

# Attachment 3

*Testimony on Health Practitioners  
Substance Abuse Programs*



**California State Board of Pharmacy**

1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834  
Phone (916) 574-7900  
Fax (916) 574-8618  
www.pharmacy.ca.gov

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

March 12, 2008

The Honorable Mark Ridley-Thomas  
Chair, Senate Business, Professions and  
Economic Development Committee  
California State Senate  
State Capitol, Room 2053  
Sacramento, CA 95814

Dear Senator Ridley-Thomas

Provided below are the Board of Pharmacy's responses to your questions regarding the board's Pharmacist Recovery Program.

Before I provide the board's responses, I want to emphasize that the Pharmacists Recovery Program is considered a valuable enforcement option for the board. For this board, the program is not a diversion program. Instead, discipline continues while the board achieves immediate public protection because the program closely oversees the participants in a manner that the board could not do even when licensees are on probation. Where pursuit of discipline is not possible because of lack of evidence or substantial enough violation that would warrant discipline, the board will refer individuals to the program in lieu of discipline. And lastly, individuals can enter the program unknown to the board to initiate and seek treatment.

1. *What type of clinical diagnostic evaluation does the impaired health care providers receive?*

The board's Pharmacist Recovery Program (PRP) is just that, a recovery program designed to allow a California-licensed pharmacist or pharmacist intern to achieve recovery without compromising public safety. To achieve this goal, the board requires a clinical diagnostic evaluation on every participant as part of their initial enrollment into the PRP. The current contract with Maximus details the parameters of this evaluation, and specifies that it must be conducted by a licensed practitioner. This evaluation is one element used to develop the initial treatment contract.

According to the contract, all pharmacists/interns entering the PRP will be evaluated by:

- a licensed registered nurse with experience in chemical dependency or mental illness,
- a certified alcohol and drug consultant, and/or
- a licensed clinician qualified and experienced in chemical dependency evaluation and treatment.

Assessment of an applicant includes an in-take evaluation that is conducted over the telephone and then a comprehensive face-to-face evaluation occurs with a licensed clinician assessor.

The initial in-take evaluation is conducted telephonically within 10 business days of application to the program by a clinical case manager who will collect pertinent and demographic data on the applicant, chemical use, last usage, medical history, physician and prescription information, employment history, any previously attended treatment programs, 12-step recovery participation and all relevant information necessary to determine the need for clinical intervention.

A clinical assessor then conducts an in-person assessment of each applicant within 30 days of application. The assessments are conducted in accordance with acceptable practice standards for chemical dependency and mental health assessments and are conducted by licensed clinicians experienced in chemical dependency, mental illness or both.

2. *How is the decision made to refer the health care provider into the diversion program?*

A self-referral gets into the program voluntarily. About one third of our participants are voluntary referrals to the program. The board sought a statutory change a few years ago that authorizes the board to review these cases, but in general, self-referrals are managed by the contractor as defined in the scope of the contract agreement. The board does, on a limited basis use an "in-lieu of " referral, but only for lesser violations where disciplinary action would likely not be pursuable.

The majority of the board's referrals into the program are disciplinary, and ultimately, the participant is required to participate in the program as a result of either a stipulated agreement or discipline imposed by an administrative law judge and later ratified by the board. Often licensees, recognizing that the board is going to continue to pursue discipline against them, join the PRP before being mandated into the program by a stipulation or decision.

A licensee's voluntary participation in the PRP is a factor in deciding an appropriate disciplinary penalty to include mandatory participation and successful completion of the program as a term of probation. If participation is required as a condition of a disciplinary settlement, a board-referred participant is required to enroll in the program and remain in compliance with the requirements of the program as mandatory conditions. If not, a petition to revoke probation is pursued.

3. *Who pays for participation in the program? Are any costs paid by the Board by licensee fees?*

A pharmacist or intern participating in the PRP is required to pay a monthly administrative fee to offset the PRP program costs incurred by the board. This fee is currently \$75 to participants. The \$75 fee is deducted from the \$250 monthly fee per participant charged to the board by the contractor. In rare hardship cases, the board will pay for the full \$250 monthly administrative costs of an individual's PRP costs.

The board's source of revenue for this program comes almost exclusively from renewal fees of the board's licensees: about 70 percent of board operations are funded by renewal fees. (All application processing and review functions are funded by application fees that are assessed at the level required to provide the service.)

In addition, PRP participants are fully responsible for the cost of random body fluid testing, inpatient or outpatient treatment, attendance at health support group meetings, and any other treatment contract requirements that have a cost associated with them.

4. *Describe when a referral into the diversion program would be confidential and when it would not be.*

Licensees who voluntarily seek admission into the program are confidential referrals and enter into the program without the knowledge of the board. This also includes those for whom the board will not pursue discipline (called "in lieu of" participants). However, the contractor must report self-referrals to the board's program manager if the contractor determines that the licensee poses a threat to the health and safety of the public. (B & P Code section 4362(b)) .

A board-referred participant who enters the PRP as a condition of probation is not confidential. The participant's records, progress and status in the PRP are available to the board. However, any participant's records are not available to the public pursuant to B & Professions Code section 4372.

5. *What types of practice restrictions are placed on the health care provider during their evaluation and during participation in the diversion program and when may they return to practice?*

Either during the initial in-take and assessment process or also during participation in the program, a participant's contract requirements may include: a 100 percent restriction from the practice of pharmacy, reduced work hours, restrictions on the type of pharmacy practice setting, levels of supervised practice required, identification of work site monitor, or no access to controlled substances. Work restrictions are also placed on participants as a result of in-patient hospital stays, aftercare programs, relapses and other critical non-compliance with the treatment contract.

Practice restrictions differ during both the evaluation phase and participation phase. Some restrictions are mandated as part of the terms and conditions of probation that are imposed. Practice restrictions differ to meet the individual needs of each participant while balancing consumer protection. For example, a probation referral is mandated into the program. If a participant is able to document sobriety for a significant period of time as well as demonstrated recovery, it is neither in the best interest of the participant, nor is it enhancing public protection to automatically suspend such an individual from practice since he or she may be two years into recovery at this point.

6. *Who is responsible for worksite monitoring and observation of the impaired licensee?*

A pharmacist, who is in a supervisory capacity or at least one management step above the PRP participant, will be identified as a work site monitor and must be approved by the board. The work site monitor must be aware of the PRP contract and provide regular assessment of the participant's work performance to the clinical case manager. For board-referred participants, the worksite monitors' reports are provided to the board's PRP program manager.

The work site monitor must have overlapping work hours as specified by the individual treatment contract.

A participant is also required to attend health support group meetings. The health support group facilitator observes the participant's behavior and participation in-group, and reports to the clinical case manager monthly on the participant's progress within the group. The clinical case manager meets monthly with the board's PRP program manager to review all aspects of the participant's compliance with recovery terms.

All board-mandated participants in the program as a result of a board decision are also subject to random inspections by board inspectors (probation monitoring). As part of these random inspections, board inspectors speak with the work site monitor. The board's pharmacist inspectors monitor participants' compliance with the PRP program requirements and compliance with disciplinary probationary terms and conditions. Board inspectors conduct face-to-face interviews of these participants at the worksite to ascertain compliance and to observe behavior. These interviews are conducted monthly for the first six months and then on a quarterly basis thereafter.

7. *What are the requirements of drug testing including the frequency of testing and the methods used for testing?*

The contract details the random drug testing requirements. The board does not have a set number of tests detailed in either the contract or regulation because a participant's progress in the program drives the appropriate frequency. Typically participants in the program have testing frequencies of at least 18 per year, but most

participants are required to provide closer to 24 – 36 per year, depending on where a participant is in his or her recovery program. Sometimes even more frequent testing may be required. These drug screens are used to confirm abstinence from prohibited substances.

The participant is required to call the drug-testing vendor every day in order to determine if he or she is required to test that day. The clinical case manager and board's program manager may order additional drug tests as appropriate. Back-to-back tests are also ordered periodically, to ensure abstinence.

The contractor is required to ensure qualitative urine substance abuse tests that conform to current drug testing standards from the National Institute for Drug Abuse and the Department of Transportation. Observed and unobserved urine testing as well as other drug testing techniques are also used (e.g., hair, sweat, saliva, blood).

8. *What action is taken by the board if test results are positive and there is a relapse?*

For confirmed relapse episodes with confirmed positive body fluid results, the contractor will immediately contact the participant, and if practicing, immediately suspend his or her practice and then notify, within 24 hours, the board's program manager who will issue instructions for further action. Participants typically suspended from practice are also subject to "90 meetings in 90 days" or completion of an aftercare or residential treatment program. Relapse restrictions typically also include an increase in the frequency of drug testing and sometimes counseling sessions.

In some cases of relapse, the board has been successful in negotiating the automatic revocation of a license for confirmed positive drug screens.

9. *When and under what circumstances would the health provider be terminated from the program?*

Participants are immediately terminated from the program if they are deemed a public risk, but can also be terminated from the program if they are unable to sustain recovery or are unable to successfully complete the PRP.

In accordance with B&P Code section 4369, a participant can be terminated from the program for any failure to comply with the treatment contract, if a determination is made that the participant is failing to derive benefit from the program. Other non-compliance with the requirements of the pharmacists recovery program may also result in the termination of the pharmacist's or intern pharmacist's participation in the pharmacists recovery program.

For any termination resulting from non-compliance that is not deemed a public risk, the contractor must provide an in-depth written analysis and justification for the participant's unsuccessful completion.

The contract with the vendor details how non-compliance is to be reported. However, positive drug screens must be reported to the board within 24 hours of receipt as well as any determination by the contractor that a participant poses a threat to the public.

The board reports statistics quarterly during public meeting materials on participants in the recovery program, including the number and type of referrals, the number of treatment contracts reviewed as well as the number of closures in the program. It is difficult to state how the board reports success in the program. For example, termination from the program may not be considered a success by the participant who is unable to maintain sobriety, but could be viewed as a success for consumers.

10. How is non-compliance in the diversion program reported to the board?

When a participant is in non-compliance and poses an immediate public risk, the clinical case manager communicates to the diversion program manager via e-mail or telephonically.

For incidents of non-compliance not posing a public threat and where the participant is not immediately removed from practice, the contractor notifies the participant at the time that the non-compliance has been documented and explains the ramifications of the non-compliance to the participant. Continued non-compliance will result in a letter of concern to the participant detailing all areas of non-compliance and the corrective action that must be taken. During this process, the board's program manager is continually informed via e-mail or telephonically of the participant's non-compliance. If non-compliance is not addressed and corrected within 30 days, the participant will be reassessed by the contractor and the board's diversion program manager. This may result in modifications to the rehabilitation plan and contract, or possible termination from the program.

The contractor also provides written reports to the board's program manager for monthly pharmacy review committee (PRC) meetings. This report, known as a History and Profile report must include a compliance summary, drug screen results and case notes for the previous six months.

11. *How is success in the diversion program measured?*

PRP participation is usually a two to five year commitment. The average length of time for chemical dependency is three years. The mandatory length of participation is one year. A transition phase allows the participant the opportunity to be responsible for their own recovery while still enrolled in the PRP.

During the transition phase, all limitations on the licensee's practice and all requirements of the PRP will be removed with the exception of the minimum monitoring to reasonably assure public safety, random body fluid monitoring,

monthly work site monitor reports, monthly self-reports and any specialized probation requirements.

12. *Have there been standards or regulations adopted regarding the following:*

➤ *Requirements for clinical diagnostic evaluation.*

The contract requires that participants are evaluated by a clinical case manager who holds a license in California as a registered nurse, marriage family therapist, licensed clinical social worker, psychologist or psychiatrist and is clinically competent to provide chemical dependency treatment and/or mental health services for the applicant/participant's case management and the overall compliance with treatment contracts. The clinical assessor is a qualified psychiatrist, psychologist, neuropsychiatrist, psychiatric/mental health nurse or licensed clinical social worker who holds a current license and who responsible for performing in-person assessments.

➤ *Practice restrictions during participation in the diversion program.*

The contractor has the ability to place certain practice restrictions on a participant during the course of his or her participation in the PRP. It is standard to immediately suspend a pharmacist/intern's practice upon receipt of a confirmed positive drug screen. Under the provisions of the board's disciplinary guidelines, CCR 1760 and CCR 1773, the board may also impose practice restrictions as a probationary condition of a disciplinary action.

➤ *Informing a licensee's employer about their participation in the diversion program.*

Under the terms and conditions of probation, a licensee is required to notify all present and prospective employers of the disciplinary decision and all the terms, including mandatory participation of the PRP. (CCR 1773)

Under the provisions of the contract, a participant who is working as a pharmacist/intern is required to designate a work site monitor who is in a supervisory capacity or at least one management step above the PRP participant. The work site monitor must be aware of the PRP contract and provide regular assessment of the participant's work performance to the clinical case manager.

➤ *Drug testing, including the frequency and methods used for testing and reporting results.*

See question #7 above.

➤ *Requirements for worksite monitoring and observation.*

Pursuant to the contract and board standards, the worksite monitor must be available to the participant, preferably working the same shift/hours; must have weekly contact with the participant that is scheduled randomly; must monitor participant's job performance in relation to his or her impairment; must communicate with the contractor by completing quarterly written reports, and also communicate with the board inspectors and/or the board's program manager. The worksite monitor must notify the contractor immediately if the participant exhibits a suspected relapse or unusual behavior and must communicate their concerns to the participant.

A worksite monitor's report includes information regarding:

- Whether the participant demonstrated the ability to perform procedures safely and effectively
- Whether the participant met performance time frames in completing routine activities
- Whether the participant met expectations of work quality
- Whether the participant maintained appropriate behavior and/or interpersonal relationships
- Whether the participant strictly adhered to procedures for handling
- controlled substances.

➤ *Consequences for relapse and termination from the diversion program.*

If the participant is board-referred as a condition of probation, the participant is in non-compliance with the terms of his or her probation and a petition to revoke probation may be filed by the Office of the Attorney General. (B&P Code Section 4360, 4300)

If the participant is a self-referral and terminated from the program for non-compliance or failure to derive benefit from the program, the name and license number of that participant is reported to the board (Section 4369). The board then initiates an investigation for referral to the Attorney General's Office for disciplinary action (Section 4300).

➤ *Reporting to the board of noncompliance (time-frame).*

The contractor is required to report noncompliance within the time frame requirements established in its contract with the Department of Consumer Affairs. This is discussed above under question #10.

➤ *Requirements for return to practice or reinstatement of a license if placed on probation.*

B & P Code Section 4369 requires compliance with the PRP. There must be 100 percent compliance with all contract requirements and contract addendums put in place

Senator Mark Ridley-Thomas

March 12, 2008

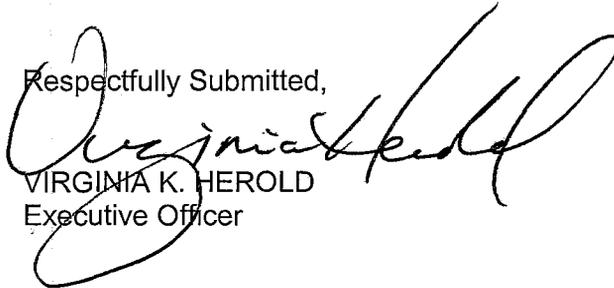
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as a result of relapse and assessment to determine that the participant is deemed safe to return to the practice of pharmacy.

Pursuant to the board's disciplinary guidelines (CCR 1760, 1763) the standard length of probation is 5 years for those licensees who are required to participate in the PRP. Compliance with all terms and conditions of probation is required for successful completion of probation and a clear, unrestricted license.

Thank you for this opportunity to provide comments about the PRP program. I will be pleased to continue to work with your staff as they evaluate these important programs.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Virginia K. Herold", written in a cursive style.

VIRGINIA K. HEROLD  
Executive Officer



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California Legislature

Senate Committee on Business, Professions & Economic Development

**MARK RIDLEY-THOMAS**

CHAIR

**AGENDA**

March 10, 2008

1:30 p.m. to 4:30 p.m.

State Capitol, Room 3191

Sacramento, California

**Subject: Review of Physicians and Health Practitioners Substance Abuse Programs**

**I. Opening Remarks**

**Senator Mark Ridley-Thomas, Chair,**

Senate Business, Professions and Economic Development Committee

**II. Presentation by California Health Licensing Boards**

**Ms. Ruth Ann Terry, Executive Officer and Ms. Carol Stanford, Diversion/Probation Program Manager, Board of Registered Nursing**

**Mr. Steve Hartzell, Executive Officer and Ms. Debi Mitchell, Diversion Program Manager, Physical Therapy Board of California**

**Ms. Virginia Herold, Executive Officer, and Ms. Ann Sondergren, former Diversion Program Manager, California Board of Pharmacy**

**Mr. Paul Riches, Executive Officer, California Board of Behavioral Sciences**

**III. Presentation by the Department of Consumer Affairs and the Maximus Program**

**Ms. Carrie Lopez, Director, Department of Consumer Affairs**

**Ms. Deanne Wertin, President, Western Region, Maximus, Inc.**

**Ms. Virginia Matthews, Project Manager, Maximus, Inc.**

**IV. Presentation by the Medical Board of California**

**Dr. Richard Fantozzi, President of the Medical Board of California and Past Chair of the Diversion Program**

**Ms. Barb Johnston, Executive Director, Medical Board of California**

**V. Presentation by the California Medical Association**

**Anthony Williams, California Medical Association**

**Dr. David Pating, Immediate Past President, California Society of Addiction Medicine**

**Dr. Jack Shale, Clinical Professor of Psychiatry, UC San Diego School of Medicine**



**VI. Education, Treatment and Wellness Perspective**

**Dr. Shannon Chavez, Medical Director, UC San Diego Psychiatric Outpatient Services**

**Dr. Elinore McCance-Katz, Assistant Adjunct Professor, UC San Francisco**

**Dr. David Shearn, Director, Physician Education and Development, Kaiser Permanente**

**VII. National and Other States Perspective**

**Dr. Luis Sanchez, President, Federation of State Physician Health Programs**

**Dr. Greenberg, Medical Director, Arizona Monitored Aftercare Program**

**VIII. Response from Center for Public Interest Law**

**Ms. Julie D'Angelo Fellmeth, Administrative Director,**

Center for Public Interest Law, University of San Diego School of Law

**IX. Closing Comments from the Medical Board of California**

**Dr. Richard Fantozzi, President of the Medical Board of California and Past Chair of the Diversion Program**

**X. Open for Public Comment**

**XI. Closing Comments**

**Senator Mark Ridley-Thomas, Chair,**

Senate Business, Professions and Economic Development Committee



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Senate Committee on Business, Professions & Economic Development

**MARK RIDLEY-THOMAS**

CHAIR

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                  (Letter from the Center for Public Interest Law)



BACKGROUND PAPER

# PHYSICIAN HEALTH PROGRAMS

Prepared by  
**SARAH HUCHEL**

California Senate Office of Research  
Agnes Lee, Director  
1020 N Street • Suite 200 • Sacramento, CA 95814  
Telephone (916) 651-1500 • [www.sen.ca.gov/sor](http://www.sen.ca.gov/sor)



March 2008

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# THE MEDICAL BOARD OF CALIFORNIA DIVERSION PROGRAM

The Medical Board of California (MBC) is tasked with protecting the public. California law states that "Protection of the public shall be the highest priority of the Medical Board of California in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount."<sup>1</sup> In deference to this mandate, MBC voted unanimously on July 26, 2007, to end its diversion program beginning July 1, 2008.<sup>2</sup> This program, established in 1980, was designed to rehabilitate doctors with mental illness and substance abuse problems without endangering public health and safety.<sup>3</sup> The diversion program was audited four times between 1982 and 2007 by the Bureau of State Audits<sup>4</sup> and once in 2005 by a legislatively created enforcement monitor;<sup>5</sup> all reports concluded that the program needed substantial improvements.

As explained in greater detail beginning on page 7, MBC has developed a transition plan for current participants in the diversion program. Under the plan, new enrollment is limited. This paper describes the diversion program as it existed when it was fully operational.

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<sup>1</sup> California Business and Professions Code, Section 2001.1.

<sup>2</sup> Minutes from July 26-27, 2007, Medical Board of California meeting.

<sup>3</sup> Julianne D'Angelo Fellmeth and Thomas A. Papageorge, "Final Report, Medical Board of California Enforcement Program Monitor," November 1, 2005, p. 9.

<sup>4</sup> Auditor General of California, "Review of the Board of Medical Quality Assurance," August 1982; Auditor General of California, "The State's Diversion Programs Do Not Adequately Protect the Public From Health Professionals Who Suffer From Alcoholism or Drug Abuse," January 1985; Auditor General of California, "The Board of Medical Quality Assurance Has Made Progress in Improving Its Diversion Program; Some Problems Remain," June 1986; Bureau of State Audits, California State Auditor, "Medical Board of California's Physician Diversion Program," June 2007.

<sup>5</sup> Fellmeth and Papageorge, "Final Report, Medical Board of California Enforcement Program Monitor," November 1, 2005.

Physicians could enter the diversion program in one of three ways: a physician could (1) self-refer, (2) be referred by the Enforcement Unit of the Medical Board in lieu of discipline, or (3) be directed as part of a disciplinary order.

Confidentiality is required by statute for the first category of participants, and may be granted by MBC for those in the second—doctors may avoid public discipline if there was no evidence of patient harm and they successfully complete the program. For the third category, discipline actions are public record; the practice violation that triggered MBC's involvement would be reflected in the doctor's public file.<sup>6</sup>

The diversion program is essentially a monitoring program.<sup>7</sup> After referral, a physician undergoes a comprehensive evaluation to determine whether he or she can be accepted into the program, a decision made by the program administrator (as advised by a diversion evaluation committee). After acceptance, he or she agrees to a set of terms in a formal diversion program contract, which set the conditions for the physician's participation.<sup>8</sup> These agreements are typically for a period of five years and include as part of the treatment plan the extent to which a physician may continue medical practice.<sup>9</sup> The agreement may include inpatient detoxification, psychotherapy, and medical and psychiatric evaluation, as appropriate, but these functions were not provided directly by the diversion program.<sup>10</sup> The program instead monitored participants' compliance with the agreement with the aid of group facilitators, case managers, worksite monitors, diversion evaluation committees, and drug testing.<sup>11</sup>

While the program reported that upward of 74 percent of participants successfully completed the program,<sup>12</sup> external audits found problems with the program's core mission: monitoring. According to the state auditor and a

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<sup>6</sup> Medical Board of California, "Physician Diversion Program," March 2006.

<sup>7</sup> Julianne D'Angelo Fellmeth and Thomas A. Papageorge, "Initial Report, Medical Board of California Enforcement Program Monitor," November 1, 2004, p. 235.

<sup>8</sup> *Ibid.*, p. 243.

<sup>9</sup> Medical Board of California, "Physician Diversion Program," March 2006.

<sup>10</sup> Fellmeth and Papageorge, "Initial Report, Medical Board of California Enforcement Program Monitor," November 1, 2004, p. 235.

<sup>11</sup> Medical Board of California, "Physician Diversion Program," March 2006.

<sup>12</sup> Fellmeth and Papageorge, "Final Report, Medical Board of California Enforcement Program Monitor," November 1, 2005, p. ES-42.

legislatively created enforcement monitor,<sup>13</sup> drug tests were not performed as scheduled, the program lacked cohesive, enforceable standards for many aspects of operations, and the Medical Board itself failed to exert effective oversight.<sup>14</sup> The initial report of the Medical Board of California's Enforcement Program Monitor reported that urine collections did not occur on the random date generated in 60 percent of the files reviewed.<sup>15</sup> This may have contributed to the situation that allowed one participant to test clear over a five-month period, even though he later admitted to abusing prescription drugs during that time.<sup>16</sup>

Further, the controls in place to monitor physicians on the job were not adequately designed. The enforcement monitor's report found that though hospital and worksite monitors were designed to be the eyes and ears of the program, ensuring that participants act appropriately and perform their duties substance-free, the "Diversion Program Manual" contained no requirements that the monitors be on-site with the participants at the same time, or even meet with and talk with the physicians.<sup>17</sup> The state auditor also reported that the program did not always require a physician to immediately stop practicing following a positive drug test.<sup>18</sup>

The enforcement program monitor noted that understaffing hampered the board's abilities to effectively monitor doctors in the program. In 2002 managers had caseloads above 80.<sup>19</sup> According to MBC's program administrator, this is nearly twice the ideal number for effective management.<sup>20</sup>

Meanwhile, press reports of several high-profile cases highlighted the potential threat to public safety. For example, Dr. Brian West, a plastic surgeon, had a

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<sup>13</sup> As a result of an overall analysis of MBC, the Legislature required the appointment of an independent enforcement monitor to evaluate the board's disciplinary and enforcement system, including the diversion program (SB 1950 (Figueroa), Chapter 1085, Statutes of 2002).

<sup>14</sup> Bureau of State Audits, California State Auditor, "Medical Board of California's Physician Diversion Program," June 2007, p. 2.

<sup>15</sup> Fellmeth and Papageorge, "Initial Report, Medical Board of California Enforcement Program Monitor," November 1, 2004, p. 260.

<sup>16</sup> Ibid., p. 265.

<sup>17</sup> Ibid., p. 267.

<sup>18</sup> Bureau of State Audits, California State Auditor, "Medical Board of California's Physician Diversion Program," June 2007, p. 2.

<sup>19</sup> Fellmeth and Papageorge, "Final Report, Medical Board of California Enforcement Program Monitor," November 1, 2005, p. 175.

<sup>20</sup> Fellmeth and Papageorge, "Initial Report, Medical Board of California Enforcement Program Monitor," November 1, 2004, p. 253.

history of alcohol problems dating back to 1987.<sup>21</sup> He was arrested in 2000 on his second drunken driving offense, just weeks before performing surgery on a woman that resulted in dead stomach tissue and exposed intestines. The woman required subsequent corrective surgeries and treatment by an infectious disease doctor. According to press reports, she eventually settled a lawsuit related to Dr. West's care for \$250,000 (the maximum allowable for malpractice suits in California) in 2002. However, Dr. West admitted no fault and his attorney stated that he had no information that Dr. West ever treated patients while under the influence.<sup>22</sup> Dr. West also entered, and failed, MBC's diversion program.<sup>23</sup> As of early 2008, Dr. West was on probation but still allowed to practice.<sup>24</sup> Another individual, Dr. John Hatherley, was profiled by the *Orange County Register*.<sup>25</sup> Dr. Hatherley was a diversion program participant who relapsed six times and was kicked out of the program twice in two years.<sup>26</sup> As of February 2008, he was on probation but legally allowed to treat patients.<sup>27</sup>

On July 26, 2007, MBC voted unanimously to end the diversion program, declaring in its motion that "in light of Medical Board of California's primary mission of consumer protection, and as the regulatory agency charged with the licensing of physicians and surgeons and enforcement of the Medical Practice Act, the board hereby determines it is inconsistent with the board's public protection mission and policies to operate a diversion program...."<sup>28</sup> Dr. Richard Fantozzi, president of the Medical Board of California, was quoted in the press as

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<sup>21</sup> Before the Division of Medical Quality, Medical Board of California, Department of Consumer Affairs, State of California, Decision In the Matter of the Second Amended Accusation Against Brian Robert West, M.D., File No. 02-2001-119298, October 17, 2005.

<sup>22</sup> Daffodil J. Altan, "Under Wraps," *OC Weekly*, January 10, 2008.

<sup>23</sup> Before the Division of Medical Quality, Decision In the Matter of the Second Amended Accusation Against Brian Robert West, M.D.

<sup>24</sup> Medical Board of California, Physician Information, Brian Robert West, M.D., last updated February 12, 2008.

<sup>25</sup> Brian Joseph, "O.C. Doctor Caught Up in Diversion Program," *Orange County Register*, July 20, 2007.

<sup>26</sup> Before the Division of Medical Quality, Medical Board of California, Department of Consumer Affairs, State of California, Decision In the Matter of the Accusation and Petition to Revoke Probation Against John Anthony Hatherley, M.D., File No. D1-2002-132702, January 24, 2007.

<sup>27</sup> Medical Board of California, Physician Information, John Anthony Hatherley, M.D., last updated February 12, 2008.

<sup>28</sup> Minutes from July 26-27, 2007, Medical Board of California meeting.

stating, "The public now demands transparency. Why should doctors be protected in secrecy when consumer safety hangs in the balance?"<sup>29</sup>

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<sup>29</sup> Marcus Wohlsen, Associated Press, "More Scrutiny for California Doctors Facing Drug or Alcohol Discipline," *San Jose Mercury News*, January 24, 2008.

# THE MEDICAL BOARD OF CALIFORNIA

## DIVERSION TRANSITION PLAN

The diversion program officially sunsets on June 30, 2008.<sup>30</sup> Medical Board staff indicates that, as of the next day, any doctors referred to MBC due to substance abuse issues will be investigated.<sup>31</sup> If the evidence warrants, an accusation will be filed, and the matter will be resolved through the disciplinary process.<sup>32</sup> This process may be revised in the future; at the time of this writing, the board is planning further discussions about succession programs.<sup>33</sup>

The board approved a Diversion Transition Plan on November 2, 2007, to accommodate the 203 physicians already in the program.<sup>34</sup> All individuals received a letter alerting them to the end of the diversion program. The plan was organized according to the three ways in which individuals were accepted into the program.<sup>35</sup>

### 1. Self-Referred Physicians

The Diversion Transition Plan split these participants into two categories: those with at least three years of sobriety and those without. For the former,

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<sup>30</sup> Memorandum from Kimberly Kirchmeyer, deputy director of the Medical Board of California, to the Diversion Committee Members, November 1, 2007.

<sup>31</sup> Barb Johnson, executive director of the Medical Board of California, e-mail to author, Subject: Diversion and MBC, February 8, 2008.

<sup>32</sup> Ibid.

<sup>33</sup> Notes from MBC meeting, January 31-February 1, 2008. The board anticipates discussing alternatives to the now-defunct diversion program after staff reviews the presentations from the Diversion Summit on January 24, 2008.

<sup>34</sup> Memorandum from Kimberly Kirchmeyer, November 1, 2007.

<sup>35</sup> Ibid. Note: The plan was approved by the full MBC Board (with amendment relating to the time period for biological fluid testing) on November 2, 2007. The Diversion Transition Plan also included provisions for physicians attending similar programs in other states. For these participants, existing board staff will continue to liaison with those states' programs.

participants will be evaluated by a Diversion Evaluation Committee (DEC), and if the DEC recommends and the program administrator approves, the individual will be deemed to have successfully completed the program and discharged. For those with less than three years of sobriety, participants would receive a letter to "highly encourage" them to seek entrance into another monitoring or treatment program to assist them in maintaining sobriety.

## **2. Physicians Who Were Referred Into the Diversion Program From Enforcement in Lieu of Discipline**

- (a) Newly-referred individuals will be informed that, although they may enter the program, the program will not be operational long enough to give them enough time to complete the requisite three years of sobriety for program completion. Thus, they may enter the program, but after June 30, 2008, they will be referred to the attorney general's office (enforcement) for further action.
- (b) Current participants with at least three years of sobriety may request a recommendation of completion from their DEC. If the program administrator agrees with the DEC that the participant has been compliant with the program, the individual will receive a letter of completion.
- (c) Participants who joined the program in advance of the transition plan's adoption and have less than three years' sobriety will receive a notice that they must join another program that will monitor their recovery so that the board may honor the "diversion" provision of their original participation. The successor program must meet the board's current standards. The notice will further state that the board endorses a "zero-tolerance" policy on positive drug screenings. Failure to enroll in a continuing program or abstain from drugs and/or alcohol may be grounds for discipline.

## **3. Physicians Directed Into the Diversion Program as Part of a Disciplinary Order**

- (a) MBC will no longer approve participation in the diversion program as a condition of discipline or receiving a probationary license. Additionally,

the board sent a letter requesting that administrative law judges no longer order participation in the diversion program as a condition of probation. Instead, administrative law judges must issue stipulations with conditions that require probationers to abstain from drugs and alcohol and submit to biological fluid testing.

- (b) Beginning July 1, 2008, the diversion component of past discipline orders will become null and void and will no longer be considered a condition of probation. However, those individuals tasked with participation are required to obtain a drug screening service that will liaison with the board to ensure the participant's sobriety. Failure to do so will be grounds to file a petition to revoke probation.

## OTHER CALIFORNIA HEALTH PROVIDER DIVERSION PROGRAMS

The California Department of Consumer Affairs (DCA) is the umbrella agency for most of the licensing bodies in California, including MBC.<sup>36</sup> While MBC houses its diversion program within the board itself, other boards outsource these functions. DCA currently manages a master contract<sup>37</sup> with a publicly traded corporation for six boards' and one committee's diversion programs: the Board of Registered Nursing, the Dental Board of California, the Board of Pharmacy, the Physical Therapy Board of California, the Veterinary Medical Board of California, the Osteopathic Medical Board of California, and the Physician Assistant Committee. The individual boards oversee the programs, but services are provided by the contractor.

These boards' diversion programs follow the same general principles of MBC's diversion program. Health practitioners with mental illnesses or substance abuse issues may be referred in lieu of discipline or self-refer into the programs and receive help with rehabilitation. After an initial evaluation, individuals accept a participation agreement and are regularly monitored in various ways, including random drug testing, to ensure compliance. DCA's current private contractor, Maximus, provides the services that MBC kept in-house: medical advisors, compliance monitors, case managers, a urine testing system, reporting, and record maintenance.<sup>38</sup>

The DCA master contract standardizes certain tasks, such as designing and implementing a case management system, maintaining a 24-hour access line, and

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<sup>36</sup> See California Department of Consumer Affairs, "About Us," "Boards and Bureaus," at [www.dca.ca.gov/about\\_dca/entities.shtml](http://www.dca.ca.gov/about_dca/entities.shtml).

<sup>37</sup> The current contract expires June 30, 2008. DCA released an RFP for these same services in late 2007 and is scheduled to award the new contract on March 28, 2008.

<sup>38</sup> Maximus, General Requirements, proposal for Department of Consumer Affairs, 2003, p. 3-1, 3-11, 3-13.

providing initial intake and in-person assessments,<sup>39</sup> but the planning and execution of the programs are tailored to each board according to their needs and mandates. Each board specifies its own policies and procedures.

Maximus generally has a less hands-on approach to managing the diversion programs than MBC attempted. Maximus reports that caseloads range from 100 to 200 per clinical case management team.<sup>40</sup> (The MBC program administrator suggested 49 cases as the most prudent figure for best management for the Medical Board.<sup>41</sup>) Maximus also limits its in-person resources; for example, in the program design for the Board of Registered Nursing, Maximus specifies that they will conduct in-person reassessments by telephone unless otherwise requested by the board.<sup>42</sup> Also, the contractor performs unobserved, as well as observed, drug screening.

The following are examples of two DCA Board programs:<sup>43</sup>

### **The Board of Registered Nursing**

The Board of Registered Nursing (BRN) manages the largest diversion program of the DCA boards. As of January 2008, the board licensed over 350,000 registered nurses. Including all the subspecialties (nurse practitioners, clinical nurse specialists, and nurse midwives, to name a few) the number exceeds 430,000.<sup>44</sup> At any given time, approximately 450 nurses are in BRN's diversion program.<sup>45</sup> BRN finds that rehabilitating nurses through the program is less expensive than proceeding with the disciplinary process.<sup>46</sup>

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<sup>39</sup> Maximus, proposal for Department of Consumer Affairs, 2003, p. ES-1, ES-4, 2-3, 3-2.

<sup>40</sup> Ibid., p. 2-2, 2-3. Maximus guarantees no more than 150 participants per case management team for the Dental Board, per request. The Board of Registered Nursing specified in its recent RFP that caseloads should not exceed 130 participants per clinical case manager, down from 150 participants in the previous contract.

<sup>41</sup> Fellmeth and Papageorge, "Initial Report, Medical Board of California Enforcement Program Monitor," November 1, 2004, p. 253.

<sup>42</sup> Maximus, proposal for Department of Consumer Affairs, 2003, p. 4-2.

<sup>43</sup> All representations are as according to the DCA boards.

<sup>44</sup> Board of Registered Nursing, [www.rn.ca.gov/about\\_us/stats.shtml](http://www.rn.ca.gov/about_us/stats.shtml).

<sup>45</sup> Carol Stanford, diversion/probation program manager for BRN, memorandum to author, February 14, 2008.

<sup>46</sup> Ibid.

BRN's diversion program is voluntary.<sup>47</sup> Participants may self-refer or are given the option to participate in lieu of discipline (there is no participation as a condition of enforcement, as in MBC's diversion program).<sup>48</sup> Nurses are ineligible to participate if they have caused patient harm as a result of impairment. The program also excludes individuals who have been previously disciplined for substance abuse or mental illness and, unlike MBC's diversion program, does not readmit participants who have been previously terminated from BRN's program or any other similar program for noncompliance.<sup>49</sup>

When first entering the program, participants are told to cease practice immediately until they can be evaluated more completely by the DEC.<sup>50</sup> Even after evaluation, participants are not allowed to return to work until they are deemed "safe,"<sup>51</sup> and all monitoring and treatment programs are in place—usually 3 to 12 months.<sup>52</sup> Maximus also provides administrative functions for nurse support groups at the board's direction.<sup>53</sup>

The terms of the contract dictate that Maximus provide observed and unobserved urine testing 24-hours-a-day. In the event of a positive test, Maximus must report to a DEC within one business day. A DEC will then make a decision as to whether to alter the participant's participation agreement.<sup>54</sup>

Participants must pay \$25 per month to defray the program costs, as well as any expenses related to rehabilitation, such as drug testing, treatment, psychiatric or medical evaluations, and nurse support group attendance. Average participation is 3.5 to 4 years.<sup>55</sup>

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<sup>47</sup> Board of Registered Nursing, "What Is the Diversion Program?" [www.rn.ca.gov/diversion/whatisdiv.shtml](http://www.rn.ca.gov/diversion/whatisdiv.shtml).

<sup>48</sup> Board of Registered Nursing, "Frequently Asked Questions" [www.rn.ca.gov/diversion/div-faqs.shtml](http://www.rn.ca.gov/diversion/div-faqs.shtml).

<sup>49</sup> Ibid.

<sup>50</sup> Ibid. Similar to MBC's program, DEC's offer recommendations for the acceptance, denial, or termination of participants (California Business and Professions Code Section 2770.7). There are 13 DEC's throughout the state that meet regularly to design rehabilitation programs for participants.

<sup>51</sup> Ibid.

<sup>52</sup> Stanford, memorandum to author, February 14, 2008.

<sup>53</sup> Maximus, proposal for Department of Consumer Affairs, 2003, p. 4-5.

<sup>54</sup> Ibid., p. 4-4.

<sup>55</sup> Board of Registered Nursing, "Frequently Asked Questions."

## The Board of Behavioral Sciences

The Board of Behavioral Sciences (BBS) operates on a purely enforcement model; it does not treat substance abuse different from any other practice violation. The board does not contract with an outside vendor, nor does it have in-house capabilities to offer treatment, detailed monitoring, or drug testing services. Following an offense, an accusation is publicly filed against a licensee and the discipline process proceeds.<sup>56</sup>

BBS publishes disciplinary guidelines that set the minimum and maximum penalties for practice violations.<sup>57</sup> "Impaired ability to function safely due to mental illness or physical illness affecting competency or chemical dependency" and "chemical dependency/use of drugs with client while performing services" are two violation categories. For each, the maximum penalty is revocation or denial of license. However, BBS has a range of options to discipline the licensee while addressing the underlying disease. In the event of a chemical dependency, BBS may recommend a psychological or psychiatric evaluation, therapy, a rehabilitation program, and fluid testing.<sup>58</sup> BBS does not contract with any one program to offer this assistance.<sup>59</sup> Picking a recovery program and drug testing facility is up to the licensee, though BBS may provide a resource list. BBS is kept apprised of the licensee's progress so that it may determine if he or she is complying with the terms of the discipline agreement. Individuals have a strong incentive to comply, for license revocation is usually the next step.<sup>60</sup>

BBS has between 30 and 40 total enforcement cases a year, and chemical dependency issues represent a small fraction of that figure.<sup>61</sup> BBS reports that the "vast majority" of licensees are successful in completing the terms of their agreement.<sup>62</sup>

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<sup>56</sup> Executive director, Board of Behavioral Sciences, e-mail to author, February 21, 2008.

<sup>57</sup> "Disciplinary Guidelines," State of California, Department of Consumer Affairs, Board of Behavioral Sciences, May 21, 2004, p. 1.

<sup>58</sup> Ibid., p. 6.

<sup>59</sup> Executive director, Board of Behavioral Sciences, e-mail to author, February 21, 2008.

<sup>60</sup> Ibid.

<sup>61</sup> Ibid.

<sup>62</sup> Ibid.

## OTHER STATES' PHYSICIAN HEALTH PROGRAMS

California's diversion program and, by extension, the term "diversion" is generally understood to refer to a program in which doctors agree to a rehabilitative plan in lieu of discipline for mental or substance abuse issues. Many states operate similar programs, and the dominant term that has emerged to describe them is "physician health programs" (PHPs).<sup>63</sup> This term is not rigidly defined and may include not only diversion and monitoring but broader health concepts, such as education and outreach, as well.<sup>64</sup>

The American Medical Association began encouraging states to develop programs as early as 1974 to address physician impairment, but the movement did not gain momentum until the 1990s.<sup>65</sup> Today, 48 of 50 states have PHPs.<sup>66</sup> The basic PHP process consists of a referral, an investigation to see if participation is warranted, followed by an intervention, evaluation, and treatment based on a monitoring contract. The typical duration of participation is five years.<sup>67</sup>

Based on a 2007 nationwide survey, in cooperation with the Federation of State Physician Health Programs, 54 percent of PHPs are managed by independent, nonprofit foundations, and the rest are run by state medical associations or

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<sup>63</sup> Gregory E. Skipper, M.D., presentation: "Lessons from Physician Health Programs in the USA: Results from a National Study—Contingency Management May Be the Key to Improved Outcomes," 2007.

<sup>64</sup> Ibid., and Greg Skipper, M.D., "Update on the National PHP Study—Blueprint for Lasting Recovery," *Physician Health News*, The Official Newsletter of the Federation of State Physician Health Programs, vol. 12, no. 1, April 2007.

<sup>65</sup> Peter A. Mansky, M.D., "Physician Health Programs Help Stem the Tide of Suicide," *Physician Health News*, The Official Newsletter of the Federation of State Physician Health Programs, vol. 11, no. 1, March 2006.

<sup>66</sup> Skipper, presentation, 2007.

<sup>67</sup> Ibid.

regulatory licensing boards.<sup>68</sup> All the programs surveyed had some agreement, formal or otherwise, with their state licensing board, and all require random drug testing.<sup>69</sup> Sources of funding are similarly diverse; most PHPs are supported primarily by the state licensing board, but malpractice insurance, participant fees, private contributions, and foundations also make up their budgets.<sup>70</sup>

Virginia is one state which includes diversion as an element of its PHP; the Health Practitioners' Intervention Program (HPIP) allows participants to self-refer, enter as an alternative of enforcement (diversion), or as a condition of enforcement.<sup>71</sup> Participants are not allowed to practice medicine during their initial assessment and early stages of treatment<sup>72</sup> and, if a relapse occurs, participants must refrain from practice immediately.<sup>73</sup> HPIP ensures random urine testing by setting frequencies based on a yearly, not monthly, figure.<sup>74</sup>

The following are profiles of two state programs that offer different models from MBC's diversion program:

### **Arizona**

The Arizona Medical Board's primary statutory duty is to protect the public. However, in executing this duty, the board is also mandated by law to rehabilitate, in addition to discipline, physicians.<sup>75</sup> The Arizona Medical Board contracts with a private corporation to run its PHP, which is called the Monitored Aftercare Program (MAP).<sup>76</sup>

MAP has two tracks: confidential and nonconfidential, though the monitoring for each is essentially the same.<sup>77</sup> Physicians who self-refer and face no disciplinary actions are eligible to participate in the program confidentially. These doctors sign a "Stipulated Rehabilitation Agreement." This agreement itself is not a

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<sup>68</sup> Skipper, presentation, 2007.

<sup>69</sup> Ibid.

<sup>70</sup> Ibid.

<sup>71</sup> *Orientation Handbook: Virginia Health Practitioners' Intervention Program*, p. 4.

<sup>72</sup> Ibid., p. 5.

<sup>73</sup> Ibid., p. 14.

<sup>74</sup> Ibid., p. 16.

<sup>75</sup> Arizona Revised Statutes, Section 32-1403.

<sup>76</sup> Greenberg & Sucher PC is the contractor. This same corporation runs similar programs for the Arizona State Board of Dental Examiners.

<sup>77</sup> Michel A. Sucher, M.D., e-mail to author, February 21, 2008.

disciplinary action, but a physician may be disciplined if the agreement is violated.<sup>78</sup> Physicians ordered as a condition of enforcement sign a consent agreement for probation.<sup>79</sup>

On both tracks, individuals must agree to attend group therapy classes; 12-step or other self-help group meetings; abstain from alcohol, unapproved medicines, and poppy seeds; submit to random drug testing; and notify the board in advance of any absences that would interfere with drug testing. If a participant relapses, he or she is required to cease practice until the completion of a long-term inpatient or residential treatment program and board approval.<sup>80</sup>

MAP typically has 100 participants at any given time, 50 percent of whom are self-referred. MAP's contractor provides initial assessments, drug testing, group therapy, case management, self-help meetings, 24-hour availability, and the expertise of a diversion committee.<sup>81</sup> Case managers handle no more than 30–40 cases at any one time, and participants bear the full cost. The contractor works closely with the medical board regarding individual patient treatment decisions, procedures, and testing requirements.<sup>82</sup> The board also reserves the right for the contractor to provide immediate intervention in cases of emergency.<sup>83</sup> In addition to urine samples, MAP also tests hair, blood, breath, and sweat. The contractor reports a 92 percent success rate after five years, and 79 percent after 10 years.

## Illinois

The Illinois Professionals Health Program (IPHP) was started by the Illinois State Medical Society and is now operated by an independent, nonprofit health care delivery system.<sup>84</sup> The company, Advocate Medical Group, does not have a contract with the state medical board,<sup>85</sup> but is rather deemed the sole physician

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<sup>78</sup> Before the Arizona Medical Board, Stipulated Rehabilitation Agreement: Non-Disciplinary and Confidential (sample order).

<sup>79</sup> Sucher, e-mail to author, February 21, 2008.

<sup>80</sup> Before the Arizona Medical Board, Stipulated Rehabilitation Agreement: Non-Disciplinary and Confidential (sample order).

<sup>81</sup> Michel A. Sucher, M.D., and David G. Greenberg, M.D., M.P.H., presentation to the Diversion Summit, "California Physicians Health Program," January 24, 2008.

<sup>82</sup> Sucher, e-mail to author, February 21, 2008.

<sup>83</sup> Request for proposal from the Arizona Medical Board, "The Arizona Medical Board Monitored Aftercare Program," September 2006.

<sup>84</sup> Martin Doot, M.D., medical director, Illinois Professionals Health Program, e-mail to author, Subject: IPHP, February 12, 2008.

<sup>85</sup> Federation of State Physician Health Programs, [www.fsphp.org/illinois.html](http://www.fsphp.org/illinois.html).

“approved aftercare program.”<sup>86</sup> This company does contract with the state for PHP-like services for pharmacists, dentists, veterinarians, and other professionals, though on varying program terms.<sup>87</sup>

Physicians may self-refer to IPHP or be referred by a treater, medical group, hospital, family member, or colleague. Because the program is entirely separate from the licensing board, a true self-referral may get treatment without any involvement or knowledge of the state. However, the licensing board is made aware if something occurs that triggers a mandatory report (for example, a patient complaint or an action by a hospital against the physician’s hospital privileges). At that point, the licensing board may offer an “agreement to care and counseling,” which is a confidential diversion-type plan that would send the physician to IPHP with certain terms, or the physician may face discipline, which is public.

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<sup>86</sup> Doot, e-mail to author, February 12, 2008.

<sup>87</sup> Ibid.

## POLICY CONSIDERATIONS

It has been reported that, generally, physicians face substance abuse rates similar to those in the general public.<sup>88</sup> The prevalence for chemical dependence (excluding nicotine) in physicians is 10–15 percent,<sup>89</sup> and at any given time 3.8 percent are actively struggling with substance abuse.<sup>90</sup>

### **Should Participation in Treatment Programs Be Confidential?**

At issue is whether the public can or should know if a physician is participating in a substance abuse or mental health program. Presently, most state PHPs divide participants into three tracks: (1) a physician with no pending disciplinary actions may self-refer to a substance abuse or mental illness program for treatment with absolute confidentiality. As long as the participant follows the rules of the PHP, his or her involvement in the program will not be made public; (2) a physician who enters a mental health or substance abuse program as a result of a practice violation is not granted confidentiality. Instead, the action that caused the disciplinary order and participation in the PHP program itself is public; and (3) a physician who participates in a PHP program in lieu of a public disciplinary order is granted confidentiality.

Proponents of confidentiality—such as the California Medical Association, the California Psychiatric Association, and the California Society of Addiction Medicine—advocate confidentiality for participants as a way to encourage

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<sup>88</sup> Karen Domino, Thomas Hornbein, et al., eds., “Risk Factors for Relapse in Health Care Professionals With Substance Use Disorders,” *JAMA*, March 23/30, 2005, vol. 293, no. 12.

<sup>89</sup> *Ibid.*

<sup>90</sup> Gregory E. Skipper, M.D., e-mail to author, February 8, 2008. “Incidence of Addiction Among Physicians,” from *Addiction Among Physicians and the Physician Health Programs That Manage Their Care*, editor, Gregory E. Skipper, M.D.

physicians to self-refer before their addictions cause patient harm.<sup>91</sup> The Federation of State Medical Boards also argues that confidentiality should be part of modern medical practice acts, provided that the physician is participating satisfactorily in an approved and medically directed treatment program.

On the other hand, critics of confidentiality argue that there is little hard evidence that supports the idea that confidentiality is essential to successful physician treatment. For example, although approximately 3.8 percent of physicians are struggling with substance abuse issues at any given time,<sup>92</sup> PHPs nationwide capture only a fraction of that population.<sup>93</sup> Others reject the argument that granting confidentiality encourages physicians to self-refer into treatment programs, pointing out that in reality very few participants are true self-referrals.<sup>94</sup> For example, a national survey in conjunction with the Federation of State Physician Health Programs found that 75 percent of PHP participants were referred to the program by someone else or otherwise "coerced."<sup>95</sup>

## How Should the Program Be Structured?

As noted previously, 54 percent of states' PHPs are managed by independent, nonprofit foundations, and the rest are run by state medical associations or regulatory licensing boards.<sup>96</sup>

The California Medical Association, in conjunction with the California Psychiatric Association and the California Society of Addiction Medicine, has proposed a new California PHP operated by a formal, legislatively sanctioned, nonprofit entity. Under the proposal, the entity is independent but publicly

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<sup>91</sup> CMA, CSAM, CPA, "Framework: Public Protection and Physician Health Program," October 2007; Brian Joseph, "Joe Dunn's Diversion Crusade," *Orange County Register*, January 24, 2008.

<sup>92</sup> Skipper, e-mail to author, February 8, 2008.

<sup>93</sup> Skipper, e-mail to author, February 29, 2008. Nationwide, PHPs are currently monitoring approximately 9,000 physicians in the United States; this represents approximately 1 percent of all physicians.

<sup>94</sup> Julie D'Angelo Fellmeth, e-mail to author, February 12, 2008.

<sup>95</sup> Skipper, presentation, 2007. The study found that participants were referred to PHPs as follows: by a regulatory board, 22 percent; hospital (administration or medical staff), 18 percent; self (with coercion), 14 percent; colleague or partner outside hospital, 14 percent; self (without apparent coercion), 11 percent; treatment centers, 7 percent; other, 9 percent.

<sup>96</sup> Skipper, presentation, 2007.

accountable and regularly audited for clinical and fiscal integrity.<sup>97</sup> This arrangement is consistent with the structure of the majority of state PHPs which are arranged to enable the medical associations or licensing boards to be involved in the treatment and monitoring process.

## **How Should Treatment Programs Be Funded?**

In fiscal year 2004–05, MBC’s diversion program cost almost \$1.2 million. This was funded entirely by California licensees and represented treatment for 232 physicians.<sup>98</sup> (Physicians paid some individual treatment costs not included in this figure.) Nationwide, most PHPs are supported primarily by the state licensing board. Funds from medical associations, hospitals, malpractice insurance, fees paid by individuals enrolled in treatment programs, private contributions, and foundations also make up their budgets.<sup>99</sup>

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<sup>97</sup> CMA, CSAM, CPA, “Framework: Public Protection and Physician Health Program,” October 2007.

<sup>98</sup> Fellmeth and Papageorge, “Final Report, Medical Board of California Enforcement Program Monitor,” November 1, 2005, p. 165.

<sup>99</sup> Skipper, presentation, 2007.



February 29, 2008

The Honorable Mark Ridley-Thomas, Chair  
Senate Committee on Business, Professions, and Economic Development  
State Capitol, Room 2053  
Sacramento, CA 94814

re: Issues Related to Health Care Practitioner "Diversion" Programs

Dear Senator Ridley-Thomas:

Thank you for speaking at the Medical Board of California's (MBC) "Diversion Summit" on January 24. I spoke at the Summit as well; my testimony is attached. I attach as well a December 2007 Associated Press article that was widely published by media outlets across the nation (list included), and several other recent articles about MBC's decision to abolish its Diversion Program and move in a new direction.

The attached media articles reflect the fact that MBC's decision — made by that Board after two failed performance audits in the past three years, and at the behest of numerous patients who were injured by impaired physicians who were (unbeknownst to them) participating in the Program and permitted to practice medicine without adequate monitoring — has prompted nationwide reexamination of the viability of these widespread "diversion" programs at medical and other health care licensing boards.

At the Summit, you mentioned that you are considering legislation in this area. Having studied the diversion programs at health care boards for about 15 years, and having had the unique opportunity to audit MBC's Diversion Program as Medical Board Enforcement Program Monitor, I hope you will consider the following factors in fashioning your legislation.

**Theories Disproved By 27 Years Of Experience Should Be Abandoned**

Preliminarily, I respectfully urge you not to introduce the proposal to create a new MBC diversion program backed by the California Medical Association (CMA) and the California Society for Addiction Medicine (CSAM). That skeletal proposal — unveiled for the first time during the public comment period at the Medical Board's November 2007 meeting, and unembellished with any details at the January 24 Diversion Summit or to this day — contains all of the hallmarks of the failed program, including confidentiality of Program participation from patients and the use of

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5998 Alcalá Park, San Diego, CA 92110-2492 ■ Phone: (619) 260-4806 ■ Fax: (619) 260-4753  
717 K Street, Suite 509, Sacramento, CA 95814-3408 ■ Phone: (916) 444-3875 ■ Fax: (916) 444-6611  
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apparently-unlimited MBC physician licensing fees (which would otherwise be spent on enforcement) to support the Program in “blank check” fashion.

The primary argument of CMA/CSAM in support of the creation of a new program — again, a *confidential* program that *diverts* substance-abusing doctors away from discipline — is that, without such a program, impaired physicians will not seek help by “self-referring” into the program before they hurt patients. Although this argument sounds plausible in theory, the fact is that the Medical Board’s Diversion Program has never over its long history been successful in enticing self-referrals into voluntary participation.

My experience as MBC Enforcement Monitor is instructive on this point. When I audited the Program, we analyzed the files of 60 different Program participants (fully one-quarter of the entire Program population), including the 20 most recent intakes into the Program. Of those 20 physicians, only one was a true self-referral. About half were initially classified as self-referrals, but they had actually been prompted to “self-refer” because they knew the Board would soon learn of (and these examples are from actual cases) their arrest for DUI or crack cocaine possession, an adverse report from their employer under section 805 or 821.5, or a complaint from a registered nurse who observed them practicing while under the influence. From my direct observation, I would estimate that no more than 10% of the population of the Diversion Program were true self-referrals; the vast majority of participants were ordered to be there by the Medical Board as a condition of probation or were referred there by enforcement staff in lieu of disciplinary action.

Moreover, the Diversion Program attracted only a fraction of the number of probably-impaired physicians in California during its existence, *even though it offered the confidentiality that directly led to the injury of numerous patients who were denied information about their doctor’s participation*.

This is not simply my opinion. In his opening remarks at the Summit, MBC President Dr. Richard Fantozzi cited the relevant statistics: “There are 127,000 doctors licensed in California, with approximately 100,000 in active practice. Based on these numbers, experts estimate that 10,000–14,000 or more doctors practicing in California suffer from some degree of substance abuse in their career, and a significant proportion are in need of treatment at any given time. The average number of substance-abusing physicians in the Diversion Program at any given time was about 250, leaving greater than 95% practicing undetected and most likely not in treatment.” Clearly, the hard data prove that the confidentiality of the Program did *not* entice drug- or alcohol-abusing physicians to come forward voluntarily. While the Program failed to address the tip of the iceberg, the confidentiality aspect served only to prevent consumers from protecting themselves from dangerous physicians.

In addition, CMA and CSAM have proven that they are not capable of designing or running a diversion program. For 24 years, these organizations actually controlled the “Liaison Committee” to the Medical Board’s Diversion Program. Created in 1982, that Committee’s purpose was ostensibly to provide policy advice to the non-addiction-medicine-specialist members of the Medical

Board (who are legally responsible for overseeing the Program) and the non-physician staff of the Program. Within a short time, however, the Committee — to the exclusion of the Medical Board and its Division of Medical Quality (and contrary to Business and Professions Code section 2346) — became the primary overseer of the Diversion Program. The Committee was in place during four of the five failed audits of the Program — yet it took no action whatsoever to address or even acknowledge any of the very serious problems identified in any of those four audits. After spending 24 years ignoring persistent problems that were repeatedly identified, CMA and CSAM now seek legislation creating a program that is virtually identical to the failed Diversion Program and the failed diversion concept. Further, the CMA/CSAM proposal fails to address any of the deficiencies that were identified in either the 2004 or 2007 audits. As you know, Senator, the devil is in the details here — and CMA/CSAM have failed to provide you with any of them.

### **Anecdotal Evidence vs. Five Comprehensive Audits**

In your remarks on January 24, you noted that MBC's Diversion Program has not always been a failure in that it has assisted some participants to recover from substance abuse. I do not deny that some physicians entered the Program in good faith and with a will to recover, and overcame their addiction while in the Program. However, the findings and data in all five independent audits of the Program over 27 years reveal that the Program never consistently protected the public (and its participants) with airtight monitoring mechanisms to detect breaches by participants who have no will to kick their habit. The recovery of a few physicians over 27 years likely came at the expense of injury to many patients at the hands of participants who were not committed to recovery and were not adequately monitored.

In any event, it is easy for the Program and its supporters to trot out a physician or two who are willing to go public, admit to their problems, and sing the praises of the Program. That is what the Program does whenever it is questioned or challenged; I have seen this on a dozen occasions over the past 21 years that I have personally monitored the Medical Board. What I would like to see the Program do is trot out the other 2,000 physicians who have ever participated in the Diversion Program: How many are actually practicing medicine safely today? How many have relapsed into substance abuse? How many have died from it? The sad fact is that neither the Program nor the Board can do this. The Program does absolutely no tracking of its "graduates" (either successful or unsuccessful) after they leave the Program, and it has no idea whether it is effective in assisting physicians to recover from substance abuse in the long term.

This touting of a "success rate" without any underlying facts extends far beyond the Medical Board; I have seen numerous other boards advertise a misleading "success rate" for their privately-administered diversion programs. In 1998, I attended a national conference on health professional diversion programs, at which Dr. Richard Fuller from the National Institute of Alcohol Abuse and Alcoholism admonished some programs for "lying with statistics" about their "success rate," and revealed ways in which health care boards misleadingly calculate their "success rates": (1) they track and report only on graduates who have a good prognosis (e.g., a stable family environment, employment, and an intact social structure), and are likely to stick with their commitment to sobriety;

(2) they report only on “easily located” graduates; this inflates the “success rate” because those who are easily located are generally doing better than those who are difficult to locate; (3) they keep the follow-up period as short as possible, e.g., three months or shorter; (4) they avoid control or comparison groups; (5) they use a liberal definition of “success”; and (6) they rely solely on self-reporting by the graduate; they don’t require drug tests or talk to workplace monitors or others in a position to be candid. Dr. Fuller stated that a credible “success rate” would be based on a yearlong (at least) follow-up of all program graduates (not just the easily located ones) which is not based solely on self-reporting and includes random drug tests and interviews with workplace monitors and others who come in contact with former diversion program participants.

Respectfully, Senator, this fact bears repeating. *Neither MBC’s Diversion Program nor any of the other programs contracted out to the private sector have ever tracked any of their “graduates” or, for that matter, the many participants who flunk out.* No one can make a credible, substantiated claim that these programs actually help health care practitioners to recover from substance abuse. On the other hand, all five audits of MBC’s program conducted over 27 years repeatedly demonstrated and documented the intractable flaws in the program — and they are not capable of being fixed.

### **Suggested Options for Legislation**

I know you and your staff are planning to convene a hearing on these issues, which will include a spotlight on the parameters of the diversion programs operated by other non-MBC healthcare agencies. I applaud you for recognizing that (a) the Medical Board is not the only California health care licensing board that must deal with the problem of the impaired licensee, (b) all health care boards must come to grips with this problem — it is clearly not going away, and (c) health care boards can and should establish consistent, uniform, and enforceable standards to address this problem. Following that hearing, I hope you will consider the following options for your legislation:

**(1) an independent audit of the non-MBC diversion programs.** First, I believe your legislation should require an external, independent audit of the diversion programs run for seven health care boards by the private-sector company Maximus. To my knowledge, that company’s performance in operating these programs has never been audited; nor was the performance of Maximus’ predecessor contractor. Clearly, the significant problems of the Medical Board’s program were identified only through multiple external audits (the last of which was performed by the Bureau of State Audits as directed in SB 231 (Figueroa) of 2005). As the Medical Board learned, it is one thing to listen to program staff extol the virtues of a program; it is quite another to face up to actual facts as found by an independent auditor. Although Business and Professions Code section 156.1 authorizes the Department of Consumer Affairs to audit its diversion program contractor, it has never done so. Although these programs are run by well-intentioned staff at many boards, even they are not privy to the details of the operation as actually conducted by a private contractor. We urge you to apply to the non-MBC programs the same level of vigilance as has been applied to MBC’s program.

**(2) preventive education.** Your legislation should also require education on substance abuse prevention / wellness for health care practitioners — both while they are studying for their license and after they obtain it (through continuing education). Such a requirement would serve the entire licensee population (and not just the tip of the iceberg participating in diversion) by alerting them to the stressors and other factors that may lead to substance abuse; and it would certainly protect consumers better than a confidential diversion program. Again, board statutes and regulations are all over the map; some boards require such education, while others do not. In January 2008, MBC passed a motion supporting the education concept; its Education Committee is scheduled to explore specific options at a meeting on March 5.

**(3) require the development of uniform standards to guide all agencies in addressing the problem of the impaired licensee.** Finally, boards should be required to develop and enforce standards in key areas that can guide the operation of a diversion program or that can replace one entirely. No board — not even boards that have operated diversion programs for decades — has ever done this.

As the data cited above demonstrate, few licensees self-refer into diversion programs. Most impaired licensees do not come to the attention of their regulator until the problem has become acute — they are the subject of an adverse report by their employer, they have been arrested and/or convicted of DUI or drug possession, or they are the subject of a complaint concerning substance abuse. When an agency detects an alleged substance-abusing licensee in this manner, it must investigate that allegation. If that allegation is substantiated, that board now has a seriously impaired licensee on its hands.

In the best interest of the public and the licensee, that board must remove that licensee from practice and set in motion a series of actions designed to enable the licensee to recover while protecting the public. In this regard, a board is not limited to revocation or suspension of the license. Depending on the circumstances, boards have broad discretion to negotiate a stipulated probationary license with terms and conditions of probation that ensure abstinence and recovery and patient safety, all at the same time. Moreover, the terms of probation can evolve over time as a physician improves or (hopefully not) relapses. However, in my view, impaired licensees should not be permitted to practice secretly in unrestricted fashion; their practice should be restricted in a public fashion.

To address substance abuse, state licensing boards need not establish, attempt to run or even oversee, and/or pay for a complicated “program” per se. Boards have many choices in this area, because the private sector offers a vast array of drug/alcohol treatment, testing, monitoring, and rehabilitation programs. Occupational licensing boards have no expertise in any of these things; in my view, they should leave these activities to the private sector and instead develop enforceable standards that can be applied to impaired licensees as they (hopefully) move toward recovery.

Regardless of whether a board chooses to operate a program itself, outsource the operation of a program to the private sector, or address the problem without the costs and constraints of a formal program, that board absolutely must establish enforceable standards that protect patients and

to which all must adhere. Ideally, those standards would be consistent and uniform from board to board (to ensure consistent treatment of substance-abusing licensees and enable independent external performance audits), and they should change and evolve — always remaining state-of-the-art — as the science of chemical dependency, detection, and treatment evolves.

Senator, no board has ever established any such standards. I have studied the impairment programs of a number of different health care licensing boards. Regrettably, most statutes creating such programs are based directly on the Medical Board's statutes (which, as Enforcement Monitor, I characterized as "skeletal at best"). Although the Medical Board has adopted a few regulations to flesh out those statutes, they are — for the most part — nonsubstantive restatements of the statutes (and the regulations of other health care boards largely mimic those of the Medical Board).

None of those statutes or regulations even identify, much less address or govern, the mechanisms that purport to monitor participant compliance with his/her contract and the rules of the program, *e.g.*, drug testing, group meeting attendance, worksite monitoring standards, etc. None of those statutes or regulations set forth consistent standards for the handling of participants when they fail to comply with the contracts they have signed or the rules of the Program. For example — and astonishingly — no statute or regulation in place at any board sets forth consequences for relapse. For decades, all of these matters have been left to the discretion of program staff or volunteer "diversion evaluation committees" which have been allowed (unlawfully, as discussed below) to make decisions on a case-by-case basis.

I believe your legislation should require health care boards confronting the issue of substance-abusing licensees to establish in regulation enforceable standards in the following key areas. These standards can and should be adopted regardless of whether a board chooses to operate a "program" per se, outsource the operation of a program to the private sector, or simply enforce the standards. In fact, I would go further and suggest something unprecedented: Your legislation should create a committee composed of members of all health care boards, and charge that committee with drafting enforceable regulations in the following areas that all of the boards would then adopt pursuant to the Administrative Procedure Act rulemaking process:

◆ ***requirement for clinical diagnostic evaluation*** — no board statute or regulation specifies the type of clinical diagnostic evaluation that an impaired licensee should receive. Such a licensee should be required to undergo a comprehensive physical/mental/psychiatric evaluation by a physician who is trained in addiction medicine (or team of qualified professionals) and who makes recommendations about (1) the medically necessary treatment regimen for that licensee (*e.g.*, inpatient detoxification? outpatient therapy? sober living facility?); (2) the licensee's fitness for work; and (3) conditions for resumed practice. A serious program run by a public agency interested in protecting patients and enabling a licensee to recover would treat this problem seriously and require a thorough and professional evaluation.

◆ ***a "cease practice" requirement*** — when a government agency detects an impaired licensee and requires that person to come to grips with his/her addiction, that agency must

temporarily remove that licensee from practice. No reasonable agency whose priority is public protection should allow that licensee to continue practicing until (1) the comprehensive clinical diagnostic evaluation described above is completed; (2) key decisions regarding treatment, monitoring, and fitness for return to work have been made and implemented; and (3) appropriate monitoring mechanisms are in place. Yet no agency has ever adopted regulations requiring a mandatory “cease practice” at the beginning of recovery to enable licensees to focus solely on treatment and recovery. Although the Board of Registered Nursing says its diversion program requires an automatic “cease practice” period until the licensee has been evaluated by a diversion evaluation committee, that policy has never been adopted in regulation.

◆ *board/program communication with licensee’s employer* — in this area, board policies are all over the map. While the Medical Board’s Diversion Program routinely requires all participating physicians to sign releases authorizing the Program to communicate with the physician’s employer (and in fact requires participants to inform all employers of their participation and to secure “monitors” at every worksite), the Board of Registered Nursing cites its program’s confidentiality for its inability to talk to a nurse’s employer, and asks a participating nurse to voluntarily inform their employer. It seems commonsense that employers should be informed about employee participation in a diversion program, so that employers can assist as a partner in monitoring the participant’s compliance and protecting patients.

◆ *all aspects of the drug testing process* — drug testing is the primary objective determinant of a licensee’s compliance with his/her agreement (and/or the terms of a board’s order, in the case of probation) to abstain from all use of alcohol and prohibited drugs. However, in this critically important area, no agency has adopted enforceable and/or consistent standards concerning any aspect of the drug testing process, including frequency of testing, the method by which licensees are informed of the need to be tested, or the number of hours between the time the licensee is informed of the requirement and the actual test. No standard requires specimen collectors to be trained and/or certified. No standard specifies where drug tests must occur; requires that the collection must be observed by the collector (despite the plethora of Internet sites where anyone may purchase clean urine samples and “adulterants” that can mask the presence of drugs or drug metabolites); dictates the location of the laboratory that tests the specimen; or specifies how quickly the specimen should be sent to the laboratory, how quickly the lab should turn the results around, and/or the type of “panel” that the testing lab should utilize in testing the specimen.

While federal standards require “sensitive employee” drug tests to be performed in an observed fashion at a professional lab by a trained collector in full compliance with proper “chain of custody” procedures, the Medical Board used untrained collectors who did not collect specimens on the random date generated by a computer, but instead collected them on days that could be anticipated by participants. They collected urine samples at a Denny’s or McDonald’s, and inexplicably sent those samples to a lab in Utah. It took an average of six days from the collection of the sample to the receipt of the results — during which time the tested physician could be practicing full-time. As we now know from the June 2007 Bureau of State Audits report, MBC’s program lacked any meaningful controls over the ability of participants and collectors to unilaterally

manipulate collection dates.

Significantly, all California health care boards test for “relapse” — this translates into very infrequent testing (two or three times per month) on a purportedly random basis (which, as we now know, is easily gamed by participants by their ability to predict when testing is least/most likely to occur, and/or through their manipulation of lax “vacation” policies of the program). However, other private sector programs test for “abstinence” — this means routine testing every 36-48 hours (depending on the participant’s drug of choice) to ensure abstinence. Inasmuch as all board programs demand that participants abstain from use of drugs/alcohol as a term of the contract, it is unclear why none of them test for abstinence.

◆ ***group meeting attendance requirements*** — several boards require impaired licensees to attend twice-weekly group meetings of similarly-situated impaired health care professionals. Although these meetings are facilitated by counselors, no statute or regulation requires that these counselors be licensed or certified to practice therapy in any way. Although some boards require licensure or certification, it is unclear whether those boards consistently require and maintain updated proof of licensure/certification of those who are expected to provide therapy. Further, several boards require supplemental attendance at Alcoholics/Narcotics Anonymous meetings. State-required attendance at AA meetings, whose “twelve-step” doctrine tends to be religious in nature, has recently been ruled unconstitutional by a federal appellate court.<sup>1</sup> States must offer alternatives to programs of this nature.

◆ ***meaningful worksite monitor qualifications and standards*** — the Medical Board requires impaired physicians to secure a “worksite monitor” once they return to medical practice; it is unclear whether any other board requires this monitoring mechanism. Although highly touted by the Medical Board as a supplemental monitoring mechanism, MBC adopted no standards governing the qualifications of worksite monitors and/or their duties and responsibilities. As a result, MBC’s program approved individuals with a clear conflict of interest — for example, they were hired and fired by the participant — as “worksite monitors.” And MBC never adopted regulations or policies requiring the worksite monitor to visit (announced or unannounced), speak with, lay eyes on, or telephone — ever — the impaired physician. The worksite monitor was simply required to file quarterly reports of his/her “observations” without requiring anything meaningful in the way of observation.

◆ ***consequences for relapse*** — astonishingly, no board or program has ever adopted any standards that establish consequences for relapse. What should happen to a licensee who has been ordered to or has agreed to abstain from drugs/alcohol but who breaches that agreement? How many “bites of the apple” should that licensee be given before consequences are imposed? One? Two? “Three strikes and you’re out”? What should those consequences be? Removal from practice? Increased frequency of testing and/or meeting attendance? Referral to enforcement? No board or program has any standards in this area.

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<sup>1</sup> *Inouye v. Kemna*, 504 F.3d 705 (9th Cir. 2007).

◆ ***standards for termination from the program*** — the statutes creating most diversion programs provide that a participant may be terminated from diversion (and presumably referred to enforcement) if he/she fails to comply with his/her contract in any way. This is meaningless. Participants violate the terms and conditions of their contracts (and/or their probation) every day, in both significant and insignificant ways, and they are not terminated from these programs. Yet no board has adopted any regulations specifying the type, level, degree, or number of instances of noncompliance which would constitute grounds for termination from the program.

This is a critically important issue that has been, again, relegated to case-by-case decisionmaking by the various boards sponsoring these programs. Barring an interim suspension order, termination from a diversion program and referral to enforcement means nothing but further interminable disciplinary proceedings while an impaired practitioner continues to practice. As MBC Enforcement Monitor, I recommended that impaired physicians be required to sign a “Penal Code section 1000”-type agreement in which they admit self-abuse of drugs/alcohol (which is grounds for discipline) and surrender their license. That agreement would be deferred while the physician complies with his/her diversion contract. However, upon significant noncompliance, that agreement would be activated and the license would be immediately surrendered without further disciplinary proceedings. MBC failed to consider this suggestion.

◆ ***if a board uses a private-sector program, standards for communication from the program to the board*** — all of the non-MBC health care boards use Maximus to administer their impaired practitioner programs. However, no board has established clear standards defining the occasions upon which Maximus must communicate with the board or its staff. When? Upon a relapse? Upon other noncompliance with the terms and conditions of the contract? How quickly must Maximus communicate with the board or its staff after the violative event?

This is also an important but overlooked issue. At the Dental Board, Maximus apparently is not even required to report instances of noncompliance committed by probationers who have been ordered by the Board to participate in its Diversion Program (according to a January 24, 2008 Dental Board staff memo, “currently, the Enforcement Unit is not provided information from the Diversion program when a probationer is in violation of their probation terms”). This is appalling.

◆ ***“return to work” standards*** — assuming that an impaired licensee is not permitted to practice while in the early stages of recovery, boards must adopt standards that licensees must meet when they seek to return to practice. For what length of time must the licensee demonstrate rigorous drug testing and actual clean testing? For what length of time must the licensee demonstrate attendance at group meetings, and/or required psychotherapy? What monitoring mechanisms will continue and/or be added or enhanced after a licensee returns to work? How many hours per week will the licensee be permitted to work? What kind of showing is required when the licensee seeks to expand those work hours toward full-time? No board has adopted any standards in this area.

◆ ***standards for reinstatement of the license*** — assuming that the licenses of impaired individuals are on probation during the first two or three years of participation (or until sobriety is

stabilized), boards must be prepared and have standards in place when participants petition to reinstate their license. How many years of clean testing, group meeting attendance, and successful work performance must the petitioner demonstrate?

◆ *consistent and proper use of “diversion evaluation committees”* — some diversion programs use diversion evaluation committees (DECs) to assist with program decisionmaking; others do not. Some DECs are regional committees consisting of local experts on substance abuse; the Board of Pharmacy convenes a single “Pharmacy Review Committee” consisting of two staff members and a representative of the private company that administers the Board’s diversion program.

These committees, consisting of private parties, are intended to assist in program decisionmaking in an advisory capacity. However, because the individual boards have established no standards to guide program decisionmaking, each DEC operates in a vacuum; no standards exist to guide their consideration of individual participant matters that ensure that their recommendations are fair, consistent, and protective of the public interest. No DEC knows how another DEC has acted in a similar matter. No caselaw, precedent, or standards exist anywhere to guide them.

Exacerbating this problem is the fact that the statutes, regulations, and/or policies of several boards inappropriately delegate state police power to DECs by enabling them to make “decisions” or “determinations” concerning the extent to which a state licensee may practice — decisions which are not thereafter reviewed and/or ratified by a state official. This “unlawful delegation” of state governmental police power to private parties is a serious antitrust violation. The Medical Board purged its statute and regulations of all such language in 2000 (SB 1554 (Figueroa), Chapter 836, Statutes of 2000). All other boards utilizing DECs should do the same.

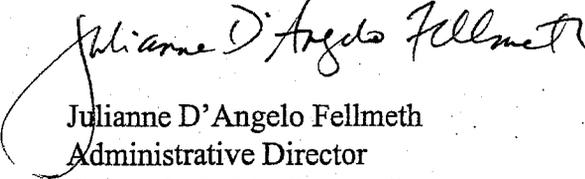
◆ *confidentiality* — by far the most contentious issue is the extent to which impaired licensees participating in a diversion program should be permitted to participate in confidentiality from their patients. All diversion programs guarantee confidentiality to self-referrals and to those who have been detected by enforcement but referred to diversion in lieu of discipline. As noted above, CMA/CSAM insist that confidentiality is necessary to entice self-referrals into seeking assistance. However, as demonstrated above, the “carrot” of confidentiality has not been successful in luring 95% of probably-impaired physicians into the Medical Board’s program; I doubt if the data are different at other agencies.

How is it possible that state agencies charged with public protection as their highest (and, indeed, “paramount”) priority are permitted to operate programs that divert impaired licensees from the discipline track, refer them into a secret program which may not adequately monitor their behavior or performance, and allow them to practice while still in the fragile stages of recovery? I submit to you that the entire concept is flawed and failed. Indeed, it is preposterous. Confidential “diversion” does not protect patients, and is certainly not the role of the state. It is the antithesis of the purpose of the state, which is to protect patients.

The CMA/CSAM proposal addresses exactly none of these standards; it fails to even recognize that they are needed. The Medical Board — which spent 27 years avoiding these decisions in favor of punting them to its Diversion Program and the Liaison Committee — is now prepared to establish standards in these areas. We believe your legislation should require other boards to join with the Medical Board and adopt consistent standards that protect the public.

Thank you for your consideration of this letter and the options I have suggested. If you need additional information, please do not hesitate to contact me at (619) 260-4806.

Sincerely,



Julianne D'Angelo Fellmeth  
Administrative Director  
Center for Public Interest Law

Former Medical Board Enforcement Monitor

cc: The Honorable Mike Eng, Chair, Assembly Business and Professions Committee  
Bill Gage, Chief Consultant, Senate Committee on Business, Professions and  
Economic Development  
Ross Warren, Chief Consultant, Assembly Business and Professions Committee  
Carrie Lopez, Director, Department of Consumer Affairs  
Richard Fantozzi, M.D., President, Medical Board of California  
Barbara Johnston, Executive Director, Medical Board of California

Testimony of Julianne D'Angelo Fellmeth  
Center for Public Interest Law  
University of San Diego School of Law

at the

**DIVERSION PROGRAM SUMMIT**  
Medical Board of California  
Sacramento, California ~ January 24, 2008

Good morning. My name is Julie D'Angelo Fellmeth and I represent the Center for Public Interest Law at the University of San Diego School of Law. I am also the former Medical Board Enforcement Monitor.

Thank you for your important decision last July to abolish the Diversion Program for substance-abusing physicians, and for convening this Summit today.

You have crossed a bridge. After 27 years and five failed audits, the Program is off the table. You now have the luxury of stepping back and doing what I advised you to do in the very first of the ten recommendations I made on this program back in my November 2004 report: "Based on the information contained in this and prior reports on the Diversion Program, the Medical Board must reevaluate whether the 'diversion' concept is feasible, possible, and protective of the public interest."

I suggest to you that the diversion concept is none of those things, and that it should never again be on your table.

Today, you've been presented with a number of options as to how you should approach the issue of the impaired physician. Of course, you have been asked by physician organizations to let them design and run a new program for you, and their proposal contains all of the hallmarks of the failed Diversion Program you just abolished, including confidentiality. And let me remind you that for 24 of the past 27 years, your Diversion Program was overseen by a "Liaison Committee" consisting of representatives from the California Medical Association and the California Society for Addiction Medicine. The Liaison Committee existed and was overseeing the Program during four of the five failed audits – and yet it did nothing to address any of the deficiencies found in any of those four audits.

The concepts they espouse sound great – who can disagree with getting help for impaired doctors? Treatment? Recovery? Wellness? Better doctors = better patients? More health care?

But translating those concepts into a nuts-and-bolts on-the-ground program that protects patients and is effective in assisting doctors recover is an extraordinarily difficult task at which they have failed too.

So what should you – the Medical Board – do now? Having thought about these issues for over 15 years, and having had the unique opportunity to audit the Diversion Program for two years, I offer you this advice:

1. The Medical Board should not run any kind of monitoring program for substance-abusing physicians. That is not your job.
2. Nor should it oversee such a program.
3. Nor should it pay for such a program.
4. The Medical Board should never again consider diverting substance-abusing physicians from discipline.
5. And last but not least, the Medical Board should not conceal the identities of physicians who are in treatment or recovery, and who have come to the attention of the Board's enforcement program.

None of this is your job. You are a government agency – a regulatory board that patients must be able to trust. Your core functions are licensing and discipline. You barely have sufficient resources to do those things well; you should not allow them to be siphoned off to fund other things that are not your job.

Should other people run programs that offer drug treatment, monitoring, and testing? Absolutely! Others already do, and now that you are out of the picture, I expect new programs to pop up. In fact, they're here today – you've already heard from them. Should you anoint one to the exclusion of all others? Absolutely not! Let the private sector handle this.

Rather than competing with the private sector, you should focus on researching state-of-the-art standards and requirements for the mechanisms that will replace the Diversion Program.

For example, you need standards in the area of drug testing. Last November, you – as a board – decided that rather than sending impaired physicians to the Diversion Program, you would instead require them to (1) abstain from all use of drugs/alcohol and (2) undergo “random observed drug testing.”

But you went 27 years without ever setting any nuts-and-bolts standards for the drug testing carried out by the Diversion Program. Your Diversion Program was using untrained collectors who consistently did NOT test on the random date generated by a computer. Drug tests were conducted in Denny's or McDonalds, and the samples were sent to a lab in UTAH. It required an average of SIX DAYS from the date of the test to receipt of test result.

Unless you specify otherwise, that is exactly what you are going to get in the future when you require drug testing – and I submit to you that is unacceptable and does not protect the public. You can't

just require drug testing without establishing clear standards for what kind of drug testing is acceptable to you. Those standards are out there. State and federal regulatory agencies have developed them. You need to learn about them and insist on them.

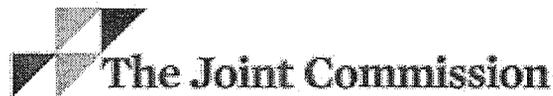
You also need standards that define the consequences for relapse. Again, you went 27 years without setting any standards in this area — you were content to let the Diversion Program handle that on a case-by-case basis. But now you've got to squarely confront that question: What should your staff do when a probationer who has been required to undergo testing tests positive? What should the Attorney General's Office do? How many chances will that doctor get? What will you require?

The bottom line? The private sector already offers treatment, monitoring, and drug testing programs. Your job as the Medical Board is to detect an impaired physician and remove or restrict that doctor's medical practice in a way that is transparent to his patients. What happens after that is up to that doctor. That is his business, not yours. But when he returns to you and petitions for reinstatement of his license, you must have standards in place that require that doctor to demonstrate (1) lengthy and rigorous testing for abstinence, (2) a lengthy period of actual abstinence, and (3) a demonstrated commitment to a sober lifestyle. That's where you should focus your attention — on the development of standards and requirements for the mechanisms that will replace the Diversion Program.

Thank you.

# Attachment 4

## ***Medication Errors/Sentinel Event Alert***



## Sentinel Event Alert

Issue 39, April 11, 2008

### Preventing pediatric medication errors

Errors associated with medications are believed to be the most common type of medical error and are a significant cause of preventable adverse events. Experts agree that medication errors have the potential to cause harm within the pediatric population at a higher rate than in the adult population. For example, medication dosing errors are more common in pediatrics than adults because of weight-based dosing calculations, fractional dosing (e.g., mg vs. Gm), and the need for decimal points.

"Research shows that the potential for adverse drug events within the pediatric inpatient population is about three times as high as among hospitalized adults," (1) says Stu Levine, PharmD, informatics and pediatric specialist, Institute for Safe Medication Practices, an organization which serves as a resource for information on how to improve medication practices. "For this reason, health care providers must pay special attention to the specific challenges relating to the pediatric population."

A new study—the first to develop and evaluate a trigger tool to detect adverse drug events in an inpatient pediatric population—identified an 11.1 percent rate of adverse drug events in pediatric patients. This is far more than described in previous studies. The study also showed that 22 percent of those adverse drug events were preventable, 17.8 percent could have been identified earlier, and 16.8 percent could have been mitigated more effectively. (2)

Children are more prone to medication errors and resulting harm because of the following:

- Most medications used in the care of children are formulated and packaged primarily for adults. Therefore, medications often must be prepared in different volumes or concentrations within the health care setting before being administered to children. The need to alter the original medication dosage requires a series of pediatric-specific calculations and tasks, each significantly increasing the possibility of error.
- Most health care settings are primarily built around the needs of adults. Many settings lack trained staff oriented to pediatric care, pediatric care protocols and safeguards, and/or up-to-date and easily accessible pediatric reference materials, especially with regard to medications. Emergency departments may be particularly risk-prone environments for children. (3)
- Children—especially young, small and sick children—are usually less able to physiologically tolerate a medication error due to still developing renal, immune and hepatic functions.
- Many children, especially very young children, cannot communicate effectively to providers regarding any adverse effects that medications may be causing.

During calendar years 2006-2007, USP's MEDMARX® database shows nearly 2.5 percent of pediatric medication errors led to patient harm. The most common types of harmful pediatric medication errors were: improper dose/quantity (37.5 percent), omission error (19.9 percent), unauthorized/wrong drug (13.7 percent), and prescribing error (9.4 percent), followed by wrong administration technique, wrong time, drug prepared incorrectly, wrong dosage form, and wrong route. Medication errors involving pediatric patients were most often caused by: performance deficit (43.0 percent), knowledge deficit (29.9 percent), procedure/protocol not followed (20.7 percent), and miscommunication (16.8 percent), followed by calculation error, computer entry error, inadequate or lack of monitoring, improper use of pumps, and documentation errors. The MEDMARX Data Report (4) reveals that approximately 32.4 percent of pediatric errors in the operating room involve an improper dose/quantity compared with 14.6 percent in the adult population and 15.4 percent in the geriatric population. A recent study indicates that children are particularly at risk for chemotherapy medication errors. (5)

#### Risk reduction strategies

Pediatric-specific strategies for reducing medication errors include:

*Standardize and identify medications effectively, as well as the processes for drug administration.*

- Establish and maintain a functional pediatric formulary system with policies for drug evaluation, selection and therapeutic use. (6)

- \* To prevent timing errors in medication administration, standardize how days are counted in all protocols by deciding upon a protocol start date (e.g., Day 0 or Day 1).
- \* Limit the number of concentrations and dose strengths of high alert medications to the minimum needed to provide safe care.
- \* For pediatric patients who are receiving compounded oral medications and total parenteral nutrition at home, ensure that the doses are equivalent to those prepared in the hospital (i.e., the volume of the home dose should be the same as the volume of the hospital prepared products).
- \* Use oral syringes to administer oral medications. The pharmacy should use oral syringes when preparing oral liquid medications. Make oral syringes available on patient care units when "as needed" medications are prepared. Educate staff about the benefits of oral syringes in preventing inadvertent intravenous administration of oral medications.

*Ensure full pharmacy oversight—as well as the involvement of other appropriate staff—in the verifying, dispensing and administering of both neonatal and pediatric medications.*

- \* Assign a practitioner trained in pediatrics to any committee that is responsible for the oversight of medication management.
- \* Provide ready access, including website access, to up-to-date pediatric-specific information for all hospital staff. This information should include pediatric research study data, pediatric growth charts, normal vital sign ranges for children, emergency dosage calculations, and drug reference materials with information about minimum effective doses and maximum dose limits.
- \* Orient all pharmacy staff to specialized neonatal/pediatric pharmacy services in your organization. (7)
- \* Provide a dosage calculation sheet for each pediatric critical care patient, (8), (9) including both emergency and commonly used medications. (7)
- \* Develop preprinted medication order forms and clinical pathways or protocols to reflect a standardized approach to care. Include reminders and information about monitoring parameters.
- \* Create pediatric satellite pharmacies or assign pharmacists and technicians with pediatric expertise to areas or services such as neonatal/pediatric critical care units and pediatric oncology units. (1), (7) At a minimum, pediatric medications should be stored and prepared in areas separate from those where adult medications are stored and prepared.

*Use technology judiciously.*

- \* Use methods to ensure the accuracy of technology that measures and delivers additives for intravenous solutions, such as for total parenteral nutrition.
- \* If dose and dose range checking software programs are available in hospital or pharmacy information systems, enable them to provide alerts for potentially incorrect doses.
- \* Medications in automated dispensing cabinets that do not undergo appropriate pharmacist review should be limited to those needed for emergency use and/or to those medications under the control of a licensed independent prescriber, as specified in Joint Commission standard MM 4.10.
- \* Recognize that the use of infusion pumps, or smart pumps, is not a guarantee against medication errors. Appropriate education for nurses, pharmacists and other caregivers regarding these technologies is important for all institutions caring for pediatric patients.
- \* To prevent adverse outcomes or oversedation, use consistent physiological monitoring – particularly pulse oximetry (10) – while children are under sedation during office-based procedures. Use age- and size-appropriate monitoring equipment and follow uniform procedures under the guidance of staff appropriately trained in sedation, monitoring and resuscitation.
- \* Providers are encouraged to develop bar-coding technology with pediatric capability. Potential errors should be carefully considered while adapting this technology to pediatric processes and systems. For example, a pediatric bar-coding solution must be able to provide readable code for small-volume, patient-specific dose labels.

#### **Existing Joint Commission requirements**

As part of National Patient Safety Goal 2B, Joint Commission accredited organizations are required to follow The Joint Commission's Official "Do Not Use" Abbreviations List. In addition, Goal 3 (Improve the safety of using medications) and Goal 8 (Accurately and completely reconcile medications across the continuum of care) establish several medication standardization, identification and communication

requirements that are especially important in pediatrics and neonatology. Three Sentinel Event Alerts also address specific issues relating to pediatric medication errors. (11), (12), (13)

#### Other Joint Commission suggested actions

The Joint Commission offers the following suggested actions to prevent pediatric medication errors and their related adverse events in pediatric care settings:

1. Since patient weight is used to calculate most dosing (either as weight-based dosing, body surface area calculation, or other age-appropriate dose determination), all pediatric patients should be weighed in kilograms at the time of admission (including outpatient and ambulatory clinics) or within four hours of admission in an emergency situation. Kilograms should be the standard nomenclature for weight on prescriptions, medical records and staff communications.
2. No high risk drug should be dispensed or administered if the pediatric patient has not been weighed, unless it is an emergency.
3. On inpatient medication orders and outpatient prescriptions, require prescribers to include the calculated dose and the dosing determination, such as the dose per weight (e.g., milligrams per kilogram) or body surface area, to facilitate an independent double-check of the calculation by a pharmacist, nurse or both. (7) Exceptions to this are medications that do not lend themselves to weight-based dosing, such as topicals, ophthalmics, and vitamins.
4. Whenever possible, use commercially available pediatric-specific formulations and concentrations. When this is not possible, prepare and dispense all pediatric medications in patient-specific "unit dose" or "unit of use" containers, rather than in commercially available adult unit doses. (7) For oral liquid preparation medications, use oral syringes to ensure correct dosage.
5. Clearly differentiate from adult formulations all products that have been repackaged for use in pediatric populations. (14) Use clear, highly visible warning labels. To prevent overdoses, keep concentrated adult medications away from pediatric care units. Avoid storing adult and pediatric concentrations in the same automated dispensing machine/cabinet drawer.
6. Ensure comprehensive specialty training for all practitioners involved in the care of infants and children, as well as continuing education programs on pediatric medications for all health care providers. Training and education should include information on how adverse effects should be reported. (6), (15)
7. Communicate verbally and in writing information about the child's medication to the child, caregivers and parents/guardians, including information about potential side effects. Ask the caregiver/parent/guardian to repeat back their understanding of the drug and how it is to be administered. Encourage the asking of questions about medications.
8. Have a pharmacist with pediatric expertise available or on-call at all times.
9. Establish and implement medication procedures that include pediatric prescribing and administration practices.

Should a serious error or adverse event occur, the organization should conduct a root cause analysis and develop and implement a corrective action plan which should be monitored to assure that it is effective. The Joint Commission also encourages apology and transparency about the error with both staff and the families involved.

In addition, The Joint Commission encourages pharmaceutical manufacturers to develop pediatric-specific formulations as well as to standardize the labeling and packaging for all types of medications. (14) Researchers are encouraged to conduct additional research on interventions to reduce pediatric medication errors, especially in emergency departments, ambulatory clinics and home environments. (13)

In conclusion, since parents and caregivers play an extremely important role in the health care of children, The Joint Commission encourages parents and caregivers to seek out information and ask questions about their child's medications and to repeat back instructions to clinicians in order to ensure understanding about the drug, dosages, timing and routes of administration. This is done both to reassure staff that parents or caregivers have a true understanding of the medications the child is taking and, most importantly, to ensure that everyone involved can safely administer medications to this most vulnerable population.

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bcc  
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### Development, Testing, and Findings of a Pediatric-Focused Trigger Tool to Identify Medication-Related Harm in US Children's Hospitals

**OBJECTIVES.** The purposes of this study were to develop a pediatric-focused tool for adverse drug event detection and describe the incidence and characteristics of adverse drug events in children's hospitals identified by this tool.

**METHODS.** A pediatric-specific trigger tool for adverse drug event detection was developed and tested. Eighty patients from each site were randomly selected for retrospective chart review. All adverse drug events identified using the trigger tool were evaluated for severity, preventability, ability to mitigate, ability to identify the event earlier, and presence of associated occurrence report. Each trigger and the entire tool were evaluated for positive predictive value.

**RESULTS.** Review of 960 randomly selected charts from 12 children's hospitals revealed 2388 triggers (2.49 per patient) and 107 unique adverse drug events. Mean adverse drug event rates were 11.1 per 100 patients, 15.7 per 1000 patient-days, and 1.23 per 1000 medication doses. The positive predictive value of the trigger tool was 3.7%. Twenty-two percent of all adverse drug events were deemed preventable, 17.8% could have been identified earlier, and 16.8% could have been mitigated more effectively. Ninety-seven percent of the identified adverse drug events resulted in mild, temporary harm. Only 3.7% of adverse drug events were identified in existing hospital-based occurrence reports. The most common adverse drug events identified were pruritis and nausea, the most common medication classes causing adverse drug events were opioid analgesics and antibiotics, and the most common stages of the medication management process associated with preventable adverse drug events were monitoring and prescribing/ordering.

**CONCLUSIONS.** Adverse drug event rates in hospitalized children are substantially higher than previously described. Most adverse drug events resulted in temporary harm, and 22% were classified as preventable. Only 3.7% were identified by using traditional voluntary reporting methods. Our pediatric-focused trigger tool is effective at identifying adverse drug events in inpatient pediatric populations.



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## First DataBank Launches Campaign to Focus Public and Industry Attention on Medication Error Prevention

Company will donate money to non-profit organizations supporting medication error prevention outreach and education for HIMSS attendees wearing custom wristband

SAN BRUNO, Calif., Feb. 19 /PRNewswire/ -- First DataBank, a leading provider of drug information databases, today announced the launch of a new brand awareness campaign to focus public and industry attention on the prevention of medication errors. The campaign will be unveiled at the Healthcare Information and Management Systems Society (HIMSS) 2008 Annual Conference & Exhibition to be held February 24-28, in Orlando, Florida.

First DataBank's campaign theme, "A World Free of Medication Errors," is intended to focus industry and public attention on how the intended use of the company's medication information at the point of care may play a key role in the prevention of medication errors. The company is a pioneer in the development of drug information databases used throughout healthcare in clinical decision support. Experts estimate that as many as 98,000 people die each year from medical errors that occur in hospitals and a significant number of those deaths are due to medication-related errors.

A key component of the public awareness effort is a tie-in to two non-profit organizations that share First DataBank's mission of medication error prevention. At the HIMSS 2008 Annual Conference, attendees visiting the First DataBank booth will receive a custom-designed wristband and a brochure describing the "A World Free of Medication Errors" campaign mission. Throughout every public event in which First DataBank participates in 2008, the company will set aside five dollars toward each wristband distributed that will be shared equally by two non-profit organizations. The two organizations chosen by First DataBank to share in the funds raised throughout the campaign year are: FLAAME: Families Launching Action Against Medication Errors and the Josie King Foundation.

"The employees at First DataBank are passionately committed to improving patient safety and healthcare quality in everything we do," said Don Nielsen, M.D., President, First DataBank. "The knowledge that our drug information plays a significant role in the prevention of harmful medication errors was our inspiration for this campaign and our hope is that it motivates others to join with us," he continued.

"On behalf of the Josie King Foundation, we are honored to have been selected to be part of First DataBank's campaign to raise public and industry awareness of medication errors," said Sorrel King, co-founder of

the Josie King Foundation named to honor of her young daughter, Josie, who died from a medical error. "I speak to hundreds of clinicians working in hospitals around this country on this subject every year since Josie's death and there is always more information to share, and more teaching to be done. The donation from First DataBank's campaign will support these ongoing educational efforts," she stated.

#### About FLAAME: Families Launching Action Against Medication Errors

FLAAME was founded in 2007 to heighten public and health care industry awareness of errors made on both sides of the prescription counter. Co-founded by Cathy Horton, whose career, family life and health were thrown into turmoil following a medication error. FLAAME'S mission is to eliminate instances of prescription errors, medication use errors and negative drug interactions through awareness programs, education, lobbying and web-based resources. For more information about FLAAME visit <http://www.flaame.org>.

#### About The Josie King Foundation

The Josie King Foundation was founded in 2001 by Sorrel and Tony King, after their young daughter, Josie, died of medical errors at Johns Hopkins University Hospital. The Josie King Foundation's mission is to prevent others from dying or being harmed by medical errors. By uniting healthcare providers and consumers, and funding innovative safety programs, the foundation's hope is to create a culture of patient safety, together. For more information about the Josie King Foundation visit <http://www.josieking.org>.

#### About First DataBank

First DataBank, a subsidiary of Hearst Corporation, drives patient safety and healthcare quality by providing drug databases that are used within information systems that touch every aspect of healthcare. For 30 years, we have partnered with system developers to integrate and optimize our drug information to improve user workflow and enhance clinical decision making by those entrusted with treating patients at the point-of-need. For more information about First DataBank, call 800-633-3453 or visit <http://www.firstdatabank.com>.

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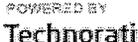
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## HOSPITALS TACKLE HIGH-RISK DRUGS TO REDUCE ERRORS

March 5, 2008; Page D1  
WALL STREET JOURNAL

Hospitals are taking steps to prevent errors in the use of so-called high-alert medications -- those that, when given in the wrong dose or used incorrectly, have the highest risk of seriously harming or even killing a patient.

Many of the high-alert medications are the most essential to hospitals. Among them are drugs to prevent blood clots, sedate patients, relieve pain and stabilize diabetics. But incorrect use of these drugs can lead to disasters, such as the accidental overdoses of heparin, an anticlotting drug, that killed three infants at an Indiana hospital in 2006 and threatened the newborn twins of actor Dennis Quaid this past November.

High-dose heparin was repackaged (right) to make errors less likely.

While there are 19 categories of high-alert medications, according to the Institute for Safe Medication Practices, studies show that about eight medications, including heparin, account for 31% of all medication errors that harm patients.

Now, amid growing awareness of medication mistakes and pressure from safety groups, hospitals are scrambling to overhaul their safety practices. They are working with drug makers to redesign confusing packages and eliminating multiple concentrations of the same drug from supply cabinets. They are also investing in bar coding and systems that let staffers check the accuracy of medication orders at patients' bedsides and see other information, such as allergies, that could cause adverse reactions.

In perhaps the most challenging step, hospitals are tackling the "grab and go" culture in busy hospitals that evidence increasingly shows causes errors. Doctors, nurses and pharmacy staffers often give out medications without fully reading the labels, evaluating patients' risks, or checking one another's work. "For each one of these errors to reach a patient, six to eight slip-ups have occurred somewhere in the system, and each one of those steps is an opportunity for someone to intervene," says Kerry Butler, quality and medication-safety officer at Saint Thomas Health Services in Nashville, Tenn., a unit of nonprofit health-care system Ascension Health.

Saint Thomas is one of a number of hospitals establishing "behavioral accountability" standards for staffers, with acronyms like STAR -- for Stop, Think, Act, Review. Hospitals are also adding strict new policies, such as requiring two staffers to check before certain drugs are given to patients and creating new training programs to help staffers intercept errors and respond faster when mistakes do occur.

The Institute for Healthcare Improvement, a Cambridge, Mass., nonprofit that sponsors health-care quality programs, has created a guide for hospitals on how to prevent harm from high-alert medications, focusing on four categories

of medications that it says are most frequently used and have the greatest potential for harm: anticoagulants, narcotics, insulin and sedatives.

The Joint Commission, which accredits hospitals, is requiring that hospitals have programs in place by the end of this year to reduce the likelihood of harm from anticoagulation therapy using drugs like heparin.

But Mike Cohen, president of the Institute for Safe Medication Practices, which monitors and analyzes errors and maintains an updated list of high-alert medications, says that safety efforts are largely voluntary and that too few hospitals have invested in technologies such as bar coding that could sharply reduce errors.

Hospitals are also calling on patients and families to act as a final line of defense, keeping a watchful eye on medications and asking nurses to verify their accuracy -- especially when infants and children are involved. "Kids are changing every day, and administering medications in doses according to size and weight adds a new level of complexity," says Charles Homer, a professor at Harvard University and chief executive of the National Initiative for Children's Healthcare Quality.

While hospitals have always had to deal with potentially dangerous medications, the introduction of thousands of new drugs in a growing range of doses, concentrations and packages has increased the likelihood of error, Mr. Cohen says.

For example, nurses often flush the tubes used to deliver intravenous medications to infants with a low-dose heparin product to keep the catheters from clotting. But at Methodist Hospital in Indianapolis, three infants that were treated in the neonatal intensive-care unit died in 2006 after a technician accidentally replaced 10-unit-per-milliliter vials in a medicine dispenser with vials containing 10,000 units per milliliter. Six different nurses took out the medications, assuming them to be the correct dose because of their placement in the cabinet, and flushed the infant's catheters. By the time the mistake was discovered, it was too late.

Methodist, facing investigations and lawsuits tied to the deaths, acted quickly to publicly disclose the errors and retrained its staff in rigorous prevention policies. It installed a system to bar-code medications, as well as an automated refilling system for medication storage cabinets and a scanner for verifying medication at the bedside. It also replaced the 10,000-unit heparin vial with a heparin-filled syringe that can't be confused with the smaller dose, and two health-care workers must now look at a dose of heparin before it is administered to a newborn.

The hospital is sharing its strategy for dealing with the errors with other hospitals, including a teleconference March 10 sponsored by IHI. Says Valerie Shahriari, director of risk management and patient safety for Methodist parent Clarian Health: "If this happened to us, it can happen to other hospitals, and we think people can learn from our experience."

In the case of the Quaid twins, who survived a heparin overdose at Cedars-Sinai Medical Center in Los Angeles in November, the family is suing heparin marketer Baxter International Inc., saying that the error was a result of confusion by hospital staffers over similar packaging used for its low-dose Hep-Lock IV flushing product and a 10,000-unit vial.

Baxter says it hopes to resolve the lawsuit and work with patients and hospitals to further improve safety. In February 2007, the company sent out a safety alert to its customers, warning of the potential for error; in October, it changed its packaging to more sharply set apart different heparin

concentrations, adding snap-off caps so that nurses must take an extra step when opening it. It also varied the colors, enlarged the font size, and stamped "Not for Lock Flush," referring to the low-dose flushing product, on large-dose vials. But hospital staffers "still have to read the labels, no matter what we do," says Debra Bello, senior director of global medical and clinical affairs for Baxter's medication-delivery business.

(In an unrelated development, Baxter is recalling heparin vials amid a Food and Drug Administration investigation of reports of allergic reactions and deaths that appear to be linked to manufacturing problems.)

Cedars-Sinai has also taken steps to overhaul safety practices, after an internal investigation concluded that staffers failed to follow any of its policies on verifying medication before dispensing and administering the heparin in the case of the Quaid twins. About 1,800 nurses and all its pharmacy technicians were required to undergo retraining on high-alert-medication policies and pass a written test. It also has replaced heparin with a saline solution for flushing catheters.

Other hospitals are taking steps now to prevent such errors. Duke University Hospital is using "mistake-proofing" strategies such as stocking standardized concentrations of medicines and premixed doses and using "smart pumps" that deliver an alert if a mistake is made in entering a dose. It has also adopted the Six Sigma methodology, used by manufacturers to minimize errors, to identify what could go wrong with high-alert medications and develop prevention plans. The hospital, which already has a computerized system used by doctors to enter medication orders, is now adding a medication-administration system that will let nurses view all the information about a patient and make it easier to avoid errors at the bedside, according to Judy Prewitt, chief nursing officer.

Write to Laura Landro at [laura.landro@wsj.com](mailto:laura.landro@wsj.com)

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# Prescribing Errors

■ **Angie S. Graham, PharmD, FCSHP**

Drug Information Coordinator, Department of Pharmacy, Stanford Hospital & Clinics  
Assistant Clinical Professor of Pharmacy, University of California, San Francisco  
Please address correspondence to Angie Graham at AnGraham@stanfordmed.org.

## Continuing Education

The Institute of Medicine estimates that 1 million preventable adverse drug events occur annually in the United States. Although the best data come from studies conducted in hospitals, the problem of medication errors is probably larger in other settings. Every stage of the medication-use process is vulnerable to errors, but the steps most frequently associated with errors are prescribing and administration.<sup>1</sup> This article will review the literature on prescribing errors in different settings with a focus on the Institute of Medicine's (IOM) Preventing Medication Errors report. Pharmacists can serve not only as the first line of defense against individual prescribing errors but also as leaders in systems approaches to preventing prescribing errors.

The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health-care professional, patient, or consumer. Such events may be related to professional practice, health-care products, procedures, and systems, including prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.<sup>2</sup> A definition of prescribing errors has also been developed by a group of practitioners using a 2-stage Delphi technique: "A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice."<sup>3</sup>

Although many medication errors do originate with prescribers, determining who made the error is ultimately less important than determining why. Targeting the under-

## Learning Objectives

*At the completion of this article, the reader should be able to:*

1. Identify the incidence of prescribing errors in various care settings
2. Recognize the types of prescribing errors reported most commonly in the literature
3. List the interventions that have been recommended for reducing prescribing errors during hospital care, ambulatory care, and long-term care
4. State the opportunities for pharmacists to reduce medication errors in hospitals
5. Recognize potential barriers to reducing medication errors

lying causes supports a systems approach to medication errors. Michael Cohen, president of The Institute for Safe Medication Practice, identified 10 key system elements as having the greatest impact on medication use:

1. Patient information
2. Drug information
3. Medication-related communication
4. Drug labeling, packaging, and nomenclature
5. Drug standardization, storage, and distribution
6. Medication delivery device selection, use, and monitoring
7. Environmental factors
8. Staff competency and education
9. Patient education
10. Quality improvement processes and risk management.<sup>4</sup>

In keeping with these 10 key system elements, the IOM recommended the following in all settings to reduce medication errors: reference information accessible at the point of care, prescribing managed electronically, technologies effectively used and well designed, patient-specific medication information communicated at all hand-offs of care, error monitoring, and a safety culture.<sup>1</sup>

## Hospital Care

Among the IOM's findings in their *Preventing Medication Errors* report was that, on average, each hospitalized patient in America experiences 1 medication error every day. Studies show that the average preventable adverse drug event rate in United States (U.S.) hospitals ranges from 3.7 to 84.1 per 1,000 admissions. Between 380,000 and 450,000 preventable adverse drug events are thought to occur each year in U.S. hospitals, resulting in total annual costs of \$3.5 billion and average extra inpatient costs of \$5,857 per patient.<sup>1</sup>

## Error Rates – Hospital Care

Rates of prescribing errors in hospital studies vary widely, but for the most part, the studies that found the highest rates were the ones with the most comprehensive detection methods, suggesting that the higher estimates are probably more accurate. Across various studies, the rates have been found to be 12.3 – 1,400 prescribing errors per 1,000 admissions, 0.61 – 53 prescribing errors per 1,000 orders, and 1.5 – 9.9 prescribing errors per 100 opportunities for errors. Prescribing errors for hospitalized pediatric

patients have been detected in 4.2% to 30% of all orders, depending on the study. In an investigation of pediatric emergency departments, 10% of all children experienced a prescribing error.<sup>1</sup>

### Key Findings – Hospital Care

In one study of 4,768 medication errors occurring over 5 years in hospital cardiology wards, 1,102 could be attributed to a particular health-care discipline. Of these, 692 (62.8%) were associated with prescribers, including physicians and physician assistants. Three hundred seventy-four (54%) of the errors attributed to prescribers were classified as admission errors, defined as errors related to unintended changes in drugs or doses from what the patient was taking before admission. Another 284 (41%) were attributed to lack of drug knowledge, and 28 (4%) were related to errors at discharge.<sup>5</sup>

In another study of 264 preventable adverse drug events and 334 errors among adult admissions to 11 medical and surgical units in 2 tertiary hospitals over 6 months, most errors occurred in the physician ordering stage of the medication use process (39%). The most common error types were wrong dose (28%), wrong choice (9%), and wrong drug (9%). The underlying causes of the prescribing errors were most often lack of knowledge of the drug (36%), lack of information about the patient (24%), rule violations (19%), and slips and memory lapses (11%).<sup>6</sup>

A systematic evaluation of every third prescribing error detected and averted by pharmacists in a large teaching hospital over 1 year found an error rate of 3.99 per 1000 orders. Dosing errors accounted for the largest proportion of all errors and included both overdoses (41.8% of all errors) and under doses (16.5% of all errors). Prescribing medications to which the patient was allergic (12.9%) and prescribing inappropriate dosage forms were the next most common error types. The drug classes most frequently involved with prescribing errors were antimicrobials (39.7%), cardiovascular drugs (17.5%), and gastrointestinal drugs (7.3%). The patient factors typically associated with drug or dose errors were advanced age, renal impairment, and patient weight. Underlying factors thought to contribute to the prescribing errors were lack of knowledge of the drug (30%), lack of knowledge of the patient (29.2%),

and problems with calculations and rate/unit expressions (17.5%). Among 43 severe errors, 83.7% involved prescribing a drug to which the patient was allergic and 17.7% involved dose calculation problems.<sup>7</sup>

A study of 10-fold dosing errors in a large tertiary teaching hospital detected 0.51 10-fold prescribing errors per 100 total admissions and 0.83 10-fold dose prescribing errors per 1,000 total patient days. For adults, the rate was 0.52 per 100 admissions and 0.77 per 1,000 patient days. Among pediatric patients, 0.53 10-fold dosing errors were found per 100 admissions and 0.98 were found per 1,000 patient care days. Errors were potentially severe in 45% of cases and were overdoses 61% of the time.<sup>8</sup>

Lack of training on prescribing safety may contribute to the high rate of prescribing errors observed to date. In one study, 82% of medical students and house staff at a large teaching institution said they learned about safe prescribing simply by copying orders written by other physicians. In questionnaires of medical residents, interns, and students, the conditions they thought contributed to prescribing errors were being in a hurry (84%), being interrupted (66%), excessive workload (55%), fatigue (43%), incomplete knowledge of the medication (34%), and incomplete knowledge of the patient (29%).<sup>9</sup> Despite these questionnaire results, no correlation was detected between the prescribing error rate and number of hours worked or between the prescribing error significance and number of hours worked in a study of 43 medical residents and 45,366 orders.<sup>10</sup> These findings are in contrast to studies in pharmacists, in whom the risk of dispensing errors has been shown to increase with increased workload.<sup>11,12,13</sup>

Finally, although much of the literature on prescribing errors in hospitals has focused on errors of commission, a growing body of evidence suggests that there is a considerable problem with errors of omission and specifically with underutilization of appropriate therapies. Significant findings cited in the IOM's *Preventing Medication Errors* report were that, for patients admitted for a myocardial infarction, only 85-93% were given aspirin within 24 hours of hospitalization; only 53-93% were discharged with an aspirin prescription; only 66-78% were given a beta-blocker within 24 hours of hospitalization; only 53-83% were discharged

with a beta blocker; and only 51-73% were discharged with an ACE inhibitor. Appropriate prophylactic antibiotics for surgery were prescribed when indicated in 70-98% of patients, and thromboembolic prophylaxis was carried out when indicated for procedures in 5-90% of cases.<sup>1</sup>

### Improvement Strategies – Hospital Care

The first and most important approach that hospital pharmacy leadership can take to reduce the medication error problem in general is to offer evidence-based clinical pharmacy services associated with error reductions. In Bond's survey of approximately 1,000 hospitals and 400,000 medication errors, the clinical pharmacy services associated with decreased medication errors were managing drug protocols, managing adverse drug reactions, participating in medical rounds, providing a formal drug information service, and taking drug admission histories. Hospitals providing these services had reductions in their medication error rates of 13% to 51%, depending on the service. Increased staffing of clinical pharmacists per occupied bed was also associated with decreased medication errors. The authors advocated the use of their results as a template for restructuring hospital pharmacies to reduce medication errors and improve patient safety.<sup>14</sup>

Pharmacists and pharmacy services are a component of the IOM's medication error prevention strategies. The *Preventing Medication Errors* report concluded that there was good evidence to support pharmacist participation on hospital rounds. Good evidence was also found to support the effectiveness of stand-alone clinical decision support systems and of computerized physician order entry with built-in clinical decision support systems, based on reductions in medication errors of 13-86% and in preventable adverse drug events of 17-62% across various studies. Interventions that were characterized as promising were smart intravenous pumps and bar coding.<sup>1</sup>

Although quality study data supporting efficacy in the hospital setting are available only for a handful of medication-safety interventions like clinical decision support, a variety of other recommendations have been made based on preliminary data or expert opinion. These include computerized physician order entry, unit dosing, standardized

prescription writing, prescribing rules, elimination of dangerous abbreviations, written protocols for high-alert medications, and verbal order standards and limits. Beyond these interventions, most organizations recommended a systems approach to medication safety, a culture of safety, and improved error identification and reporting.<sup>1</sup>

Several non-pharmacy national organizations offer recommendations for clinical pharmacy services to reduce medication errors in the hospital setting. A selected list is available in Table 1.<sup>1</sup> The endorsement of specific pharmacy services by these national organizations can be used to justify new or expanded pharmacy roles to hospital administration.

The Agency for Healthcare Research and Quality is a division of the federal government's Department of Health & Human Services. Their report, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*, identified 2 pharmacy services as having a high potential impact on reducing medication errors and adverse drug events: pharmacist consultation services and information transfer between inpatient and outpatient pharmacies. High impact interventions were defined as those that targeted either a patient population of greater than 1% of hospitalized patients (about 300,000 patients per year) or a patient safety problem that could result in death or disability. Anticoagulation services and clinics for warfarin, which are often managed by pharmacists, were also categorized as high-impact interventions. Several other interventions that were classified as high impact are either components of the medication distribution process or present opportunities for pharmacists to develop new clinical services. These include: implementing computerized physician order entry with clinical decision support and automated medication dispensing devices; limiting antibiotic use; improving perioperative glucose control, perioperative beta-blocker use, and venous thromboembolism prophylaxis; and providing geriatric consult services and pain services. Medium impact interventions were defined as those that targeted 0.01% to 1% of hospitalized patients (about 3,000 to <300,000 patients per year) or a patient safety problem that might result in reversible adverse effects if an effective prevention strategy were not available. Within this category, possible opportunities for pharmacists

were developing computer monitoring for adverse drug reactions, heparin nomograms, and unit-dose distribution systems, and improving pneumococcal vaccination and antibiotic prophylaxis for surgeries.<sup>15</sup>

The Institute for Healthcare Improvement (IHI) advocated three specific pharmacy services to improve the core processes for ordering medication in hospitals. First, they supported the implementation of pharmacy-based dosing for certain medications, starting with one high-risk medication, demonstrating benefits, and then expanding to physician-approved protocols or guidelines for other medications as appropriate. The IHI recognized that pharmacists could interpret patient-specific information such as age, weight, and laboratory test results that could affect dose selection; save both pharmacist and physician time by managing dosing themselves; and decrease certain types of errors. Second, the Institute recommended assigning pharmacists to patient care units. Activities at the unit level would include assisting physicians with new orders, educating other health-care professionals and patients, and participating in all patient safety activities, including rounds and safety briefings. The recommendations noted, however, that pharmacists should be assigned to as few units as staffing resources would allow so that unit-based activities could be implemented effectively. The third pharmacy service recommended by the IHI was pharmacy-based dosing for renal patients. Similar to the recommendations for pharmacy-based dosing of high-risk medications, IHI acknowledged that pharmacists have adequate training to interpret renal function studies and apply findings when determining appropriate doses. Again, the IHI recommended pharmacy-based dosing not only to allow prescribers more time for other clinical activities and reduce pharmacist time spent contacting physicians for dose

adjustment requests, but also to reduce the risk of adverse events. The use of physician-supported protocols or guidelines was recommended, as well as ensuring the availability to pharmacists of all renal function information in real time.<sup>16</sup>

Beyond the inclusion of pharmacists in hospital rounds, which was characterized as an intervention supported by good evidence, the IOM recognized several pharmacy-specific services that have been promoted as reducing medication errors during hospital care. A medium strength recommendation was to have a pharmacist available on call after hours of pharmacy operation. Recommendations that were acknowledged but that were characterized as having limited evidence were having a central pharmacist supply high-risk intravenous medications and pharmacy-based admixture systems, pharmacist counseling of hospitalized patients, and pharmacist review of all medication orders before first doses are given.<sup>1</sup>

The Institute for Safe Medication Practices (ISMP) advocates a leadership role for pharmacists in developing medication-related communication tools.<sup>17</sup> At a minimum, the ISMP states that all prescription orders should include the following required elements: the patient's full name and location, the patient's clinical information (weight, age, allergies), the drug name, the drug strength in metric units by weight for solids and by concentration for liquids, the dosage form, the dispensing amount in metric units, the directions for use (route, frequency), the drug's purpose or indication, and the number of refills or duration of therapy.<sup>18</sup> Specific recommendations for the safe design and use of preprinted order sets have been published and are summarized in Table 2.<sup>18</sup> The IOM further recommends that pharmacists work in cooperation with information technology departments and others to develop safe electronic communications

**Table 1. Organizations with Published Clinical Pharmacy Service Recommendations to Reduce Medication Errors in Hospitals<sup>1</sup>**

Agency for Healthcare Research and Quality
Institute for Healthcare Improvement
Institute of Medicine
Institute for Safe Medication Practices
National Quality Forum
Pathways for Medication Safety

**Table 2. Recommendations for the Safe Design and Use of Preprinted Order Sets<sup>18</sup>**

Involve an interdisciplinary team of individuals involved in the medication use process to develop the order sets
Ensure consistency with organizational policy
Use generic names for drugs
Avoid jargon and nicknames for drugs (banana bag)
Avoid use of common allergens whenever possible
Avoid use of dangerous abbreviations and dose designations
Express doses in metric weight (mg)
List doses per square meter or area under the curve for chemotherapy orders when a calculated dose must be entered. Include daily dose and number of days for multi-day chemo regimens
List the dose by weight for pediatric orders when dose must be calculated
Spell drug names correctly, and include a space between names and doses and between doses and units
Specify the purpose of the drug whenever possible
Use professional quality fonts and print styles to improve readability
When multiple medication choices are listed, develop a consistent system for indicating that a choice was not selected
Omit lines on the backs of order forms
Include a tracking number and revision date on the form
Do not use preprinted orders prepared by pharmaceutical companies
Ensure that order forms are easily accessible
Review preprinted order forms every 2 or 3 years or when protocols change

**Table 3. Safe Expression of Drug Names and Doses in Electronic Orders<sup>17</sup>**

List products by the FDA-approved generic name using lower case letters, unless "tall-man" letters are specifically recommended.

Only specify the drug salt if multiple salts are on the market. If the salt is part of the name, list the generic name first and salt second (eg, "phenytoin sodium" or "phenytoin Na" instead of "sodium phenytoin" or "Na phenytoin")

When appropriate, list brand names in a second field using all upper case letters. Do not include trademark symbols.

List suffixes that are part of the brand name in both the generic name and brand name fields (eg, bupropion XL and Wellbutrin XL).

Exclude dangerous abbreviations and dose designations.

Avoid abbreviations for drug names.

Use "tall-man" letters to help distinguish between look-alike names in order lists.

If the drug name, strength, dosage form, and dosage units will appear together, express them in this order: Generic name, brand name, strength, dose (if different from strength), and dosage form.

If the drug name, strength, dosage form, and dosage units appear together, always insert a space between them for ease of reading.

standards for medication orders. They have issued guidelines for safe expression of drug names and doses in electronic medication orders, as shown in Table 3.<sup>17</sup> A checklist of computerized physician order entry system requirements for supporting safe order communications is provided in Table 4.<sup>17</sup>

In the National Quality Forum's *Safe Practices for Better Healthcare, 2006 Update*, key practices are recommended that have been proven effective and of potential benefit in improving health-care safety. Among these is a minimum standard for pharmacist participating in medication management systems, which would include working with other disciplines to establish and maintain a drug formulary, being available for consultation by prescribers at the point of medication ordering, reviewing medication orders, preparing and dispensing medications, assuring safe storage, and monitoring medication use. Beyond the minimum standard, the National Quality Forum recommended that pharmacists offer recommendations for and promote medication safety throughout their organizations, review all medication orders except in select cases outlined by the Joint Commission, oversee all medication preparation and storage, ensure a safe working environment throughout the medication use process, provide 24-hour telephone access to a pharmacist even if the pharmacy is closed, and lead safety initiatives around look-alike/sound-alike medications and concentrated electrolytes.<sup>19</sup>

The Pathways for Medication Safety, a joint effort of the American Hospital Association, the Health Research and Educational Trust, and the IOM, with financial support from the Commonwealth Fund, offered numerous detailed recommendations for the basic pharmacy functions within the medication use process, such as product purchasing, storage, labeling, and dispensing. Of interest was the number of clinical pharmacy services endorsed by the Pathways evaluation tools for administrators/managers, physicians, and risk-management professionals. Recommendations included: having pharmacists routinely adjust medication doses for patients with hepatic or renal impairment; making pharmacists available on patient care units to assist prescribers with drug selection, to answer questions from nurses, to counsel patients on their medications, and to track high-risk patients or patients on

high-risk medications; involving pharmacists in the provision of in-services to medical staff; and having pharmacists provide in-service programs on new medications to nurses.<sup>20</sup>

### Ambulatory Care

The IOM estimated that 530,000 preventable adverse drug events occur each year in the U.S. in the ambulatory care setting. The annual cost of these adverse drug events was estimated at \$887 million nationally or \$1,983 per event.<sup>1</sup>

### Error Rates and Key Findings – Ambulatory Care

When *Preventing Medication Errors* was released in 2006, it was estimated that 21% of all ambulatory care prescriptions contained at least 1 prescription writing error.<sup>1</sup> In a recent systematic review of all types of preventable adverse drug events in ambulatory care, the largest proportion of errors originated in the prescribing stage, accounting for 64.7% of all preventable adverse drug events and 56% of all preventable adverse drug events causing hospital admission.<sup>21</sup>

In a retrospective review of 1,411 hand-written prescriptions over 5 months from an internal medicine clinic, 386 (27.4%) contained 1 or more errors or potential errors. Because some prescriptions had more than 1 error, the total error number was 463 and the rate was 32.8%. Ninety percent were considered potential errors, representing circumstances with the capacity to cause an error, such as missing information or illegible writing. The percentage of errors that reached the patient was 6.9%, and the percentage that caused harm was 0.2%. Only 21% of errors were categorized as clinical errors. Most commonly, these involved prescribing a contraindicated drug for a patient 65 years of age or older, according to the Beers criteria. The most severe clinical errors involved drug-disease interactions and lack of appropriate laboratory monitoring.<sup>22</sup>

Among ambulatory Medicare patients aged 65 or older and being cared for by a multispecialty group practice, 13.8 preventable adverse drug events occurred per 1,000 person-years. Of the preventable adverse events, the error originated in the prescribing stage in 58.4% of cases. The most common prescribing error types included wrong drug

or wrong therapeutic choice (27.1%), wrong dose (24%), and drug interaction (13.3%).<sup>23</sup>

In a study of 4 adult primary care practices affiliated with an academic medical center, 7.6% of 1,879 prescriptions had a prescribing error. The most common types of errors were incorrect or missing dose (54%) or frequency (18%). In total, 19% of all prescriptions contained a prescribing error or rule violation, defined as a failure to follow preset prescribing guidelines, such as including a route of administration. Error rates were similar to those observed at sites with basic computerized order entry, but a physician review panel judged that up to 97% of the errors could have been prevented by a computerized order entry system that included decision support.<sup>24</sup>

Information on prescribing errors for ambulatory pediatric patients is limited. In one study, 15% of children seen in a pediatric outpatient clinic were given a prescription that contained a potential dosing error for a common medication.<sup>1</sup>

### Improvement Strategies – Ambulatory Care

Medication reconciliation, medication education programs, prescribing aids, practice guidelines, physician-pharmacist collaborative services, patient medication management reports, error reporting programs, and electronic prescribing with alerting functions and field limits have all been proposed as interventions to reduce prescribing errors in the ambulatory care setting.<sup>1</sup> Data on the impact of these interventions is limited, however.

### Long-Term Care

About 1.6 million Americans reside in the nation's 18,000 nursing homes, where 800,000 preventable adverse drug events are estimated to occur each year.<sup>1,25</sup> An estimated 0.01-0.04 preventable adverse drug events occur per patient per month, equivalent to 0.02-0.1 adverse drug events per 100 admissions.<sup>1</sup>

**Table 4. CPOE System Requirements that Support Safe Order Communications<sup>17</sup>**

Data fields have ample space so that abbreviations for drug names, units, administration routes, and frequencies do not have to be abbreviated.
A data field is included that requires the prescriber to enter the drug indication for PRN medications, look-alike name medications, and medications with multiple uses.
The system provides a way to alert prescribers of specific warnings or to provide clinical notes for medications.
Searches can be performed by generic name, brand name, common synonyms, and mnemonics, all of which link to a list organized by generic name. Within generic name listings, drugs are further categorized by dosage form.
The system allows a clear way to communicate a desired deviation from standard administration times.
A data field is included that requires the prescriber to enter the desired dosage form.
The system links drugs to appropriate administration routes only (eg, the system does not allow an intrathecal route selection for vincristine).
A dose selection field is provided in addition to a field for selecting product strength.
All labels and reports, including medication administration records, print the generic name of the drug with brand name as an optional choice.
The system allows for safe ordering of complex dosing regimens, such as tapering schedules, and expresses these orders in a way that is easy to understand for the purposes of dispensing and administering the medication.
The prescriber can specify a time or date to start a drug that is different from the time the order was entered.
The system links ancillary drug therapies to the primary drug therapy (eg, opioids are linked with laxatives) and allows for automatic discontinuation of the ancillary drugs when the primary drug is discontinued.
The system makes it possible to put medication orders on hold for specified conditions and to communicate when a drug is being held.
The system allows for complete access to free texting in the pharmacy and nursing systems but only limited access in CPOE.

**Error Rates and Key Findings – Long-Term Care**

In a 4-month study of 631 errors among 2,731 incident reports submitted by nurses from 23 nursing homes, the most common error types were dose omission (32%), overdose (14%), underdose (7%), wrong patient (6%), wrong product (6%), and wrong strength (6%). The error types with the most serious outcomes were wrong patient errors, dose omissions, and overdoses. Of

all incidents, only 2% occurred during the prescribing phase of the medication use process.<sup>26</sup>

Errors of omission in the long-term care setting may be particularly problematic. The IOM found that 62-75% of assisted-living facility residents with congestive heart failure were not receiving an angiotensin-converting enzyme inhibitor. Seventy-six percent with a past history of myocardial infarction were not receiving beta-blockers,

and 60.5% were not receiving aspirin. Of patients in assisted living facilities with a history of stroke, 37.5% had no anticoagulant or antiplatelet agent. Sixty-one percent with osteoporosis were not receiving calcium. Only 53% of ideal candidates with atrial fibrillation were receiving warfarin. Between 45% and 80% of patients had unrelieved pain. Only 15% on nonsteroidal anti-inflammatory drugs were receiving gastroprotective agents.<sup>1</sup>

**Improvement Strategies – Long-Term Care**

Educational visits appear to be a promising intervention for improving prescribing practices and patient outcomes in long-term care, as well as involving pharmacists in medication management. The best evidence to date is for pharmacist involvement in managing specific conditions like diabetes. Interventions to reduce medication errors in the long-term care setting include regulation, educational initiatives, physician feedback, medication management programs, and implementation of technology.<sup>1</sup>

**General Recommendations for Good Prescribing**

In addition to the specific recommendations for reducing medication errors that have been provided by the Institute of Medicine, Institute for Safe Medication Practices and others, the World Health Organization issued a practical manual on good prescribing practices. The Guide to Good Prescribing aimed to improve the overall quality of prescribing, addressing both medication safety and rational use of therapeutics.<sup>27</sup> A modified version was recently published by the American Academy of Family Physicians.<sup>28</sup>

Although geared toward undergraduate medical students entering clinical rotations, the World Health Organization's *Guide to Good Prescribing* can serve as a practice model for interdisciplinary safety teams, who could potentially incorporate the recommendations into systems initiatives, and can be useful for any prescriber interested in best practices. The contents were field tested in a sample of over 200 medical students at 7 universities around the world, from Kathmandu to San Francisco, and shown to significantly improve students' performance in tackling complex patient medication problems. The *Guide to Good*

**CSHP New Members  
November – December 2007**

New Member	Recruiter	New Member	Recruiter	New Member	Recruiter
<i>Diablo</i>		<i>Southern California</i>		Monica Iskandar	Stephanie Zi
Gira Bhayari	—	John Albus	—	Geoffrey Ponting	Stephanie Zi
Megan Brown	—	Shetal Desai	—	Asna Shaikh	Stephanie Zi
Elizabeth David	—			Lusha Yu	Stephanie Zi
Raymund deJesus	—	<i>UCSD</i>		Ryan Martelino	Stephanie Zi
Satyajit Erram	—	Karen Anderson	—	Allen Ngo	Stephanie Zi
		Elysia Au	—	Jennifer Murphy	Stephanie Zi
<i>Golden Gate</i>		Andrea Backes	—	Susan Byun	Stephanie Zi
Cristina Pomeroy	—	Azadeh Bamshad	—	Natalie Noto	Stephanie Zi
Michelle Padtke	—	Marie Carter	—	Becky Ngu	Stephanie Zi
Mimosa Tran	—	Cathy Chang	—	Andrew Lee	Stephanie Zi
		Annie (Zhiyu) Chen	—	Alena Clarke	Stephanie Zi
<i>Inland</i>		Megan Chynoweth	—	Leslie Sirmian	Stephanie Zi
Evelyn Tesoro	—	James Connor	—	Tamara Lenhoff	Stephanie Zi
		Heather Cox	—	Katie Gazlay	Stephanie Zi
<i>Orange County</i>		Mallory Cruz	—	Melissa Kusaka	Stephanie Zi
Martin Breen	—	Jennifer Currello	—	Amy Lui	Stephanie Zi
John Samimi	—	Krishma Dhillon	—	Lynn Chen	Stephanie Zi
		Hanleh Farid	—	Van Thao Nguyen	Stephanie Zi
<i>Pacific University</i>		Shida Hashemi	—	Helaine Kwong	Stephanie Zi
Ederlyn Dia	—	Wendy Hong	—	Sharon Shamseldi	Stephanie Zi
Ciarissa Wong	—	Roya Jamshedd	—	Ashley Fong	Stephanie Zi
		Fauzia Khan	—	Nikolai Dahl	Stephanie Zi
<i>Quatra County</i>		Sherry Kim	—	Lauren Gold	Stephanie Zi
Beth Chang	—	Robin Kinnear	—	Cynthia Foust	Stephanie Zi
Doris Wong	—	Laura Lafranchise	—	Jennifer Phan	Stephanie Zi
		Jennifer Lai	—	Danielle Parmley	Stephanie Zi
<i>San Diego</i>		Angeli Lam	—	Venus Manalo	Stephanie Zi
Kari Stonely	—	Helen Le	—	Angela Anson	Stephanie Zi
		Thanh Le	—	Lindsay Holte	Stephanie Zi
<i>San Fernando Valley</i>		Gwendolyn Le	—	Serena Huntington	Stephanie Zi
Ann Palos	—	Soo Jin Lee	—	Ngoc-Vy Duong	Stephanie Zi
		Faith Lin	—	Jamie Kuo	Stephanie Zi
<i>Sierra</i>		Jane Liou	—	Joel Martin	Stephanie Zi
Genevieve Franco	—	Joyce Luk	—	Larry Arias	Stephanie Zi
Christopher Hartz	—	Mindi Messinger	—	Pei-Yu Lee	Stephanie Zi
Lloyd Smith	—	Hien (Kay) Nguyen	—	Amy Rikimaru	Stephanie Zi
		Diem Nguyen	—	Bailey Cimino	Stephanie Zi
<i>Sacramento Valley</i>		Irina Olshanskaya	—	DeAnna Sosnowski	Stephanie Zi
Maureen Lloy	—	Trevor Perry	—	Wendy Jenkins	Stephanie Zi
Zoua Vang	—	Nicole Reynolds	—	Jelyn Evangelista	Stephanie Zi
Chau Nguyen	—	Rebecca Romasco	—	Cathryn Walker	Stephanie Zi
Maryann Xiong	—	Courtney Shakowski	—	Patrick Tokuyama	Stephanie Zi
Jade Larot	—	Ancong Shen	—	Annie Yang	Stephanie Zi
Marylupe Gallardo	—	Cynthia Shin	—	Janet Chon	Stephanie Zi
Pavel Mantsevich	—	Kamyar soleymani	—	Allison Mruk	Stephanie Zi
Duy Pham	—	Linda Tang	—	Leslie Tieu	Stephanie Zi
Jaytika Nand	—	Vy Tran	—	Hai-Au Liu	Stephanie Zi
Juvenile Sutton	—	Laura Tsu	—	Walter Valdes	Stephanie Zi
Phuong Vo	—	Euphemia Uhegbu	—	David Seki	Stephanie Zi
James Olney	—	Sherilyn VanOsdol	—		
Kelsey Filippo	—	Stephanie Webb	—	<i>USC</i>	
Janeth Abero	—	William Wong	—	Vincent Razon	—
Rob Finn	—	Vivian Yeung	—	Jessica Abraham	—
Rany Ky	—				
John Lamb	—	<i>UCSF</i>		<i>Western University</i>	
Elias Sanchez	—	Usha Desiraju	—	Simon Ahn	—
Jim Walsh	—	Megan McCurdy	Stephanie Zi	Jeong Chang	—
Katrina Williams	—	Amy Mckaskle	—		
		Diana Nguyen	Stephanie Zi		
<i>San Diego</i>		Son Huynh	Stephanie Zi		
James Herron	—	Elliott Gorelick	Stephanie Zi		
		Grant Kim	Stephanie Zi		

*Prescribing* advocates developing a personal repertoire of medications, following a systematic 6-step approach to treating patients, and keeping up-to-date on drug therapy.<sup>27</sup>

### Selecting a Personal Drug List

One of the basic foundations of the *Guide to Good Prescribing* is the concept of personal drugs or "P-drugs." P-drugs represent a physician's predetermined drugs of first choice for particular indications, much like a drug formulary within a health system or hospital. The routine use of selected medications allows for improved familiarity and potentially reduced errors.<sup>27</sup>

The first step in selecting a P-drug is to define the diagnosis. Next, the prescriber should determine the ultimate therapeutic goal. Goals may include disease prevention, symptom management, disease modification, or cure. The ideal therapeutic goal should always be kept in mind. For example, although many oncology drugs are initially approved for marketing based on studies of surrogate endpoints like tumor response, the ultimate goal is usually prolonged survival.<sup>27</sup>

The prescriber can then consider the entire universe of potential drug therapy options and narrow the choices, primarily by considering the drug's proven efficacy in achieving the ultimate goal of therapy. For some conditions, the time to onset of efficacy can be relevant. The next criteria to consider are safety, suitability, and cost. Although suitability can be patient-specific, a general preference for oral dosage forms and drugs that require fewer doses per day will likely accommodate more patients than injectable products, for example, or drugs with complex dosing schedules.<sup>27</sup>

Based on these factors, it is then possible to choose an active substance and dosage form, a standard schedule for administration, and a standard treatment duration that will meet the needs of most patients. An advantage of this level of forethought is that, in working through the best choices for the average patient, the clinician will encounter and consider the choices that may be important for more unusual patients.<sup>27</sup> In hospital or long-term-care settings with closed formularies, many of these steps may have already been completed for the prescriber,

narrowing the range of therapy options requiring exploration.

### Treating Patients

The World Health Organization (WHO) advocated a 6-step approach to treating patients: defining the patient's problem, setting the therapeutic objective, determining whether the usual P-drug is appropriate for a specific patient, starting therapy, providing relevant information to the patient, and monitoring or stopping the therapy. New practitioners were cautioned not to merely copy the prescriptions written by more senior prescribers but to work through the steps themselves.<sup>27</sup>

**Step 1:** Define the problem. The patient's problem can be determined by listening to the patient's chief complaints or questions, taking a thorough history, observing the patient, and conducting physical examinations and lab tests. In addition to a symptom or disease requiring treatment, the underlying problem could also be an adverse drug effect, evidence of poor compliance, the need for a drug refill, a psychological prob-



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**Table 5. Potential Drug Information Sources and Factors to Consider<sup>27</sup>**

Reference books	Frequency of new editions, comparative therapeutic data, expense
Drug compendia	Completeness, frequency of new editions, comparative therapeutic data, and expense
National drug lists and guidelines	Availability within the U.S., currency
Drug formularies	Comparative therapeutic data, cost information
Drug bulletins	Funding source, inclusion of practical recommendations
Medical journals	General versus specialized scope, peer review, funding source
Verbal information from specialists, colleagues, or pharmacists	Availability of the individual, application to practice
Drug information centers	Resources available to the center, center affiliation
Computerized information sources	Update frequency, hardware and software requirements
Pharmaceutical industry information sources	Inherent bias, time costs, need for critical evaluation

**Table 6. National Organizations that Track Medication Errors<sup>29</sup>**

The Food and Drug Administration 5600 Fishers Lane Rockville MD 20857-0001 1-800-332-1088 www.fda.gov/medwatch/how.htm	The Food and Drug Administration accepts reports from consumers and health professionals about the products it regulates through MedWatch, a safety information and adverse event reporting program.
Institute for Safe Medication Practices 1800 Byberry Rd., Suite 810 Huntingdon Valley, PA 19006-3520 215-947-7797 www.ismp.org/Pages/Consumer.html	The Institute for Safe Medication Practices accepts reports from consumers and health professionals related to medication and publishes newsletters on medication errors and patient safety.
U.S. Pharmacopeia www.medmarx.com 12601 Twinbrook Parkway Rockville, MD 20852 1-800-822-8772 www.usp.org	The Medication Errors Reporting (MER) Program is a voluntary national medication error reporting program.

*Pharmacists in work settings without routine reporting systems should consider sharing medication error experiences with national organizations that can use the data to its best effect.*

lem, an interest in disease prevention, or some combination of these. Many problems will not require drug therapy at all.<sup>27</sup>

**Step 2:** Set the goal of therapy. Goals should be obtainable and should match the underlying problem. When the patient is engaged in a discussion of the therapeutic goals, compliance can improve.<sup>27</sup>

**Step 3:** Determine whether the P-drug is appropriate. This step allows for tailoring of drug therapy beyond the prescriber's usual drugs of choice. Considerations include whether the drug can be expected to be effective for the particular patient's situation, whether convenience or other factors are likely to affect compliance, and whether safety concerns specific to the particular patient, such as drug-drug or drug-disease interactions, are a barrier to use. Even if the P-drug is appropriate, this step should include an assessment of the standard dose and duration of treatment, which might need adjustment. If the P-drug would be effective only with a difficult dosing regimen or extended duration of treatment, selecting an alternative agent might be warranted.<sup>27</sup>

**Step 4:** Initiate therapy by writing the prescription or order. The WHO mandates the inclusion on the prescription of the patient's age if the patient is a child or senior adult. The use of the generic name instead of the brand name and of the local language instead of Latin is encouraged, and the use of decimals, abbreviations, and vague instructions like "as directed" or "as before" is discouraged.<sup>27</sup>

**Step 5:** Provide information, instructions, and warnings. The WHO supports patient education as a method for ensuring optimal drug use. A patient who understands the expected benefits of a medication, its adverse effects, how to use it, safety precautions, and monitoring requirements is more likely to comply with therapy, to avoid medication errors, and to appropriately seek help if problems arise.<sup>27</sup>

**Step 6:** Monitor or stop treatment. Some therapies will require specific laboratory or other monitoring; in other cases, monitoring can be accomplished passively, by having the patient call if the drug does

not appear to be working, or actively, at a routine follow-up visit. If the patient's problem has been solved, such as when an infection is cured, drug therapy can be stopped. Effective and well-tolerated treatments for ongoing medical problems can be continued, while ineffective therapies should prompt a reassessment of the original diagnosis, therapeutic objective, drug selection, prescription, patient instructions, and monitoring plan.<sup>27</sup>

### Staying Current on Drug Therapies

Similar to the strategy for selecting a list of P-drugs, the WHO recommended that all prescribers make an inventory of the drug information resources available to them, weigh their advantages and disadvantages, and establish a repertoire of reliable and familiar sources. The guidelines identified the potential information sources and factors to consider when evaluating their utility, as shown in Table 5. For the average practitioner, regular use of at least 1 journal, 1 book, and 1 bulletin, supplemented with information from therapeutics committees

or specialists, was promoted as a way to stay up-to-date on drug therapies. Additional resources could be tapped for specific patient care dilemmas.<sup>27</sup>

### Barriers to Reducing Prescribing Errors Reporting Limitations

The less a problem is understood, the more difficult it can be to solve. Under-reporting of prescribing errors is probably significant. In a study of 3,875 incident reports from 2 hospitals, only 1.9% of all reports were filed by physicians, even though physicians were the providers involved in potentially preventable incidents 16% of the time. Two theories were advanced for why hospital incident reports likely underestimate errors involving physician care: (1) Traditionally, hospitals have addressed issues with physician care through peer review, credentialing, and morbidity and mortality conferences, and (2) physicians are thought to be the most likely to identify a physician error, and their participation in reporting is consistently low.<sup>29</sup>

Based on surveys of 120 internal medicine physicians at an academic medical center, Schectman and Plews-Ogan reported that only 65% and 52% of physicians and medical residents, respectively, had filed an adverse event or near-miss report in the past year, even though 60% and 75% of them, respectively, had witnessed at least 3 events or near misses during that time period. Only 39% said they knew how to report an adverse event or near miss. The top 3 barriers to reporting cited by physicians were uncertainty about the reporting mechanism, lack of actual harm to the patient, and reporting being too difficult or too time consuming.<sup>30</sup>

Reporting is universally endorsed as a way to improve awareness and understanding of the medication error problem. Pharmacists in work settings without routine reporting systems should consider sharing medication error experiences with national organizations that can use the data to its best effect. National organizations that track medication error reports are listed in Table 6.<sup>31</sup>



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## Technology Limitations

A recent systematic review comparing prescribing errors with hand-written and computerized physician orders showed that the rates of prescribing the wrong drug did not decrease after implementing computerized physician order entry.<sup>32</sup> Although basic computerized physician order entry can decrease errors downstream from the prescriber, order entry systems without clinical decision support may have limited benefits in the prescribing stage of the medication use process.

An important distinction that is emerging for clinical decision support systems is basic versus advanced systems. Basic clinical support usually provides a checking system for doses, interactions, allergies, formulary status, and therapy duplication. More advanced clinical decision support systems can guide dose selection for patients with advanced age or renal dysfunction, check for drug-pregnancy or drug-disease interactions, and prompt appropriate laboratory test ordering.<sup>33</sup>

Focus groups have shown that physicians were skeptical about the ability of clinical information technologies in general to reduce medication errors. They believed that the solutions offered by current technologies did not fit the underlying problems leading to medication errors, that current software

and hardware applications had significant limitations, and that new technologies brought new and different error risks. Many physicians had negative impressions of the impact of information technologies on their time. They were particularly concerned that computerized physician order entry systems take more time to use than manual systems and that computerized physician order entry shifted the burden of data entry to them from ancillary staff such as unit clerks.<sup>34</sup>

## Knowledge Limitations

The *Preventing Medication Errors* report identified knowledge deficits among both patients and providers as a major barrier to safe and effective medication use. It further pointed out that attitudes could be a barrier, giving the example of patients' and providers' different beliefs about medication use. The report advocated sweeping changes to strengthen patients' ability to self manage their medications. The IOM called upon government agencies to provide resources for patient drug information and medication self-management, including standardized and widely available drug information leaflets, internet-based health information resources, national drug information telephone help lines, and community-based health resource centers.<sup>1</sup>

## Practical Limitations

Practical problems, such as patients' inability to pay for their medications and the burdens imposed on prescribers by third party payers, were also cited in the *Preventing Medication Errors* report as barriers to optimal medication use. Health-care organizations were encouraged to provide complete patient information and decision support tools to patients and providers. The government, industry, and regulatory bodies were encouraged to improve drug product labeling, medication information communication, and standards for health information technology and to motivate the adoption of medication safety technologies and safe practice standards. Finally, the IOM recommended increased funding for the government to fully research medication errors across the various care settings.<sup>1</sup>

## Summary/Conclusion

Medication errors are a source of considerable mortality, morbidity, and health-care costs in the U.S. today. Many of these errors originate in the prescribing stage of the medication use process. Opportunities exist for pharmacists to intercept prescribing errors and to lead systems-based approaches to reducing their incidence. Strategies for tackling the problem of medication errors are available from The Institute of Medicine and other national and international organizations. ♦

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# Attachment 5

## ***Enforcement Statistics***

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2007/2008

**Workload Statistics**                      **July-Sept**   **Oct-Dec**   **Jan-Mar**   **Apr-June**   **Total 07/08**

**Complaints/Investigations**

Initiated	401	336	324		1061
Closed	443	362	587		1392
Pending (at the end of quarter)	1056	1030	838		838

**Cases Assigned & Pending (by Team)**

Compliance Team	55	102	67		67
Drug Diversion/Fraud	73	114	123		123
Probation/PRP	71	92	95		95
Mediation/Enforcement	146	154	114		114

**Application Investigations**

Initiated	69	51	119		71
Closed					
Approved	38	49	47		134
Denied	14	3	5		22
Total*	51	52	52		155
Pending (at the end of quarter)	207	208	275		275

**Citation & Fine**

Issued	197	174	411		782
Citations Closed	142	129	179		450
Total Fines Collected	\$143,070.00	\$155,825.00	\$197,350.00		\$496,245.00

\* This figure includes withdrawn applications.

\*\* Fines collected and reports in previous fiscal year.

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2007/2008

**Workload Statistics**                      **July-Sept**   **Oct-Dec**   **Jan-Mar**   **Apr-June**   **Total 07/08**

**Administrative Cases** (by effective date of decision)

Referred to AG's Office*	27	15	37		25
Pleadings Filed	20	32	16		20
<b>Pending</b>					
Pre-accusation	57	36	54		64
Post Accusation	60	67	66		62
<b>Total</b>	<b>117</b>	<b>114</b>	<b>131</b>		<b>141</b>
<b>Closed**</b>					
<b>Revocation</b>					
Pharmacist	2	1	0		2
Pharmacy	1	9	0		1
Other	4	0	6		4
<b>Revocation, stayed; suspension/probation</b>					
Pharmacist	4	1	4		4
Pharmacy	0	0	0		0
Other	0	0	0		0
<b>Revocation, stayed; probation</b>					
Pharmacist	2	2	2		2
Pharmacy	1	0	1		1
Other	0	1	0		0
<b>Suspension, stayed; probation</b>					
Pharmacist	0	0	0		0
Pharmacy	0	0	0		0
Other	0	0	0		0
<b>Surrender/Voluntary Surrender</b>					
Pharmacist	0	2	0		0
Pharmacy	1	0	0		1
Other	1	2	2		1
<b>Public Reproval/Reprimand</b>					
Pharmacist	0	0	0		0
Pharmacy	0	0	0		0
Other	0	0	0		0
Cost Recovery Requested	\$54,145.50	\$34,655.00	\$49,398.00		\$138,198.50
Cost Recovery Collected	\$52,838.60	\$22,679.60	\$27,915.35		\$103,433.55

\* This figure includes Citation Appeals

\*\* This figure includes cases withdrawn

# Board of Pharmacy Enforcement Statistics Fiscal Year 2007/2008

**Workload Statistics**                      **July-Sept    Oct-Dec    Jan-Mar    Apr-June    Total 07/08**

## Probation Statistics

Licenses on Probation

Pharmacist	108	108	110		108
Pharmacy	5	6	5		6
Other	16	13	15		13
Probation Office Conferences	18	5	13		23
Probation Site Inspections	44	56	26		100
Probationers Referred to AG for non-compliance	1	0	0		1

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 03/31/08)

Program Statistics

In lieu of discipline	0	0	0		0
In addition to probation	5	3	2		10
Closed, successful	3	4	1		8
Closed, non-compliant	0	1	1		2
Closed, other	3	2	1		6
Total Board mandated Participants	54	56	55		55
Total Self-Referred Participants*	18	16	20		20
Treatment Contracts Reviewed	53	50	51		154

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 March 31, 2008

# California State Board of Pharmacy

## Citation and Fine Statistics

### July 1, 2007 – April 7, 2008

**818 Citations have been issued so far this fiscal year**

Total dollar amount of fines issued this fiscal year  
\$ 1,453,900.00

Total dollar amount of fines collected  
\$496,245.00\*

\*This amount also reflects payment of the citations issued before July 1, 2007.

The average number of days from date case is opened until a citation is issued is **238**

Average number of days from date case is routed to Citation Unit to date citation is issued **58**

Average number of days from date citation is issued to date citation is closed is **63**

#### Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
815	223	7	217	107	157	10	23	6

#### Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
16	10	2	1	3	10	13*	10	0

\*Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

## Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	40%	1716 - Variation from prescription	36%	1716 - Variation from prescription	25%
1707.2 – Duty to consult	7%	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	8%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	9%
1707.2 Duty to consult	6%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	7%	4115(e) - Pharmacy technician license required	5%
1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	5%	1707.2 – Duty to consult	5%	4081(a) - Records of dangerous drugs kept open for inspection	4%
4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	4%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	4%	4125-1711 - Pharmacy quality assurance program required/Quality assurance program	4%
1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors...	4%	4125-1711 - Pharmacy quality assurance program required/Quality assurance program	4%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	4%
1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	4%	1707.3 – Duty to review drug therapy	3%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors...	4%
1707.3 – Duty to review drug therapy	4%	1715 – Self-assessment of a pharmacy by the pharmacist-in-charge	3%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	4%
4115(e) - Pharmacy technician license required	3%	1711 (d) -Quality assurance program finding shall be used to develop systems to prevent medication errors...	3%	1715 – Self-assessment of a pharmacy by the pharmacist-in-charge	4%
4125/1711 - Pharmacy quality assurance program required/Quality assurance program	2%	4115(e) - Pharmacy technician license required	3%	1304.11 – Inventory requirements	3%

# Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There have been fifteen office conferences held so far this fiscal year

Number of requests	254
--------------------	-----

Number scheduled	254
------------------	-----

Number appeared	179
-----------------	-----

Number Postponed	53**
------------------	------

\*\*Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	16
Failed to appear	6

## Office Conference between July 1, 2007 and April 7, 2008

Total number of citations affirmed	89
------------------------------------	----

Decision	Total citations	Total dollar amount reduced
Modified	39	\$12,400.00
Dismissed	39	\$22,350.00
Reduced to Letter of Admonishment	3	\$0.00

Please note nine cases are pending a decision due to additional investigation being required.

# Attachment A

*Minutes of the January 23, 2008  
Enforcement Committee*



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**STATE BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
ENFORCEMENT COMMITTEE MEETING  
MINUTES**

**DATE:** January 23, 2008

**LOCATION:** Town & Country Resort and Convention Center  
500 Hotel Circle North  
San Diego, CA 92108

**COMMITTEE MEMBERS PRESENT:** Stanley Goldenberg, RPh, Chairperson  
William Powers, Public Member  
Ruth Conroy, PharmD  
Rob Swart, PharmD  
D. Timothy Dazé, Esq., Public Member

**OTHER BOARD MEMBERS PRESENT:** Kenneth H. Schell, PharmD  
Andrea Zinder, Public Member  
Susan L. Ravnar, PharmD  
Henry Hough, Public Member  
Robert Graul, RPh  
Stanley C. Weisser, RPh  
Shirley Wheat, Public Member  
James Burgard, Public Member

**STAFF PRESENT:** Virginia Herold, Executive Officer  
Karen Cates, Assistant Executive Officer  
Robert Ratcliff, Supervising Inspector  
Judith Nurse, Supervising Inspector  
Joan Coyne, Supervising Inspector  
Joshua Room, Deputy Attorney General  
Spencer Walker, DCA Staff Counsel  
Anne Sodergren, Legislation and Regulation Manager  
Karen Abbe, Public and Licensee Education Analyst  
Tina Thomas, Staff Analyst

## **CALL TO ORDER**

Chairperson Goldenberg called the meeting to order at 4:52 p.m.

### **A. DEVELOPMENT OF AN ETHICS COURSE FOR PHARMACISTS, MODELED AFTER THAT DEVELOPED BY THE MEDICAL BOARD OF CALIFORNIA**

Mr. Goldenberg referred to information provided in the meeting materials regarding development of an Ethics Course for Pharmacists. The purpose of the course will be to use it as an enforcement option when establishing discipline parameters for licensees.

Dr. Ravnan and Dr. Swart served on a board subcommittee to review ethics course options. The board evaluated the need to develop a course for pharmacists similar in structure to that used by the Medical Board for physicians. The board will need to promulgate regulations for this program or secure statutory requirements. Staff will develop draft language to establish this program statutorily and bring it to the Enforcement Committee for comment.

Mr. Goldenberg asked if there were any comments from the board to add to the written materials provided in the packet. There were none.

### **B. DISCUSSION REGARDING PHARMACIST/TECHNICIAN REGISTRY FIRMS USED TO STAFF PHARMACIES**

Mr. Goldenberg referred to a problem of unlicensed or suspended pharmacists working in pharmacies that have been placed by pharmacist registry companies. He also referred to unlicensed pharmacy technicians working in pharmacies placed by "temp" agencies.

Ms. Herold noted that this is an item that was brought to the Enforcement Committee as a proposed legislative solution. Board staff is interested in developing the requirements for a registration program for those firms that place pharmacists and pharmacy technicians in pharmacies on a temporary basis.

Ms. Herold stated that registries periodically place unlicensed/suspended pharmacists and pharmacy technicians when making temporary placements in pharmacies. The board has no jurisdiction over a registry; it can only discipline a pharmacist or pharmacy technician placed and the pharmacist in charge (PIC) hiring the individual. Registering the companies that employ these individuals would provide recourse for the board to discipline a registry for placing a suspended/unlicensed pharmacist or pharmacy technician. The current situation leaves the public and the profession at risk without a consequence.

Supervising Inspector Bob Ratcliff added that community pharmacies and hospital pharmacies use personnel placed by registries under the assumption that the personnel is currently licensed to practice. In their contracts with registries, pharmacies state that they

understand that the registry is providing appropriately licensed personnel. The PIC does not necessarily confirm the status of someone's license, after they have been placed in the pharmacy by the registry.

Dr. Ratcliff stated that this problem has been identified during board inspections, and has become a matter of consumer safety.

A discussion ensued regarding the severity of this problem. A board member noted that often a registry will notify a pharmacy of the name of a pharmacist that will be placed, yet a different pharmacist will report for duty. This prevents a PIC from doing any type of background check or license check prior to personnel arriving on-site.

The board supported the idea of registering or otherwise tracking these contract placement agencies to prevent unlicensed or suspended personnel from serving the public.

In answer to a question from a board member, Ms. Herold noted that the penalty for a pharmacist found working in a pharmacy with a suspended license would likely be revocation of his/her license. A pharmacist found working in a pharmacy with a license that had not been renewed could result in a cite and fine, depending on the circumstances. Ms. Herold emphasized that due diligence is the responsibility of the employment registry placing these individuals, although the employing pharmacy is also responsible. The registries should regularly update their records.

Mr. Room recommended criminal action if there is widespread evidence of an agency or registry employing suspended or unlicensed pharmacists. Unlicensed practice is an underlying criminal violation; aiding or abetting unlicensed practice of pharmacy would also be a potential criminal violation.

MOTION: Direct board staff to develop a legislative solution regarding pharmacy personnel registries including those firms that place pharmacists and pharmacy technicians in pharmacies on a temporary basis.

M/S: POWERS/DAZÉ

SUPPORT: 4 OPPOSE: 0

### **C. DISCUSSION REGARDING THEFT OF PRESCRIPTION MEDICINE FROM SUPPLY CHAIN PARTNERS**

Mr. Goldenberg referred to the issue of thefts of prescription drugs from common carriers, and the fact that drugs stolen from transportation companies end up in the supply chain. Diversion of medication from common carriers is an issue of consumer safety.

Ms. Herold noted that drug wholesalers either have contract carriers like FedEx, or they use their own carriers. She gave an example of a pharmacy that received a shipment of medication, but the pharmacist did not open the box to verify the contents received. Controlled substances were missing from the shipment, and the pharmacy later notified the board of the discrepancy. The board subsequently cited and fined the pharmacist and the wholesaler.

Mr. Goldenberg commented on the lack of authority of the board to require a background check of a transportation carrier.

Dr. Conroy spoke about the difference between PICs receiving controlled substance orders via FedEx versus directly from a wholesaler. She gave an example of a shipment directly from Cardinal, which would result in the Cardinal carrier waiting for the PIC to check the contents of the shipment. When an order arrives via FedEx, it is unlikely that the FedEx driver will wait for the PIC to check the contents of the shipment of controlled substances. Dr. Conroy emphasized that items missing from a shipment, whether the discrepancy was found while the driver was there or had left, would still result in items missing from a shipment. Citing and fining a pharmacist for not checking the contents of a box while the driver is present does not prevent drugs from being diverted; instead, it punishes the person who is the victim of a crime, not the person who diverted the drugs.

Mr. Powers suggested that the authority to resolve this problem extends beyond the board, such as the DEA or local police.

Dan Lucent, representing Walgreens, stated that a problem has persisted in that a box is opened and items are missing from the order. Determining when, where, and how the product was diverted has been an issue for Walgreen's. They recruited the assistance of the FBI who subsequently planted a "mole" in a large delivery company. The investigation revealed five employees illegally diverting products. Mr. Lucent suggested that the board ask for assistance from an outside agency such as the FBI to assist in enforcement efforts.

Mr. Room suggested that pedigree requirements would help deter these problems. He said that pedigree would assist in determining where in the supply chain that drugs are diverted.

A suggestion was made to bring attention to the issue of diversion in an issue of *The Script*.

Steve Gray, representing Kaiser Permanente, spoke about deliveries made to loading docks of hospitals. A delivery to a loading dock must subsequently be delivered to the hospital pharmacy within 24 hours. He noted a persistent problem that Kaiser is having with a national common carrier in getting that carrier to make their deliveries directly to hospital pharmacies so that pharmacists can sign for the deliveries. They have been in contact with FedEx, DHL, and UPS, regarding California's requirements. Dr. Gray noted that drug diversion is more likely to occur when shipments are made to large loading docks and the boxes must pass through several hands before finally reaching a pharmacy.

Dr. Gray suggested that the board send a letter to major transportation carriers referring to California's requirements. He also referred to advance shipping notices, and that pharmacists compare the products received against the advance shipping notices to determine if products are missing. Dr. Gray gave an example of a diversion problem that resulted in identification of people in a manufacturer's shipping department; the products were not properly packaged before being sent to wholesalers.

Mr. Dazé spoke about the possibility of regulating common carriers that deliver pharmaceutical products.

Mr. Room advised that some common carriers are licensed as wholesalers, with regard to those who store or manipulate products. He warned there could be federal preemption issues on direct regulation of common carriers, but he will research the matter further.

Mr. Room also suggested that Dr. Gray submit a written request to the board regarding his ideas to address the issue. The request would include proposed language for the board to consider regarding a letter to major carriers, and background information to help shape the content of the letter.

A representative from Albertson's/Savon, concurred with remarks made by Mr. Lucent regarding drug diversion from common carriers. He stated that the DEA is facing the same jurisdictional quandary that the board is currently discussing. Common carriers are under the jurisdiction of the FBI because they carry controlled substances across state lines. He noted an effort underway to regulate common carriers either by registering with the DEA in a new category, or by changing the DEA 106 form to allowing common carriers to be identified as a potential contributing factor to loss of controlled substances. He suggested that the board draft a letter of support to the DEA on this issue.

Mr. Room asked the representative from Albertson's/Savon to provide the referenced background information regarding DEA's efforts to the board for review.

#### **D. DISCUSSION OF THE IMPACT OF PHARMACY REBATES OR "GIFTS" TO PATIENTS TO TRANSFER PRESCRIPTIONS**

Mr. Goldenberg referred to pharmacies that offer rebates or cash gift cards for new or transferred prescriptions. He emphasized that the practice results in fragmented care for consumers that transfer prescriptions from pharmacy to pharmacy. A complete medication profile is important so that pharmacists can protect patients against adverse drug events.

Mr. Goldenberg expressed concern that a pharmacist can be disciplined by the board for a clerk or technician providing a rebate to a Medicaid or Medicare patient, even if the pharmacist had no knowledge of the transaction.

Mr. Room advised that it is a violation of federal law to provide a prescription transfer rebate to a patient when all or part of the prescription will be paid by Medicaid or Medicare.

Mr. Goldenberg noted that as a result of these problems, coupons and rebates for prescription transfers are not accepted in some other states.

Ms. Herold suggested consumer education be used first to warn people of the dangers of repeatedly transferring prescriptions, which can result in inadequate medication profiles. A legislative solution to the problem could be met with opposition from consumer groups.

Mr. Powers noted that the board should help consumers understand that it is a health issue, not a financial issue. He recommended that board staff contact New York, New Jersey, and Massachusetts regarding their history with the coupon/rebate issue. Board staff should report back to the Enforcement Committee with their findings.

Supervising Inspector Judi Nurse suggested that pharmacist education be used to help pharmacies identify when the coupons/rebates can be accepted. She also referred to confusion of pharmacists regarding federally subsidized prescriptions.

Mr. Room referred to the July 2007 issue of *The Script* and that an article in that issue related to coupons/rebates for prescription transfers.

Ms. Herold clarified that the article stated, "Title 42 of the United States Code, sections 1320a-7b prohibits the offer of any remuneration directly or indirectly, overtly or covertly, in cash or in kind to induce a person to order a service or item for which payment may be made wholly or partially under a Federal health care program (e.g., Medicare, Medicaid, Medi-Cal). Anyone violating this code may be guilty of a felony and subject to a fine or imprisonment or both."

Mr. Graul noted that in his experience, consumers do not repeatedly transfer prescriptions to take advantage of coupons and rebates. He has found that new stores or stores that are underperforming and trying to get new business offer the coupons. Mr. Graul stated that there are relatively few customers that bounce back and forth from pharmacy to pharmacy, in response to coupons or rebates.

Kathy Lynch, representing CPhA, noted that the issue of coupons/rebates is becoming a more prevalent issue for independent pharmacists. She spoke about the applicable exclusions that should be printed on the back of the coupons/rebates. Ms. Lynch offered to bring relevant information on the issue to the next Enforcement Committee Meeting.

Dr. Gray noted that when patients reach the donut hole, they are more likely to use the coupons/rebates. He also noted that the coupons could be used in a positive way because patients are encouraged to have all their prescriptions filled in one place. He recalled that board policy prohibited the use of coupons regarding prescription transfers, but later dropped the issue because it lacked the authority to do so.

Dr. Gray emphasized that this issue is complex and it has drug benefit structure and design implications, federal verses state law implications, and other issues regarding what

constitutes an inducement to transfer a prescription. He also noted that there could be an inducement to having a doctor call a new prescription in to a particular pharmacy. So the issue of inducement does not just affect transferred prescriptions.

Mr. Goldenberg stated that the matter would be put on the agenda for the next Enforcement Committee Meeting.

#### **E. REQUEST FOR WAIVER OF 16 CCR SECTION 1713(A) TO PERMIT PHARMACY HOMECARE NETWORK TO DELIVER MEDICATION TO HOMES OF DELIVERY PERSONNEL FOR LATER DELIVERY TO PATIENTS**

Ronald Marks spoke on behalf of Pharmacy Homecare Network. Mr. Marks serves as legal counsel representing Pharmacy Homecare Network regarding their request to ship prescription medicine to delivery drivers for later delivery to patients. California Code of Regulations 16 CCR Section 1713(a) provides that no licensee shall participate in any arrangement whereby prescription medicine is left at or picked up from or delivered to a place not licensed as a retail pharmacy. Section 1713(b) allows the board to waive Section 1713(a) for good cause shown.

The meeting materials included a letter from Mr. Marks to the board dated June 12, 2007 referring to 16 CCR Section 1717(e). For clarification, that section was moved to section 1713, and is the subject of Mr. Marks' remarks to the committee.

Mr. Marks stated that Pharmacy Homecare Network is located in Los Angeles. Some of the patients they serve live in San Diego and are fluent in Russian, though some also speak some English. Mr. Marks further stated that the owner of Pharmacy Homecare Network speaks Russian, as do his pharmacists and pharmacy technicians.

Current procedures of Pharmacy Homecare Network include sending medications via UPS to their delivery personnel. Mr. Marks identified Pharmacy Homecare Network delivery personnel present, Eco Sakianski and Leonid Fasman, both of whom speak Russian. Mr. Marks stated that both men were longtime employees of Pharmacy Homecare Network, one with nine years employment history with the company and the other with eleven. He explained that medications delivered to Pharmacy Homecare Network delivery personnel on any particular day are then delivered to patients later on that same calendar day.

Mr. Marks argued that delivery of medications to patients by Pharmacy Homecare Network personnel instead of via UPS was beneficial to those patients for several reasons. He referred to a language barrier because the patients speak Russian and UPS drivers generally do not. He also referred to elderly patients that cannot reach the door in time to respond to a UPS driver, and that they may not open their doors because they don't recognize the UPS driver.

Mr. Marks noted that UPS drivers who cannot make a delivery to a patient leave a note on the patient's door, and bring the item(s) back to the warehouse where they are stored. He

emphasized that the UPS note left on the door is written in English, and stressed that the language barrier is a problem.

Mr. Marks supported Pharmacy Homecare Network's current procedures whereby their drivers provide personal service and there is assurance that patients receive medications they need. He referred to a board investigation of Pharmacy Homecare Network on a matter relating to this procedure, which resulted in a citation and fine, and his position was that the board's finding was incorrect. Mr. Marks questioned whether board investigators had the information they needed to make the finding.

Mr. Room advised that the committee could hear the request, but any action subsequently taken by the full board would be prospective, not retroactive. He also noted that the previous citation and fine referred to by Mr. Marks had not yet reached a conclusion, due to a pending appeal.

Mr. Marks clarified that Pharmacy Homecare Network was appealing the citation and fine, but was also asking for a temporary waiver from the board pending the outcome of that appeal. He advised that Pharmacy Homecare Network wanted to continue its current procedures in the meantime.

Mr. Room recommended that the board not comment on the propriety of the activity in question relating to 16 CCR Section 1713(a). The board should not hear the facts of an appeal still pending because it could compromise the citation and appeal. Mr. Room further stated that the Enforcement Committee did not have authority to grant a waiver. The Enforcement Committee could only make a recommendation to the full board as to whether this type of activity should be permitted in the future.

Mr. Goldenberg recommended that Pharmacy Homecare Network or their representative(s) return to the Enforcement Committee after conclusion of their appeal, if they want to revisit the issue at that time.

MOTION: That the matter regarding the request from Pharmacy Homecare Network to waive 16 CCR 1713(a) be tabled until conclusion of their pending appeal of a cite and fine on the same matter.

M/S: DAZÉ/POWERS

SUPPORT: 4 OPPOSE: 0

## **F. REQUEST FROM INSTYMEDS REGARDING 72-HOUR DISPENSING RESTRICTION**

Gregory Matzen spoke on behalf of InstyMeds. Mr. Matzen serves as legal counsel to InstyMeds regarding their request for an exemption from the 72-hour dispensing restriction. The meeting materials included correspondence to the board from Mr. Matzen relating to a request for exemption of Business and Professions Code Section 4068(a)(1) and (6) and

Health and Safety Code Section 1261.6(e)(1). The InstyMeds Prescription Medication Dispenser System (system) is an automated prescription medication dispensing system, mainly used in hospital emergency settings. The system dispenses a full treatment regimen of acute medications (i.e., antibiotics, analgesics, etc.) to patients.

Mr. Matzen noted that the Enforcement Committee Meeting agenda item did not accurately reflect the reason for their appearance. He stated that InstyMeds was not seeking exemption of Business and Professions Code Section 4170(a)(5) as shown on the agenda. He said they were asking for clarification of a niche in the law, not a waiver of the law.

Mr. Matzen stated that they were seeking clarification of Business and Professions Code Section 4068(a)(1) and (6) and Health and Safety Code Section 1261.6(e)(1). He spoke about a request made to InstyMeds from a rural hospital. The hospital was seeking a prescription dispensing machine for installation in their emergency room. Health and Safety Code Section 1261.6(e)(1) refers to a patient "of the facility" meaning a patient in that facility. Mr. Matzen argued that a patient in the emergency room was not a patient of the facility until or unless the patient is "admitted." He stressed that patients in the emergency room would not be patients in the facility.

Mr. Room advised that neither the board nor a committee of the board could offer an interpretation of the law. Individual parties can hire their own legal counsel who will provide an interpretation of the law. As a general matter, dispensing is limited to pharmacists, with certain limited conditions under which prescriber dispensing is permitted. Those conditions are enumerated by statute (i.e., dispensing from an office or during an emergency). There are currently no provisions permitting dispensing from an emergency room to a patient for more than a 72-hour supply of medicine. Mr. Room said that if that ability to dispense to an out-patient were desired, that would require a change in the law.

Ms. Herold noted that Mr. Matzen's letter dated June 22, 2007 specifically requested an exemption of Business and Professions Code Section 4068(a)(1) and (6) and Health and Safety Code Section 1261.6(e)(1).

Mr. Matzen clarified that he was no longer seeking a waiver, but instead, was seeking clarification because the regulations did not currently address this particular situation.

Mr. Powers stated that Mr. Room's comments provided clarification.

Matt Sneller, PharmD, spoke for InstyMeds, noting that the company had been in business for several years. They have approximately 80 prescription dispensing machines located in several states, the majority of which are in hospital emergency rooms. They also have machines installed in urgent care clinics and one small surgery center.

Dr. Sneller said that a rural hospital outside Bakersfield requested installation of an InstyMeds machine. That facility does not have 24-hour pharmacy services. The facility has a hospital pharmacy with a pharmacist present at all times. However, the hospital pharmacy does not do any "out-patient" dispensing. Dr. Snell gave an example of a

72-hour supply of a narcotic like Vicodin as opposed to a 72-hour supply of an antibiotic like Amoxicillin that should be taken for 10 days. Patients who have the full prescription in hand from the start are more likely to take the medication as directed for the full course of the prescription.

Mr. Goldenberg noted that since there had been no motion, there would be no action taken by the Enforcement Committee on this issue at this time.

#### **G. COMMITTEE MEETING SCHEDULE FOR 2008**

Ms. Herold advised that information would be posted on the board's Web site regarding the next scheduled meetings of the Enforcement Committee and next full board meeting.

#### **H. ENFORCEMENT STATISTICS**

Mr. Goldenberg noted that the meeting materials contained the board's Enforcement Statistics for Fiscal Year 2007/08.

#### **I. MISC ITEM**

Mr. Goldenberg advised that information regarding variations of quantity of a prescription was brought to the board's attention. He gave an example of a prescription written for 30 doses of a given drug, with 10 refills. He asked if a pharmacist could dispense a 90-day supply of the tablets, which would be three refills at one time. He noted that this is allowable by many Medicare Part D plans.

Ms. Herold noted that the board's inspectors considered this question several times in previous months. They indicate that if a prescriber desires a patient to receive 90-day supply, the prescriber needs to write a 90-day supply. In the case of writing a prescription with 10 refills, the prescriber did not write "fill a 90-day supply."

There was a discussion among board members regarding pharmacists filling prescriptions up to the quantity of that prescribed.

No further action was taken by the board.

#### **ADJOURNMENT**

Mr. Goldenberg adjourned the Enforcement Committee Meeting at 6:06 p.m.

# Attachment

***THIRD QUARTERLY REPORT ON COMMITTEE  
GOALS FOR 2007/08***

# 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. Mediate all complaints within 90 days (for cases closed during quarter).						
		<u>N</u>	<u>&lt; 90 days</u>	<u>&lt; 120 days</u>	<u>&lt; 180 days</u>	<u>Longer</u>	<u>Average Days</u>
	Qtr 1	211	171	25	12	2	57
			(81%)	(12%)	(6%)	(1%)	
	Qtr 2	90	78	10	2	0	47
			(87%)	(11%)	(2%)	(0%)	
	Qtr 3	109	84	2	3	20	115
			(77%)	(2%)	(3%)	(18%)	
	Qtr 4						
	2. Investigate all cases within 120 days (for cases closed during quarter).						
		<u>N</u>	<u>&lt; 120 days</u>	<u>&lt; 180 days</u>	<u>&lt; 270 days</u>	<u>Longer</u>	<u>Average Days</u>
	Qtr 1	235	167	20	37	11	91
			(71%)	(8%)	(16%)	(5%)	
	Qtr 2	263	165	50	23	25	139
			(63%)	(19%)	(9%)	(10%)	
	Qtr 3	291	196	36	36	23	125
			(67%)	(13%)	(13%)	(8%)	
	Qtr 4						

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	N	< 180	< 270	< 365	> 365
Closed, no additional action	184	171	11	2	0
Cite and/or fine letter of admonishment	237	209	21	7	0
Attorney General's Office	24	15	7	2	0
Qtr 2	N	< 180	< 270	< 365	> 365
Closed, no additional action	146	137	7	1	1
Cite and/or fine letter of admonishment	199	163	15	10	11
Attorney General's Office	8	4	2	2	0
Qtr 3	N	< 180	< 270	< 365	> 365
Closed, no additional action	177	145	13	4	15
Cite and/or fine letter of admonishment	192	165	15	7	3
Attorney General's Office	31	10	11	6	4
Qtr 4	N	< 180	< 270	< 365	> 365
Closed, no additional action					
Cite and/or fine letter of admonishment					
Attorney General's Office					

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>18</td> <td>54</td> <td>0</td> <td>3</td> </tr> <tr> <td>Qtr 2</td> <td>18</td> <td>56</td> <td>61</td> <td>4</td> </tr> <tr> <td>Qtr 3</td> <td>20</td> <td>55</td> <td>2</td> <td>1</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>2. Administer the Probation Monitoring Program.</p> <table border="1"> <thead> <tr> <th></th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Individuals</td> <td>123</td> <td>121</td> <td>124</td> <td></td> </tr> <tr> <td>Sites</td> <td>6</td> <td>6</td> <td>6</td> <td></td> </tr> <tr> <td>Tolled</td> <td>25</td> <td>31</td> <td>23</td> <td></td> </tr> <tr> <td>Inspections Conducted</td> <td>44</td> <td>56</td> <td>26</td> <td></td> </tr> <tr> <td>Successfully Completed</td> <td>2</td> <td>2</td> <td>4</td> <td></td> </tr> <tr> <td>Petitions to Revoke Filed</td> <td>2</td> <td>0</td> <td>0</td> <td></td> </tr> </tbody> </table> <p>3. Issue all citations and fines within 30 days.</p> <table border="1"> <thead> <tr> <th></th> <th>N</th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>&gt; 90 days</th> <th>Average Days</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>188</td> <td>1 (.5%)</td> <td>11 (6%)</td> <td>77 (41%)</td> <td>99 (53%)</td> <td>94</td> </tr> <tr> <td>Qtr 2</td> <td>175</td> <td>1 (1%)</td> <td>0 (0%)</td> <td>44 (25%)</td> <td>130 (74%)</td> <td>102</td> </tr> <tr> <td>Qtr 3</td> <td>414</td> <td>15 (4%)</td> <td>74 (18%)</td> <td>17 (4%)</td> <td>308 (74%)</td> <td>100</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>4. Issue letters of admonishment within 30 days.</p> <table border="1"> <thead> <tr> <th></th> <th>N</th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>&gt; 90 days</th> <th>Average</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>50</td> <td>20 (40%)</td> <td>24 (48%)</td> <td>4 (8%)</td> <td>2 (4%)</td> <td>38</td> </tr> <tr> <td>Qtr 2</td> <td>24</td> <td>0 (0%)</td> <td>4 (17%)</td> <td>14 (60%)</td> <td>6 (25%)</td> <td>87</td> </tr> <tr> <td>Qtr 3</td> <td>1</td> <td>1 (100%)</td> <td>0 (0%)</td> <td>0 (0%)</td> <td>0 (0%)</td> <td>1</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></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	18	54	0	3	Qtr 2	18	56	61	4	Qtr 3	20	55	2	1	Qtr 4						Qtr 1	Qtr 2	Qtr 3	Qtr 4	Individuals	123	121	124		Sites	6	6	6		Tolled	25	31	23		Inspections Conducted	44	56	26		Successfully Completed	2	2	4		Petitions to Revoke Filed	2	0	0			N	30 days	60 days	90 days	> 90 days	Average Days	Qtr 1	188	1 (.5%)	11 (6%)	77 (41%)	99 (53%)	94	Qtr 2	175	1 (1%)	0 (0%)	44 (25%)	130 (74%)	102	Qtr 3	414	15 (4%)	74 (18%)	17 (4%)	308 (74%)	100	Qtr 4								N	30 days	60 days	90 days	> 90 days	Average	Qtr 1	50	20 (40%)	24 (48%)	4 (8%)	2 (4%)	38	Qtr 2	24	0 (0%)	4 (17%)	14 (60%)	6 (25%)	87	Qtr 3	1	1 (100%)	0 (0%)	0 (0%)	0 (0%)	1	Qtr 4						
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Petitions to Revoke Filed	2	0	0																																																																																																																																				
	N	30 days	60 days	90 days	> 90 days	Average Days																																																																																																																																	
Qtr 1	188	1 (.5%)	11 (6%)	77 (41%)	99 (53%)	94																																																																																																																																	
Qtr 2	175	1 (1%)	0 (0%)	44 (25%)	130 (74%)	102																																																																																																																																	
Qtr 3	414	15 (4%)	74 (18%)	17 (4%)	308 (74%)	100																																																																																																																																	
Qtr 4																																																																																																																																							
	N	30 days	60 days	90 days	> 90 days	Average																																																																																																																																	
Qtr 1	50	20 (40%)	24 (48%)	4 (8%)	2 (4%)	38																																																																																																																																	
Qtr 2	24	0 (0%)	4 (17%)	14 (60%)	6 (25%)	87																																																																																																																																	
Qtr 3	1	1 (100%)	0 (0%)	0 (0%)	0 (0%)	1																																																																																																																																	
Qtr 4																																																																																																																																							

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	0
Qtr 2	0	0	1
Qtr 3	0	0	0
Qtr 4			

6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.

	30 days	60 days	> 60 days	<u>N</u>
Qtr 1	0	0	1	1
Qtr 2	1	0	1	2
Qtr 3	0	0	0	0
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.

	<u>N</u>	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	<u>Average</u>
Qtr 1	13	5 (39%)	3 (23%)	4 (31%)	1 (8%)	0 (0%)	448 days
Qtr 2	26	16 (62%)	8 (31%)	2 (8%)	0 (0%)	0 (0%)	360 days
Qtr 3	13	6 (46%)	2 (15%)	2 (15%)	2 (15%)	1 (8%)	484 days
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:	<p data-bbox="349 220 1461 283">1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.</p> <table border="1" data-bbox="349 283 1461 514"> <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>387</td> <td>3,648</td> <td>50%</td> </tr> <tr> <td>Qtr 2</td> <td>366</td> <td>3,758</td> <td>52%</td> </tr> <tr> <td>Qtr 3</td> <td>320</td> <td>3,689</td> <td>51%</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p data-bbox="349 546 1461 609">2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.</p> <table border="1" data-bbox="349 609 1144 840"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number Inspected Late</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>60</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td>61</td> <td>0</td> </tr> <tr> <td>Qtr 3</td> <td>43</td> <td>0</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> </tr> </tbody> </table> <p data-bbox="349 871 1461 913">3. Initiate investigations based upon violations discovered during routine inspections.</p> <table border="1" data-bbox="349 913 1461 1134"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number of Investigations Opened</th> <th>Percent Opened</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>387</td> <td>14</td> <td>4%</td> </tr> <tr> <td>Qtr 2</td> <td>366</td> <td>11</td> <td>3%</td> </tr> <tr> <td>Qtr 3</td> <td>320</td> <td>15</td> <td>5%</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	387	3,648	50%	Qtr 2	366	3,758	52%	Qtr 3	320	3,689	51%	Qtr 4					Number of Inspections	Number Inspected Late	Qtr 1	60	0	Qtr 2	61	0	Qtr 3	43	0	Qtr 4				Number of Inspections	Number of Investigations Opened	Percent Opened	Qtr 1	387	14	4%	Qtr 2	366	11	3%	Qtr 3	320	15	5%	Qtr 4			
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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 &amp; 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>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.</i></p> <p><i>Jan. 2008: Board reviews requests for delay until 2011 from members of the pharmaceutical supply chain.</i></p> <p><i>Feb. 2008: Questions and Answers released. Specialized area of the Board's Website is created to consolidate e-pedigree information.</i></p> <p><i>March 2008: Board delays implementation date for e-pedigree requirements from January 1, 2009 until January 1, 2011.</i></p>

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.*
  - July 2007: *Board hears presentations on EPCglobal standards.*
  - Sept. 2007: *Enforcement Meeting has large audience (200 people). Presentations by PhRMA, GSK, Bracco, CPhA, EPCglobal, Walgreens, Rite Aid, CVS, rXcel, and HDMA. 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.*
  - 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.*
3. Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances.
  - Sept. 2006: *DEA 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 DEA 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: *DEA agrees to allow a 90-day supply of Schedule II drugs to be prescribed at one time in serial prescriptions.*
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.*
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.*
6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.
  - Sept. 2007: *Provided comments on proposed statutory requirements.*
  - Dec. 2007: *Sought DCA's support for involvement in e-prescribing by the Administration. Provided comments on proposed e-prescribing initiatives.*

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.
- June - Oct. 007: *Board works with the Department of Health Care Services to implement security forms until subsequent federal legislation delays implementation until April 2008.*
- Dec. 2007: *Meeting with Department of Health Care Services on issues involving security forms for MediCal prescriptions.*
- April 1, 2008: *Requirements that all written prescriptions for MediCal prescriptions be written on security forms containing at least one specified security component takes effect.*
- April 2008: *Subscriber alert released with information for contact resources from the California Department of Health Care Services about security forms for MediCal prescriptions.*
8. Liaison with other state and federal agencies to achieve consumer protection.
- 1st Qtr 07/08: *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.*
- 2nd Qtr 07/08: *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.*
- 3rd Qtr 07/08: *Bimonthly meeting with the Department of Health Care Services continue.*  
*Board works with the Drug Enforcement Administration on joint investigations and received specialized training.*
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.*