³

Despite this initial flurry of activity, progress slowed once the media moved on to the next crisis. When the IOM published a follow-up report in March 2001, the release barely registered.¹⁴ By 2004, the deadline for the IOM's goal of a 50% reduction in errors, no national medical error reporting bills had been passed and the initial outrage surrounding the report had faded. Movement towards systematic change to the health-care system remained "frustratingly slow."¹⁵

Today our country has an opportunity for dramatic changes to our fragmented healthcare system. Health reform to ensure that all Americans have access to high quality health care should also include significant and active mandates to reduce medical harm.

Preventable Medical Harm: The IOM defined medical error as the failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan (including failure to use a plan) to achieve an aim (error of planning).¹ Specific types of medical errors highlighted in the IOM report included error in the administration of treatment, failure to employ indicated tests, and avoidable delays in treatment.² The IOM agreed that many health care-acquired infections (HAIs)³ are preventable, but relegated discussion of HAIs to an appendix of the report. In this report we use the term preventable medical harm to explicitly include both HAIs and other medical errors.

¹ Kohn, 1999, p. 28.

² Kohn, 1999, p. 36.

³ While the term "healthcare associated infections" is used by medical professionals, it obscures the cause-and-effect relationship under discussion. For clarity we use "healthcare acquired infections" to refer to infections that patients contracted while interacting with the healthcare system. Most studies and information about healthcare-acquired infections focus specifically on hospital-acquired infections.

⁹ Kohn, 1999, p. 4.

¹⁰ "Clinton orders task force to seek reduction in medical errors," CNN.com, 12/7/1999. Internet source: <http://archives.cnn.com/1999/HEALTH/12/07/medical.errors.02/index.html> (Accessed 3/16/09).

¹¹ *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*, Report of the Quality Interagency Coordination Task Force, February 2000. Internet Source: <http://www.quic.gov/report/errors6.pdf> (Accessed 2/27/09).

¹² Kenagy, John W. and Gary C. Stein. "Naming, Labeling, and Packaging of Pharmaceuticals," *Am J Health-Syst Pharm* 58(21):3033-3041, 2001.

Shuren, Allison Weber. "Health care delivery errors: Patient safety falls prey to politics," *J Pediatr Health Care*. 15, 42-44, 2001.

¹³ 106 Congress. "Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year 2001 Conference Report To Accompany H.R. 4577," U.S. Washington DC: Governmental Printing Office, p. 149.

¹⁴ Millenson, M L. "Pushing the profession: how the news media turned patient safety into a priority," *Qual. Saf. Health Care* 2002;11:57-63

¹⁵ Leape, Lucian L. and Donald M Berwick. "Five Years After To Err Is Human: What Have We Learned?" *JAMA*, May 18, 2005—Vol 293, No. 19.

¹ Kohn LT, Corrigan JM, Donaldson M, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: Institute of Medicine; 1999, p. 1.

² Davis, Bob, and Julie Appleby. "Medical mistakes 8th top killer," *USA Today*, 11/30/99.

³ Weiss, Rick. "Medical Errors Blamed for Many Deaths; As Many as 98,000 a Year In U.S. Linked to Mistakes," *The Washington Post*, 11/30/99.

⁴ "Preventing Fatal Medical Errors," Editorial. *New York Times*, 12/1/99.

⁵ "Hospital Error's High Costs; Experts Say Better Quality Controls Might Save Countless Lives. Washington, Are You Listening?" Editorial. *LA Times*, 12/5/99.

⁶ Dentzer, Susan. "Media Mistakes in Coverage of the Institute of Medicine's Error Report," *Effective Clinical Practice*, November/December 2000.

⁷ Kaiser/Harvard Health News Index, November/December 1999 vol.4, No.6. Kaiser Family Foundation. Internet source: <http://web.archive.org/www.kff.org/content/2000/1565/HNI+Nov-Dec1999.pdf> (Accessed 4/16/09).

⁸ Kohn, 1999, p. 58.

Behind the Statistics: Real Lives

Lewis Blackman was 15 years old when his family brought him to the hospital for elective surgery. The surgery was predicted to be short, and he brought the book "Dune" to read while he recovered. Four days later he was dead; an autopsy revealed his abdomen was filled with almost three liters of blood and digestive fluids from an undiagnosed perforated ulcer. The ulcer had gone undiagnosed by the doctors-in-training attending Lewis despite indications of trouble for more than thirty hours prior to his death. Medical experts hired by Lewis's mother later said that his symptoms should have suggested a routine blood test that would have uncovered the problem.¹ A failure to order an indicated test is a medical error.²

As we reference the statistics of medical error in this report, remember that behind each number is the life of someone like Lewis.

One of the most widely cited statistics from To Err is Human was the estimate that "at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors."³ What does this statistic mean? Where did it come from?

The number used by the IOM was based on two studies which performed after-the-fact reviews of a sample of medical records (one study in New York, the other in Utah and Colorado) to estimate the rate of preventable injuries caused by medical management. This preventable injury rate was applied to the 33.6 million hospital admissions in the U.S. to calculate the overall magnitude of medical errors.

The resulting 44,000 - 98,000 estimate has become one of the most widely cited statistics on medical error, but it is not without its critics. Several subsequent articles attacked the subjective nature of the estimate of whether or not a patient death could be attributed to a particular error.⁴

Nevertheless, defenders of the estimate focus on two reasons that the figures are far more likely an under-estimate of the magnitude of the problem of preventable medical harm in this country: First, the chart review process only catches errors that are recorded in the medical record, and evidence of many errors does not appear in the record. Second, the IOM number accounts for only medical harm in hospitals, and much health care is delivered outside of that setting.⁵

The medical error rate used to calculate the IOM's national estimate has also been supported by newer studies in Canada, Australia, and other developed countries. Based on the current state of knowledge of medical harm, two recent patient safety textbooks estimate that 5% of hospital admissions experience some type of adverse error, 30% of which cause consequen-

1 Monk, John. "How a hospital failed a boy who didn't have to die" The State, Columbia, South Carolina. Sunday, Jun. 16, 2002, p. A1, A internet source: <http://www.lewisblackman.net/> (Accessed 4/2/09).

2 Kohn, 1999, p. 36.

3 Kohn, 1999, p. 26.

4 McDonald CJ, Weiner M, Hui SL. "Deaths due to medical errors are exaggerated in the Institute of Medicine report." JAMA. 2000;284:93-5.

See also: Sox HC, Woloshin S. How many deaths are due to medical error? Getting the number right. Effective Clin Pract. 2000;6:277-283.

5 Quality of Health Care in America Committee "The Institute of Medicine Report on Medical Errors: Misunderstanding Can Do Harm" Medscape General Medicine 2(3), 2000. 9/19/2000.

tial harm.⁶ This estimate implies that more than half-a-million people in the U.S. were harmed by preventable medical errors last year.⁷

Studies of specific errors also suggest the IOM report underestimates the magnitude of medical harm. Some hospital-acquired infections were identified in the studies used by the IOM, yet the report hardly mentions them. In an appendix to the report, CDC statistics are given: 2 million hospital patients and 1.5 million long-term care patients are infected each year.⁸ Most of these are now believed to be preventable.⁹ A 2007 CDC study estimated that 99,000 deaths in the US in 2002 were associated with HAIs.¹⁰ The IOM study found that 7000 deaths each year are caused by preventable medication errors.¹¹

The lack of a reliable measurement of medical harm is a major challenge that must be addressed. But don't confuse the magnitude with the impact. We know the impact of the problem today. Just ask Lewis Blackman's family.

6 Wachter, Robert M. *Understanding Patient Safety* McGraw-Hill 2008, p. 10.

Vincent, Charles, *Patient Safety* Elsevier, 2006, p. 42.

7 Author's calculations. 37.1 M (US Hospital Admissions in 2007) X 10% (of which are adverse events) X 50% (of which are preventable) X 30% (of which cause consequential harm) = 556,500

2007 US Hospital Admissions Information from "Fast Facts on US Hospitals" Internet Source: http://www.aha.org/aha/content/2008/pdf/fast_facts_2008.pdf (Accessed 4/3/09)

8 Kohn, 1999, p. 268.

9 The CDC estimates as many as 70% are preventable: Scott, R. Douglas II, "The Direct Medical Cost of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention," Division of Healthcare Quality Promotion, National Center for Preparedness, Detection, and Control of Infectious Diseases, Coordinating Center for Infectious Diseases Centers for Disease Control and Prevention, March 2009, p. 7.

10 Klevens et al. "Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002," Public Health Reports Vol. 122 March-April 2007.

11 Kohn, 1999, p. 2

Ernst, Frank R. and Amy J. Grizzle "Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model," J Am Pharm Assoc 41(2):192-199, 2001.

Are we safer today than we were a decade ago? Are we doing what is necessary to end needless suffering from preventable medical harm? It is our search for answers to these questions that drives this report.

The IOM recommended dozens of changes to make our health-care system safer. In this report we evaluate how the country has fared on select recommendations we believe necessary to create a health-care system free of *preventable medical harm*.

We evaluate progress on the following IOM recommendations:

Prevent medication errors: Make the production, regulation, prescribing, and delivery of medications safer.

Create accountability through transparency: Identify and learn from medical harm through both mandatory and voluntary reporting systems.

Measure the problem: Establish a 'national focus' to track progress on patient safety.

Expect more: Raise standards for improvements and competency in patient safety for doctors and nurses and health-care organizations, like hospitals.

Preventing Medication Errors

Implement safe medication practices.

To Err is Human identified medication errors, "as a substantial source of preventable error in hospitals."¹⁶ The report recommended stronger oversight by the Food and Drug Administration (FDA) to address safety issues connected with drug packaging and labeling, similar named drugs, and post marketing surveillance by doctors and pharmacists.¹⁷ In 2006 the IOM returned to the issue, publishing "Preventing Medication Errors," a report that reiterated many of the recommendations of the 1999 report and concluded that at least 1.5 million preventable medication errors cause harm in the United States each year. The 2006 report estimated that medication errors in hospitals alone cost \$3.5 billion a year.¹⁸

Drug Confusion Errors

Medication errors include administering or prescribing the wrong drug, wrong dose, or wrong route of administration to a patient. These include cases in which drugs are provided without regard to drug allergies or interactions with other medications the patient may be taking.¹

1 Hicks, R.W., Becker, S.C., & Cousins, D.D. (Eds.). (2008). *MEDMARX* data report. A report on the relationship of drug names and medication errors in response to the institute of medicine's call for action. Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia, Preface.

Many medication errors are caused by the confusion of medicines with similar names, such as primidone (a seizure medication) and prednisone (an anti-inflammatory medication). For example, the similarities of these names led to the death of an adolescent in California in a case reported in 2004, despite the fact that the potential for primidone-prednisone confusion had been identified three years earlier.^{19,20} The confusion continues. A 2008 report listed Prednisone as commonly confused with 12

other drugs²¹

Packaging and design can also contribute to drug confusion errors. In a high profile case in 2007 the twin babies of actor Dennis Quaid and his wife were given 1,000 times the prescribed dose of the blood thinner heparin. According to Quaid's testimony before Congress, the couple sued the drug manufacturer, charging that the manufacturer was negligent in packaging different doses of the product in similar vials

with similar blue labels.²² The court dismissed the case on jurisdictional grounds and it is now on appeal. This problem was not new. A year before, a similar mix-up occurred when six infants in a newborn intensive care unit at an Indianapolis hospital were given excessive doses of heparin, leading to the death of three of them, and two infants at the same Indianapolis hospital had received a similar overdose in 2001.²³ After the Indianapolis deaths, the manufacturer issued a letter warning hospitals of the potential for confusion, but the packaging was not changed for at least 12 months and the same packaging was still being used in the hospital treating the Quaid children.²⁴ After the Quaids threatened to sue the hospital where their twins were treated, the hospital agreed to pay the family \$750,000 and invested \$100 million in new technology to prevent similar harm in the future.²⁵ Regulators fined the hospital for failure to follow its own safety policies.²⁶

Most victims of medication error do not have the same ability to drive media attention and prompt action. There were 25,530 look-alike and/or sound-alike drug confusion errors reported to two drug error reporting systems in the four years 2003-2006; drug labeling and packaging contributed to 7.8% of look-alike and/or sound-alike errors.²⁷ With a problem of this magnitude, we need a systematic solution to address all of the confusion errors, not just the few that get media attention.

The FDA has tested new drugs for potential name confusion since 1999 and monitors the market for instances of confusion, but few existing names are changed.²⁸ In an unusual action in 2005 the FDA called for the Alzheimer's drug Reminyl to be renamed after confusion with the diabetes drug Amaryl was implicated in two patient deaths. Reminyl was renamed Razadyne.²⁹

The current statistics on look-alike/sound-alike error demonstrates that the FDA's effort is inadequate. The FDA is conducting a pilot program to expand pre-market drug testing to include name confusion evaluation by third parties, but the

22 Orinstein, Charles "Dennis Quaid files suit over drug mishap" Los Angeles Times 12/5/2007.

Testimony of Dennis Quaid and Kimberly Quaid Before the Committee on Oversight and Government Reform of the United States House of Representatives, May 14, 2008; <http://oversight.house.gov/documents/20080514103204.pdf>.

23 Martin, Deanna "3rd Ind. preemie infant dies of overdose" Associated Press 9/20/2006 Internet Source: http://www.boston.com/news/nation/articles/2006/09/20/3rd_baby_dies_from_drug_overdose_in_ind/ (Accessed 4/15/09)

Testimony of Dennis Quaid and Kimberly Quaid, 2008, p. 4.

24 Deutsch, Jonathan "IMPORTANT MEDICATION SAFETY ALERT BAXTER HEPARIN SODIUM INJECTION 10,000 UNITS/ML AND HEP-LOCK U/P 10 UNITS/ML" Dear Healthcare Provider Letter, Baxter, 2/6/2007. Internet Source: http://www.fda.gov/medwatch/safety/2007/heparin_DHCP_02-06-2007.pdf (Accessed 4/15/09)

25 Lin, Rong-gong "Dennis Quaid says 'time is running short,' is considering suing Cedars-Sinai" LA Times, 3/28/08 Internet Source: <http://articles.latimes.com/2008/mar/28/local/me-quaid28> (Accessed 4/15/09)

"Dennis Quaid's Medical Nightmare," The Oprah Winfrey Show, 2/19/2009. Internet Source: <http://www.oprah.com/slideshow/oprahshow/20090219-tows-dennis-quaid/5> (Accessed 4/12/09)

"Dennis & Kimberly Quaid Agree To \$750,000 Settlement From Cedars Sinai Medical Center," December 15, 2008; http://www.accesshollywood.com/dennis-and-kimberly-quaid-agree-to-750000-settlement-from-cedars-sinai-medical-center_article_12649. (Accessed 5/8/09)

26 "Quaid Hospital Case Closed," World Entertainment News Network, 1/9/09.

27 Hicks, 2008, pp. 179, 193.

28 Holquist, Carol "How FDA reviews drug names" Drug Topics, 4/2/2001. Internet Source: <http://www.fda.gov/CDER/drug/MedErrors/reviewDrugNames.pdf> (Accessed 4/14/2009)

Cohen, Robert, Newhouse news, "What's in a name," 8/11/08.

29 Associated Press "J&J changes Alzheimer's drug name to avoid confusion" April 11, 2005.

16 Kohn, 1999, p. 182.

17 Kohn, 1999, p. 136.

18 Aspden P, Wolcott J, Bootman JL, Cronenwett LR (eds), Committee on Identifying and Preventing Medication Errors: *Preventing Medication Errors: Quality Chasm Series*. Institute of Medicine of the National Academies. Washington, National Academy Press, 2006, pp. 112, 117.

19 Pestaner, JP "Fatal mix-up between prednisone and primidone." Am J Health Syst Pharm. 2004 Aug 1;61(15):1552.

20 "Use Caution—Avoid Confusion" USP Qual Rev. No. 76, March 2001.

21 Hicks, 2008, p. 186

pilot program won't be finished until 2011, 12 years after the original IOM report highlighted the problem.³⁰ In addition, this FDA effort doesn't address the problem of look-alike/sound-alike drugs already on the market.

Are they Watching?

We may all have the best of intentions, but knowing we're being watched makes a difference in our actions. At the beginning of a study of ICU staff at an Australian hospital, only 12.4% of patient contacts were preceded by a hand washing. When informed that their hand washing was being monitored and group hand-washing rates were posted in the ICU, hand washing occurred prior to 68.3% of patient contacts, a more than five-fold improvement.¹

Publishing the hand washing rates of individual doctors would likely have stimulated even greater improvement. A study of Wisconsin hospitals found that hospitals subject to publicly reported facility-specific quality measures put more effort into quality improvement activities than hospitals receiving confidential reports on their quality measures. This was especially true for low-performing hospitals.²

1 Tibballs, James "Teaching hospital medical staff to handwash" Medical Journal of Australia. April 1996. Internet Source: <http://www.mja.com.au/public/issues/apr1/tibballs/tibball.html> (Accessed 3/14/09).

2 Hibbard, Judith H., Jean Stockard, and Martin Tusler "Does Publicizing Hospital Performance Stimulate Quality Improvement Efforts? Results from a study in Wisconsin suggest that making performance information public stimulates quality improvement." Health Affairs Vol. 22, No. 2, March/April 2003.

E-prescribing systems can be used by individual doctors in outpatient settings as well as those working within a hospital system.

A 2008 survey of American Hospital Association members found that only 17% had a CPOE system in place and operational in all units of the hospital. Another 38% had partially operational systems or plans for systems, but al-

Consumers Union believes the FDA should use its authority to rigorously set and enforce the naming, labeling, and packaging standards necessary to reduce drug confusion errors among new and existing drugs.

Another means to reduce drug confusion errors is the use of technologies such as Computerized Physician Order Entry (CPOE) systems to write prescriptions and Bar-Code Medication Administration (BCMA) technology to check that patients get the right medication. Both technologies are estimated to cut medication errors in half or more.³¹ CPOE systems can identify and warn prescribing physicians of medication allergies or interactions, remove the challenge of handwritten records, and provide decision support on standardized dosing.³² CPOE systems can be electronically linked to pharmacies to directly transmit prescriptions, a process called "e-prescribing."³³

most half (45%) of respondents had no plans to implement a CPOE system.³⁴ The IOM called for all health-care providers to be using e-prescribing by 2010.³⁵ A federal law passed in 2008 offers bonus Medicare payments to physicians who use e-prescribing beginning this year. Doctors not using e-prescribing will face reductions in Medicare payments in 2012.³⁶

While technology such as e-prescribing and bar-coding are not a panacea for medication errors, they hold promise to improve medication safety. The 2009 economic stimulus bill provided \$19.2 billion for health information technology, which may encourage adoption of such systems.³⁷

Drug Error Reporting Systems

Several voluntary reporting systems collect information on patient harm from medication, including FDA MedWatch, the ISMP Medication Errors Reporting Program (ISMP-MERP), and Quantros MEDMARX. While useful for learning about medication errors, some researchers believe that fewer than 1 in 100 are reported to these voluntary systems.³⁸ Although some state adverse event reporting laws include medication errors, no national system suitable for tracking progress on medication errors exists.

In 2008, Bruce Lambert, a Professor at the University of Illinois at Chicago, commented:

"Despite all the focus on prevention, there is little evidence of large-scale improvement in the wrong-drug error rate. We are not suggesting that no one has been successful at minimizing these errors, it is just that few have been able to demonstrate convincing evidence of success, especially on a national scale. ... This represents a serious gap in current knowledge about medication safety. The lack of a valid, reliable, and efficient method for detecting name confusion errors is the main reason for this gap in our knowledge. It is a fundamental principle of quality control that if a process cannot be measured, it cannot be improved." [Emphasis added]³⁹

The bolded quote sums up a fundamental tenet of this report. As with other preventable medical harm, the lack of a mandatory, validated, and public (MVP) reporting system leaves us in the dark on whether or not we are making meaningful progress in eliminating preventable medication errors. (The concept of MVP reporting systems are discussed in more detail below.)

30 Department of Health and Human Services Food and Drug Administration "Pilot Program To Evaluate Proposed Name Submissions; Concept Paper" Federal Register Vol. 73, No. 195, October 7, 2008.

31 Kohn, 1999, p. 191.

Poon et al. "Medication Dispensing Errors and Potential Adverse Drug Events before and after Implementing Bar Code Technology in the Pharmacy" Annals of Internal Medicine 9/19/2006 Vol. 145, NO.6, pp. 426-434.

32 Wachter, Robert M. *Understanding Patient Safety* Lange. 2008, pp. 139-140.

33 Virk, Pushwaz et al. "Analyzing Transaction Workflows in an ePrescribing System" AMIA 2006 Symposium Proceedings, p.- 1129.

34 Jha AK et al. "Use of Electronic Health Records in U.S. Hospitals." N Engl J Med. 2009 Mar 25

35 Aspden, 2006, p. 211

36 Park, Carolyne. "Rx by computer moving to state Plan created to cut errors, costs." Arkansas Democrat-Gazette 8/4/08

37 Robert Steinbrook, M.D. "Health Care and the American Recovery and Reinvestment Act," N Engl J Med. Vol. 360 n.11 pp. 1057-1060 3/12/2009

38 Hicks, 2008, p. 12.

39 Hicks, 2008, pp. 11-12.

Hospital Acquired Infection Reporting Systems:

Recently passed state hospital infection disclosure laws will increase public accountability on Healthcare Acquired Infections (HAIs). Some 26 states now have mandatory reporting systems for HAIs.¹ All of these states require public disclosure of hospital-specific rates of select HAIs, and 12 state laws require systems to validate the data for accuracy.² Nebraska, Nevada, and Arkansas have passed laws that require hospitals to report infection data to state agencies, but this information is not disclosed to the public.³

Preliminary evidence in Pennsylvania – the only state reporting on all types of HAIs - shows public reporting is an effective tool for reducing infections: Pennsylvania's overall infection rate decreased by eight percent following two consecutive years of reporting comparable infection data.

Each state has established its own reporting program, although most are collecting data on similar types of infections via the CDC's National Healthcare Safety Network (NHSN), essentially creating a national standard for collecting information on this type of medical harm.^{4,5}

While much work remains, progress towards a National MVP (Mandatory, Validated, and Public at the facility level) reporting system for HAIs is underway.

1 "Reporting of Hospital Infection Rates," Consumers Union, October 2008. Internet Source: http://www.consumersunion.org/campaigns/Map_SHI_state_laws_10-08.pdf. (Accessed 3/27/09)

2 Validating states: CO, FL, IL, NY, NH, OH, OR, PA, RI, SC, TX, VT. Other states may be attempting to validate the data, but their laws do not specifically call for it.

3 "Summary of State Laws on Hospital-Acquired Infections," Consumers Union, October 2008. Internet Source: <http://www.consumersunion.org/campaigns/CI%20Summ%20of%20HAIs%20state%20reporting%20laws%20as%20of%2010-08.pdf>

4 Besser, Richard E., "CDC's role in Preventing Healthcare Associated Infections," Testimony before the US House Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, 4/1/09, p. 3. http://appropriations.house.gov/Witness_testimony/LHHS/Richard_Besser_04_01_09.pdf. (Accessed 4/12/09)

Stricof, Rachel, "New York State Approach to Health care Associated Infection Surveillance, Prevention, and Public Reporting," p. 3, Testimony before the US House Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, http://appropriations.house.gov/Witness_testimony/LHHS/Rachel_Stricof_04_01_09.pdf. (Accessed 4/12/09)

5 GAO, "Health-Care-Associated Infections in Hospitals: An Overview of State Reporting Programs and Individual Hospital Initiatives to Reduce Certain Infections," GAO-08-808 (Washington, D.C.: Sept. 2008), pp. 1, 11

Prevent Medication Errors - Conclusion

Progress on medication errors falls short of the IOM's vision. While the FDA reviews new drug names for potential confusion, high levels of error remain. Electronic prescribing systems have not been widely adopted, and no national reporting system for medication mistakes at the facility level exists that is Mandatory, Validated, and Public.

Create Accountability Through Transparency

Identify and learn from preventable medical harm through both mandatory and voluntary reporting systems.

Imagine two hospitals in your town. One slashed medication errors in half by investing in a computerized system to assist doctors with prescription writing (eliminating the no-

torious "doctor scribble" problem). The other cuts costs by buying cheap ballpoint pens that smudge during prescription writing, leaving the orders illegible and doubling the rate of dispensing errors. Do you want to know which hospital is which?

You are not alone. Ninety-two percent of Americans believe that hospitals should be required to report serious medical errors, and 63% believe the reports should be public.⁴⁰ The IOM specifically recommended public reporting of harmful medical errors so that the public could hold local health-care systems (such as hospitals) accountable and encourage improvement.

The IOM panel recommended two separate national reporting systems: A mandatory and public reporting system designed to encourage *accountability*, (i.e. creating external pressure for change) and a voluntary and confidential system designed to facilitate *learning* about errors.⁴¹

Progress on reporting since 1999 has been almost entirely focused on voluntary, confidential, or aggregate reporting systems designed to facilitate learning about errors. Seventeen states had established confidential reporting systems by the time a federal framework for such "learning" systems was created in the Patient Safety and Quality Improvement Act of 2005.⁴² This law prohibits the release of information about medical harm collected by Patient Safety Organizations (PSOs) and shields hospitals that report harm.⁴³ Finally implemented in 2008, any information collected by PSOs will not be publicly disclosed by hospital or health-care facility. Under this system hospitals can learn from their mistakes, but you can't.

The PSO system joins a reporting world crowded with confidential, learning-oriented systems. The Joint Commission (a private membership and accreditation body) collects information on certain errors causing serious injury or death in its Sentinel Event Database; the reports are voluntary and the information collected remains confidential.⁴⁴ Over 13 years this database has only received 113 reports of serious hospital-acquired infections, which CDC studies estimate claim almost 99,000 lives each year.⁴⁵ The electronic Patient Safety Reporting System was developed for Veterans Administration facilities. The identities of health-care facilities reporting to the system are confidential and it is operated

40 The Kaiser Family Foundation/Agency for Healthcare Research and Quality/Harvard School of Public Health "National Survey on Consumers' Experiences With Patient Safety and Quality Information" November 2004.

41 Kohn, 1999, pp. 86-89.

42 CT, FL, GA, KS, MD, ME, NJ, NV, OH, OR, PA, RI, SC, SD, TN, UT, WA.

Rosenthal, Jill and Mary Takach. "2007 Guide to State Adverse Event Reporting Systems." The National Academy for State Health Policy. December 2007.

43 "President Signs Patient Safety and Quality Improvement Act of 2005" Press Release. 7/29/2005. Internet Source: <http://georgewbush-whitehouse.archives.gov/news/releases/2005/07/20050729.html> (Accessed 3/16/09).

AHRQ website: <http://www.pso.ahrq.gov/regulations/regulations.htm>; Patient Safety and Quality Improvement Act of 2005, Public Law 109-41 109th Congress, <http://www.pso.ahrq.gov/statute/pl109-41.htm>. (Accessed 5/13/09)

44 The Joint Commission. "Sentinel Event Policy and Procedures" July 2007, pp. 1, 6, 7.

45 The Joint Commission. "Sentinel Event Statistics as of: December 31, 2008," Internet Source: http://www.jointcommission.org/NR/rdonlyres/241CD6F3-6EF0-4E9C-90AD-7FEAE5EDCEA5/0/SE_Stats12_08.pdf (Accessed 4/12/2009)

Klevens, 2007.

external to the Veterans Administration (by NASA).⁴⁶ These two systems mirror the internal secret systems operated by most hospitals; a recent survey indicates that 98% of hospitals operate some type of internal reporting system for medical harm.⁴⁷ The voluntary, confidential nature of these systems prevents assessment of whether they have any impact on the safety of patients.

The National Quality Forum (NQF) is a private membership group that works to set "national priorities and goals for performance improvement," and publishes a list of voluntary consensus standards related to patient safety.⁴⁸ In 2002 the NQF endorsed a list of medical events that should "never occur." This list, now formally called the list of "serious reportable events" is often referred to as the "Never Event" list. The list currently contains 28 serious medical errors.⁴⁹ State reporting systems based on this list cover only a small subset of preventable medical harm.

A national mandatory and public reporting system facilitating public accountability does not exist, although fragmented progress has been made at the state level. As of October 2007, 25 States and the District of Columbia operated some type of medical error reporting system. Almost half of these states use a variation of the "Never Event" list to determine what type of medical harm must be reported.⁵⁰

Of the 26 mandatory medical error reporting systems, to date, only four publicly report facility-specific information on their websites.⁵¹ Facility specific reporting is essential to facilitating accountability, and when this report uses the term "public" reporting, we refer to facility-specific reporting. Consider if Consumer Reports tested 50 cars and found some performed well and others unsafe, but refused to reveal which cars were which. The public would not be served by such evaluation. Error information is not useful unless it is publicly tied to the entity where the harm occurred.

Minnesota is one state that publishes facility-specific information about patient harm on a state Minnesota Department of Health website.⁵² Seventy-two percent of Minnesota facilities surveyed in 2008 felt that the Minnesota error reporting law made them safer than they had been when reporting began in 2003. One respondent said, "(Our) focus was always on patient safety, however now safety efforts are better

understood by more of our staff and we prioritize this work ahead of other work. Data is helping us to create more sense of urgency for this work."⁵³

The magnitude of certain events reported to the Minnesota system is on the low end of what would be expected from national estimates of the incidence of medical harm. For example, only one death and five significant disabilities resulting from medication errors in hospitals were reported in the 2008-reporting year. This may reflect underreporting to the system. Minnesota health officials do not perform regular audits to validate the reporting level, although they do compare event reports to death records and consumer complaints.⁵⁴ Without validation, diligent reporters may appear to perform more poorly than their peers who simply fail to report at all. More than half of states with reporting systems acknowledged that underreporting occurs in their system.⁵⁵

Validation, generally through random chart audits or regular comparison to claims and billing data, counters systematic underreporting by participants. As of January 2008, only three states reported performing on-site audits to validate compliance. (Sixteen states reported using more limited validation techniques.)⁵⁶ Validation programs must be active, ongoing and funded to be effective. The New York City Comptroller recently reported that the state was not sufficiently enforcing or funding its reporting system, stating the ability of the state program "to more broadly improve the quality of care and reduce unnecessary costs has been seriously compromised" by these shortcomings.⁵⁷

We do not have national reporting systems with the three elements needed for accountability: Mandatory, Validated, and Public at the facility level (MVP). MVP reporting systems are needed to create the external pressure needed to create systemic change. (See sidebar: HAI Reporting Systems)

MVP reporting would represent a sea-change in a health-care system accustomed to hiding errors.⁵⁸ Only 14% of doctors support public reporting of medical errors.⁵⁹ Shortly after the IOM report, the New York Times reported that both the American Medical Association and the American Hospital Association "vehemently opposed mandatory reporting of errors."⁶⁰ Much of this resistance is driven by concerns that public reporting would lead to frivolous lawsuits.

The best way to prevent negligence claims is to put systems in place to prevent medical harm. Legal claims are filed on behalf of a small fraction of patients who sustain

46 Patient Safety Reporting System Website. "Program Overview." Internet Source: <http://www.psr.sarc.nasa.gov/flashsite/programoverview/index.html> (Accessed 4/5/09)

47 Farley et al. "Adverse-event-reporting practices by US hospitals: results of a national survey." *Qual. Saf. Health Care* 2008;17:416-423. (Author's calculation of weighted average of critical access and non-critical access respondents.)

48 National Quality Forum "Mission - About - National Quality Forum," Internet Site: <http://www.qualityforum.org/about/mission.asp> (accessed 3/16/09).

The National Quality Forum "Safe Practices for Better Healthcare," 2009. Internet Source: <http://www.qualityforum.org/projects/ongoing/safe-practices/> (Accessed 4/20/09).

49 "National Quality Forum Updates Endorsement of Serious Reportable Events in Healthcare," Press Release. National Quality Forum. 10/16/2006 Internet Source: <http://www.qualityforum.org/pdf/news/prSeriousReportableEvents10-15-06.pdf> (Accessed 3/31/09)

50 Rosenthal, Jill and Mary Takach. "2007 Guide to State Adverse Event Reporting Systems," The National Academy for State Health Policy. December 2007, p. 1.

51 NY, MN, MA, IN. See http://www.safepatientproject.org/2009/05/state_medical_error_report_lin.html

Rosenthal, Jill and Mary Takach. "2007 Guide to State Adverse Event Reporting Systems," The National Academy for State Health Policy. December 2007.

52 Minnesota Dept. of Health "Patient Safety - Minnesota Dept. of Health" Internet Source: <http://www.health.state.mn.us/patientsafety/> (Accessed 3/16/09).

53 "Adverse Health Care Events Reporting System: What have we learned? 5-YEAR REVIEW," Minnesota Dept. of Health. January 2009. pp. 2, 9.

54 Lisa McGiffert interview with Diane Rydrych, MN Department of Health. 4/14/09.

55 "Adverse Events In Hospitals: State Reporting Systems," The Office of Inspector General of the Department of Health and Human Services. December 2008, pp. 12-13.

56 "Adverse Events In Hospitals: State Reporting Systems," 2008, pp. 12-13.

57 "The High Cost of Weak Compliance With the New York State Hospital Adverse Event Reporting and Tracking System" Office of New York City Comptroller. 2009, pp. 27-29.

58 Gibson, Rosemary, and Singh, Janardan Prasad, *Wall of Silence*. 2003, pp. 136-138.

59 Blendon, Robert J., et al. "Views of Practicing Physicians and the Public on Medical Errors" *New England Journal of Medicine*. Volume 347:1933-1940, 12/12/2002 Number 24.

60 Pear, Robert "Clinton to Order Steps to Reduce Medical Mistakes," *The New York Times* 2/22/2000.

injury through medical negligence. Of those filed, many do not result in an award.⁶¹ Thus the legal system compensates patients for a miniscule portion of the injury sustained, and at tremendous personal cost. While physician and hospital resistance has slowed adoption of the IOM accountability reporting recommendations, experience with reporting lowers this resistance. A survey of hospital officers found that those in states with mandatory reporting systems were three times more likely to support facility-specific public reporting than hospitals without experience with mandatory reporting.⁶² Today, many states have passed tort reform laws that significantly increase the burden on people who have been harmed by medical care and protect doctors from suits over all but the most egregious behaviors.⁶³ With such a weakened civil justice system, and a weak and inadequate administrative oversight system in most states, public reporting of preventable medical harm – and the embarrassment that might accompany the public release of poor results – is today perhaps the only accountability measure we have that is both effective and reliable.

MVP reporting systems are necessary to hold all health-care facilities equally accountable for patient safety. Consumers Union recommends mandatory validated and public reporting of preventable medical harm (health care-acquired infections and medical errors), at the state and national level.

Accountability through Transparency - Conclusion

While a network of hospital-acquired infection disclosure systems is beginning to emerge, the scope of these only covers a small portion of the HAIs occurring. Medical error reporting systems currently in place fail to create external pressure for change. Most states do not publicly report facility-specific errors and many do not include a validation requirement. Twenty-four states do not have any medical error reporting requirements in place and 24 states do not require HAI reporting. The federal Patient Safety and Quality Improvement Act of 2005 is voluntary and keeps the medical error information gathered by Patient Safety Organizations confidential, thereby removing a key incentive for safety improvement.

Measure the Problem

Establish a 'national focus' to track progress on patient safety.

When products are connected with deaths, we investigate whether there are changes in them that might prevent accidents in the first place or minimize the harm from accidents when they happen. The seat belt, the child car seat, and many technical innovations were engineered into cars, for

example, based on this approach to accident prevention. Today, a car's National Highway Traffic Safety Administration "safety rating" is a key characteristic that buyers examine before they lay down their money. Health care has enjoyed no such national safety review.

"There is no cohesive effort to improve safety in health care," lamented the IOM in 1999.⁶⁴ The report stressed that the fundamental problem was not that individual doctors made errors. The fundamental problem was the failure of the health-care system to monitor these errors, anticipate them, and minimize the harm to patients. This failure, the IOM noted, required a national focus on fixing the health-care system, not just the errors of individual practitioners. The IOM recommended creation of a Center for Patient Safety within the federal Agency for Healthcare Research and Quality (AHRQ).⁶⁵

A Simple Checklist.

Consider the case study of one common type of medical harm — preventable bloodstream infections. In early 2004, researchers measured catheter-associated infections across a set of Michigan-affiliated Intensive Care Units (ICUs) and found 7.7 bloodstream infections occurred for every 1000 days of catheter use. A statewide safety initiative called "Michigan Health and Hospital Association (MHA) Keystone: ICU" set a goal of reducing catheter-associated bloodstream infections. Inspired by and coordinated with the successful research of Dr. Peter Pronovost and others at Johns Hopkins, MHA Keystone instituted a short checklist of best-practices related to catheter use and empowered nurses to ensure that doctors were following those practices. The initiative then tracked catheter-associated bloodstream infection rates in 103 participating ICUs.⁶⁶

The overall results were stunning. Bloodstream infections across the participating ICUs dropped to 1.4 per 1000 days of catheter use, less than 20% of the rate prior to implementation of the checklist and double-checking procedures.⁶⁷ MHA Keystone estimates that the initiative saved nearly 1,800 lives over four years.⁶⁸

While the aggregate results were impressive, results were mixed across facilities. A year and a half after the study began, MHA reported at least 50% of the participating ICUs had completely eradicated catheter-associated bloodstream infections. A quarter of the ICUs, however, still had infection rates of 2.4 per 1000 days or higher.⁶⁹ Unfortunately, MHA Keystone does not identify which facilities lagged

64 Kohn, 1999, p.75.

65 Kohn, 1999, p. 9.

66 Pronovost P, Needham D, Berenholtz S, Sinopoli D, Haitao C, Cosgrove S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med* 2006;355:2725-32. Internet Source: <http://content.nejm.org/cgi/content/full/355/26/2725>. (Accessed 4/16/09)

Berenholtz SM, Pronovost PJ, Lipsett PA, et al. Eliminating catheter-related bloodstream infections in the intensive care unit. *Crit Care Med* 2004;32:2014-2020.

67 Author's calculations. $1.4/7.7 = 18\%$. Note that the hospitals used as a starting benchmark were a subset of the hospitals in the MHA Keystone project.

68 2008 Annual Report. MHA Keystone Center for Patient Safety and Quality, p. 6; four-year estimate was for 2004-2008.

69 Pronovost, 2006, p. 2730.

61 Studdert, David M. et al "Claims, Errors, and Compensation Payments in Medical Malpractice Litigation" *N Engl J Med* May 2006;354:2024-33.

62 Weissman et al, "Error Reporting and Disclosure Systems: Views From Hospital Leaders," *JAMA*. 2005;293(11):1359-1366.

63 American Tort Reform Association, Medical Liability Reform, <http://www.atra.org/issues/index.php?issue=7338>. (Accessed 5/11/09)

Public Citizen, "The Inequitable Impact Of Non-Economic Damage Caps: Three Academic Studies Demonstrate Severely Injured and Female Patients Are Hurt the Most," 2005.

behind, preventing the public from discerning the hospitals with zero bloodstream infections from the ones without significant progress.

While the MHA Keystone: ICU initiative was not an MVP program as envisioned by this report, the results were widely reported and the process changes instituted by Keystone are now the focus of several national initiatives.⁷⁰ Dr. Pronovost won a MacArthur genius award for his work.⁷¹ The project was recognized as a success in part because it measured the impact of its work. Without evidence of improvement, the initiative's changes may not have been continued by the participating ICUs, let alone spurred a national movement to adopt the process changes.

This is one local example of the type of focus the IOM envisioned at the national level. The panel recommended creation of an agency that would be a 'national focal point' on safety in health care, much the way MHA Keystone: ICU was a focal point for bloodstream infections in Michigan. This agency would research and promote best-practices for patient safety and, crucially, track and report our nation's progress towards ending preventable medical harm.

Tracking National Progress.

The AHRQ is the closest federal agency to the IOM's vision of a "Center for Patient Safety" coordinating national resources on patient safety.⁷² AHRQ is charged with enhancing "the quality, appropriateness, effectiveness of health services" in the U.S. It funds numerous research projects on quality and safety and publishes the "National Healthcare Quality Report," (NHQR) to discuss and quantify progress on patient safety.⁷³

The NHQR estimates national progress on patient safety primarily through claims data on patients in the Medicare system, hospital billing data from the states, and various other sources like vital statistics and census data.⁷⁴ It discloses no provider or facility-specific information – all data is presented in the national or state aggregate. The agency's Patient Safety Indicators focus attention mostly on surgical errors, and does not use data contained in less accessible forms (such as patient charts).⁷⁵ The data is also stale; the 2008 report (published in 2009) discusses patient safety data only through 2006. Such delays are a chronic problem with health data and reduce the relevance of the report as a

feedback mechanism. Widespread adoption of health information technology would allow more timely and accurate information from clinical records. In the meantime, much can be gleaned from claims data and hospitals should be held accountable for ensuring the data is accurate. The lack of timely, facility-specific information also limits its use as a tool for consumers in making health care decisions.

The 2008 NHQR report estimates that patient safety declined by almost 1% a year over the six years after the IOM report, but states "[d]ata remain incomplete for a comprehensive national assessment of patient safety." In what is an indicator of how little progress has been made towards accounting for preventable medical harm, the latest AHRQ report still uses the IOM's 1999 work as the best estimate of the magnitude of medical errors.⁷⁶

Without comprehensive measures of progress, we can't say if the indicators examined by the NHQR data accurately represent the state of patient safety as a whole. While 17 of the 38 indicators tracked by AHRQ have declined somewhat over the last six years, in some areas not referenced by NHQR, there is evidence that patient safety is getting rapidly, not slowly, worse.⁷⁷ For example, the number of hospital discharges with *Clostridium difficile*-associated infections, which are primarily regarded as health care-acquired infections, more than doubled from 2001 to 2005.⁷⁸

The 1999 IOM report contemplated tracking national progress on patient safety through a periodic survey of medical records, following the methods of the academic research that provided the basis for the IOM's original estimate 44,000-98,000 annual deaths from medical errors.⁷⁹ Such a periodic national survey has not been implemented and may be impractical, although the adoption of electronic medical records may make such a survey less costly and less labor intensive.

A national MVP reporting system on preventable medical harm would be able to fill the measurement role of a national survey. Variations in current reporting in voluntary systems may be due to changes in reporting compliance rather than changes in error rates; validation of mandatory systems minimizes such variation. A national MVP reporting system would have the additional benefit of tracking progress at the local, as well as national, level. As discussed above, such a system does not yet exist.

Measure the Problem - Conclusion

Ten years after *To Err is Human*, we have no national entity comprehensively tracking patient safety and we are unable

70 Brody, Jane. E. "A Basic Hospital To-Do List Saves Lives," The New York Times, January 22, 2008. Internet Source: <http://www.nytimes.com/2008/01/22/health/22brod.html> (Accessed 4/16/09)

"AHRQ Awards \$3 Million To Help Reduce Central Line-Associated Bloodstream Infections in Hospital ICUs," Press Release, October 1, 2008. Agency for Healthcare Research and Quality, Rockville, MD. Internet Source: <http://www.ahrq.gov/news/press/pr2008/clabipr.htm> (Accessed 4/12/09)

71 "2008 MacArthur Fellows: Peter Pronovost," MacArthur Foundation Website. Internet Source: <http://www.macfound.org/fellows/2008/pronovost> (Accessed 4/15/09)

72 Kohn, 1999, pp. 78-79.

73 US Code Title 42, CHAPTER 6A, SUBCHAPTER VII, Part A, § 299. Internet Source: http://www4.law.cornell.edu/uscode/42/uscode_sec_42_0000299----000-.html (accessed 3/16/09).

Agency for Healthcare Research and Quality website. "2007 National Healthcare Quality & Disparities Reports" Internet Source: <http://www.ahrq.gov/qual/qrd07.htm> (Accessed 3/16/09).

74 AHRQ website, NHRQ State Snapshots, Interpretation of Results, Examination of data sources, <http://statesnapshots.ahrq.gov/snapshots/interpretation.jsp?menuid=39&state=ID#examination> (Accessed 5/11/09)

75 AHRQ Quality Indicators – Guide to Patient Safety Indicators. Rockville, MD: Agency for Healthcare Research and Quality, 2003. Version 2.1, Revision 2, (October 22, 2004). AHRQ Pub.03-R203. p. 23.

76 Agency for Healthcare Research and Quality. "2008 National Healthcare Quality Report." Rockville, MD: U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality; May 2009. AHRQ Pub. No. 09-0001, pp. 8-9, 101.

77 AHRQ, May 2009, p. 9.

78 Elixhauser, Anne and Michael Jung. "Clostridium Difficile-Associated Disease in U.S. Hospitals, 1993-2005" Healthcare Cost and Utilization Project Statistical Brief #50. April 2008

79 Kohn, 1999, p. 83.

to tell if we are any better off than we were a decade ago. AHRQ is attempting to do this. But without the comprehensive breadth needed to assess the problem, it falls short of what is needed.

Expect More

Raise standards for competency in patient safety for health-care professionals (like doctors and nurses) and health-care organizations (like hospitals).

Professional standards in health care are set by government agencies, purchasers, and professional peer groups. In 1999, the IOM recommended a greater focus on patient safety by regulators, accreditors and purchasers. The report called for periodic examinations of doctors and nurses to assess "both competence and knowledge of safety practices."⁸⁰ Over the past ten years, efforts to improve competency in patient safety standards have come mostly from the private sector. These efforts are laudable, but results are fragmented and no systematic process exists to promote and measure national improvement.

Fragmented Progress

The Institute for Healthcare Improvement (IHI)'s 100,000 Lives Campaign and subsequent Five Million Lives Campaign were created to stimulate and measure the impact of improved patient safety practices. This private non-profit provided tools and technical support to more than 3,700 hospitals, and the doctors and nurses working there, that agreed to provide IHI with measures of success on at least one of 12 patient safety practices supported by the campaigns.⁸¹ A network of "mentoring" hospitals shared information regarding methods for system changes. These campaigns introduced many hospital workers to life-saving practices, though IHI did not reveal which hospitals implemented which practices. IHI publicized anecdotal evidence of the positive outcomes of the campaign, but did not provide the public with the results at individual hospitals.⁸² Even though this was the broadest patient safety effort of the past decade, the decision to withhold specific validated results for the public makes it impossible to assess the full impact it had on improving the safety of patients.

Not all progress is private. One promising action – withholding payments to hospitals when patients are harmed – was recently initiated by Medicare, the largest health care purchaser in America. In October 2008, Medicare stopped paying for certain preventable hospital acquired conditions. These conditions include several hospital-acquired infections and some of the "never events" endorsed by the

National Quality Forum (NQF), such as surgeries performed on the wrong patient or part of a body and blood transfusions with the wrong blood type.⁸³

Medicare's no pay policy has increased pressure for accountability, and given some time could have a significant impact on Medicare patients and costs. Numerous states and private health plans are following suit by adopting similar no pay policies for some or all of the Medicare and NQF preventable adverse events.⁸⁴

A similar, but private, effort to use purchaser power to improve patient safety began shortly after the publication of *To Err is Human*. Several large employers formed The Leapfrog Group, which now includes many of the nation's largest corporations and some public agencies. The group agreed "to base their purchase of health care on principles that encourage quality improvement among providers."⁸⁵ Leapfrog publishes annual surveys rating the compliance of responding hospitals with specific quality and safety standards, and uses the collective purchasing leverage of its members to stimulate improved quality and safety.⁸⁶

Insuring continuing provider competency is an important step towards creating a safe health-care system, and ongoing competency examination has been adopted by many specialty licensing boards. The American Board of Medical Specialties (ABMS) member boards require physicians to demonstrate specialty-specific skills, knowledge, and use of best-practice care to maintain their specialist certification.⁸⁷ The ABMS has recently added a patient safety self-assessment program to their recertification cycle, although the standards do not take effect until 2010.⁸⁸

Systematic Failure

Despite the action taken by the ABMS, these continuing competency standards do not apply to the 15% of physicians not certified by one of the 24 ABMS member boards, or those physicians 'grandfathered' prior to the adoption of the standards.⁸⁹ These remaining doctors, as well as nurses and other health-care professionals, are primarily licensed at the

80 Kohn, 1999, pp. 11-12.

81 "Reaping the Harvest: A Review of the 5 Million Lives Campaign's First Year... and a Preview of What's to Come," The Institute for Healthcare Improvement. Undated Brochure. Internet Source: <http://www.ihl.org/NR/rdonlyres/A528208C-8B71-4559-BFF3-F1FBDC4CD11C/0/ReapingtheHarvestBrochureFINALwebedition.pdf> (Accessed 4/12/09).

IHI website. Overview, 5 million Lives Campaign, <http://www.ihl.org/IHI/Programs/Campaign/Campaign.htm?TabId=1> (Accessed 5-11-09).

82 "New Results from IHI Programs" The Institute for Healthcare Improvement Website Internet Source: <http://www.ihl.org/IHI/Results/NewfromIHIPrograms/#HAI> (Accessed 4/12/09).

83 Tsai, Joyce. "Medicare, insurers to stop reimbursing for errors," Dallas Business Journal. 10/17/08. Author's note: Medicare policy withholds additional payment follow patient harm, but will not pay at all for wrong surgery: wrong patient, wrong site, wrong procedure.

84 Brown, Jill. "Blue Cross Plans, Providers Work to Develop 'Never-Events' Policies," AIS's Health Business Daily. 11/3/08. Internet Source: <http://www.aishhealth.com/Bnow/hbd110308.html>. (Accessed 4/15/09)

Wolke, Anna "Infection Correction," State Legislatures Magazine. April 2009. Internet Source: http://www.ncsl.org/magazine/articles/2009/09slapr09_infection.htm#me, p. 22. (Accessed 4/15/09)

85 "Leapfrog Members," Leapfrog Group Website. Internet Source: http://www.leapfroggroup.org/for_members/who_are_members. (Accessed 4/12/09)

"The Leapfrog Group Fact Sheet" Internet Source: http://www.leapfroggroup.org/about_us/leapfrog-factsheet. (Accessed 3/29/09)

86 Leapfrog Group website, "For Members" Leapfrog Group Website. Internet Source: http://www.leapfroggroup.org/for_members. (Accessed 4/12/09)

Leapfrog Group website, "What does Leapfrog ask hospitals?" http://www.leapfroggroup.org/for_consumers/hospitals_asked_what. (Accessed 3/29/09)

87 "ABMS Maintenance of Certification," American Board of Medical Specialties. Internet Source: http://www.abms.org/Maintenance_of_Certification/ABMS_MOC.aspx (Accessed 3/30/09)

88 "New Standards Adopted to Elevate Physician Life-Long Learning Assessment for the ABMS Maintenance of Certification (MOC) Program" Press Release 3/26/09. Internet Source: http://www.abms.org/News_and_Events/Media_Newsroom/Releases/release_NewMOCStandards_03262009.aspx (Accessed 3/30/09)

89 American Board of Medical Specialties. "American Board of Medical Specialties Board Certification Editorial Background," Internet Source: http://www.abms.org/news_and_events/media_newsroom/pdf/abms_editorialbackground.pdf (Accessed 5/5/09)

state level. The IOM report called for such licensing bodies to "implement periodic re-examinations and re-licensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices."⁹⁰

No state medical boards require routine testing of skills and competency.⁹¹ Requirements for license renewal are generally limited to continuing education, despite research indicating that continuing education alone has little or no impact on practitioner competency.⁹² Once practitioners earn medical license, they may never have to demonstrate their medical competency again. Professionals can become incompetent over time because they don't keep up with current medical knowledge, they suffer from drug addiction, alcoholism or mental illness, or they just weren't that good in the first place and their shortcomings only become evident as they treat patients day after day. Without ongoing testing, these kinds of problems may not be recognized by licensing agencies before serious harm occurs.

This compares poorly with standards in other high-risk fields. Ironically, New York City police officers must demonstrate firearms proficiency in requalification tests at least twice a year.⁹³ The Federal Aviation Administration (FAA) requires airline pilots to pass ongoing proficiency testing;⁹⁴ this testing is often implemented through the use of flight simulators. The technology for medical care training simulators exists and pending federal legislation envisions more of this kind of learning.⁹⁵ Nevertheless, the use of medical care simulation to assess physician competency is not widespread and is not required for maintaining a license.

Hospital accreditation is another systematic attempt, like licensing, to ensure competency and adoption of patient safety standards. The Joint Commission adopted priorities and protocols to increase patient safety as accreditation standards in 2002.⁹⁶ These "National Patient Safety Goals" focus on the health care delivery process.⁹⁷

Limited information on each hospital's performance on these goals is available to the public.* Several studies have outlined shortcomings in the ability of the Joint Commission to detect serious deficiencies in its accreditation process. For example, a 2004 study by the GAO found that the Joint Commission failed to identify 60% of severe deficiencies in infection control procedures identified by state survey agencies.⁹⁸ [*Revised 05/22/09]

Finally, national leaders in patient safety remain concerned about the lack of competency in patient safety. In October 2008, the Lucian Leape Institute, founded by the National Patient Safety Foundation to provide strategic direction for the field of patient safety, held a meeting of experts on Medical Education Reform.⁹⁹ Discussions centered around the need to change the culture of medical education as well as the need to educate physicians on best practices supported by clinical research ("evidence-based medicine"). The meeting sought ideas for improving the patient safety competency of doctors, which most participants agreed as essential to reducing medical harm. The Institute intends to issue a report summarizing the recommendations of the roundtable, but it has not yet been released.¹⁰⁰

Expect More - Conclusion

There has been some piecemeal action on patient safety by peers and purchasers, but no comprehensive national action by regulators, especially in regards to the IOM's practitioner competency recommendations. There is no evidence to assure the public

that physicians, nurses, and other health-care providers are any more competent in patient safety practices than they were ten years ago. Relying on private organizations to provide increased awareness and improved patient safety practices is an arbitrary and fragmented process. Nothing is in place to assure the public that a health-care professional is competent. It is practicing 21st century medicine with 19th century oversight.

Conclusion:

National Failure on Patient Safety

Almost ten years ago, *To Err is Human* described the magnitude of the medical error problem in the U.S. health-care system. Despite a decade of work, we have no reliable evidence that we are any better off today. More than 100,000

90 Kohn, 1999, pp. 134-135.

91 Our review of news reports and academic literature on continuing competency failed to identify any states requiring routine testing of physicians after receiving their initial license. We did find some references to voluntary programs.

92 Swankin, David, Rebecca Arnold LeBuhn, Richard Morrison. "Implementing Continuing Competency Requirements for Health Care Practitioners" AARP Public Policy Institute, July 2006, p. 9.

93 Rostker et al. "Evaluation of the New York City Police Department Firearm Training and Firearm-Discharge Review Process," RAND, 2008, p. xviii.

94 Code of Federal Regulations. 14CFR121.915 (b)(1)(f) U.S. Government Printing Office. January 1, 2008. Internet Source:

http://edocket.access.gpo.gov/cfr_2008/janqtr/14cfr121.915.htm (Accessed 3/16/09)

95 The Enhancing SIMULATION Act of 2009, H.R. 855 (111th Congress).

Press Release "Forbes Reintroduces Bipartisan Legislation to Reduce Health Care Costs," 2/17/2009.

96 The Joint Commission Website. "Facts about the National Patient Safety Goals," Internet Source: http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/npsg_facts.htm (Accessed 3/16/09)

97 "Standards Improvement Initiative (SII): Chapter Outline; National Patient Safety Goals (NPSG); Program: Hospital," Joint Commission. Pre-publication copy. 2008

98 GAO "Medicare: CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals" GAO-04-850 July 2004, p. 14.

See also: OIG "The External Review of Hospital Quality: The Role of Accreditation" OEI-01-97-00051. July 1999, p. 2.

99 Press Release "Lucian Leape Institute Thought Leaders Define Strategies for Patient Safety," National Patient Safety Foundation. 10/30/08. Internet Source: <http://www.npsf.org/pr/pressrel/2008-10-30.php> (Accessed 4/15/09)

100 Comments of conference attendee Lisa McGiffert, Consumers Union. 4/12/09.

patients still needlessly die every year in U.S. hospitals and health-care settings – infected because of sloppy compliance with basic cleanliness policies, injured by failure to follow simple checklists for safety – the equivalent of a national disaster every week of every year.¹⁰¹

Since the IOM report was issued, there have been countless task forces, conferences, editorials, and even episodes of Oprah focused on patient safety. But action on key recommendations has been sluggish, leaving us without reliable means to track our progress or hold the local health-care systems accountable for ending preventable patient harm. We have failed to make the systematic changes in health care needed to end preventable medical harm.

Next Steps

Patients, consumer organizations, and advocates alarmed by the lack of public accountability surrounding patient safety have issued a Patients' Call to Action to underscore the need for implementing the IOM's key recommendations, including:

- effective action by the FDA, drug manufactures, hospitals, doctors, and other health-care providers to prevent medication errors;
- increased accountability through mandatory, validated and public reporting of preventable medical harm, including health care-acquired infections; and
- better training in patient safety for doctors and nurses.

Consumers Union's Safe Patient Project

Consumers Union's Safe Patient Project (www.safepatientproject.org) builds on the success of its Stop Hospital Infections campaign. It seeks to eliminate medical harm in our health-care system through public disclosure of health-care outcomes (such as hospital-acquired infection rates and incidents of medical errors) and information about health-care providers (such as complaints against and license violations of physicians and hospitals). The campaign also works to improve drug safety by ensuring that consumers have full information about prescription drugs by strengthening oversight of the FDA and by ending practices that create conflicts of interest, such as drug company gifts to doctors.

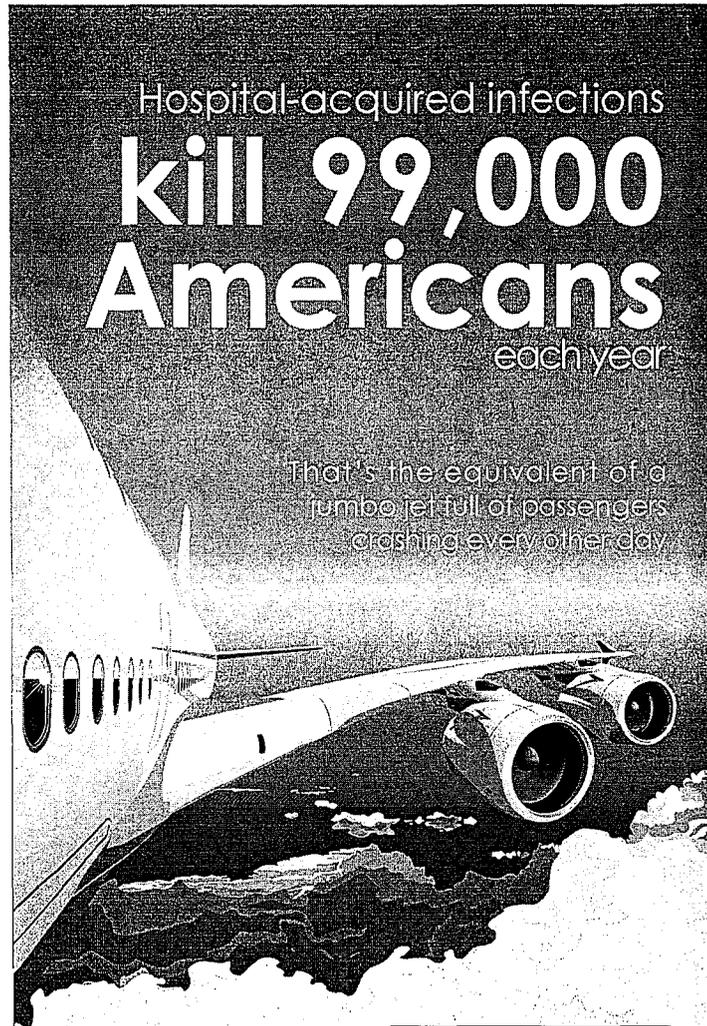
Consumers Union's Stop Hospital Infections campaign (www.stophospitalinfections.org) was launched in 2003 and has led a national consumer movement for public disclosure of infection rates in hospitals and other health-care facilities. To date, 26 states have enacted laws requiring publication of certain infection rates by hospital, and eight states have issued reports.¹

¹States that have passed laws: AL, CA, CO, CT, DE, FL, IL, MA, MD, MN, MO, NJ, NY, NH, OH, OK, OR, PA, RI, SC, TN, TX, VA, VT, WA, WVA (from "Summary of State Laws on Hospital-Acquired Infections," Consumers Union, May, 2009. Internet Source: http://cu.convio.net/hospital_infection_closure_laws)

States that have issued reports: CO, FL, MA, MO, NY, PA, SC, VT. (See also: <http://www.stophospitalinfections.org/learn.html>)

¹⁰¹ We have adopted the 100,000 annual estimate as the absolute minimum lower boundary of deaths due to medical harm in hospitals in the United States. This includes 99,000 annual deaths from hospital-acquired infections estimated by the CDC plus 2,039 deaths among Medicare patients alone from "accidental puncture or laceration."

When the IOM sounded the alarm in 1999 it called for immediate action and asked "Must we wait another decade to be safe in our health system?"¹⁰² Ten years later, we find ourselves asking the same question. As the nation begins to reform our health-care system, we have an opportunity to take effective and accountable action to make health care safer for all Americans. The time to act is now. We cannot wait another decade.



Safe Patient Project.org

Imagine the government response if planes started dropping from the sky.

Why isn't Washington doing more to protect patients from deadly hospital infections?



Safer patient care must be a priority in any health reform package passed by Congress, including:

- Increased public accountability for hospital infections and medical errors
- Better training in patient safety for doctors and nurses
- Aggressive action to prevent medication errors

To learn more, sign the petition and find out how you can help, visit:

www.SafePatientProject.org

¹⁰² Kohn, 1999, p. 5.

Attachment 8

*2008 Report of the California
Research Advisory Panel*

THIRTY-EIGHTH ANNUAL REPORT

of the

RESEARCH ADVISORY PANEL OF CALIFORNIA

2008



Prepared for the

LEGISLATURE AND GOVERNOR

RESEARCH ADVISORY PANEL OF CALIFORNIA

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This report represents a consensus among Panel members acting as individual experts. It does not represent policies or positions of the appointing agencies nor have those agencies been consulted by the Panel during its function or during the preparation of this report.

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SUMMARY OF 2008 PANEL ACTIVITIES

During 2008 the Panel reviewed thirty research study submissions. Twenty-eight were approved by the Panel. Among twenty-eight approved studies, thirteen studies were Academic research studies including six Substance Abuse Treatment research protocols and fifteen studies were Clinical Drug Trial research protocols.

Sixty research studies were completed or, in a few cases, terminated in 2008, Panel approval was withdrawn and they were closed on the Panel's records.

At the end of 2008 the Panel was monitoring 79 active research projects. Note Appendices A, B, and C for specific listings.

As part of the Panel's supervisory responsibility, ongoing projects are monitored by means of annual reports, Significant Adverse Event (SAE) reports and site visits. Approval may be withdrawn if the study deviates significantly from the approved protocol.

Table 1 is a list of the studies approved by the Panel in 2008 and Table 2 is a list of the studies closed by the Panel in 2008.

SELECTED RESEARCH FINDINGS

Below are brief summary reports of several Panel approved projects which are of interest and indicative of the types of controlled substance and substance abuse treatment research projects currently ongoing in California:

Dr. Jon D. Levine, M.D., Ph.D. and colleagues at the Department of Oral and Maxillofacial Surgery at UC San Francisco, have completed a study titled "Mechanisms Pain Control: V. Analgesic Combinations for Post-Operative Pain-Kappa Opioids and Morphine". The results of this study were recently published in the *Journal of Pain* and summarized with the following findings:

For the last several years we have studied the mechanism(s) that could explain sex differences in the analgesic effect of kappa opioids, which are known to produce significantly greater analgesia in women than in men. A major clue in this investigation was the finding that co-administration of a low dose of the opioid antagonist naloxone (Narcan) with a kappa opioid eliminates the sex differences and enhances the analgesia in both men and women. The current project was designed to investigate whether a low dose of the mu-opioid agonist morphine would enhance or diminish kappa-mediated analgesia. We found that

morphine enhanced nalbuphine analgesia at a dose that did not itself produce significant analgesia. Since the side-effect profile of kappa opioids compares favorably (including less addiction potential) to that of the more widely used mu-opioids, this research could lead to effective pain management alternatives where mu-opioids alone are contraindicated.

Dr. Lawrence Toll, Ph.D. and colleagues at the Receptor Pharmacology Department of SRI International, Menlo Park, California have completed a study titled "Biochemical Studies into Opiate Efficacies" The results of this study were recently published in the *British Journal of Pharmacology* and summarized with the following abstract:

Compounds that activate both NOP and μ -opioid receptors might be useful as analgesics and drug abuse medications. Studies were carried out to better understand the biological activity of such compounds. Binding affinities were determined on membranes from cells transfected with NOP and opioid receptors. Functional activity was determined by (35S)GTP γ S binding on cell membranes and using the mouse was deferent preparation *in vitro* and the tail flick antinociception assay *in vivo*. Compounds that bind to both μ -opioid and NOP receptors have antinociceptive activity but the relative contribution of each receptor is unclear. These experiments help characterize compounds that bind to both receptors, to better understand the mechanism behind their biological activities, and identify new pharmacological tools to characterize NOP and opioid receptors.

Dr. Walter Ling, M.D. and colleagues at the Integrated Substance Abuse Programs at UCLA have provided the Panel with the following summary of ongoing research titled "Optimizing outcomes using Suboxone for Opiate Dependence"

The approval of buprenorphine (combined with naloxone as Suboxone) by the FDA enables physicians in the United States to provide a pharmacotherapy treatment to opioid-dependent patients in private medical settings. Buprenorphine's wide acceptance and implementation by physicians has been slower than expected, however, and this may be due in part to the nature and necessity of providing comprehensive treatment for opioid-dependent patients. Lessons learned from methadone maintenance make it clear that simply providing opioid substitution does not address the behavioral components of dependence. While there is no lack of behavioral treatment facilities for substance abuse in the United States, what is lacking is an integrative approach to the treatment of opioid dependence using pharmacotherapy in conjunction with proven behavioral treatment strategies. Following a two-week stabilization and baseline period, this project will randomize 240 participants into 4

behavioral treatment groups featuring treatment that includes tools to address thinking and behavior (cognitive behavioral therapy; CBT) and treatment that rewards positive behavior change through the use of goods or services (contingency management therapy; CM). The four groups include: 1) CBT, 2) CM, 3) CBT + CM, 4) No CBT or CM (standard medical management). A universal, manual-guided psychosocial standard of care for buprenorphine pharmacological treatment allows for ethical inclusion of a “no-CBT or CM therapy” condition and closely resembles the current standard of psychosocial care delivered with opioid treatment using Suboxone. Behavioral therapies will be delivered for 16 weeks (to study week 18) in conjunction with continued care with Suboxone. An additional 16 weeks of treatment using Suboxone (to study week 34) will ensue during which no CBT or CM therapies are provided. All participants enter a buprenorphine taper and return at study week 52 for long-term follow-up evaluations. Outcomes for the trial include illicit drug use (urine drug samples collected three times per week during the first 18 weeks), during craving, retention (days in the protocol), psychiatric status (depression, mood), HIV risk behaviors, and treatment feasibility ratings. Results will be used to recommend strategies to optimize buprenorphine treatment outcomes and promote integration of pharmacotherapy and psychosocial/behavioral treatment strategies for physicians and for behavioral treatment facilities treating opioid-dependent patients.

TABLE 1

RESEARCH STUDIES
APPROVED IN 2008

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Danilyn Angeles, Ph.D. Loma Linda University Loma Linda, CA	A Double-blind randomized Clinical Trial on the Use of Pre-emptive Morphine Infusion in Asphyxiated Term and Near-Term Infants
Richard De La Garza, II, Ph.D. UCLA ISAP Los Angeles, CA	Rivastigmine and Donepezil as Potential Treatments for Cocaine Addiction
Mohammad Diab, M.D. UCSF Dept of Orthopaedic Surgery San Francisco, CA	Panel Approved Research Project
Keith Heinzerling, M.D. UCLA Dept of Family Medicine San Francisco, CA	Pharmacogenomics and Medication Development for Methamphetamine Dependence
Scott Irwin, MD, PhD San Diego Hospice & Palliative Care San Diego, CA	Panel Approved Research Project
Ronald Krauss, M.D. Children's Hospital Oakland Oakland, CA	Rimonabant Effects on Hepatic Lipoprotein Production
Kimberley Lakes, Ph.D. UC Irvine Irvine, CA	The Effects of Vyvanse on Brain Hemodynamics and Reading

Table 1 Cont.

PI / Sponsor

Title of Study / Clinical Drug
Trial Protocol

John E. Mendelson, M.D.
CPMC APRL
San Francisco, CA

Clinical Pharmacology of 3,4-
methylenedioxyamphetamine (MDA)

Mark Rollins, MD, PhD
UCSF Dept of Anesthesia
San Francisco, CA

Supplemental Oxygen: A Reduction in Pulse
Oximetry Sensitivity or an Increased Margin
of Safety?

AcelRx Pharmaceuticals
Redwood City, CA

A Multi-Center, Randomized, Placebo-
Controlled Phase II Study to evaluate the
Clinical Efficacy, Safety, and Tolerability of
ARX-F01 Sublingual Sufentanil Nanotabs TM
in Patients Undergoing Major Abdominal
Surgery
(AcelRx ARX-C-005)

BioDelivery Sciences
Raleigh, NC

Open-Label, Long-Term Extension Study for
Treatment of Breakthrough Cancer Pain with
BEMA Fentanyl
(BioDelivery FEN-290)

Catalyst Pharmaceuticals
Coral Gables, FL

Vigabatrin for Treatment of
Methamphetamine Dependence: A Phase II
Study
(Catalyst CPP-02001)

Endo Pharmaceuticals
Chadds Ford, PA

An Open-Label, Ascending, Two-Part, Single-
and Multiple-Dose Evaluation of the
Safety, Pharmacokinetics, and Effectiveness
of Oxymorphone For Acute Postoperative
Pain in Pediatric Subjects
(Endo EN3203-010)

Table 1 Cont.

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Endo Pharmaceuticals Chadds Ford, PA	An Open-Label Safety and Tolerability Study of Immediate-Release and Extended-Release Oxymorphone in Opioid-Tolerant pediatric Subjects with Chronic Pain (Endo EN3202-036)
Johnson & Johnson Cypress, CA	A Pivotal Bioequivalence Study Assessing Transdermal D-TRANS Fentanyl 100 μ g/h Matrix System to DURAGESIC Fentanyl 100 μ g/h Reservoir System After Single Application in Healthy Subjects (J & J FEN-PAI-1019)
Johnson & Johnson Titusville, NJ	A Randomized, Double-blind, Placebo- and Active- Controlled, Parallel-arm, Multicenter Study in Subjects With End-Stage Joint Disease to Compare the Frequency of Constipation Symptoms in Subjects Treated with Tapentadol IR and Oxycodone IR Using a Bowel Function Patient Diary (J&J R331333-PAI-3020)
Johnson & Johnson Austin, TX	A Randomized, Double-Blind, Active-and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Tapentadol Immediate-Release Formulation in the Treatment of Acute Pain from Bunionectomy (J&J R331333-PAI-3018)

Table 1 Cont.

PI / Sponsor

Title of Study / Clinical Drug
Trial Protocol

Neuromed Pharmaceuticals
Conshohocken, PA

A Phase III, Flexible-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Osteoarthritis Pain (Neuromed NMT 1077-302)

NIDA
Bethesda, MD

Phase 2, Double-Blind, Placebo-Controlled Trial of Bupropion for Methamphetamine Dependence (NIDA-MDS-Bupropion Meth-0001)

Ortho-McNeil Janssen
Irvine, CA

Double-Blind, Randomized, Placebo-Controlled, Crossover Study Evaluating the Academic, Behavioral and Cognitive Effects of CONCERTA on Older Children with ADHD (The ABC Study) (OMJSA CONCERTA-ATT-4069)

Ortho-McNeil Janssen
Irvine, CA

A Randomized, Double Blind, Placebo- and Oxycodone Immediate Release (IR) - Controlled Study of Tapentadol IR for the Treatment of Acute pain Caused by Vertebral Compression Fractures Associated with Osteoporosis (OMJSA R331333-PAI-3021)

Table 1 Cont.

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
QRxPharma Chapel Hill, NC	A Double-Blind, Randomized, Multi-Center, Repeat-Dose, Comparison of the Analgesic Efficacy & Safety of the Opioid Combination Q8003 to each of the Individual Milligram Components (Oxycodone & Morphine) in the Management of Acute Moderate to Severe Pain Following Bunionectomy Surgery (QRxPharma Q8003-021)
QRxPharma Bedminster, NJ	A Double-Blind, Randomized, Multi-Center, Repeat Dose, Placebo Controlled Study to Compare the Analgesic Efficacy and Safety of the Opioid Combination Q8003 to Each of the Individual Milligram Components (Oxycodone and Morphine) and Placebo in the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery (QRxPharma Q8003-015)
Shire Pharmaceuticals Philadelphia, PA	A Phase III Randomized, Double-Blind, Multicenter, Parallel-Group, Placebo-Controlled, Forced-dose Titration, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-305)

Table 1 Cont.

<u>PI/ Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Shire Pharmaceuticals Philadelphia, PA	A Phase III, Open-Label, Extension, Multicenter, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-306)
Shire Pharmaceuticals Wayne, PA	A Phase IIIb Randomized, Double-Blind, Multi-center, Placebo-controlled, Dose Optimization, Crossover, Safety and Efficacy Workplace Environment Study of Lisdexamfetamine Dimesylate (LDX) in Adults with Attention-Deficit Hyperactivity Disorder (ADHD) (Shire SPD489-316)
Titan Pharmaceuticals Mississauga, ON Canada	An Open-Label, Multi-Center Study of Probuphine in Patients with Opioid Dependence (Titan PRO-808)
Titan Pharmaceuticals Mississauga, ON Canada	An Open-Label, Multi-Center Extension Study of Probuphine in Patients with Opioid Dependence (Titan PRO-809)

TABLE 2

RESEARCH STUDIES CLOSED OR
DISCONTINUED IN 2008

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Gayle Baldwin, Ph.D. UCLA ISAP Los Angeles, CA	Cocaine Dependency and Enhanced Susceptibility to HIV Infection
Phillip E. Bickler, MD, PhD UCSF Dept of Anesthesia San Francisco, CA	Inhaled carbon dioxide and apnea during intravenous sedation
Richard De La Garza, II, Ph.D. UCLA ISAP Los Angeles, CA	Rivastigmine and Donepezil as Potential Treatments for Cocaine Addiction
Ronald Ellis, MD, PhD UCSD HIV Neurobehavior Research Ct. San Diego, CA	Ronald Ellis, MD, PhD UCSD HIV Neurobehavior Research Ct. San Diego, CA
Douglas Fry NORAC Azusa, CA	Panel Approved Research Project
Richard A. Houghten, Ph.D. Torrey Pines Inst./Molecular Study San Diego, CA	Biochemical Basis for the CNS Actions of Methaqualone
Ari Kalechstein, Ph.D. UCLA ISAP Los Angeles, CA	Methamphetamine Dependence: Treating Neurocognitive Impairment

Table 2 Cont.

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
George F. Koob, Ph.D. The Scripps Research Institute La Jolla, CA	Central Mechanisms of Opiate Reinforcement and Dependence
George F. Koob, Ph.D. The Scripps Research Institute La Jolla, CA	Neuronal Substrates of Cocaine Reward
Ronald Krauss, M.D. Children's Hospital Oakland Oakland, CA	Rimonabant Effects on Hepatic Lipoprotein Production
Richard Lenart Innovacon San Diego, CA	Development of urine and/or oral-fluid based in-vitro diagnostic tests to detect the presence of the controlled substances MDMA, GHB and THC
Richard Lenart Innovacon San Diego, CA	Development of urine and/or oral-fluid based in-vitro diagnostic tests in the form of lateral flow rapid test format to detect controlled substances commonly abused and misused by individuals
Mark T. Leibowitz, M.D. CA Clinical Trials Medical Group Glendale, CA	A Randomized, Open-label, Cross-Over Study to Characterize the PK of Fentanyl From Single Doses of Non-colored Fentanyl Buccal Tabs over the Dose Range of 100mcg thru 800mcg in Healthy Japanese Subjects Residing in the US

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Jon Levine, MD, PhD UCSF San Francisco, CA	Mechanisms of Pain Control: V. Analgesic Combinations for Post- Operative Pain—Kappa Opioids and Morphine
Edythe London, Ph.D. UCLA ISAP Los Angeles, CA	Modafinil as a Treatment for Methamphetamine Dependence: Initial Safety, Subjective Effects, and Brain Functioning - Pilot study
John E. Mendelson, M.D. CPMC APRL San Francisco, CA	Is There an Acute MDMA Single Dose Withdrawal Syndrome?
Pierre-Yves Michellys, Ph.D. Genomics Institute of the Novartis San Diego, CA	Use of Selected DEA Schedule I Controlled Substances as a Building Blocks in the Synthesis of Novel Chemical Entities in Support of Biological Studies
Karen Miotto, M.D. UCLA ISAP Los Angeles, CA	GHB: Effects, Withdrawal and Treatment
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Assessment of GVG for the Treatment of Methamphetamine Dependence
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Phase I Clinical Trial with OROS-MPH for Methamphetamine Dependence

Table 2 Cont.

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	An evaluation of the presence of psychotic symptoms in response to experimental administration of methamphetamine or placebo in the laboratory
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	A Pilot Study of Prazosin for Cocaine Dependence
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	The Dual Deficit Hypothesis of Stimulant Dependence: An Experiment Assessment in Human Volunteers
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Laboratory Models of Cocaine Self Administration
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Double-Blind, Randomized, Placebo-Controlled Trial of Rivastigmine (Exelon) as a Potential Medication for Methamphetamine Abuse
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	A Human Laboratory Assessment of the Safety and Potential Efficacy of Nopicastat (SYN117) in Cocaine-Dependent Volunteers Receiving Cocaine
Thomas F. Newton, M.D. UCLA ISAP Los Angeles, CA	Methamphetamine Dependence: A Novel Laboratory Model

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Karno Ng, Ph.D. California State University San Marcos San Marcos, CA	New Qualitative and Quantitative Methods for the Detection of Gamma-hydroxybutyrate (GHB)
Mark Perrone, Ph.D. Genomics Institute of the Novartis San Diego, CA	Application for Non-Human Research Using Schedule I Controlled Substance - Effects of Novel Agents on Food Intake, Weight Gain and Weight Loss in Rodents, Determination of Stimulation and Blockade of CB1 Receptor
Robert Ramage Microgenics Corporation Fremont, CA	Use of Schedule I Controlled Substances for Cross Reactant Studies and Investigation of Customer Inquiries
Marylou Solbrig, M.D. UC Irvine Irvine, CA	Panel Approved Research Project
David L. Valentine, Ph.D. UCSB Department of Earth Science Santa Barbara, CA	Perindopril - Methamphetamine Interaction Study
AcelRx Pharmaceuticals Redwood City, CA	A Multicenter, Randomized, Placebo- Controlled, Crossover Study for the Evaluation of the Safety and Efficacy of ARX-F02 Compared to Placebo in the Treatment of Cancer Breakthrough Pain (AcelRx ARX-C-003)

Table 2-Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Acura Pharmaceuticals
Austin, TX

A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter, Repeat-dose Study of the Safety & Efficacy of OxyADF (oxycodone HCl and niacin) Tablets for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Patients
(Acura AP-ADF-105)

Alpharma Pharmaceuticals
Piscataway, NJ

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Efficacy Study of Kadian NT (Morphine Sulfate Plus Naltrexone Hydrochloride Extended-Release) Capsules in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee
(Alpharma ALO-KNT-301)

Alpharma Pharmaceuticals
Piscataway, NJ

A Long-Term, Open-Label, Safety Study of Kadian NT (Morphine Sulfate Plus Naltrexone Hydrochloride Extended-Release) Capsules in Subjects with Chronic Moderate to Severe Nonmalignant Pain
(Alpharma ALO-KNT-302)

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Archimedes Development Nottingham, UK	A Multicenter, Placebo-Controlled, Double-Blind, Two-Phase Crossover Study of Nasalfent (Fentanyl Citrate Nasal Spray) in the Treatment of Breakthrough Cancer Pain (BTCP) in Subjects Taking Regular Opioid Therapy (Archimedes CPO43/06/FCNS)
Archimedes Development Nottingham, UK	An Open-Label Study Investigating Long- Term Safety and Tolerability of Nasalfent (Fentanyl Citrate Nasal Spray) in the Treatment of Breakthrough Cancer Pain (BTCP) in Subjects Taking Regular Opioid Therapy (Archimedes CPO45/06/FCNS)
Catalyst Pharmaceuticals Coral Gables, FL	Vigabatrin for Treatment of Cocaine Dependence: A Phase II Study
Cognition Pharmaceuticals San Diego, CA	A Randomized, Double-Blind, Placebo- Controlled, Dose, Titration Study to Assess the Safety, Tolerability, and Efficacy of C105 in Persons with Multiple Sclerosis with Cognitive Impairment (Cognition 22029)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Endo Pharmaceuticals
Chadds Ford, PA

An Open-Label, Two-Stage, Phase II Study to Explore the Titration Schedule for Transitioning Opioid-Experienced patients with Non-Malignant Moderate to Severe Chronic Pain from Current Opioid Therapy to the Sufentanil Transdermal Therapeutic System (STTS) (Endo EN3270-201)

Grunenthal
Austin, TX

A Randomized Withdrawal, Active- and Placebo-Controlled, Double-Blind, Multi-Center Phase III Trial Assessing Safety and Efficacy of Oral CG5503-PR* in Subjects with Moderate to Severe Chronic Malignant Tumor-Related Pain (Grunenthal KF5503/16)

Javelin Pharmaceuticals
Cambridge, MA

A Randomized, Double-Blind, Active- and Placebo-Controlled, Study of the Analgesic Efficacy & Safety of Repeated Dosing of MNS075 (Intranasal Morphine), IV Morphine and Placebo in Patients with Acute Post-Operative Pain after Elective Orthopedic Surgery (Javelin MOR-003)

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Johnson & Johnson Titusville, NJ	A Randomized, Double-blind, Active- and Placebo-Controlled, Parallel Group, Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of CG5503 Immediate-Release (IR) Formulation In Subjects Awaiting Primary Joint Replacement Surgery for End-Stage Joint Disease (J&J R331333-PAI-3002)
NIDA Rockville, MD	A Two-Phase Randomized Controlled Clinical Trial of Buprenorphine/Naloxone Treatment Plus Individual Drug Counseling for Opioid Analgesic Dependence (NIDA CTN Protocol 0030)
NIDA Bethesda, MD	Phase 2, Double-Blind, Placebo-Controlled Trial of Topiramate for the Treatment of Methamphetamine Dependence (NIDA-MDS-Topiramate/meth0001)
NIDA Bethesda, MD	Phase 2, Double-Blind, Placebo-Controlled Trial of Modafinil for the Treatment of Methamphetamine Dependence (NIDA/VA CSP #1026)

Table 2-Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Novartis Pharmaceuticals
East Hanover, NJ

An open-label, behavioral- treatment
-controlled evaluation of the effects of
extended release methylphenidate (Ritalin
LA) on the frequency of cytogenetic
abnormalities in children 6-12 year of age
with ADHD
(Novartis CRIT 124D2201)

Purdue Pharma
Stamford, CT

A Multi-center, Randomized, Double-
blind, Placebo-controlled Study with an
Open-label Run-in to Assess the Efficacy,
Tolerability, and Safety of BTDS 10 or
BTDS 20 Compared to Placebo in Opioid-
naive Subjects with Moderate to Severe,
Chronic Pain due to Osteoarthritis of the
Knee
(Purdue BUP3025)

Purdue Pharma
Stamford, CT

A Multi-center, Randomized, Double-
blind, Placebo-controlled Study with an
Open-label Run-in to Assess the Efficacy,
Tolerability, and Safety of BTDS 10 or
BTDS 20 Compared to Placebo in Opioid-
naive Subjects with Moderate to Severe,
Chronic Low Back Pain
(Purdue BUP3024)

QRxPharma
Austin, TX

A Placebo-Controlled, Randomized,
Double-Blind Study of the Safety and
Efficacy of Q8003 in The Management of
Post-Bunionectomy Pain
(QRxPharma Q8003-007)

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
QRxPharma Austin, TX	A Double-Blind, Multi-Center Extension Study to Evaluate the Safety and Efficacy of Q8003 in Patients with Acute Moderate to Severe Pain (QRxPharma Q8003-010)
Shire Pharmaceuticals Wayne, PA	An Open-Label, Randomized Study of the Pharmacokinetics of <i>d</i> -Methylphenidate and <i>l</i> -Methylphenidate After Single and Multiple Doses of Methylphenidate Transdermal System (MTS) or CONCERTA® Administered to Children and Adolescents Ages 6 to 17 Years with Attention-Deficit Hyperactivity Disorder (ADHD) (Shire SPD485-106)
Shire Pharmaceuticals Wayne, PA	A Phase IIIb, Long-Term, Open-Label, Multi-Center, Extension Study Designed to Evaluate the Safety and Efficacy of Methylphenidate Transdermal System (MTS) in Adolescents aged 13-17 years with Attention-Deficit/Hyperactivity Disorder (ADHD) (Shire SPD485-410)
Shire Pharmaceuticals Wayne, PA	A Prospective, Open-Label, Multi-Center, Dose-Optimization Study Evaluating the Efficacy, Safety and Tolerability of Vyvanse 20-70mg in Children aged 6-12 Diagnosed with ADHD (Shire SPD489-310)

Table 2 Cont.

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Shire Pharmaceuticals Wayne, PA	A Phase IIIb Randomized, Double-Blind, Multi-center, Placebo-controlled, Dose Optimization, Crossover, Safety and Efficacy Workplace Environment Study of Lisdexamfetamine Dimesylate (LDX) in Adults with Attention-Deficit Hyperactivity Disorder (ADHD) (Shire SPD489-316)
Titan Pharmaceuticals Mississauga, ON Canada	A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of Probuphine in Patients with Opioid Dependence (Titan PRO-805)
Titan Pharmaceuticals Mississauga, ON Canada	An Open-Label, Multi-Center Extension Study of Probuphine in Patients with Opioid Dependence (Titan PRO-807)
Titan Pharmaceuticals Mississauga, ON Canada	An Open-Label, Multi-Center Study of Probuphine in Patients with Opioid Dependence (Titan PRO-808)
Titan Pharmaceuticals Mississauga, ON Canada	An Open-Label, Multi-Center Extension Study of Probuphine in Patients with Opioid Dependence (Titan PRO-809)

APPENDIX A

CURRENTLY OPEN (*through December 31, 2008*)
SCHEDULE I AND SCHEDULE II
NON-HUMAN AND ACADEMIC HUMAN
RESEARCH STUDIES

<u>Principal Investigator</u>	<u>Title of Study</u>
Mark A. Agius, M.D. UC. Davis Davis, CA	Cannabis for Spasticity/Tremor in MS: Placebo Controlled Study
Danilyn Angeles, Ph.D. Loma Linda University Loma Linda, CA	A Double-blind randomized Clinical Trial on the Use of Pre-emptive Morphine Infusion in Asphyxiated Term and Near-Term Infants
James T. Arnold, Ph.D. Systems and Techniques Lab. Palo Alto, CA	Panel Approved Research Project
Selena E. Barrett, Ph.D. Ernest Gallo Clinic & Research Ctr. Emeryville, CA	The role of cannabinoids and ibogaine in the treatment of alcoholism and drug addiction
Nancy E. Buckley, Ph.D. California State Polytechnic Univ. Pomona, CA 91768	The cannabinoid system and the modulation of T cell and macrophage Functions
Jeremy S. Caldwell, Ph.D. Genomics Institute San Diego, CA	High-Throughput Screening of Known Drugs for Novel Biological Activity in Cell-based Assays

Appendix A Cont.

<u>Principal Investigator</u>	<u>Title of Study</u>
Arthur K. Cho, Ph.D. UCLA School of Medicine Los Angeles, CA	Studies on Distribution and Metabolism of Narcotics in Animals
Kent S. Chu, Ph.D. YJ Bio-Products Cordova, CA	Immunochromatographic Test Device for THC and LSD
Laura Colin Biostride, Inc. Redwood City, CA	Panel Approved Research Project
Mohammad Diab, M.D. UCSF Dept of Orthopaedic Surgery San Francisco, CA	Panel Approved Research Project
Robert Edwards, M.D. UCSF School of Medicine San Francisco, CA	Panel Approved Research Project
Aaron Ettenberg, Ph.D. UC Santa Barbara Santa Barbara, CA	Dopamine Involvement in Opiate and Stimulant Drug Reinforcement
Frederick D. Frankel, Ph.D. UCLA ISAP Los Angeles, CA	Social Skills Training for Medicated Children
Douglas Fry The Norac Co., Inc. Azusa, CA	Panel Approved Research Project

<u>Principal Investigator</u>	<u>Title of Study</u>
Jean Gehricke, Ph.D. UC Irvine Irvine, CA	The Reinforcing Mechanisms of Smoking in Adult ADHD
Mark A. Geyer, Ph.D. UC San Diego La Jolla, CA	Behavioral and Cytoflourimetric Studies of Psychoactive Drugs in Rats
Charles S. Grob, M.D. Harbor UCLA Medical Center Torrance, CA	Effects of Psilocybin in Terminal Cancer Patients with Anxiety
Kanthi F. Hettiarachchi, Ph.D. SRI International Menlo Park, CA	Analysis of Cannabinoids
Scott A. Irwin, MD, PhD San Diego Hospice/ Palliative Care San Diego, CA	Panel Approved Research Project
Reese Jones, M.D. UCSF Langley Porter Institute San Francisco, CA	Pilot Study of LSD in Healthy Volunteers
Thomas B. King Alexza Molecular Delivery Corp. Palo Alto, CA	Development of an FDA Approved Dronabinol Pharmaceutical Product for Inhalation Delivery
Lorin Koran, M.D. Stanford University, School of Medicine Stanford, CA	Double-Blind Trial of Acute & Intermediate-Term Dextro-Amphetamine versus Caffeine Augmentation in Treatment-Resistant Obsessive-Compulsive Disorder

Appendix A Cont.

Principal Investigator

Title of Study

Kimberley D. Lakes, Ph.D.
UC Irvine
Irvine, CA

The Effects of Vyvanse on Brain
Hemodynamics and Reading

Nancy M. Lee, Ph.D.
CPMC Research Center
San Francisco, CA

Panel Approved Research Project

Daniel Levin, Ph.D.
Norac Pharma
Azusa, CA

Panel Approved Research Project

Marie Lin, Ph.D. R.Ph.
Lin-Zhi International, Inc.
Sunnyvale, CA

Lin-Zhi Immunoassay Development Study

James T. McCracken, M.D.
UCLA NPI
Los Angeles, CA

An 8-Week, Randomized, Double-Blind
Comparison of Twice-Daily Guanfacine,
Once-Daily d-Methylphenidate ER (Focalin
XR) and the Combination, with a 12 Month
Open-Label Extension for the Treatment of
ADHD in Pediatric Subjects Aged 7 to 14
years

John Mendelson, M.D.
UCSF/CPMC
San Francisco, CA

Is There an Acute MDMA Single Dose
Withdrawal Syndrome?

John Mendelson, M.D.
UCSF/CPMC
San Francisco, CA

Steady State Kinetics of l-Methamphetamine
and Validation of Sensitivity of Dose
Estimation

<u>Principal Investigator</u>	<u>Title of Study</u>
Robert Messing, M.D. Ernest Gallo Clinic & Research Ctr Emeryville, CA	Protein kinase C epsilon (PKCe) in Responses to Cannabinoids
Stephen Morairty, Ph.D. SRI International Menlo Park, CA	Intranasal administration of gamma-hydroxybutyrate
Karel Z. Newman, Ph.D. Biosite Incorporated San Diego, CA	Development of In-vitro Immunoassays for the Detection of Abused Substances
Stanley M. Parsons, Ph.D. UC Santa Barbara Santa Barbara, CA	Rapid Detection of 4-hydroxybutyrate
John M. Polich, Ph.D. The Scripps Research Institute La Jolla, CA	Marijuana CNS Effects in Low- and High-Risk Adults
Mark Rollins, MD, PhD UCSF Dept. of Anesthesia San Francisco, CA	Supplemental Oxygen: A Reduction in Pulse Oximetry Sensitivity or an Increased Margin of Safety?
Dorit Ron, Ph.D. Ernest Gallo Clinic & Research Ctr Emeryville, CA	Signaling Pathways Involved in the Mechanism of Action of the Anti-Addictive Drug Ibogaine
Matthew A. Schreiber, M.D., Ph.D. Ernest Gallo Clinic & Research Ctr Emeryville, CA	Pharmacological and genetic study of the effects of 3,4-methylenedioxymethamphetamine (MDMA) using a model organism, the nematode <i>Caenorhabditis elegans</i>

Appendix A Cont.

Principal Investigator

Title of Study

Lawrence Toll, Ph.D.
SRI International
Menlo Park, CA

Biochemical Studies into Opiate Efficacies

Stephen Van Dien, Ph.D.
Genomatica, Inc.
San Diego, CA

Panel Approved Research Project

Mark Wallace, M.D.
UC San Diego
San Diego, CA

Efficacy of Inhaled Cannabis for the
Treatment of Painful Diabetic Peripheral
Neuropathy

Jennifer L. Whistler, Ph.D.
Ernest Gallo Clinic & Research Ctr.
Emeryville, CA

Endocytosis and Cannabinoid Receptors

Jennifer L. Whistler, Ph.D.
Ernest Gallo Clinic & Research Ctr.
Emeryville, CA

Endocytosis and Opioid Receptors

Timothy Wigal, Ph.D.
UC Irvine
Irvine, CA

Brain Dopamine Function in Adults with
Attention Deficit/Hyperactivity Disorder
(ADHD)

Barth Wilsey, M.D.
UC Davis Medical Center
Sacramento, CA

The Analgesic Effect of Vaporized Cannabis
on Neuropathic Pain

APPENDIX B

CURRENTLY OPEN (*through December 31, 2008*)
SCHEDULE II CLINICAL DRUG TRIAL STUDIES

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
AcelRx Pharmaceuticals Redwood City, CA	A Multi-Center, Randomized, Placebo- Controlled Phase II Study to evaluate the Clinical Efficacy, Safety, and Tolerability of ARX-F01 Sublingual Sufentanil NanoTabs TM in Patients Undergoing Major Abdominal Surgery (AcelRx ARX-C-005)
Biodelivery Sciences Morrisville, NC	An open label, long-term treatment evaluation of the safety of BEMA fentanyl use for breakthrough pain in cancer subjects on chronic opioid therapy (BioDelivery FEN-202)
Endo Pharmaceuticals Chadds Ford, PA	A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy & Safety of EN3267 for the Treatment of Breakthrough Pain in Opioid Tolerant Cancer Patients Followed by a 12-Months Non-Randomized, Open-Label Extension to Assess LT Safety (Endo EN3267-005)
Endo Pharmaceuticals Chadds Ford, PA	A Multiple-Dose, Non Randomized, Open-Label, Multicenter Study to Evaluate the Long-Term Safety and Effectiveness of EN3267 in the Treatment of Breakthrough Pain in Cancer patients (Endo EN3267-007)

Appendix B Cont.

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Endo Pharmaceuticals Chadds Ford, PA	An Open-Label Safety and Tolerability Study of Immediate-Release and Extended-Release Oxycodone in Opioid-Tolerant pediatric Subjects with Chronic Pain (Endo EN3202-036)
Endo Pharmaceuticals Chadds Ford, PA	An Open-Label, Ascending, Two-Part, Single- and Multiple-Dose Evaluation of the Safety, Pharmacokinetics, and Effectiveness of Oxycodone For Acute Postoperative Pain in Pediatric Subjects (Endo EN3203-010)
GW Pharmaceuticals Wiltshire, UK	A double blind, randomized, placebo controlled, parallel group dose-range exploration study of Sativex® in relieving pain in patients with advanced cancer, who experience inadequate analgesia during optimized chronic opioid therapy (GW GWCA0701)
Insys Therapeutics Phoenix, AZ	A Randomized, Double-Blind, Placebo-Controlled Multi-Center Study to Evaluate the Safety and Efficacy of Fentanyl Sublingual Spray (Fentanyl SL Spray) for the Treatment of Breakthrough Cancer Pain (Insys INS-05-001)
Insys Therapeutics Phoenix, AZ	Open-Label, Multi-Center Safety Trial of Fentanyl Sublingual Spray (Fentanyl SL Spray) for the Treatment of Breakthrough Cancer Pain (Insys INS-06-007)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Johnson & Johnson Titusville, NJ	Open-Label Extension, Single-Arm, Flexible-Dosing, Phase III Trial with CG5503 Extended-Release (ER) in Subjects with Moderate to Severe Chronic Pain (J&J R331333-PAI-3010)
Johnson & Johnson Austin, TX	A Randomized, Double-Blind, Active-and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Tapentadol Immediate-Release Formulation in the Treatment of Acute Pain from Bunionectomy (J&J R331333-PAI-3018)
Johnson & Johnson Titusville, NJ	A Randomized, Double-blind, Placebo- and Active- Controlled, Parallel-arm, Multicenter Study in Subjects With End-Stage Joint Disease to Compare the Frequency of Constipation Symptoms in Subjects Treated with Tapentadol IR and Oxycodone IR Using a Bowel Function Patient Diary (J&J R331333-PAI-3020)
Johnson & Johnson Titusville, NJ	A Pivotal Bioequivalence Study Assessing Transdermal D-TRANS Fentanyl 100 ug/h Matrix System to DURAGESIC Fentanyl 100 ug/h Reservoir System After Single Application in Healthy Subjects (J&J FEN-PAI-1019)

Appendix B Cont.

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Neuromed Pharmaceuticals Raleigh, NC	A Phase III, Variable-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Chronic Low Back Pain (Neuromed NMT 1077-301)
Neuromed Pharmaceuticals Conshohocken, PA	A Phase III, Flexible-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Osteoarthritis Pain (Neuromed NMT 1077-302)
OMJSA Irvine, CA	Double-Blind, Randomized, Placebo-Controlled, Crossover Study Evaluating the Academic, Behavioral and Cognitive Effects of CONCERTA on Older Children with ADHD (The ABC Study) (OMJSA CONCERTA-ATT-4069)
OMJSA Raritan, NJ	A Randomized, Double Blind, Placebo- and Oxycodone Immediate Release (IR) - Controlled Study of Tapentadol IR for the Treatment of Acute pain Caused by Vertebral Compression Fractures Associated with Osteoporosis (OMJSA R331333-PAI-3021)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Purdue Pharma Stamford, CT	A Multi-Center, Inpatient, Open-Label, within Subject Dose Titration Study to Characterize the Pharmacokinetics/Pharmacodynamics, Safety and Efficacy of Hydromorphone HCl Oral Solution in Subjects from 28 Days to 16 Years of Age, Inclusive, Who Require Opioid Analgesics for Post-Operative Pain (Purdue HMP4009)
QRxPharma Bedminster, NJ	A Double-Blind, Randomized, Multi-Center, Repeat Dose, Placebo Controlled Study to Compare the Analgesic Efficacy and Safety of the Opioid Combination Q8003 to Each of the Individual Milligram Components (Oxycodone and Morphine) and Placebo in the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery (QRxPharma Q8003-015)
QRxPharma Chapel Hill, NC	A Double-Blind, Randomized, Multi-Center, Repeat-Dose, Comparison of the Analgesic Efficacy & Safety of the Opioid Combination Q8003 to each of the Individual Milligram Components (Oxycodone & Morphine) in the Management of Acute Moderate to Severe Pain Following Bunionectomy Surgery (QRxPharma Q8003-021)

Appendix B Cont.

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Shire Pharmaceuticals Wayne, PA	A Phase III Randomized, Double-Blind, Multicenter, Parallel-Group, Placebo-Controlled, Forced-dose Titration, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-305)
Shire Pharmaceuticals Wayne, PA	A Phase III, Open-Label, Extension, Multicenter, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Adolescents Aged 13-17 with Attention Deficit/Hyperactivity Disorder (ADHD) (Shire SPD 489-306)
Shire Pharmaceuticals Wayne, PA	A Phase IIIb, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Dose-Optimization, Cross-Over, Analog Classroom Study to Assess the Time of Onset of Vyvanse™ in Pediatric Subjects aged 6-12 Diagnosed with Attention-Deficit/Hyperactivity Disorder (Shire SPD489-311)

APPENDIX C

CURRENTLY OPEN (*through December 31, 2008*) RESEARCH STUDIES ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

<u>Investigator or Sponsor</u>	<u>Description or Title of Research Study</u>
Gantt P. Galloway, Pharm.D. CPMC APRL San Francisco, CA	A Pilot Trial of Modafinil for Treatment of Methamphetamine Dependence
Gantt P. Galloway, Pharm.D. CPMC APRL San Francisco, CA	A Pilot Trial of Dextroamphetamine for Treatment of Methamphetamine Dependence
Alan Gevins, D. Sc. SAM Technology San Francisco, CA	Realtime Neural Monitor for Drug Abuse Research
Keith Heinzerling, MD, MPH UCLA ISAP Los Angeles, CA	Pharmacogenomics and Medication Development for Methamphetamine Dependence
Walter Ling, M.D. UCLA ISAP Los Angeles, CA	Optimizing Outcomes Using Suboxone for Opiate Dependence
Walter Ling, M.D. UCLA ISAP Los Angeles, CA	Double-Blind, Placebo-Controlled Trial of Prometa Pharmacotherapy for the Treatment of Methamphetamine Abuse
Edythe London, Ph.D. UCLA Los Angeles, CA	A Human laboratory Assessment of the Safety and Potential Efficacy of Varenicline in Methamphetamine- Dependent Volunteers Receiving Methamphetamine

Steven Shoptaw, Ph.D.
Semel Inst of Neuroscience & Human
Behavior
11075 Santa Monica Blvd.
Los Angeles, CA 90025

A Randomized, Double-Blind, Placebo-
Controlled Evaluation of Bupropion vs
Placebo for the Treatment of
Methamphetamine Dependence

CATALYST Pharmaceuticals
Chapel Hill, NC

Vigabatrin for Treatment of
Methamphetamine Dependence: A
Phase II Study
(Catalyst CPP-02001)

National Institute on Drug Abuse
(NIDA)
Bethesda, Maryland

Starting Treatment with Agonist
Replacement Therapies (START)
(NIDA CTN Protocol 0027)

National Institute on Drug Abuse
(NIDA)
Bethesda, Maryland

Phase 2, Double-Blind, Placebo-
Controlled Trial of Bupropion for
Methamphetamine Dependence
(NIDA-MDS-Bupropion Meth-0001)

APPENDIX D

SECTIONS CONCERNING THE RESEARCH ADVISORY PANEL FROM THE CALIFORNIA HEALTH AND SAFETY CODE

Sec. 11213. Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose 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.

Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

Sec. 11362.9. California Marijuana Research Program; legislative intent; creation; research proposals; establishment; powers and duties; Scientific Advisory Council (In pertinent part)

(d) If the program is administered by the Regents of the University of California any grant research proposals approved by the program shall also require review and approval by the research advisory panel.

(f) All personnel involved in implementing approved proposals shall be authorized as required by Section 11604.

(g) Studies conducted pursuant to this section shall include the greatest amount of new scientific research possible on the medical uses of, and medical hazards associated with, marijuana. The program shall consult with the Research Advisory Panel analogous agencies in other states, and appropriate federal agencies in an attempt to avoid duplicative research and the wasting of research dollars.

Sec. 11374. Every person who violates or fails to comply with any provisions of this division, except one for which a penalty is otherwise in this division specifically provided, is guilty of a misdemeanor punishable by a fine in a sum not less than thirty dollars (\$30) nor more than five hundred dollars (\$500), or by imprisonment for not less than 15 nor more than 180 days, or by both.

Appendix D Cont.

Sec. 11392. Spores or mycelium capable of producing mushrooms or other material which contains psilocyn or psilocylin may be lawfully obtained and used for bona fide research, instruction, or analysis, if not in violation of federal law, and if the research, instruction, or analysis is approved by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Sec. 11478. Marijuana may be provided by the Attorney General to the heads of research projects which have been registered by the Attorney General, and which have been approved by the Research Advisory Panel pursuant to Section 11480.

The head of the approved research project shall personally receipt for such quantities of marijuana and shall make a record of their disposition. The receipt and record shall be retained by the Attorney General. The head of the approved research project shall also, at intervals and in the manner required by the Research Advisory Panel, report the progress or conclusions of the research project.

Sec. 11480. The Legislature finds that there is a need to encourage further research into the nature and effects of marijuana and hallucinogenic drugs and to coordinate research efforts on such subjects.

There is a Research Advisory Panel which consists of a representative of the State Department of Health Services, a representative of the California State Board of Pharmacy, a representative of the Attorney General, a representative of the University of California who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a private university in this State who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a statewide professional medical society in this state who shall be engaged in the private practice of medicine and shall be experienced in treating controlled substance dependency, a representative appointed by and serving at the pleasure of the Governor who shall have experience in drug abuse, cancer, or controlled substance research and who is either a registered nurse, licensed pursuant to Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code, or other health professional. The Governor shall annually designate the private university and the professional medical society represented on the Panel. Members of the Panel shall be appointed by the heads of the entities to be represented, and they shall serve at the pleasure of the appointing power.

Sec. 11480. Cont.

The Panel shall annually select a chairman from among its members.

The Panel may hold hearings on, and in other ways study, research projects concerning marijuana or hallucinogenic drugs in this state. Members of the Panel shall serve without compensation, but shall be reimbursed for any actual and necessary expenses incurred in connection with the performance of their duties.

The Panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of marijuana or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of marijuana pursuant to Section 11478.

The Panel may withdraw approval of a research project at any time, and when approval is withdrawn shall notify the head of the research project to return any quantities of marijuana to the Attorney General.

The Panel shall report annually to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and, where available, the conclusions of the research project.

Sec. 11481. The Research Advisory Panel may hold hearings on, and in other ways study, research projects concerning the treatment of abuse of controlled substances.

The Panel may approve research projects, which have been registered by the Attorney General, concerning the treatment of abuse of controlled substances and shall inform the chief of such approval. The Panel may withdraw approval of a research project at any time and when approval is withdrawn shall so notify the chief.

The Panel shall, annually and in the manner determined by the Panel, report to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and where available, the conclusions of the research project.

Sec. 11603. The Attorney General, with the approval of the Research Advisory Panel, may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceedings to identify the individuals who are the subjects of research for which the authorization was obtained.

Appendix D Cont.

Sec. 11604. The Attorney General, with the approval of the Research Advisory Panel, may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

Attachment 9

CURES Goes Online

State of California • Department of Justice

OFFICE OF THE ATTORNEY GENERAL

Edmund G. Brown Jr.

News Release

September 15, 2009

FOR IMMEDIATE RELEASE

Contact: (916) 324-5500

Brown Unveils Real-Time Statewide Prescription Drug-Monitoring System

LOS ANGELES - Continuing his effort to curb prescription-drug abuse, Attorney General Edmund G. Brown Jr. today unveiled a new internet-based prescription-monitoring database that provides physician pharmacists and law enforcement officers a powerful technology to stop "drug seekers" from obtaining prescription drugs.

"The recent deaths of Anna Nicole Smith and Michael Jackson have made clear to the whole world just how dangerous prescription drug abuse can be," said Brown. "Today, my office is inaugurating a high-tech monitoring system that will enable doctors and law enforcement to identify and stop prescription-drug seekers from doctor-shopping and abusing prescription drugs."

The state's secure database, known as the Controlled Substance Utilization Review and Evaluation System (CURES), contains more than 100 million entries representing controlled substances (Schedule II, III and IV) dispensed in California. Controlled substances are classified under federal guidelines based on potential for abuse and accepted medical use in treatment in the United States and international treaties.

Prescription Drug-Monitoring Database

Today's launch of the online CURES database is part of Brown's effort to curb prescription-drug abuse in the state and make it easier for doctors to track their patients' prescription-drug history. The database gives health professionals (doctors, pharmacists, midwives, and registered nurses), law enforcement agencies and medical profession regulatory boards instant computer access to patients' controlled-substance records. This replaces the state's previous system that required mailing or faxing written requests for information. Each year, more than 60,000 such requests are made to the Attorney General's office.

Each database record contains a patient's dispensed drug record, including:

- Drug Name
- Date Filled
- Quantity, Strength and Number of Refills
- Pharmacy Name and License Number
- Doctor's Name and DEA Number
- Prescription Number

Under the new system, a pain-management physician examining a new patient complaining of chronic back pain would be able to instantly look up the patient's controlled-substance history to determine whether the patient legitimately needs medication or is a "doctor shopper." "Doctor shoppers" are prescription-drug addicts who visit dozens of doctors to obtain multiple prescriptions for drugs. In the

past, the doctor's request could take several days for a response. Now with CURES instant access, doctors can identify doctor shoppers and other prescription-drug abusers before they write them another prescription. Law enforcement can also flag a person in the database to alert physicians to potential abusers.

Last year, the Attorney General's office provided more than 64,000 Patient Activity Reports to authorized subscribers.

Growing Problem of Prescription-Drug Abuse

With 7,500 pharmacies and 158,000 prescribers reporting prescription information annually, CURES is the largest online prescription-drug monitoring database in the United States. Its goal is to reduce drug trafficking and abuse of dangerous prescription medications, lower the number of emergency room visits due to prescription-drug overdose and misuse, and reduce the costs to healthcare providers related to prescription-drug abuse.

Prescription-drug abuse costs the state and health insurers millions of dollars each year. The National Survey on Drug Use and Health estimates that 20 to 30 percent of California's drug abusers primarily use prescription drugs. In addition, a 2005 survey by the Drug Abuse Warning Network estimates that non-medical use of pharmaceuticals accounted for more than 500,000 emergency room visits in California, an enormous drain on the state's healthcare system.

According to the latest Department of Justice "Drug Trends" report, Valium, Vicodin, and Oxycontin are the most prevalent pharmaceutical drugs obtained fraudulently. Vicodin and Oxycontin are the two most abused pharmaceutical drugs in the United States.

CURES Success Stories

Prescription-drug abuse can have serious consequences for both abusers and the public. Each year, hundreds of people die from prescription-drug overdose in California. Dozens more are injured or killed by prescription-drug abusers who are driving under the influence of medication. The problem is on the rise; recent studies have found that teens are increasingly more likely to have abused prescription drugs than most illicit drugs.

Last year, Brown and the CURES team targeted the top 50 doctor shoppers in the state, who averaged more than 100 doctor and pharmacy visits to collect massive quantities of addictive drugs like Valium, Vicodin, and Oxycontin. The crackdown led to the arrest of dozens of suspects, including Frankie Greer 53, who visited 183 doctors and 47 pharmacies to feed a prescription-drug habit that included some of the most dangerous painkillers in lethal combinations. In a one-year period, Greer sought out multiple doctors at hospital emergency rooms to prescribe her more than 4,830 hydrocodone tablets, 2,210 oxycodone tablets and 156 Oxycotin pills, along with a variety of additional addictive painkillers.

In May 2009, the CURES team worked with the Ventura County Sheriff's Office to provide detectives with the prescribing history of Dr. Bernard Bass, a Burbank doctor accused of writing hundreds of fraudulent prescriptions to feed his patients' drug addictions. Seven of his patients died from prescription-drug overdoses. Following an investigation that included the CURES report of the prescriptions he had written, Dr. Bass faced criminal charges, lost his medical license and surrendered his license to prescribe controlled substances.

CURES can also alert law enforcement and licensed medical professionals to signs of illegal drug diversions. Last fall, Brown's office teamed up with the Simi Valley Police Department to investigate Rick Washington, known to police for his violent history, street gang-affiliation and previous drug-trafficking arrests. The 12-month investigation revealed a criminal conspiracy in which Ricky Washington and associates had stolen the identities of eight doctors, which they used to illegally write prescriptions. The

drug-trafficking group also stole the identities of dozens of innocent citizens, designating them as "patients" in order to fill the fraudulent prescriptions. The drug ring obtained more than 11,000 pills of highly addictive drugs like Oxycontin and Vicodin.

For more information on the California Department of Justice Bureau of Narcotic Enforcement and California's current prescription drug monitoring system visit: <http://ag.ca.gov/bne/CURES.php>.

For doctors and other authorized healthcare and prescription-drug providers, visit ag.ca.gov for more information on CURES and how to register.

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OFFICE OF THE ATTORNEY GENERAL

BNE

Guidelines for Combating Prescription Drug Abuse and Fraud

Intervention Tips

- Early identification of patients at risk to abuse drugs.
- Identify prescription abuse when it exists. Don't wait.
- Help patients recognize the problem.
- Set recovery goals.
- Seek appropriate treatment.

CURES
 P.O. Box 161089
 Sacramento, California 95816
 Phone 916 319-9062
 Fax 916 319-9448



CURES PROGRAM
 BUREAU OF NARCOTIC ENFORCEMENT

Guidelines for Combating Prescription Drug Abuse and Fraud

The following guidelines may assist you in safely and effectively combating prescription drug abuse/fraud:

- Remember that prescription drugs are historically over prescribed to illegitimate patients and under prescribed to legitimate patients. Do not hesitate to confront a patient with your concerns or "Just Say No."
- Conduct thorough patient examinations, interviews/assessments, and document your findings.
- Use the Medical Board of CA standard of care in managing pain patients.
- Store controlled substance prescription pads in a secure (locked) location. Remember, prescription pads are like money in the bank.
- Be aware that a stolen prescription pad equates to a drug of choice for a drug seeker and money for a dealer.
- Report theft or loss of prescription pads to California Security Prescription Program (securityprinter@doj.ca.gov).
- Do not prescribe controlled substances to family/friends.
- Document all controlled substances prescribed, administered or dispensed.
- Photocopy all controlled substance prescriptions and place a copy in the patient file.
- Obtain a Patient Activity Report from the CURES program or obtain the names, phone numbers, and office phone numbers of other physicians treating or prescribing controlled substances to your patient.
- Develop a patient pain agreement.
- Develop a flow chart indicating: expected time of symptom relief/actual time of symptom relief.
- Prescribe only the minimum quantity necessary to treat a suspicious patient until he/she can schedule an office visit.
- When prescribing controlled substances, check appropriate boxes indicating refill and quantity amounts. Consider manually writing out the prescribing amounts.
- Contact your local police department if you suspect an individual is seeing multiple doctors, "doctor shopping," and/or receiving excessive amounts of controlled substances.

Potential Indicators of Prescription Drug Abuse/Fraud

- Patients hesitant or unclear about pertinent personal information:
 - Home address
 - Phone number
 - Date of birth
 - Social security number
 - Unable to provide government photo ID
- Patient requesting specific controlled substances.
- Repeatedly running out of medication early.
- Notice rapid request for increases in controlled substances.
- After-hour, holiday or weekend requests for controlled substances.
- Unscheduled refills being requested.
- Unwillingness to try nonopioid treatments.
- Ongoing use after medical problem has been resolved.
- Engaging in doctor shopping activity.
- Moving from one primary care physician to another frequently.
- Evidence of withdrawal symptoms visible at appointments.
- Forging prescriptions from nonmedical or multiple medical sources.

Attachment 10

Enforcement Statistics 2009-10

Board of Pharmacy Enforcement Statistics

Fiscal Year 2009/2010

Workload Statistics July-Sept Oct-Dec Jan-Mar Apr-June Total 09/10

Complaints/Investigations

Initiated	520				520
Closed	1087				1087
Pending (at the end of quarter)	2346				2346

Cases Assigned & Pending (by Team)

Compliance Team	85				85
Drug Diversion/Fraud	60				60
Probation/PRP	25				25
Mediation/Enforcement	5				5
Criminal Conviction	1277				1277

Application Investigations

Initiated	167				167
Closed					
Approved	39				39
Denied	33				33
Total*	90				90
Pending (at the end of quarter)	420				420

Citation & Fine

Issued	495				495
Citations Closed	210				210
Total Fines Collected	\$298,575.00				\$298,575.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics

Fiscal Year 2009/2010

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 09/10**

Administrative Cases (by effective date of decision)

Referred to AG's Office*	78				78
Pleadings Filed	49				49
Pending					
Pre-accusation	160				160
Post Accusation	138				138
Total	205				205
Closed**					
Revocation					
Pharmacist	3				3
Pharmacy	0				0
Other	3				3
Revocation, stayed; suspension/probation					
Pharmacist	2				2
Pharmacy	2				2
Other	0				0
Revocation, stayed; probation					
Pharmacist	1				1
Pharmacy	0				0
Other	1				1
Suspension, stayed; probation					
Pharmacist	0				0
Pharmacy	0				0
Other	0				0
Surrender/Voluntary Surrender					
Pharmacist	0				0
Pharmacy	0				0
Other	1				1
Public Reproval/Reprimand					
Pharmacist	0				0
Pharmacy	0				0
Other	0				0
Cost Recovery Requested	\$43,046.75				\$43,046.75
Cost Recovery Collected	\$38,423.20				\$38,423.20

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics

Fiscal Year 2009/2010

Workload Statistics

July-Sept Oct-Dec Jan-Mar Apr-June Total 09/10

Probation Statistics

Licenses on Probation

Pharmacist	106				106
Pharmacy	6				6
Other	14				14
Probation Office Conferences	22				22
Probation Site Inspections	36				36
Probationers Referred to AG for non-compliance	2				2

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 9/30/09)

Program Statistics

In lieu of discipline	0				0
In addition to probation	1				1
Closed, successful	5				5
Closed, non-compliant	0				0
Closed, other	3				3
Total Board mandated Participants	50				50
Total Self-Referred Participants*	27				27
Treatment Contracts Reviewed	48				48

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of September 30, 2009

Attachment 11

First Quarterly Update of the Enforcement Committee Goals

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1	Achieve 100 percent closure on all cases within 6 months.						
Measure:	Percentage of cases closed.						
Tasks:	1. Complete all desk investigations within 90 days (for cases closed during quarter).						
		<u>N</u>	< 90 days	< 120 days	< 180 days	Longer	<u>Average Days</u>
	Qtr 1	710	351	10	26	323	364
			50%	1%	4%	45%	
	Qtr 2						
	Qtr 3						
	Qtr 4						
	2. Complete all field investigations within 120 days (for cases closed during quarter).						
		<u>N</u>	< 120 days	< 180 days	< 270 days	Longer	<u>Average Days</u>
	Qtr 1	269	121	34	56	58	208
			45%	13%	21%	22%	
	Qtr 2						
	Qtr 3						
	Qtr 4						
	Data is calculated from date received to the date the report was accepted by SI/Manager. Does not include split cases.						

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Qtr 1	<u>N</u>	< 180	< 270	< 365	> 365
Closed, no additional action	357	172	67	36	82
Rap sheet/CCU - 4301 letters and license denials	168	10	4	9	145
Cite and/or fine letter of admonishment	358	249	18	17	74
Attorney General's Office	90	6	11	15	58
Qtr 2	<u>N</u>	< 180	< 270	< 365	> 365
Closed, no additional action					
Rap sheet/CCU - 4301 letters and license denials					
Cite and/or fine letter of admonishment					
Attorney General's Office					
Qtr 3	<u>N</u>	< 180	< 270	< 365	> 365
Closed, no additional action					
Rap sheet/CCU - 4301 letters and license denials					
Cite and/or fine letter of admonishment					
Attorney General's Office					
Qtr 4	<u>N</u>	< 180	< 270	< 365	> 365
Closed, no additional action					
Rap sheet/CCU - 4301 letters and license denials					
Cite and/or fine letter of admonishment					
Attorney General's Office					

Data is calculated from date received to date closed or referred to the AG.
Does not include split cases.

Objective 1.2	Manage enforcement activities for achievement of performance expectations.																																									
Measure:	Percentage compliance with program requirements.																																									
Tasks:	<p>1. Administer the Pharmacists Recovery Program.</p> <table border="1"> <thead> <tr> <th></th> <th>Voluntary Participants</th> <th>Participants Mandated Into Program</th> <th>Noncompliant, Terminated From Program</th> <th>Successfully Completed Program</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>27</td> <td>50</td> <td>3</td> <td>5</td> </tr> <tr> <td>Qtr 2</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program	Qtr 1	27	50	3	5	Qtr 2					Qtr 3					Qtr 4																				
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<p>These data are actual number of citations and letters of admonishment (LOA) issued. One investigation may have multiple licensees that are issued a citation or LOA (split cases).</p>																																										

5. Obtain immediate public protection sanctions for egregious violations.

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	0	0	2
Qtr 2			
Qtr 3			
Qtr 4			

6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.

	30 days	60 days	> 60 days	N
Qtr 1	0	0	0	0
Qtr 2				
Qtr 3				
Qtr 4				

Objective 1.3

Achieve 100 percent closure on all administrative cases within 1 year.

Measure:

Percentage of administrative cases closed within 1 year.

	N	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
Qtr 1	14	4 29%	6 48%	0 0%	3 21%	1 7%	542
Qtr 2							
Qtr 3							
Qtr 4							

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/08.																				
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.																				
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.																				
	<table border="1"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Aggregate Inspections This Cycle</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>351</td> <td>4,273</td> <td>62%</td> </tr> <tr> <td>Qtr 2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Number of Inspections	Aggregate Inspections This Cycle	Percent Complete	Qtr 1	351	4,273	62%	Qtr 2				Qtr 3				Qtr 4			
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	Qtr 1	351	4,273	62%																	
	Qtr 2																				
	Qtr 3																				
	Qtr 4																				
	* Decrease due to new licenses issued for CVS/Long's buyout.																				
	2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.																				
	<table border="1"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number Inspected Late</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>76</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td></td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> </tr> </tbody> </table>		Number of Inspections	Number Inspected Late	Qtr 1	76	0	Qtr 2			Qtr 3			Qtr 4							
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Qtr 2																					
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3. Initiate investigations based upon violations discovered during routine inspections.																					
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Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	<p>1. Monitor the implementation of e-pedigree on all prescription medications sold in California.</p> <p><i>Sept. 28, 2006: Board convenes third Workgroup on Implementation of E-Pedigree Meeting. Presentations provided by EPCglobal, McKesson, Supervising Inspector Nurse and Johnson and Johnson.</i></p> <p><i>Sept. 30, 2006: Governor signs SB 1476 which delays implementation of e-pedigree requirements until 2009, requires serialization and interoperability and notification to the board whenever counterfeit drugs are discovered.</i></p> <p><i>Oct. 6, 2006: FDA provides presentation on federal pedigree requirements at board-hosted NABP District 7 & 8 Meeting.</i></p> <p><i>Dec. 2006: Board convenes fourth Workgroup on Implementation of E-Pedigree Meeting. Presentations made by EPCglobal, McKesson, AmerisourceBergen and Cardinal. Pilot testing e-pedigree systems underway at each of the three large wholesalers. Standards for electronic pedigree to be finalized by January 2007 by EPCglobal.</i></p> <p><i>Jan. 2007: EPCglobal finalizes electronic messaging standards for electronic pedigrees.</i></p> <p><i>Feb. 2007: EPCglobal convenes regional meeting with hospitals to discuss implementation issues of e-pedigree in these facilities. Hospitals are encouraged to join the board's Workgroup on Implementation of E-Pedigree Meetings.</i></p> <p><i>March 2007: Two board members and executive staff meet with nine EPCglobal representatives to walk through EPCglobal's messaging standards and business scenarios. The standard complies with California's e-pedigree requirements although some questions remain about situation-specific criteria.</i></p> <p><i>Board convenes fifth Workgroup on Implementation of E-pedigree Meeting. Presentations are made by EPCglobal, AmerisourceBergen and SupplyScape.</i></p> <p><i>May 2007: Board presents information at the National Association of Boards of Pharmacy annual meeting on California's electronic pedigree requirements in both a poster session and a full presentation to the full assembly.</i></p> <p><i>June 2007: Board convenes sixth Workgroup on E-Pedigree Meeting, with the largest attendance of any prior meeting. Presentations were made by EPCglobal, Pfizer, Walgreens and PhRMA. Hospital pharmacies were specifically invited to attend this meeting.</i></p> <p><i>July 2007: Board hears presentations on EPCglobal standards.</i></p> <p><i>Sept. 2007: Enforcement Meeting has large audience (200 people). Presentations by PhRMA, GSK, Bracco, CPhA, EPCglobal, Walgreens, Rite Aid, CVS, rfXcel, and HDMA.</i></p> <p><i>Federal legislation enacted for the FDA supports California requirements. Major presentations made on California's standards to LogiPharma (Philadelphia) and HDMA Subcommittee of board meets with EPCglobal representatives on standards.</i></p> <p><i>Oct. 2007: Major presentations at EPCglobal Conference in Chicago. At Board Meeting, presentations made by IBM/Amerisource Bergen, Alien Technology and EPCglobal on readiness of technology.</i></p>

- Dec. 2007:* Enforcement Committee Meeting solely dedicated to Workgroup on E-Pedigree (an eight-hour meeting). Largest meeting to date involving over 400 individuals representing all members in the pharmaceutical supply chain. Board encourages discussion of grandfathering and inference, and seeks information via a template. Industry seeks delay. Many request board to specify technology. Board releases template for readiness assessment.
- Jan. 2008:* Board reviews requests for delay until 2011 from members of the pharmaceutical supply chain.
- Feb. 2008:* Questions and Answers released. Specialized area of the board's website is created to consolidate e-pedigree information.
- March 2008:* Board delays implementation date for e-pedigree requirements from January 1, 2009 until January 1, 2011.
- April 2008:* Board sponsors legislation that will enhance some of the pedigree requirements, allowing for staggered implementation, as well as provisions for regulations on inference and grandfathering.
- June 2008:* Board meets as a public meeting rather than an Enforcement Committee Meeting to hear discussions and presentations on the status of e-pedigree implementation and to discuss and review the amendments to its e-pedigree legislation, SB 1307.
- Sept. 2008:* Governor signs SB 1307, which delays implementation until 2015-2017, and makes other modifications.
- Oct. 2008:* Board convenes workgroup on e-pedigree meeting.
- March 2009:* Board convenes workgroup on e-pedigree as part of the Enforcement Committee. Presentation made by FDA, Congressman Buyer's office, GS1 and Oracle.
- April 2009:* Board submits comments to the FDA regarding nomenclature for the unique identifier.
- 2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.**
- Sept. 2006:* Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.
- Oct. 2006:* Board adds Consumer friendly materials regarding sales of these drugs to its website.
- 3. Monitor the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances.**
- Sept. 2006:* Drug Enforcement Administration releases proposed rule to allow prescribers to issue 90 days' worth of Schedule II prescriptions at one time.
- Oct. 2006:* Board considers proposed rule.
- Nov. 2006:* Board submits letter supporting change in Drug Enforcement Administration policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.
- 2nd Qtr 07/08:* Drug Enforcement Administration agrees to allow a 90-day supply of Schedule II drugs to be prescribed at one time in serial prescriptions.
- June 2008:* Drug Enforcement Administration published proposed regulations that would provide physicians and other authorized prescribers with the option of issuing electronic prescriptions for controlled substances.
- July 2008:* Board to discuss Federal Drug Enforcement Administration's proposed rule to allow e-prescribing for controlled substances at its July board meeting.
- Sept. 2008:* Board submits comments on Drug Enforcement Administration proposed requirements for e-prescribing of controlled substances.

- 4. Evaluate establishment of an ethics course as an enforcement option.**
- June 2007: Subcommittee meets with ethicist trainer for Dental Board.*
- Aug. 2007: Subcommittee meets with Medical Boards Ethics course provider (Institute for Medical Quality).*
- Oct. 2007: Institute for Medical Quality provides information to board about program; recommendation of committee is to move forward with the specialized program. Board approves development of program at board meeting.*
- Jan. 2008: Staff compile resource materials and begin steps to develop framework for program. Board agrees to establish program.*
- April 2008: Legislation/Regulation Committee to develop draft language for a regulatory proposal. Draft language for a new regulation to be presented and reviewed at July 2008 Board Meeting.*
- July 2008: Board moves ethics regulation for 45 day notice and plans action at the October Board Meeting.*
- Oct. 2008: Board holds regulation hearing on proposed requirements for the ethics class.*
- Dec. 2008: Board releases regulation for 15 day comment.*
- Jan. 2009: Board adopts regulation.*
- April 2009: Rulemaking file compiled and submitted to the Department of Consumer Affairs for review.*
- Sept. 2009: Regulation takes effect.*
- 5. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.**
- May 2007: Board staff provides presentation at National Association of Boards of Pharmacy annual meeting on California's pedigree requirements.*
- June 2007: Board works with Center for Medicare and Medicaid Services on security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.*
- Nov. 2007: Staff meets with FDA officials to discuss California's e-pedigree requirements and new federal law for FDA's action involving pharmaceutical chain security.*
- May 2008: The Executive Officer gives a poster presentation on the board's e-pedigree requirements at the annual National Associations of Boards of Pharmacy (NABP) meeting.*
- May 2008: The Executive Officer attends a drug tracking conference of manufacturers and wholesalers and presents status of California's e-pedigree efforts.*
- June 2008: Executive staff and supervising inspector provide a presentation via videoconference at the Fourth Global Forum on Pharmaceutical AntiCounterfeiting.*
- Nov. 2008: Executive Officer Herold provides information about SB 1307 to a conference of drug manufacturers and wholesalers.*
- Dec. 2008: Executive Officer Herold provides information about SB 1307 to a conference of drug manufacturers and wholesalers and at a conference on drug distribution chain security.*
- Executive Officer Herold participates on a National Association of Boards of Pharmacy Task Force on designing patient-centered labels.*
- Board President Schell participates on a National Association of Boards of Pharmacy Task Force on drug take-back programs.*

	<p>6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.</p> <p><i>Sept. 2007: Provided comments on proposed statutory requirements.</i></p> <p><i>Dec. 2007: Sought Department of Consumer Affairs' support for involvement in e-prescribing by the Administration.</i></p> <p><i>Provided comments on proposed e-prescribing initiatives.</i></p> <p>Oct. 2008: <i>Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.</i></p> <p>Nov. 2008: <i>Board hosts conference on e-prescribing as part of department's Professionals Achieving Consumer Trust Summit. The Medical Board and Dental Board join us as sponsors.</i></p> <p>Jan. 2009: <i>Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.</i></p> <p>March 2009: <i>Pharmacists and physicians in Visalia attend first of California HealthCare Foundation's public forums on e-prescribing.</i></p> <p>7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.</p> <p>June - Oct. 2007: <i>Board works with the Department of Health Care Services to implement security forms until subsequent federal legislation delays implementation until April 2008.</i></p> <p>Dec. 2007: <i>Meeting with Department of Health Care Services on issues involving security forms for MediCal prescriptions.</i></p> <p>April 1, 2008: <i>Requirements that all written prescriptions for MediCal prescriptions be written on security forms containing at least one specified security component takes effect.</i></p> <p>April 2008: <i>Subscriber alert released with information for contact resources from the California Department of Health Care Services about security forms for MediCal prescriptions.</i></p> <p>Oct. 2008: <i>Requirements for security forms in place.</i></p>
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	<p>8. Liaison with other state and federal agencies to achieve consumer protection.</p> <p>1st Qtr 07/08: <i>Bimonthly meetings initiated with Department of Health Care Services audit staff to investigate pharmacies and pharmacists involved in MediCal fraud and drug diversion. Several joint investigations underway with state and federal agencies.</i></p> <p>2nd Qtr 07/08: <i>Bimonthly meeting with the Department of Health Care Services continue. Board inspectors attend 3-day-training with federal and state regulations on items involving fraud provided by the Office of Inspector General of the Department of Health and Human Services. Joint investigations with other state and federal agencies continue that involve the board's jurisdiction.</i></p> <p>3rd Qtr 07/08: <i>Bimonthly meetings with the Department of Health Care Services continue. Board works with the Drug Enforcement Administration on joint investigations and receives specialized training.</i></p> <p>4th Qtr 07/08: <i>Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.</i></p> <p>3rd Qtr 08/09: <i>Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.</i></p> <p>4th Qtr 08/09: <i>Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs. Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations. The federal Drug Enforcement Administration provides training to board staff on new requirements for online pharmacies selling controlled substances.</i></p>
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9. **Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public.**
- March 2008:* Second meeting with state agency stakeholders on developing components for model programs that conform with diverse state agency security and safety requirements.
- June 2008:* Supervising pharmacist inspector attended a two-day multi-disciplinary conference hosted by the Integrated Waste Management Board on drug take-back programs.
- Aug. 2008:* Executive Officer Herold speaks at conferences sponsored by the California Integrated Waste Management Board.
- Oct. 2008:* Enforcement Committee hears presentations on drug take-back programs, medical waste management processes and the take-back of sharps. Board to submit comments to California Integrated Waste Management Board on model programs for take-back programs.
- Nov. 2008:* Executive Officer provides written and verbal testimony at California Integrated Waste Management Board hearing on the model guidelines.
- Dec. 2008:* Executive Officer participates in public hearing at the California Integrated Waste Management Board on possible changes to the model guidelines adopted by the California Integrated Waste Management Board in November.
- Feb. 2009:* California Integrated Waste Management Board amends model guidelines to include provisions advanced by the board.
- Jul. 2009:* Board publishes guidelines in The Script. Mail return processes reviewed by the board.
10. **Inspect California hospitals to ensure recalled heparin has been removed from patient care areas.**
- 4th Qtr 07/08:* Board initiates inspections of 40 California hospitals looking for counterfeit heparin and unlicensed sales but discovers recalled heparin still in 40 percent of hospitals inspected. Board notifies the Food and Drug Administration and California Department of Public Health and initiates inspections of 533 hospitals during April-June. Recalled heparin is found in 94 of these facilities. Data reported to board during June Board Meeting.
- 1st Qtr 08/09:* The Script highlights problems found in heparin inspections. Citations and fines issued to facilities with recalled heparin. Work with hospitals begins to strengthen drug control within facilities.
- 2nd Qtr 08/09:* Hospitals and Pharmacists-in-Charge fined where recalled heparin was discovered by the board.
- 3rd Qtr 08/09:* First stakeholder meeting scheduled to discuss drug distribution within hospitals.
- March 2009:* First stakeholder meeting convened.
- June 2009:* Second stakeholder meeting convened. Development of model guidelines for recalls underway.
- Sept. 2009:* Stakeholder meeting convened. Recall guidelines evaluated and additional comments solicited.
- 1st Qtr 09/10:* Draft proposals for required components 7-13 developed

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| | <ol style="list-style-type: none">11. Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards.
<i>4th Qtr 08/09: Draft proposals for required components 1-6 developed.</i>12. Develop and release Request for Proposal for vendor for Department of Consumer Affairs health care boards that operate license recovery programs.
<i>4th Qtr 08/09: Provisions for Request for Proposal developed: Request for Proposal released.</i> |
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Attachment A

Minutes of the September 16, 2009 Enforcement Committee Meeting



California State Board of Pharmacy
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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE
MINUTES**

DATE: September 16, 2009

LOCATION: Samuel Greenberg Board Meeting Room
Los Angeles International Airport
1 World Way
Los Angeles, CA 90045

COMMITTEE MEMBERS

PRESENT: Robert Swart, PharmD, Chair
Ramón Castellblanch, Public Member
Randy Kajioka, PharmD
Greg Lippe, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Kristy Schieldge, DCA Staff Counsel (via conference call)
Tessa Fraga, Staff Analyst

Call to Order

Chair Swart called the meeting to order at 9:30a.m.

1. Overview of Proposals to Strengthen the Enforcement Programs of the Health Care Boards of the Department of Consumer Affairs

Chair Swart provided that over the prior nine months, the Department of Consumer Affairs (DCA) has initiated a number of proposals aimed at strengthening the enforcement activities of the health care boards. He stated that the Board of Pharmacy is one of these agencies.

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

Chair Swart provided that the first major change was prioritization of fingerprinting of all licensees. He stated 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. Chair Swart explained that it also enables boards to obtain "subsequent" arrest and conviction information if a licensee is arrested or convicted in California.

Chair Swart provided that the board 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.) for years. He stated 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. Chair Swart indicated that other boards only began fingerprinting applicants in the late 1980s and later. He explained that as a result, knowledge about serious criminal convictions involving licenses substantially related to their professional practices may not reach the licensing board and these individuals are allowed to remain in practice, risking patient safety.

Chair 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 have dramatically increased, and has exceeded the board's ability to respond timely to these cases. Chair Swart explained that as a result, the board submitted a budget change proposal early this year to ensure that it can immediately review and investigate reports of criminal convictions and arrests. He indicated that the board received 6.5 new positions effective July 1, 2009. Chair Swart stated that the last two of these positions will be filled by mid-September.

Chair 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 stated 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. Chair Swart advised that this delayed investigations. He explained that additionally the time it takes to secure complete work by the Attorney General's Office and Office of Administrative Hearings further added delays.

Chair 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.

Chair Swart provided that concurrently, 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. Chair Swart indicated that the goal is 12-18 months – a very aggressive standard, but on that the public deserves.

Chair Swart provided that the committee will have a number of discussions about the board's enforcement program. He stated that whereas the board's timelines are better than the BRNs, they are not 12-18 months for most formal discipline. Chair Swart indicated that the board needs to retool its program. He advised that the board will also need additional staff. Chair Swart indicated that as such, staff is now working on budget change proposals to augment staff so we can reach this standard.

Chair Swart provided that a joint legislative proposal, Senate Bill (SB) 294 was amended ("gutted and amended" in the parlance of the Legislature) last week that carries some of the Administration's and Senate's proposals for improving DCA's enforcement programs. He advised that the Legislative Session ended for the year on September 11, 2009.

Executive Officer Virginia Herold provided an overview of the board's enforcement program. She advised that the board will retool its program and add additional staff in order to improve the timeline for closures of formal discipline cases.

Presentation to the Committee

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.

Ms. Sodergren reviewed the current processing times for the three types of investigations including criminal conviction investigations (150-290 days), "simple" field investigations (125-200 days), and "complex" field investigations (220-390 days). She highlighted the current processing time for final dispositions based on closure type as well as the current processing time for formal discipline.

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

Ms. Sodergren provided that the board is working to identify internal improvements. She stated that these improvements include a reduction in time for the following: routing of complaints on-line, routing of draft pleadings on-line, on-line mail ballots, and the in house preparation of default decisions.

Committee Discussion

Chair Swart expressed concern about staff workload and staffing requirements in the event of a large case such as the Heparin case.

Ms. Sodergren provided that a staff augmentation would be required. She explained that a redirection of staff is needed when dealing with a public health threat.

Ms. Herold confirmed that the board would have to absorb the added workload by redirecting existing staff. She reviewed the board's current enforcement staff and their existing workload and timeframes.

Ramón Castellblanch questioned if any concern has been expressed by pharmacist organizations regarding the shortening of the timelines.

Ms. Sodergren provided that SB 294 was "gutted and amended" at the end of the legislative session and became a two-year bill. She explained that consequently, there probably has not been enough time for stakeholder groups to get involved and express their concerns.

Ms. Herold provided that stakeholder groups will have the opportunity to express their concerns. She stated that most of the board's convictions and related arrests are for DUIs. She reviewed the board's Pharmacists Recovery Program (PRP) and the requirements for PRP participants. Ms. Herold explained that the board utilizes the PRP as a monitoring program while continuing to discipline the licensee. She indicated that the Senate has set a sunset date for all diversion programs and will be evaluating the PRP.

Ms. Herold emphasized that a staff augmentation is needed in order to fulfill the board's obligations given the significant growth and increase in enforcement demands.

Randy Kajjoka asked if any of the pharmacists and technician advocacy groups have challenged the burden of proof clause within the bill.

Ms. Herold provided that board staff met with the Chief Administrative Officer of the Office of Administrative Hearings who commented that the difference between the clear and convincing evidence standard and the preponderance standard in disciplinary cases involving licensees is minor.

Kristy Schieldge, DCA Staff Legal Counsel, provided that this is a legal issue that needs increased scrutiny. She stated that the standing legal standard for administrative licensing cases is clear and convincing evidence. Ms. Schieldge indicated that this standard is typically a higher standard for the board to meet.

Dr. Kajioka sought clarification regarding random drug testing policies and the requirement for a licensee to comply with testing if a complaint has been filed.

Ms. Herold reviewed the process for the regulator making the demand versus the employer making the demand. She stated that the board's PRP participants are pulled from practice if they test positive.

Ms. Herold provided that the board and its executive officers will continue to work with the Department.

Chair Swart provided that the board is in a good position to comply with DCA's new enforcement model and to make improvements.

There was no additional committee discussion.

Public Comment

No public comment was provided.

2. Proposed Regulation to Require Notification to the Board About Prior Convictions of Pharmacists at Time of Renewal

Chair Swart provided that the Administration has been advocating that all health boards within the Department implement a plan for securing fingerprints from all licensees regardless of when they were first licensed as well as requiring licensees at time of renewal to certify that they have not been arrested for or convicted of any crime within the renewal period (two years). He stated that this information augments the information received from the courts. Chair Swart advised that this board does not have such a requirement.

Chair Swart provided that in 2001, the Department of Justice (DOJ) began transitioning to electronic submission of fingerprints, LiveScan. He indicated that fingerprint background information collected since that time is stored electronically. Chair Swart stated that pre-existing fingerprint information was not converted into this electronic format. He provided that given that full conversion of previous records is unlikely to occur, the committee should consider a recommendation to require pharmacist licensees to resubmit fingerprints as a condition of renewal.

Chair Swart provided that there was proposed legislation earlier this year authored by Senator Negrete-McLeod that would have established this requirement for departmental licensees. (The board had a support position on this bill.) He advised that the bill was stalled in a policy committee over issues involving the Contractors State License Board.

Chair Swart provided that staff proposes adding these requirements to pharmacists initially. He explained that to do this would require legislation or regulation. Chair Swart stated that staff proposes a regulation. He advised that after a two year implementation period for pharmacists, board staff recommend that the board consider imposing a similar requirement on designated representatives and pharmacy technicians.

Committee Discussion

Chair Swart sought clarification regarding the benefit for starting this process with pharmacists as opposed to technicians.

Ms. Herold explained that the pharmacist is the more influential individual. She provided that in order to update fingerprint information prior to 2001 that has not been converted into the electronic format, the board has proposed that pharmacists certify at the time of renewal that they have electronically submitted their fingerprints. Ms. Herold stated that this will apply to about 35,000 licensees over a two-year period. She indicated that the process has been divided between pharmacists and technicians in order to manage the workload.

Chair Swart suggested that the board review this process in one year to evaluate if the process can be accelerated.

The committee further discussed the fingerprint process and the availability of LiveScan.

Ms. Sodergren provided that DCA is working with DOJ to create an interface to link the LiveScan results with the licensee's records. She reviewed potential delays that may impact staff workload including rejected fingerprints and input errors.

Ms. Herold provided that the submissions will be audited.

Public Comment

No public comment was provided.

MOTION: To recommend to the board that it consider moving forward with the regulation.

M/S: Lippe/Swart

Support: 4 Oppose: 0

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

Chair Swart provided that the board has received a request from the LA County Department of Health Services seeking the ability for pharmacies serving medically indigent patients to better use the benefits of drug manufacturers' patient assistance programs.

Chair Swart provided that Dr. Amy Gutierrez, Director of Pharmacy Affairs with LA County Department of Health Services, has asked for this meeting to address an issue involving patient assistance programs.

Chair Swart provided that Dr. Gutierrez' wants to make it easier to:

1. identify and qualify patients for these programs, and
2. create a mechanism so that its pharmacies can provide these medications to patients from a pharmacy's stock immediately upon qualification, and then replace the stock when the dispensing pharmacy receives the patient assistance medication from the contracted pharmacy.

Presentation to the Committee

Dr. Amy Gutierrez provided an overview of the LA County Department of Health Services and the uninsured population that it serves. She stated that Los Angeles County has contracted with Cardinal Health to facilitate the enrollment of qualified patients in manufacturers' patient assistance programs. Dr. Gutierrez indicated that since January 2008, LA County believes it has recouped \$2 m in drug value from its participation in these programs.

Dr. Gutierrez suggested the following:

1. allow LA County pharmacy to accept these medications, dispensed directly from another pharmacy, and placing the medications onto a specially designated shelf, which will be dispensed at the patient's next pharmacy visit. An LA County pharmacy prescription label would be affixed to the medication container, in keeping with Business and Professions Code section 4052.7.
2. allow the pharmacy to receive the medication from the mail order pharmacy, and mailing out directly to the patient at the last known address. This is less optimal, as some of their uninsured patients do not always have reliable addresses.

Dr. Gutierrez sought clarification regarding whether a licensed California pharmacy can place the content of the medication container that was issued by another licensed pharmacy (e.g., Medco mail order) to a patient back into stock, provided that the medication was never handled by anyone other than the two pharmacies.

Dr. Gutierrez provided that an estimated \$8 m could be recouped per year if the suggested allowances are permitted.

Committee Discussion

Chair Swart asked if Medco has expressed any concern regarding their role with this process.

Dr. Gutierrez provided that the shipment provided by Medco is typically a replacement for medication that has already been dispensed. She indicated that medications are marked if they have been recovered and are then used for a different patient who qualifies for the program.

Dr. Kajioka expressed concern regarding contractual issues and whether the program requires that the manufacturer provide a patient specific label.

Dr. Gutierrez provided that manufacturers typically will not take back a drug with a patient specific label that was not claimed by the patient. She stated that these drugs are to be discarded or used for another patient that qualifies for the program.

Carolyn Brown, representing Cardinal Health, provided that patient assistance programs have been setup with the intent for patients to receive their medications in a timely manner.

Ms. Herold provided that the board would like to assist LA County with the requested allowances and will need to consult with its legal counsel on this issue. She indicated that the board will try to have a decision by the October Board Meeting.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, offered support for this request. He requested that Kaiser be involved to address this issue in a broader context.

Ms. Herold asked how likely it would be to have manufacturer participation.

Dr. Gray provided that, based on his opinion, manufacturers would be very interested. He commended manufacturers for their efforts in developing these programs. Dr. Gray provided an overview of the central fill system.

Ms. Herold provided that Health and Safety Code Section 150204 excludes controlled drugs.

Dr. Gutierrez provided that one record for each patient is essential for patient safety and to avoid duplicate therapy. She advised that without the requested allowances, pharmacies will have to shut down and patient care will be impacted.

There was no additional committee or public comment.

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

Chair Swart provided that Daiichi Sankyo has requested an opportunity to address the board on the use of third party logistics providers (called "3PLs").

Chair Swart provided that third party logistic providers are defined in California Business and Professions Code as:

4045. Third-Party Logistics Provider or Reverse Third-Party Logistics Provider

"Third-party logistics provider" or "reverse third-party logistic provider" means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.

Chair Swart provided that the board does not differentiate the various type of wholesaler licenses it issues (reverse distributors, wholesalers, 3PLs), so it is not known specifically how many 3PLs are licensed with the board.

Presentation to the Committee

Dean Marioccia, representing Daiichi Sankyo Inc., thanked the board for the opportunity to educate the board on the third party logistics providers process. He introduced Kristie Breed (Daiichi Sankyo Inc.) and Robert Brown (Cardinal Health - Specialty Pharmaceutical Services).

Kristie Breed, representing Daiichi Sankyo Inc., provided an overview of Daiichi Sankyo Inc. and reviewed the company's supply chain. She advised that Daiichi Sankyo owns and is responsible for products that are at the 3PL. Ms. Breed indicated that the product belongs to the customer when it is picked up from the carrier. She stated that Daiichi Sankyo will aid the customer with an investigation in the event of drug theft during transit.

Robert Brown, representing Cardinal Health - Specialty Pharmaceutical Services, provided an overview of Specialty Pharmaceutical Services and the 3PL process. He stated that the 3PL provides quality assurance, regulatory support, and inventory visibility in real-time. Mr. Brown indicated that the contract packager, Daiichi Sankyo, and Specialty Pharmaceutical Services comply with all FDA and state/federal laws.

Committee Discussion

Chair Swart asked who transports during inbound receiving.

Mr. Brown provided that inbound receiving is generally transported by a common carrier and is coordinated by the shipper.

Chair Swart sought clarification regarding whether the wholesaler pays the manufacturer or the 3PL.

Mr. Brown provided that the wholesaler pays the manufacturer.

Mr. Brown extended an open invitation to the board to visit the 3PL operation in Reno, Nevada.

Ms. Herold provided that the board would need out-of-state clearance before making a visit.

Mr. Brown explained the difference between "freight on board origin" terms and conditions and "freight on board destination" terms and conditions. He provided that Daiichi Sankyo specifies "freight on board origin" terms and conditions with its downstream customers. Mr. Brown stated that the carrier assumes the risk of loss during transit.

Ms. Herold expressed concern with the increasing thefts from common carriers.

Public Comment

Ellis Ellis sought clarification regarding other customers of Daiichi Sankyo. Mr. Brown provided that from a 3PL perspective, the customer is dependent on who the manufacturer considers as their customer. He stated that the 3PL will ship to any customer with a valid California license.

Ms. Breed provided that Daiichi Sankyo does not work at the pharmacy level. She stated that they ship around 90% of their product to wholesale customers.

Mr. Ellis asked if the customer can see the inventory electronically.

Mr. Brown provided that the customer can not see the inventory while it is in the 3PL warehouses.

Discussion continued regarding inventory control.

There was no additional committee or public comment.

5. 2008 Report of the Research Advisory Panel of California

Chair 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.

Chair Swart provided that pages 39 – 42 of this report provide the statutory mandate of the panel. He stated that the Board of Pharmacy has one representative on this panel – Dr. Peter Koo of UCSF.

No committee or public comment was provided.

6. 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

Chair Swart provided that SB 1441 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 must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.

Chair Swart provided that this committee is subject to Bagley-Keene Open Meeting Act and is comprised of executive officers and bureau chiefs from specified boards and bureaus.

Chair Swart provided that given the timeline to develop these standards, earlier this year, 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. Chair Swart indicated that the recommended standards are then vetted during a Uniform Standards Workshop, a public meeting akin to an informational hearing. He explained that the draft standards are then presented during a public meeting to the SACC for consideration and action.

Chair Swart provided that to date the SACC committee has met three times, most recently on September 1, 2009. He stated that during the meeting, the committee discussed the proposed uniform standards 7 – 12 as well as minor changes to standards previously considered by the committee. Chair Swart indicated that the next meeting of this committee is scheduled for September 30, 2009. He advised that additional SACC meetings are scheduled for:

- September 30, 2009
- November 16, 2009
- December 15, 2009

Chair Swart provided that there continue to be questions surrounding how each board will be required to implement these uniform standards, especially given that each board has separate statutory authority. He advised that the DCA legal office will be providing guidance on implementation issues as necessary.

Committee Discussion

Ms. Herold provided that goal of the SACC committee is to establish minimum standards for diversion programs to enhance consumer protection. She provided background on the formulation and the intent of the committee. Ms. Herold provided that the board's program has strong standards in place and will easily adhere to the new minimum standards.

Mr. Lippe asked if the board has designated a Diversion Program Manager for the Pharmacists Recovery Program (PRP).

Ms. Herold provided that in addition to the PRP inspector team, the board has two liaisons, Supervising Inspector Joan Coyne and Analyst Tessa Fraga, who work closely with the program's contractor to monitor the participants. She indicated that the PRP will be audited and the report will be publically released upon completion.

There was no additional committee discussion.

Public Comment

No public comment was provided.

7. Ongoing Discussion and Presentations About Prevention of Medication Errors

Chair Swart provided that recently Consumers Union published an update of the 1999 Institute of Medicine report of "To Error is Human- to Delay is Deadly," documenting the large number of medication errors in hospitals, where as many as 98,000 people die annually, needlessly, due to preventable errors.

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

Chair Swart provided that California regulators have initiated action based on the initial IOM report. 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. He stated that this is a standard component checked during all board inspections of pharmacies.

Chair Swart provided that according to preliminary data from 2008-09, about 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.

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

Chair Swart provided that the report is provided for review and possible future action by the board.

Committee Discussion

Dr. Kajioka noted the distinction between medical errors and medication errors.

Chair Swart provided that report did not address the proportion of the amount of patients receiving treatment and the number of prescriptions that have been filled in the last 10 years.

There was no additional committee discussion.

Public Comment

No public comment provided.

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

Chair 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 had 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.

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

Chair 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, the board needs to decide if it wishes to form a subcommittee to work with senior board staff in developing the program, or

whether it wishes for staff to develop the program and bring the completed product to the board.

Chair Swart provided that the next steps are to pull administrative discipline files where the violation, in part, had an ethical component (e.g., fraud, dispensing medicine without a prescription), and work with a course provider in establishing the parameters.

Chair Swart provided that the board hopes to have the course ready for administration at the end of the year.

Committee Discussion

Ms. Herold asked if the committee would like to be involved with the development of the course.

Chair Swart indicated that the subcommittee would like to be involved in the development of the course.

Chair Swart provided that Board President Schell can appoint a new member to the subcommittee as one member has resigned from the board.

There was no additional committee discussion.

Public Comment

No public comment was provided.

9. Public Comment for Items Not on the Agenda

Ellis Ellis discussed recent changes to California law regarding controlled substances. He stated that pharmacists at the hospital level are required to sign for ephedrine. Mr. Ellis asked how the state would like to control this issue.

Ms. Schieldge provided that the committee will not discuss this issue.

The meeting was adjourned at 11:48 a.m.

Third-Party Logistics Providers (3PL's): An Overview

California Board of Pharmacy
Enforcement Committee Meeting
September 16, 2009

Presented by:
Kristie Breed – Daiichi Sankyo Inc. (DSI)
Robert Brown – Specialty Pharmaceutical Services (SPS)



Agenda

- **Daiichi Sankyo (DSI)**
- **Specialty Pharmaceutical Services (SPS)**
 - **Third-Party Logistics (3PL) Overview**
- **Q & A**



Company Overview - DSI

- Daiichi Sankyo is a century-old pharmaceutical innovator – established in Japan in 1899 - one of the top 25 pharmaceutical companies in the world; with 16,250 employees worldwide

- In 1996, we formed a joint venture with the Parke-Davis division of Warner-Lambert to create a U.S. commercial organization; in 2001, we dissolved the joint venture and have grown to become an independent, fully integrated pharmaceutical company

- Daiichi Sankyo, Inc. (DSI) was established in April of 2006 as the U.S. subsidiary of Japanese pharmaceutical company Daiichi Sankyo Co., Ltd.; with 2,800 U.S. employees

- Headquartered in Parsippany, New Jersey, the company's strategic focus is on cardiovascular diseases

- DSI is licensed in California as a Drug Wholesaler

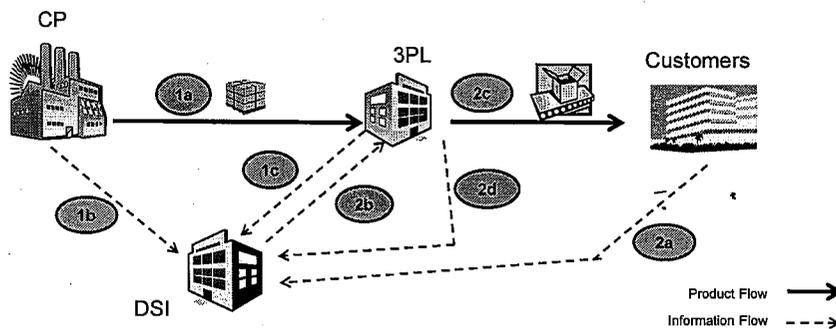
Daiichi Sankyo's Product Lines



For more information, visit www.dsi.com



DSI's Supply Chain

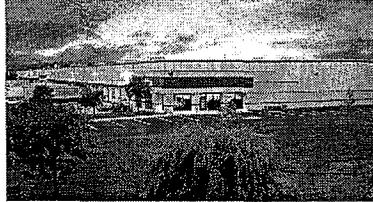


- 1a. Contract Packager (CP) packages and ships product to 3PL
- 1b. CP transmits lot/shipment information to DSI
- 1c. 3PL transmits receiving information to DSI
- 2a. Customers transmit orders to DSI via EDI
- 2b. DSI transmits orders to 3PL for fulfillment
- 2c. 3PL picks, packs and ships orders to customers
- 2d. 3PL transmits product shipment and goods movement information to DSI



Company Overview - SPS

- Founded in 1995 by Cardinal Health specifically to meet the growing and unique needs of the healthcare industry
 - Operates as an independent entity from Cardinal wholesaling business
- Licensed as a wholesale distributor in CA
- Industry leader in third-party healthcare logistics
- Programs are customized for each individual Client (Manufacturer) using the model that best meets their needs



LaVergne, TN, Distribution Center



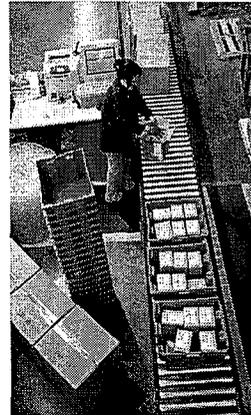
Reno, NV, Distribution Center



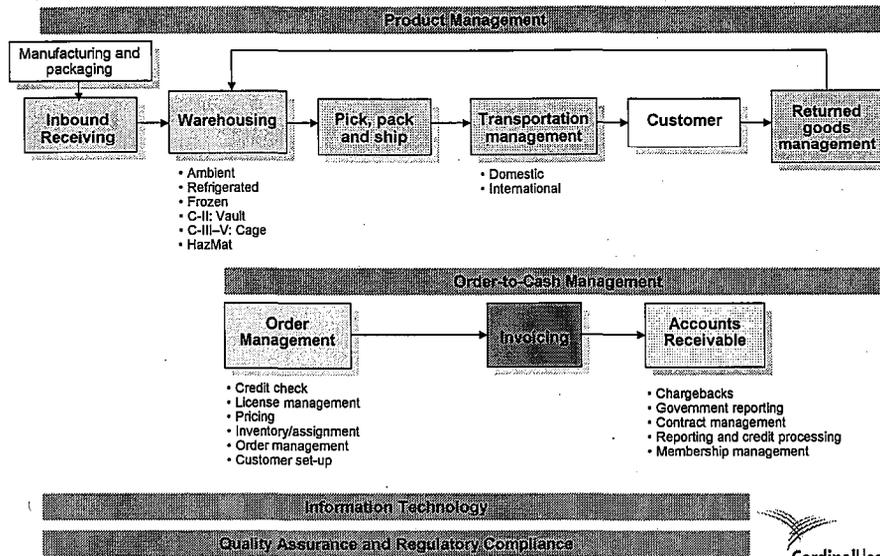
Third-Party Logistics Background

Bus. & Prof. Code §4045: Third-Party Logistics Provider or Reverse Third-Party Logistics Provider

"Third-party logistics provider" or "reverse third-party logistic provider" means an entity *licensed as a wholesaler* that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is *no change of ownership* in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers. (*Emphasis added*).



Third-Party Logistics Services



Third-Party Logistics Summary

- DSI retains ownership of product entering 3PL until it is sold to customers
- 3PL provides Quality Assurance & Regulatory support, and inventory visibility in real-time
- CP/DSI/SPS all comply with FDA and state/federal laws

Third-Party Logistics Providers (3PL's): An Overview

- Questions???
- Thank you