



**California State Board of Pharmacy**  
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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

## **Enforcement Committee Meeting Packet**

**January 23, 2008**

Stan Goldenberg, RPh, Chair and Board Member  
Bill Powers, Board President  
Ruth Conroy, PharmD, Board Member  
Tim Dazé, Esq., Board Member  
Robert Swart, PharmD, Board Member

### **A: Development of an Ethics Course for Pharmacists, Modeled After That Developed by the Medical Board of California**

At the October 2007 Board Meeting, the board voted to move forward to develop an ethics course for pharmacists as an enforcement option when establishing discipline parameters for licensees.

The board intends to develop a course for pharmacists similar in structure to that used by the Medical Board for physicians. The Medical Board's course is provided by the Institute for Medical Quality.

The course is a 22-hour specialized course that runs over one year, and costs approximately \$1,900. This model relies upon small group interaction (only 12 individuals are enrolled at any time) led by a therapist/ethicist, with personal written assessments before and for up to 12 months after completion of the two-day group session meeting with the therapist. The components are:

- Pre-program Requirements
  - Background Assessment Application
  - Baseline Assessment of Knowledge Test
  - Reading Assignment
  - Participant Expectation of Program Statement
- Two-Day Ethics Course
  - Case presentations
  - Break-out groups
  - Experimental exercises
  - Role-playing
- Longitudinal Follow up at
  - 6 months
  - 12 months

Board staff has discussed how to move forward with this course with the IMQ, which advises that a 6-9 month timeline is needed to implement the course. For the course to be meaningful to pharmacists, situations involving pharmacy (not medical practice) are needed. This will involve the use of public documents used in board disciplinary cases (accusations, stipulations and final decisions).

The board also will need to promulgate regulations for this program or secure statutory requirements. The staff recommends moving forward with omnibus provisions that could be added into our 2008 proposals. A draft will be brought to this committee meeting for review.

Early in 2007, President Powers appointed Dr. Ravnan and Dr. Swart to a subcommittee to work with staff on reviewing various ethics course options. Board staff will continue to work with this subcommittee to develop the program, which if successful with the legislation, should be in place early in 2009.

Staff discussions with staff of the IMQ indicate that the development of the course would not require significant resources from board staff; a principal duty would be to identify case scenarios that would be discussed during the course based on investigations of unethical pharmacy practices.

Once developed, the board could also offer enrollment in this course to other state boards of pharmacy that have difficulty in identifying meaningful ethics courses for disciplined pharmacists.

A copy of the Medical Board's regulation is included in **Attachment 1**, as is a description of the Institute of Medical Quality's course.

Staff will develop draft language to establish this program statutorily and bring it to the meeting for comment.

## **B. Discussion Regarding Pharmacist and Technician Registry Firms That Are Used to Staff Pharmacies**

Over the prior years, the board's inspectors have encountered unlicensed or suspended pharmacists working in pharmacies that have been placed there by pharmacist registry companies. This sometimes comes to the board's attention when investigating a complaint. For example:

1. Revoked pharmacist worked multiple shifts/days in a hospital pharmacy/pharmacies in the central valley. This was detected by the new PIC at hospital asking for contractual changes with the relief agency.
2. Unlicensed/expired pharmacy technician placed at hospital pharmacy.
3. Relief agency placed revoked pharmacist in multiple pharmacies (community and chain). Pharmacist worked multiple days and shifts over an approximate 6 month period.

The board has no redress against the entity that placed the pharmacists in the pharmacy -- leaving the public and the profession at risk without a consequence.

As such, 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.

Committee discussion is requested at this meeting before staff moves forward with developing a proposed legislative solution.

### **C. Discussion Regarding Theft of Prescription Medicine from Supply Chain Partners**

The National Association of Boards of Pharmacy recently convened a task force to discuss supply chain issues raised by cargo thefts from the transportation companies. These common carriers are often used to transport drugs from manufacturers to wholesalers and from wholesalers to pharmacies. The NABP noted that:

1. the diversion of prescription medication from common carriers presents a threat to the public health and
2. regulations regarding the distribution and delivery of prescription drugs vary by state and often do not include accountability for common carriers that distribute and deliver prescription drugs.

A copy of an article in a recent NABP newsletter is provided in **Attachment 2**. The article notes that DEA regulations requires suppliers to report controlled substances drug loses, and wholesalers are responsible for checking backgrounds of the carriers to prevent losses.

Thefts from common carriers are another way counterfeit or adulterated drugs end up in the supply chain (e.g., stolen drugs they are purchased at low prices by licensed entities). They are also a source of drugs ending up on the streets and offered for sale by Internet pharmacies.

The NABP task force is developing a report on its recommendations that will be available at the May NABP meeting and from the NABP Web site.

In California, some very large thefts have occurred, such as hijacking a truck moving prescription medicine from a wholesaler to another license entity. Theft also occurs on a smaller scale. For example, the board recently received a report from a wholesaler who reported three separate controlled substances thefts upon receipt from three different manufacturers over a six-month period, where the losses were noted by the wholesaler upon opening the boxes.

Pharmacies also receive deliveries with drugs missing. If the pharmacist fails to inventory the contents of a drug order upon receipt, the board may cite and fine the

pharmacy and pharmacist. The board has also fined wholesalers if the pharmacist discovers the problem with at the time of delivery.

**D. Discussion of the Impact of Pharmacy Rebates or “Gifts” to Patients to Transfer Prescriptions**

Pharmacies sometimes offer rebates or cash gift cards for any new or transferred prescription. The board published an article in the July 2007 *The Script* stating that such a practice is legal because the patient is getting the incentive, and there is not a “kick back” to the pharmacy. A copy of this article is in **Attachment 3**.

In recent months, the board has begun receiving complaints regarding the impact of these transfers (also in **Attachment 3**). These issues involve increased workload to the pharmacist who must transfer the prescriptions, directing pharmacist away from patient care.

An example of a gift card offer is also in **Attachment 3**. This is typical of the type of rebate offered; multiple pharmacies have offered similar gifts.

Another concern expressed is that a pharmacist could be disciplined by the board for a clerk or technician providing a rebate to a Medicaid or Medicare patient, which is specifically prohibited by federal law when the pharmacist would have no knowledge of this financial transaction (the board has disciplined no pharmacist for this).

The committee will discuss this issue.

**E. Request for Waiver of 16 CCR section 1713(a) to Permit Pharmacy Homecare Network to Depot Drugs at the Homes of Delivery Personnel for Later Delivery to Patients**

Section 1713(a) of California Pharmacy Law regulations 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 this requirement for good cause shown. (**Attachment 4**) contains this regulation.

Pharmacy Homecare Network, through its Attorney Ron Marks, is requesting the board to waive section 1713(a) so that it can ship prescription medicine to the home of a delivery driver who will then deliver it the following day (also **Attachment 4**) (note: his reference to waive section 1717(e) refers to the prior placement of this regulation before it was moved to section 1713 in late 2006).

**F. Request from InstyMeds for Waiver of California Law (Business and Profession Code Sections 4068 and 4170(a)(5) and Health and Safety Code section 1261(e)(1) to Allow for Emergency Room Dispensing of a Full Course of Medicine**

InstyMeds, through its Attorney Greg Madsen, is requesting the board to waive selected provisions of the Business and Professions Code and Health and Safety Code so that an InstyMeds machine can be used in hospitals to dispense a full medication order (and not just a 72 hour supply as law allows) whenever a patient is seen in an emergency room and the hospital pharmacy is closed. A copy of the request, various statutory references and correspondence are provided in **Attachment 5**.

Mr. Madsen is requesting waiver of statutory law, which the board lacks the authority to do (as was pointed out to him). Instead, such changes need to be enacted by the Legislature.

## **G: Enforcement Statistics**

The enforcement statistics for the Enforcement Committee for the second quarter 2007-08 are provided in **Attachment 6**.

# Attachment 1

*Development of an Ethics Course for  
Pharmacists*

**Registration & Attendance Fee:**

An application which includes a background assessment must be completed to register. This form is available at [www.imq.org](http://www.imq.org) click on Education Programs/"Professionalism Program."

**Resource Materials:**

Participants will be sent information about meeting location, the course schedule, a copy of the AMA Code of Medical Ethics and other reading materials that are required for the course.

**Fee:**

Registration fee \$1900 includes all three (3) components of the program, all required reading materials and continental breakfast and breaks at the two-day session.

**Refund:**

Cancellation must be received 21 calendar days prior to the reserved seminar date for registrants to receive a refund. The refund, less a \$500 service fee, will be mailed after the seminar. There is no refund if the cancellation notice is received at IMQ between 21 days before the seminar, and the date of the seminar. A registrant can transfer to another seminar date at no charge if the request is made at least 21 days prior to the reserved seminar.

Participants should phone (415) 882-3387 to reserve a place in one of the upcoming programs. Sessions are limited to 12 participants. Once a session has filled with pre-paid participants, others must choose an alternative date. A letter of confirmation will be mailed after receipt of the completed application with a copy of the Accusation and Decision and/or Stipulated Agreement and the program fee.

**Send the application and payment to:**

Institute for Medical Quality  
Medical Ethics Seminar  
221 Main Street, Suite 210  
San Francisco, CA 94105

**Learning Objectives:**

- Describe the ethics and law of medicine in California.
- Describe the foundations of the physician as a professional.
- Apply a variety of resources when future problems arise.
- Describe the legal and ethical dimensions of the practice of medicine in California.
- Identify and resolve ethical issues.



**INSTITUTE FOR MEDICAL  
QUALITY**

*A subsidiary of the California Medical Association*

Presents:

**IMQ  
Professionalism  
Program**

The Professionalism Program is designed to comply with the new requirements established by the Medical Board of California. The program centers on both the legal and ethical dimensions of medical practice in California. It introduces participants to a range of resources to address present or future problems.

The two-day portion of the Program will be held on Saturdays and Sundays at locations conveniently located to airports in Southern California

*The class shall not exceed a maximum of 12 participants.*

**Program Overview**

This Program consists of a Pre-Course Assessment and Testing component, a two-day Ethics Course and Longitudinal Follow-up after the Course.

Classes will include case presentations, break out groups, experiential exercises and role-playing. All class sessions must be attended. Full participation and fulfillment of all assignments are required for completion of the Program.

### Course Plan

#### Pre-Program Requirements:

- Background Assessment - Application
- Baseline Assessment of Knowledge Test
- Reading Assignment
- Participant Expectation of Program

### Day One: Saturday

Introduction - Program Outline	8:00 - 8:30
What Ethical Issues are & when do they arise?	8:30 - 10:00
Break	10:00 - 10:15
Accessing legal resources, where to look and how to use	10:15 - 12:00
Lunch (on your own)	12:00 - 1:00
The physician as a Professional	1:00 - 2:00
Using sources to analyze a situation & an introduction to resources list	2:00 - 3:00
Break	3:00 - 3:15
Decision Making Model on how to resolve Ethical Decisions – Presentations	3:15 - 5:00
Break	5:00 - 5:15
Group Project Assignment	5:15 - 6:15

### Day Two: Sunday

Group Reports	8:00 - 8:45
The Interplay of Law & Ethics	8:45 - 10:00
Break	10:00 - 10:15
Individual Work on Participant Violations	10:15 - 11:00
Small Group Application of Decision Model	11:00 - 12:00
Lunch (on your own)	12:00 - 1:00
Report out on Small Group Application	1:00 - 2:00
Role Play Exercise	2:00 - 3:00
Break	3:00 - 3:15
Concluding Session – review of seminar methods and concepts	3:15 - 4:00
Post Course Test	4:00 - 5:00

#### Longitudinal Follow-Up:

- 6 Month Follow-up
- 12 Month Follow-up

### Accreditation

The California Medical Association (CMA) is accredited by the Accreditation Council of Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

The CMA designates The Professionalism Program for a maximum of *22 AMA PRA Category I Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity. The credit may also be applied toward the CMA Certification in Continuing Medical Education.

### Faculty

**William May, PhD** is a faculty member at the University of Southern California where he specializes in medical ethics and business ethics. His primary teaching is on the main campus, but he participates in the bioethics program at the Medical School as well.

He has published books and articles on professional ethics. He has served on three hospital ethics committee and institutional review boards at LAC+USC Medical Center and the California State Human Subjects Committee from 1992 to 2004. Professor May taught an Ethics Seminar sponsored jointly by the CMA/IMQ and the Medical Board of California.

**Gregory M. Abrams, JD** received his Juris Doctor degree from University of California, Hastings College of Law in San Francisco.

Mr. Abrams is an attorney with California Medical Association and has worked on a variety of issues including professional liability and MICRA, physician reporting and warning requirements and Medical Board of California issues regarding physician discipline and unprofessional conduct. He is a contributing author of the *California Medical Association's California Physicians Legal Handbook*.



## Welcome to the online source for the California Code of Regulations

16 CA ADC § 1358.1

Term 

16 CCR s 1358.1

Cal. Admin. Code tit. 16, s 1358.1

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS  
TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS  
DIVISION 13. MEDICAL BOARD OF CALIFORNIA [FNA1]  
CHAPTER 2. DIVISION OF MEDICAL QUALITY  
ARTICLE 3. PROBATION AND REINSTATEMENT OF SUSPENDED OR REVOKED CERTIFICATES  
This database is current through 9/28/07, Register 2007, No. 39  
s 1358.1. Ethics Course Required as Condition of Probation.

A licensee who is required, as a condition of probation, to complete an ethics course shall take and successfully complete a professionalism program approved by the division that meets the requirements of this section.

(a) Approved Provider. The program provider shall be accredited by the Accreditation Council of Continuing Medical Education (ACCME), or by an entity qualified in Section 1337, to sponsor continuing medical education for physicians and surgeons and shall provide satisfactory written evidence that its professionalism program meets all of the requirements of this section.

(b) Criteria for Acceptability of Program.

(1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment. The provider shall identify the number of continuing medical education hours that will be credited upon successful completion of the program.

(2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution. The provider shall submit with its application a curriculum vitae for each instructor for approval by the division or its designee.

(3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.

(4) Methods of Instruction. The provider shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.

(5) Content. The program shall contain all of the following components:

(A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.

(B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of medicine in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.

(C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.

(D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.

(E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.

(F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.

(6) Class Size. A class shall not exceed a maximum of 12 participants.

(7) Evaluation. The program shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.

(8) Records. The provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the division or its designee.

(9) Program Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the division or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

(10) Change in Course Content or Instructor. The provider shall report to the division any change in course content or instructor within 30 calendar days after the date of that change.

## &lt;&lt;DIVISION 13. MEDICAL BOARD OF CALIFORNIA [FNA1]&gt;&gt;

[FNa1] For disposition of former Sections 1370-1375.45, see Table of Parallel Reference, Chapter 13.2, Title 16, California Code of Regulations.

## &lt;General Materials (GM) - References, Annotations, or Tables&gt;

Note: Authority cited: Section 2018, Business and Professions Code. Reference: Sections 2227, 2228 and 22 29, Business and Professions Code.

## HISTORY

1. New section filed 3-7-2005; operative 4-6-2005 (Register 2005, No. 10).

16 CCR s 1358.1, 16 **←CA ADC s 1358.1→**  
1CAC

16 **←CA ADC s 1358.1→**

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# Attachment 2

*Drug Thefts from the Supply Chain*

## Task Force Seeks to Safeguard Prescription Medication Supply Chain against Threat Posed by Cargo Theft

The states have taken great strides to safeguard the nation's medication supply chain against counterfeiting and diversion. Recently enacted laws and regulations in some states tighten licensing requirements for wholesale drug distributors and establish controls over mail-order pharmacies and Internet distributors selling medications across state lines.

Some NABP members have pointed out, however, that a significant weakness in the supply chain remains all-too-often unheeded. Potentially millions of dollars worth of prescription medications enter the black market with every incident of pharmaceutical cargo theft.

"Most of these drugs end up on the streets," says William Harvey, executive director/chief drug inspector for the New Mexico Board of Pharmacy. "It's our responsibility to prevent that from happening."

Harvey served as ex officio member of the NABP Task Force on Prescription Drug Diversion from Common Carriers, which met November 8-9, 2007, at NABP Headquarters. The task force was created as a result of a resolution passed at the

103<sup>rd</sup> Annual Meeting in May 2007, which notes (1) that the diversion of prescription medication from common carriers presents a threat to the public health, and (2) that "regulations regarding the distribution and delivery of prescription drugs vary by state and often do not include accountability provisions for common carriers that distribute and deliver prescription drugs."

The charge of the task force is to study issues surrounding the diversion of prescription drugs from common carriers or their agents during interstate and intrastate distribution and delivery to wholesalers, pharmacies, patients, and patients' agents and to recommend possible solutions.

Complicating the problem, pharmaceutical cargo thefts often go unreported, Harvey says. If a pharmacy receives an incomplete order, pharmacy personnel likely assume an error on the part of the wholesaler, who in turn typically provides the pharmacy with the missing units, attributes the error to the courier, and/or files an insurance claim for the lost inventory. The courier might report the theft to local police, but it is not clear how often these instances are reported to the state

board of pharmacy or Drug Enforcement Administration (DEA), as required of entities registered to handle controlled substances, Harvey says.

Title 21 of the Code of Federal Regulations (CFR) holds suppliers

"Most of these drugs end up on the streets. It's our responsibility to prevent that from happening."

William Harvey,  
Executive Director/  
Chief Drug Inspector  
New Mexico Board  
of Pharmacy

responsible for "reporting [to DEA] in-transit losses of controlled substances by the common or contract carrier selected pursuant to Sec. 1301.74(e), upon discovery of such theft or loss. . . . Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them."

A wholesale drug distributor might be legitimately licensed and operating within the law, but many wholesalers

use ground couriers, who might then subcontract other couriers of varying sizes and standards of professionalism to deliver the pharmaceutical cargo to various destinations after they leave the wholesaler's warehouse.

DEA holds registrants accountable for checking the backgrounds of couriers and warehouse personnel handling controlled substances. "When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses," CFR states. ". . . In addition, the registrant shall employ precautions (eg, assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses."

Shipping trade magazine *Northeast Export* lists pharmaceuticals among the top 10 targets of cargo theft, largely because of their aftermarket sales value. Harvey notes that most pharmaceutical cargo thieves target controlled substances and so-called lifestyle medications.

In most cases, law enforcement officials say, cargo thefts are inside jobs. The Crime Prevention Service for Business, of Rutgers

(continued on page 168)

nabp newsletter

### Threat Posed by Cargo Theft

(continued from page 167)

University, New Jersey, notes that cargo theft occurs most commonly in trucking and is often committed by a truck driver and a warehouse employee working together, and that cargo is at its greatest risk when it is being loaded and unloaded.

Thefts also commonly occur when trucks are left unattended, notes Barbara Goodson, senior criminal financial analyst of the Florida Law Enforcement Analyst Academy, in a June 2007 report on counterfeit prescription drugs. "These trucks have been hijacked, broken into while the driver is at lunch or dinner, the trailer has been unhitched from the cab while parked at an overnight stop, or stolen from a pharmaceutical facility warehouse," she says. "... People's health is at stake and there needs to be more security for these trucks delivering what could be life-saving medication."

In June 2007, DEA notified the boards of pharmacy of the theft of more than 16 million doses of hydrocodone combination products. A tractor-trailer traveling from Watson Pharmaceuticals, Inc manufacturing plant in Corona, CA, to its distributor in Gurnee, IL,

was stolen from a truck stop in Troy, IL.

New Mexico news source KOB.com reported in July 2007 that a Neb Ark Courier van containing 2,000 tablets of hydrocodone and approximately 200 tablets of oxycodone was stolen from outside the Lovelace Healthcare Clinic in Albuquerque, NM, while the driver was inside delivering the freight. These tablets reportedly carry a typical street value of \$10 apiece. This latest heist is the third theft of prescription pain medication the courier has encountered this year, KOB reports, noting that investigators think the thefts are an inside job.

The online news publication *e-Week* reported that police apprehended a theft ring in July 2006 near Chicago, found to have pilfered some \$2.2 million in various merchandise, including prescription medications, from courier trucks. "Thieves often follow trailers from the time they exit a plant until the driver stops for the night and then make off with the entire vehicle," *e-Week* reports. Steve Grover, director of communications at Knight Transportation in Phoenix, AZ, says in the article that the ready availability of unattended cargoes to potential thieves points to an efficiency problem in the shipping business. In the process of coordinating

manufacturer, trucker, and retail store schedules, he notes, cargoes often sit for hours or days until the store has the capacity to receive the load or the manpower to empty it.

Chris Swecker, assistant director of the Criminal Investigative Division of the Federal Bureau of Investigation (FBI), addressed the House Judiciary Committee's Subcommittee on Crime, Terrorism, and Homeland Security in March 2005 regarding FBI's efforts to curb the "nationwide problem posed by criminal enterprises involved in the theft, diversion, repackaging, and ultimate resale of consumer products," including prescription and over-the-counter medications. "The unsuspecting consumer also faces potential health and safety risks from legitimate products which may have been mishandled by the criminal enterprises who stole them for resale to consumers," Swecker states. If medications are not stored under proper conditions or are adulterated, they pose a significant health hazard to consumers when reintroduced into the retail market.

Food and Drug Administration and some drug makers are looking to radio-frequency identification of prescription medication containers to help track stolen medications, weed out counterfeits, and

maintain the integrity of the supply chain. Others point to increased security measures and uniformly enforced employee background checks to address the problem.

These and other potential remedies, as well as related regulation and enforcement issues, were the subject at hand for the NABP Task Force on Prescription Drug Diversion from Common Carriers.

The following individuals, listed here with their state boards of pharmacy, have been appointed to serve on the task force: Howard C. Anderson, Jr, RPh, chairperson, North Dakota; Wendy L. Anderson, RPh, Colorado; Jack William "Jay" Campbell IV, RPh, JD, North Carolina; John R. Dorvee, Jr, PharmD, Vermont; Edith G. "Edie" Goodmaster, Connecticut; Edward G. McGinley, RPh, New Jersey; Peter J. Orzali, Jr, RPh, Kentucky; and Frank A. Whitchurch, RPh, Kansas; William C. Harvey, RPh, ex officio member, New Mexico; and Lloyd K. Jessen, RPh, JD, Executive Committee liaison, Iowa.

The task force is now in the process of developing a report outlining its recommendations. The NABP Executive Committee will then review the task force report, which, once approved, is distributed to all member boards and posted on the NABP Web site. 

# Attachment 3

*Patient Rebates or Gifts for Transferring  
Prescriptions*

# Incentives for Transferring Prescriptions

Source:  
July 07  
The Script

The Board has received a number of inquiries related to whether a pharmacy that offers an incentive (e.g., a \$30 gift or cash card) to consumers for transferring their prescriptions to the pharmacy violates section 650 of the Business and Professions Code. Such offers do not appear to be violations because section 650 relates only to the receipt of a benefit, in the form of money or otherwise (often called a “kickback,” though this language does not appear in the statute) to a referring person or entity for referring a patient to another person or entity.

Court decisions in similar cases relating to section 650 have held that the cases were not in violation of section 650 when the patient—not the doctor—benefited directly from the incentive. While the offering pharmacy may profit from the patient’s transfer of his or her prescription, only the patient benefits from the \$30 gift card. For that reason, offering incentives of a gift card or free delivery of the patient’s prescriptions would not appear to violate the statute.

**Note:** However, 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, Medicaid). Anyone violating this code may be guilty of a felony and subject to a fine or imprisonment or both.

Prescription #1  
EXPIRES 2/31/07

**GET A FREE**  
**\$30**  
**GIFT CARD**

with any new or transferred prescription filled at this coupon.

Coupon good thru 12/31/07. Medicaid, Medicare B, PACE, PAAD, EIC and any other government funded program prescriptions are not eligible. Offer only valid when prescription is filled and paid for at time of coupon redemption. In New Jersey, offer valid only for citizens 60 years or older. Not valid in New York State or Massachusetts. Not valid on prescriptions for controlled substances where prohibited by law. Gift Card is not redeemable for cash, may not be returned, and will not be replaced if lost or stolen. Also, Gift Card may not be used for prescriptions, prescription co-pays, lottery tickets, tobacco, alcohol products, money orders, gift certificates, stamps, licenses, other mailing services and any other items excluded by law.

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"sg.pb"  
<patti.bruha2@verizon.net>  
01/04/2008 01:22 PM

To <Virginia\_Herold@dca.ca.gov>  
cc  
bcc  
Subject Pharmacy Incentive or Transfer Coupons

To the Honorable Virginia Herold, Executive Officer of the California Board of Pharmacy:

I have been a licensed pharmacist working in California for the past thirty-one years. I work for a large chain and have been a member of the UFCW Professional Relations Committee for many years working with Andrea Zinder and other union and company leaders to address and, hopefully, solve concerns to make our workplaces better, safer, and more consumer friendly.

The purpose of this letter is to express the concerns of many pharmacists from Southern California about the transfer or incentive coupons being offered by several chain pharmacies.

We have patients bringing in sometimes five or more prescriptions from several pharmacies to be transferred. Sometimes patients are bringing prescriptions with valid refills to be transferred that they are no longer taking just to obtain the coupons. The first problem that you can see with this situation is that these patients have profiles at a number of different pharmacies, none of which may be complete. The result is that not all of the pharmacists have the complete information to determine whether or not drug interactions may be present.

Another problem with the patients bringing in many transfer prescriptions is that pharmacists are spending a lot of time transferring prescriptions from pharmacy to pharmacy. This increases the work loads on these pharmacists as it takes quite a bit of time to do these transfers. With each transfer communication there is the possibility of errors in giving and receiving the information. Even the most conscientious pharmacist may hear or transcribe the information incorrectly. The receiving pharmacists also do not have the opportunity to view the original prescription. In many cases, the prescription has been transferred several times.

While all of us are deeply concerned about the high cost of prescription medications, most pharmacists and I believe that these coupons are not a good or safe solution to this concern. I would hereby propose that this practice be discontinued in California. Thank you for taking the time to read and consider these concerns.

Sincerely,

Patti L. Bruha, R.Ph.

# Attachment 4

*Request for Waiver of 16 CCR 1717(e)  
by University Specialty Pharmacy*

**RONALD S. MARKS**  
**A Professional Law Corporation**  
**21900 Burbank Boulevard, Suite 300**  
**Woodland Hills, California 91367**  
**Telephone: (818) 347-8112**  
**Facsimile: (818) 347-3834**

December 6, 2007

VIA FACSIMILE TRANSMISSION

Virginia Herold  
Executive Officer  
State Board of Pharmacy  
1625 North Market Blvd., Suite N 219  
Sacramento, CA 95834

**RE: PHARMACY HOMECARE NETWORK'S REQUEST TO APPEAR BEFORE  
THE BOARD**

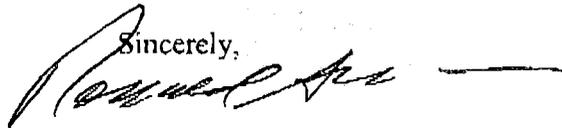
Dear Ms. Herold:

On June 12, 2007, I requested, on behalf of Pharmacy Homecare Network, that we be placed on the agenda for the meeting in Los Angeles so we could address the Board regarding the procedure for delivering medications to patients in the San Diego area. A copy of the correspondence is enclosed. We were not placed on the agenda.

It is my understanding that the next meeting is in San Diego in January. We request that we be placed on that agenda.

Thank you for your courtesy and assistance.

Sincerely,



RONALD S. MARKS

cc: Pharmacy Homecare Network

**RONALD S. MARKS**  
**A Professional Law Corporation**  
**21900 Burbank Boulevard, Suite 300**  
**Woodland Hills, California 91367**  
**Telephone: (818) 347-8112**  
**Facsimile: (818) 347-3834**

June 12, 2007

VIA FACSIMILE TRANSMISSION

Virginia Herold  
Executive Officer  
State Board of Pharmacy  
1625 North Market Blvd., Suite N 219  
Sacramento, CA 95834

***RE: CITATIONS ISSUED TO PHARMACY HOMECARE NETWORK, GREGORY  
AMBROSE AND ANNA SHPILBERG***

Dear Ms. Herold:

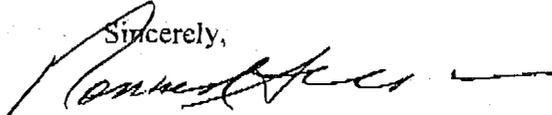
As a follow up to our office conference on June 7, 2007, enclosed please find the following:

1. The documentation requested by Judy Nurse regarding the citation issued to Anna Shpilberg and reference to the documents identified as "Issue #2" on the enclosed Response to Issues.
2. An explanation of the procedure for delivering medications to patients in San Diego which is identified as "Issue #1."

We believe that the delivery procedure complies with 1717(e) because the pharmacy has on file authorizations from these patients to have their prescriptions sent to the residence of the delivery person in San Diego who delivers the prescriptions to the patients. Therefore, the residence of the driver is a designated delivery location by the patient. Certainly, there is no risk to the medication that would be greater than having FEDEX or UPS deliver the medication to its San Diego Warehouse for delivery the following day to the patients. The patient should have the right and the authority to decide which is the best way for them to obtain their prescriptions.

If you advise appearing before the Board on this issue, we request that our appearance be scheduled for the second day of the meeting at the end of July in Los Angeles (since I believe I will be there on a Reinstatement Petition), and that we be on the agenda to discuss whether there is compliance with 1717(c) in the manner in which the medication is delivered or, in the alternative, to request a waiver "for good cause shown."

Thank you for your courtesy and assistance.

Sincerely,  
  
RONALD S. MARKS

cc: Pharmacy Homecare Network

**Board of Pharmacy  
California Code of Regulations**

Adopt Section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1713. Receipt and Delivery of Prescriptions and Prescription Medications.

→ (a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

→ (b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Note: Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

Amend Section 1717 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717. Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia. Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

- (1) a patient med pak is reused only for the same patient;
- (2) no more than a one-month supply is dispensed at one time; and
- (3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist preceptor before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.

Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

~~(e) No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~

~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~

~~(f) A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.~~

Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

- (1) Identification of pharmacist(s) transferring information;
- (2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
- (3) Original date and last dispensing date;
- (4) Number of refills and date originally authorized;
- (5) Number of refills remaining but not dispensed;
- (6) Number of refills transferred.

(g) (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code.  
Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

# Attachment 5

*Request for Waiver of B&P Code  
Section 4068(a)(1) and (6) and  
H&S Code Section 1261.6(e)(1)  
by InstyMeds*

LEWIS BRISBOIS BISGAARD & SMITH LLP

ATTORNEYS AT LAW

2500 VENTURE OAKS WAY, SUITE 200, SACRAMENTO, CA 95833  
PHONE: 916.564.5400 | FAX: 916.564.5444 | WEBSITE: www.lbbslaw.com

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INDEXED

GREGORY P. MATZEN  
DIRECT DIAL: 916.646.8204  
E-MAIL: matzen@lbbslaw.com

October 17, 2007

FILE NO.  
28898-02

Virginia Herold, Executive Officer  
California State Board of Pharmacy  
Department of Consumer Affairs  
1625 N. Market Blvd., Suite N219  
Sacramento, CA 95834

Re: **InstyMeds System's Presentation before the  
California State Board of Pharmacy's Enforcement Committee  
December 5, 2007**

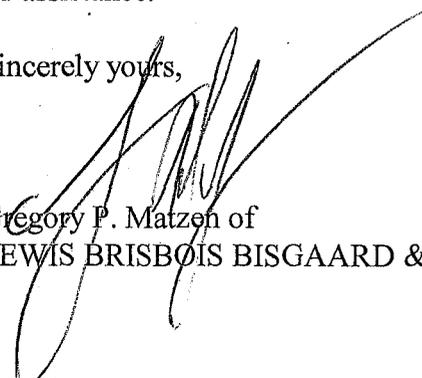
Dear Ms. Herold:

Pursuant to our earlier discussion, please be advised that my client, InstyMeds System does want to proceed with a presentation regarding its delivery system before the California State Board of Pharmacy Enforcement Committee on December 5, 2007. As you may recall, InstyMeds' initial request to be heard before the Enforcement Committee was requested for the meeting to be conducted September 20, 2007. Unfortunately, no time was available due to the Committee's complete agenda regarding Pedigree Issues as well as the proposed revisions of the Board of Pharmacy Enforcement Guidelines.

I would appreciate you confirming my clients' presence on the December 5, 2007 Agenda of the Enforcement Committee. I would also appreciate being advised as to the time and location of that meeting so I may inform my clients. Since they reside in the Midwest, travel arrangements will need to be made in advance of the hearing.

Thanks for your cooperation and assistance.

Sincerely yours,

  
Gregory P. Matzen of  
LEWIS BRISBOIS BISGAARD & SMITH LLP

GPM

cc: Mr. Matt Sneller



**California State Board of Pharmacy**  
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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

July 9, 2007

Gregory Matzen  
2500 Venture Oaks Way  
Suite 200  
Sacramento, CA 95833-3500

Dear Mr. Matzen,

This letter is a response to your letter dated June 22, 2007, which the board received on July 3. In your letter your request time on the board's July 24 board meeting agenda to address the board on behalf of your client InstyMeds.

My response in this letter follows a phone message I made to your office on Friday.

As you may know, few matters are brought directly to the board for action. Instead the board uses a committee structure to review and consider items before being brought directly to the board.

Your client's issue belongs with the Enforcement Committee. The next meeting of this committee is September 20 at the LAX Hilton.

At first glance, absent a detailed review by staff, your letter appears to request a waiver of statutory law. The board lacks this authority. However, we have not closely reviewed the matter in the short time we have had your letter.

Please let me know if you wish to attend the Sept. 20 Enforcement Meeting.

Sincerely,

A handwritten signature in black ink that reads "Virginia Herold".

VIRGINIA HEROLD  
Executive Officer

RECEIVED BY CALIF.  
BOARD OF PHARMACY

2007 JUL -3 AM 10:26

# LEWIS BRISBOIS BISGAARD & SMITH LLP

ATTORNEYS AT LAW

2500 VENTURE OAKS WAY, SUITE 200, SACRAMENTO, CA 95833  
PHONE: 916.564.5400 | FAX: 916.564.5444 | WEBSITE: www.lbbslaw.com

GREGORY P. MATZEN  
DIRECT DIAL: 916.646.8204  
E-MAIL: matzen@lbbslaw.com

June 22, 2007

FILE NO.  
28898-02

Virginia Herold, Executive Officer  
California State Board of Pharmacy  
Department of Consumer Affairs  
1625 N. Market Blvd., Suite N219  
Sacramento, CA 95834

Re: **Request for Presentation on the InstyMeds System  
Prescription Medical Dispenser as an Agenda Item  
for Board of Pharmacy Meeting July 2007**

Dear Ms. Herold:

As you are aware, I represent InstyMeds, a Minnesota corporation which has developed the InstyMeds Prescription Medication Dispenser. I have enclosed for distribution to the Board of Pharmacy members, a packet which includes a description of the InstyMeds Prescription Medication Dispenser; pertinent sections of California State Board Rules and Regulations; and Nevada Regulation Section 1. NAC 639.720, as amended, pertaining to the dispensing of formulary medication for a patient at an emergency department of a hospital without a 72-hour limitation and the hospital pharmacy being closed.

On behalf of InstyMeds, I am requesting that my client be added to the July 2007 agenda of the next Board of Pharmacy General Meeting for a Power-Point presentation of this system to seek the Board's exemption from the 72-hour dispensing restriction imposed by current pharmacy regulations in California as set forth in Business and Professions Code Section 4068(a)(1) and (6) and Health and Safety Code Section 1261.6(e)(1).

## **Purpose in Presentation to the Board of Pharmacy:**

The purpose for the presentation to the Board by InstyMeds is to discuss the merits of this dispensing system in light of California Code Section 4068(a)(1) and (6) and Health and Safety Code Section 1261.6(e)(1). These two Sections of California

CHICAGO	LAFAYETTE	LAS VEGAS	LOS ANGELES	NEW YORK	ORANGE COUNTY	PHOENIX	SAN BERNARDINO	SAN DIEGO	SAN FRANCISCO	TUCSON
312.345.1718	337.326.5777	702.893.3383	213.250.1800	212.232.1300	714.545.9200	602.385.1040	909.387.1130	619.233.1006	415.362.2580	520.202.2565

4833-9397-3505.1

Virginia Herold, Executive Officer  
Board of Pharmacy  
June 22, 2007  
Page 2

State Board Rules and Regulations restricts the use of a medication dispensing system such as InstyMeds, when utilized by a hospital, to only when the hospital pharmacy is closed and restricts the quantity of medication which can be dispensed for a patient to a 72-hour supply. The InstyMeds Prescription Medication Dispenser is designed to safely provide a patient with their entire initial prescription order rather than only a partial amount whenever the patient is being seen at the hospital emergency room.

The InstyMeds Prescription Medication Dispenser complies with all requirements set forth in California Business and Professions Code Section 4170 pertaining to dispensing requirements by a prescriber to his/her patients. The exemption that InstyMeds is seeking from the Board concerns the limitations of the 72-hour supply of medication for a patient as set forth in Section 4068(a)(6) and Section 1261.6(e)(1) and the requirement that the hospital pharmacy must be closed as set forth in Section 4068(a)(1).

As previously stated, the InstyMeds Prescription Medication Dispenser complies with all the requirements set forth by the California State Board of Pharmacy pertaining to Business and Professions Code Section 4170 pertaining to prescriber dispensing, as well as providing the patient's right to choose the dispensing site. The InstyMeds Prescription Medication Dispenser System complies with all the requirements set forth in Business and Professions Code Section 4170 pertaining to both patient safety and patient option for dispensing. Accordingly, InstyMeds is seeking consideration by the Board for modification of the 72-hour restriction which currently restricts the dispensing of medications from a prescription dispensing system such as InstyMeds to only a 72-hour supply rather than the complete prescription order.

The InstyMeds Prescription Medication Dispenser has been created and implemented in several states in keeping with the California Board's interest of protecting the patient's health, safety and welfare. Both Mr. Matt Sneller, Pharm.D., Vice President of Pharmacy Operations and Mr. Brad Biers, Regulatory Affairs Manager, have a Power-Point presentation which illustrates the pertinent patient benefits, as well as safety elements comprising the InstyMeds System, and supplements the information that has been provided in the packet prepared for each Board Member. The presentation will take approximately 15 to 20 minutes and allow the opportunity for questions and answers by Board Members, as well as those interested parties in attendance.

There is a hospital in California which is interested in implementing the InstyMeds Prescription Medication Dispenser System. However, the hospital's concern is the restriction of dispensing only a 72-hour supply of the patient's medication rather

Virginia Herold, Executive Officer  
Board of Pharmacy  
June 22, 2007  
Page 3

than the entire prescribed dosage in order to comply with California Business and Professions Code Section 4068(a)(6). InstyMeds is seeking the opportunity of demonstrating their dispensing system to the Board by either (1) obtaining an exemption for the hospital facility from the 72-hour restriction and hospital pharmacy closure as stated in Section 4068; or (2) operate a pilot project at the hospital for a set period of time during which an exemption would be provided to the facility as to the 72-hour supply restriction and hospital pharmacy closure; and/or (3) the Board's reconsideration of the basis for the 72-hour supply restriction and hospital pharmacy closure as set forth in California Code Section 4068 pertaining to prescription medication dispensed at a hospital by a system such as the InstyMeds Prescription Medication Dispenser. Such a request by InstyMeds would not be inconsistent with Business and Professions Code Section 4170 which limits a prescriber to dispensing from a medication system for his/her patient at their office.

**The InstyMeds Prescription Medication Dispenser:**

The InstyMeds Prescription Medication Dispenser System is designed with the health and safety of the patient in mind.

The InstyMeds System (the "System") is an automated prescription medication dispensing system that provides physicians with a safe and convenient method of delivering outpatient prescription services to patients in a hospital emergency setting. The System dispenses acute medications (antibiotics, analgesics, etc.) to a patient immediately after their diagnosis by the physician so that the patient can begin their medication therapy as soon as possible and thereby begin feeling better quicker.

**The InstyMeds Dispenser Operation:**

In the InstyMeds System, the only patients eligible to use the System are those who are registered at the medical facility where the dispenser is located and seen by a prescriber at that location. When a patient is initially registered at the medical facility, the registration staff will scan the patient's insurance card and register them in the InstyMeds System. The prescriber then offers the patient the opportunity to receive a printed prescription to take to a community pharmacy or an order for the InstyMeds Dispenser. Should the patient elect to use the InstyMeds System Dispenser, the prescriber will use the InstyMeds prescribing software to generate an InstyMeds order. The InstyMeds order consists of a unique seven digit code that the patient is required to enter at the Dispenser to obtain the medication, as well as patient education material about the drug being prescribed.

Virginia Herold, Executive Officer  
Board of Pharmacy  
June 22, 2007  
Page 4

As soon as the InstyMeds order is complete, the InstyMeds call center begins adjudicating the pharmacy claim. The patient then enters their seven digit code along with their birth date at the Dispenser and either pays their insurance co-pay or the standard retail price. The patient has the opportunity to pay by cash or utilize their credit/debit card. The medication is then dispensed directly to the patient.

**Dispenser Inventory:**

The InstyMeds Dispenser holds approximately 100 different medications which can be customized for each health care facility. Each medication is packaged in unit of use containers by an FDA licensed repackager (e.g. Amoxicillin 500mg #20) and is then placed in a magazine with approximately 10 containers of the same product. Each medication has a unique barcode as well as each magazine has a unique barcode. An InstyMeds subsidiary, RedPharm drug, is licensed as a drug wholesaler and sells the medications to the hospital pharmacy in full magazines. The hospital pharmacy staff (pharmacists and technicians) is responsible for the restocking of the Dispenser. A report is run that tells the restocker exactly which magazines need to be placed in the Dispenser. Upon finishing loading the magazines, the Dispenser will then scan each magazine barcode in the machine. InstyMeds monitors each facility's inventory and sends out replacement magazines when stock is running low. All inventory is located in either the secure, locked InstyMeds Dispenser or in the hospital pharmacy.

**Dispensing Process:**

The InstyMeds System utilizes a proprietary three barcode check system to ensure the accuracy and safety of the dispensing process. The first check is the barcode on the magazine of prepacked drugs, while the second check is the barcode on the actual drug container, and the final check is the barcode on the prescription label created after the first two barcode checks have passed. If any of these checks fail, the drug is rejected and the process begins again. Should the barcode check fail a second time, a printed prescription is provided to the patient to take to a community pharmacy. To date, InstyMeds has dispensed over 300,000 prescriptions without a dispensing error, due to this three check standard.

**Current Use of InstyMeds in Other States:**

The InstyMeds Prescription Dispenser has been in existence for a number of years and has successfully operated in several states. InstyMeds is now seeking to offer its services to the hospitals in California. The closest state in which the InstyMeds

Virginia Herold, Executive Officer  
Board of Pharmacy  
June 22, 2007  
Page 5

System has gone into operation is in Nevada. The Nevada State Board of Pharmacy modified Nevada Administrative Code Section 639.720(a)(6) to assure that the InstyMeds System could be operational for serving the patients at Nevada's hospitals and clinics. The Amended Section (6) of NAC 639.720 is consistent with the concerns expressed by the California Board of Pharmacy in its adoption of California Business and Professions Code Section 4068 and Article 12 - Prescriber Dispensing pursuant to Business and Professions Code Section 4170. A copy of Section 1 NAC 639.720 with the highlighted Section(6) has been provided for each Board member's review and consideration.

**Benefits of the InstyMeds Prescription Medication Dispenser:**

InstyMeds provides significant benefits to hospitals and clinics by providing a system which reduces medication errors and provides an additional service to patients. For the hospital facilities in which the system has been implemented, it has been shown to help reduce workload pressure; provide 24-hour pharmacy medication dispensing utilizing a formulary without additional staffing; eliminating expensive starter doses by allowing the initial medication order to be dispensed in its entirety; enhance patient compliance; significantly reduced physician call backs; and expedited the patient discharge from the hospital.

For patients, the InstyMeds System allows the patient to obtain their medication quickly and accurately at the point of care facility; eliminates a trip to a pharmacy when a patient is often in a worse condition as far as being sick or in pain; extends the availability of prescription medications accurately being dispensed on a 24/7 availability; enhanced safety and compliance with the dispensing of a medication to a patient in a safe, convenient fully dispensed prescription order which includes printed patient medication indication along with medication information at the point of medical care.

**Comments:**

The packets have been prepared for the Board's consideration in preparation of InstyMeds representatives' Power Point presentation on its Prescription Medication Dispensing System before the Board of Pharmacy at the next General Meeting for consideration concerning the 72-hour restriction and hospital failure for prescription medications being dispensed by a hospital in accordance with Business and Professions Code Section 4068 and Health and Safety Code Section 1261.6(e)(1).

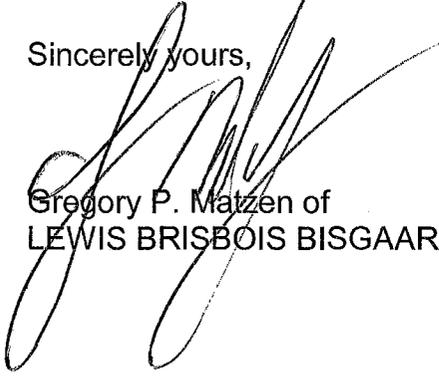
LEWIS BRISBOIS BISGAARD & SMITH LLP

Virginia Herold, Executive Officer  
Board of Pharmacy  
June 22, 2007  
Page 6

The InstyMeds Prescription Medication Dispenser System maintains that a pharmacist comply with the requirement of Business and Professions Code Section 4076, as well as the Board's record keeping requirements. All of the facts and requirements of good pharmaceutical practice, including the use of child proof containers, is consistent with the InstyMeds Prescription Medication Dispenser System.

I believe that this correspondence, as well as the enclosed documentation, addresses the issues and questions which you raised in your May 18, 2007 correspondence. I appreciate your kind consideration for the inclusion of a presentation by representatives of InstyMeds at the July Board of Pharmacy meeting.

Sincerely yours,



Gregory P. Matzen of  
LEWIS BRISBOIS BISGAARD & SMITH LLP

GPM  
Encls.



**California State Board of Pharmacy**  
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834  
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www.pharmacy.ca.gov

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

May 18, 2007

Gregory Matzen  
2500 Venture Oaks Way  
Suite 200  
Sacramento, CA 95833-3500

Dear Mr. Matzen,

This letter is a response to a letter addressed to you from Matt Sneller on InstyMed letterhead, dated March 6, 2007. You handed this letter to me during the Board Meeting on April 18, 2007.

I am not certain how you wish the board to proceed with this letter. The InstyMed letter requests a legal opinion (presumably from you) about how InstyMed can operate in California.

As you know, the board is unable to provide legal advice for every inquiry it receives. However, since the letter seemingly is asking you to prepare the legal opinion, if you provide the written opinion to us, we will review and advise you if we agree with it. In addition, it would also be helpful if you could provide a description of the machine, how it would operate, who would operate it and labeling and security systems in place that would comply with California's requirements for patient protections.

Sincerely,

A handwritten signature in black ink, appearing to read "Virginia Herold".

VIRGINIA HEROLD  
Executive Officer



March 6, 2007

Mr. Gregory Matzen, R.Ph., J.D.  
2500 Venture Oaks Way  
Suite 200  
Sacramento, CA 95833-3500

Dear Mr. Matzen,

Our Company, InstyMeds Corp., is the creator of the InstyMeds System, an automated prescription dispensing system that provides physicians a safe and convenient method of delivering outpatient prescription services at hospital emergency departments and other acute care environments. We currently have acute dispensers throughout Minnesota, Wisconsin, Iowa and North Dakota. We now have a client in California who has signed a letter of intent to install the InstyMeds System in a number of their facilities in southern California.

The different states that we operate in have chosen to regulate the InstyMeds System in a variety of different ways. Our client would like to install InstyMeds in a variety of different settings including hospital emergency rooms, ambulatory surgery centers, urgent care clinics, etc. In our cursory review of the California regulations, we believe that there are a number of different regulations that pertain to us depending on the setting. We would like to engage you to provide us an overview of current California regulations that may affect how we can operate in California. Specifically, we would like a legal opinion on how we can operate in a hospital emergency room as well as settings that are outside of the hospital emergency room such as an ambulatory surgery center. We would also like your assistance should we need to work with the California Board of Pharmacy on creating a variance for our system or potentially drafting new regulations.

We understand that you require a ~~signature~~ and would be happy to provide you this should you accept us as a client. We also reviewed your fees and are comfortable with those as well. I look forward to speaking with you soon. I can be reached at (952) 653-2528 or at [msneller@instymeds.com](mailto:msneller@instymeds.com).

Best regards,

Matt Sneller, Pharm.D.  
Vice President of Pharmacy Operations

**GREG MATZEN - California Dispensing Regulations**

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**Date:** 3/9/2007 2:49 PM  
**Subject:** California Dispensing Regulations  
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Mr. Matzen,

I'm Brad Biers, the recently hired Regulatory Affairs Manager with Insty Meds. I'm working with Matt Sneller on state dispensing regulations and he asked me to contact you with some referenced California regulations.

As you may know, it is legal for a physician/clinic to repackage and dispense prescription medication to their patients at the point-of-care so long as certain criteria are met. Most of these are explained under the **California Business & Professions Code Article 12, Section 4170**.

As you may also know, the California Pharmacy Board has a link that covers all state codes and regulations pertaining to pharmacy at [http://www.pharmacy.ca.gov/laws\\_regs/lawbook.pdf](http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf). The most pertinent regulations affecting Physician/Prescriber dispensing seem to be under the **California Business & Professions Code Articles 12, 13, and 14**.

Emergency Room Dispensing is basically covered under **California Business & Professions Code Article 3, Section 4068**.

Automated dispensing at health facilities are covered under the **California Health & Safety Code Section 1261.6**.

Also, Matt referenced some language that we have worked out with the Nevada Pharmacy Board. Here is the link; [http://bop.nv.gov/Pending\\_NRS.htm](http://bop.nv.gov/Pending_NRS.htm) and the language is under 639.720. Section 6 was basically written for us.

Feel free to respond back if you have any comments or questions and I look forward to working with you.

Brad Biers  
Regulatory Affairs Manager  
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**NAC 639.720 Mechanical devices: Use to furnish drugs and medicines for administration to registered patients in medical facility. (NRS 639.070, 639.2655)**

1. Except as otherwise provided in subsection 4, a mechanical device may be used to furnish drugs and medicines for administration to registered patients in a medical facility. The device must conform to all of the following provisions:

(a) All drugs and medicines stocked in the device must be approved for use in the device by a registered pharmacist employed by the:

(1) Medical facility in which the drug or medicine is administered; or

(2) Pharmacy that supplies the medical facility in which the drug or medicine is administered.

(b) Access to the device must be:

(1) Limited to pharmaceutical technicians, pharmaceutical technicians in training, intern pharmacists, registered pharmacists, licensed practical nurses, registered nurses or other practitioners who are:

(I) Authorized by law to prescribe or administer controlled substances, poisons, or dangerous drugs and devices; and

(II) Employed by the medical facility or pharmacy that supplies the medical facility.

(2) Monitored and controlled by the pharmacy which supplies the medical facility or the registered pharmacist who is employed by the medical facility.

(c) Each container of a drug or medicine stored in the device must be labeled in a manner which includes the information required pursuant to subsection 2 of NAC 639.476.

(d) The device must be designed in such a manner that:

(1) Each time a person obtains access to the device, it automatically prepares a record which is readily retrievable and which includes:

(I) The name, strength, quantity and form of dosage of the drug or medicine which is stocked, inventoried or removed for administration to a patient;

(II) The day and time access to the device is obtained;

(III) If a drug or medicine is removed for administration to a patient, the name of the patient;

(IV) An inventory of the drugs and medicines stored in the device; and

(V) The name of the person who obtained access to the device.

(2) Access to the device may be obtained only by a person with the use of a code which identifies that person.

2. A pharmacy which supplies drugs and medicines to a medical facility which are furnished by a mechanical device pursuant to subsection 1 shall maintain a written policy which sets forth:

(a) The duties of all persons who are authorized to obtain access to the device; and

(b) The procedure for:

(1) Maintaining the security of the drugs and medicines stored in the device during the maintenance and repair of the device;

(2) The preparation of an inventory of the drugs and medicines stored in the device; and

(3) Stocking the device with drugs and medicines.

3. A pharmacy which supplies drugs or medicines to a medical facility which uses a mechanical device to furnish drugs or medicines for administration to patients pursuant to subsection 1 shall provide written notice to the Board. The notice must include:

(a) A description of each mechanical device used by the medical facility to furnish drugs or medicines for administration to patients, including, without limitation, the name of the manufacturer of the device; and

(b) The address of the medical facility at which the mechanical device is located.

4. A pharmacy shall not stock a mechanical device with drugs or medicines and a mechanical device must not be used to furnish drugs or medicines for administration to patients until:

(a) The pharmacy has notified the Board as required by subsection 3; and

(b) The Board has issued a certificate to the pharmacy that authorizes the use of the mechanical device at the medical facility at which the mechanical device is located.

5. Each medical facility that uses a mechanical device pursuant to this section must make and maintain a record of any waste of a controlled substance in the manner provided in NAC 639.486. The record of any waste of a controlled substance may be prepared:

(a) By the mechanical device if the mechanical device is capable of making and maintaining such a record and documenting the record of the waste being witnessed by another person as provided in

paragraph (g) of subsection 1 of NAC 639.486; or

(b) As a written record.

6. As used in this section, "medical facility" has the meaning ascribed to it in NRS 449.0151.

[Bd. of Pharmacy, § 639.320, eff. 6-26-80]—(NAC A 12-21-95; 5-20-96; R017-03, 10-21-2003)

**NAC 639.725 Use of mechanical counting device for dispensing medication to be taken orally.** (NRS 639.070, 639.2655, 639.2801)

1. A mechanical counting device that is used by a pharmacy for dispensing medication to be taken orally must use one of the following methods to identify the contents of the device:

(a) The following information must be affixed to the front of each cell of the device:

- (1) The generic name or trade name of the medication;
- (2) The manufacturer of the medication;
- (3) The strength of the medication;
- (4) The expiration date of the medication;
- (5) The lot number of the medication; and
- (6) The initials of the pharmacist who:

(I) Placed the medication into the device; or

(II) Verified the correctness of the drug placed into the device when the drug was placed by a pharmaceutical technician, a pharmaceutical technician in training or an intern pharmacist; or

(b) A label that shows the generic name or trade name and the strength of the medication must be affixed to each cell of the device and a log must be kept for each cell which contains:

- (1) An identification of the cell by the name of the medication or the number of the cell;
- (2) The name of the manufacturer of the medication;
- (3) The expiration date of the medication;
- (4) The lot number of the medication;
- (5) The amount of the medication placed in the device; and
- (6) The initials of the pharmacist who:

(I) Placed the medication into the device; or

(II) Verified the correctness of the drug placed into the device when the drug was placed by a pharmaceutical technician, a pharmaceutical technician in training or an intern pharmacist.

2. The Board may prohibit a pharmacy from using a mechanical counting device for dispensing medication to be taken orally if the pharmacy does not identify the contents of the device in accordance with the provisions of subsection 1.

(Added to NAC by Bd. of Pharmacy, eff. 3-17-92; A by R039-06, 5-4-2006)

**NAC 639.730 Inspection of damaged pharmaceuticals.** (NRS 639.070) After a fire or other catastrophe in which pharmaceutical preparations, devices or appliances are damaged, the owner, operator or manager of the pharmacy shall not dispose of the damaged merchandise to any other person, until it has first been inspected and declared safe by the Board. If, in the opinion of the Board, such preparations, appliances or devices are unsafe or unfit for use, they must be destroyed.

[Bd. of Pharmacy, § 639.310, eff. 6-26-80]

**NAC 639.740 Container for dispensing prescribed medicine.** (NRS 639.070) Except for a hospital pharmacy for inpatients or in a facility for skilled nursing or a facility for extended care, all prescribed medicine must be dispensed in a container which is designed to prevent a child from opening it, if commercially available, unless the person to whom the medication is dispensed:

1. Is at least 18 years of age;
2. Specifically requests a container which is not so designed; and
3. Signs a document verifying that he made such a request.

(Added to NAC by Bd. of Pharmacy, eff. 10-17-86)

**NAC 639.742 Dispensing of controlled substances or dangerous drugs: Application by practitioner for certificate of registration; application by facility required under certain circumstances; duties of dispensing practitioner and facility relating to drugs; authority of dispensing practitioner and technician.** (NRS 639.070)

1. A practitioner who wishes to dispense controlled substances or dangerous drugs must apply to the

# Attachment 6

*Enforcement Statistics  
Second Quarter 2007-08*

# 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			737
Closed	443	362			805
Pending (at the end of quarter)	1056	1030			1030

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

Compliance Team	55	102			102
Drug Diversion/Fraud	73	114			114
Mediation Team	146	136			136
Probation/PRP	71	92			92
Enforcement	216	154			154

**Application Investigations**

Initiated	69	2			71
Closed					
Approved	38	48			86
Denied	14	2			16
Total*	51	52			103
Pending (at the end of quarter)	207	157			157

**Citation & Fine**

Issued	197	174			371
Citations Closed	142	129			271
Total Fines Collected	\$143,070.00	\$155,825.00			\$298,895.00

\* 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			25
Pleadings Filed	20	32			20
<b>Pending</b>					
Pre-accusation	57	36			64
Post Accusation	60	67			62
<b>Total</b>	<b>117</b>	<b>114</b>			<b>141</b>
<b>Closed**</b>					
<b>Revocation</b>					
Pharmacist	2	1			2
Pharmacy	1	9			1
Other	4	0			4
<b>Revocation, stayed; suspension/probation</b>					
Pharmacist	4	1			4
Pharmacy	0	0			0
Other	0	0			0
<b>Revocation, stayed; probation</b>					
Pharmacist	2	2			2
Pharmacy	1	0			1
Other	0	1			0
<b>Suspension, stayed; probation</b>					
Pharmacist	0	0			0
Pharmacy	0	0			0
Other	0	0			0
<b>Surrender/Voluntary Surrender</b>					
Pharmacist	0	2			0
Pharmacy	1	0			1
Other	1	2			1
<b>Public Reproval/Reprimand</b>					
Pharmacist	0	0			0
Pharmacy	0	0			0
Other	0	0			0
Cost Recovery Requested	\$54,145.50	\$34,655.00			\$88,801.00
Cost Recovery Collected	\$52,838.60	\$22,679.60			\$75,518.20

\* 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			108
Pharmacy	5	6			6
Other	16	13			13
Probation Office Conferences	18	5			23
Probation Site Inspections	44	56			100
Probationers Referred to AG for non-compliance	1	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 12/31/07)

#### Program Statistics

In lieu of discipline	0	0			0
In addition to probation	5	3			8
Closed, successful	3	4			7
Closed, non-compliant	0	1			1
Closed, other	3	2			5
Total Board mandated Participants	54	56			56
Total Self-Referred Participants*	18	16			16
Treatment Contracts Reviewed	53	50			103

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

\* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of September 30, 2007.

# California State Board of Pharmacy Citation and Fine Statistics July 1, 2007 – December 31, 2007

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

Total dollar amount of fines issued this fiscal year  
\$ 744,950.00

Total dollar amount of fines collected  
\$298,895.00\*

\*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 **284**

Average number of days from date case is routed to Citation Unit to date citation is issued **97**

Average number of days from date citation is issued to date citation is closed is **48**

### 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
384	131	3	100	34	57	4	13	3

### Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
11	8	0	1	1	6	5	7	0

\*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	37%	1716 - Variation from prescription	34%	1716 - Variation from prescription	10%
1707.2 – Duty to consult	7%	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	9%	4115(e) - Pharmacy technician license required	5%
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	6%	1707.2 – Duty to consult	8%	4125-1711 - Pharmacy quality assurance program required/Quality assurance program	5%
1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors...	5%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	7%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	5%
1715 – Self-assessment of a pharmacy by the pharmacist-in-charge	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	5%	1707.2 – Duty to consult	4%
1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	4%	1715 – Self-assessment of a pharmacy by the pharmacist-in-charge	4%	1707.3 – Duty to review drug therapy	4%
1793.7 - Requirements for Pharmacies employing pharmacy technicians	2%	4125-1711 - Pharmacy quality assurance program required/Quality assurance program	4%	1715 – Self-assessment of a pharmacy by the pharmacist-in-charge	4%
1717(C) - Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing...	2%	4115(e) - Pharmacy technician license required	3%	1707.2(b) - Duty to consult whenever the pharmacist deems it warranted in the exercise of his or her professional judgment	4%
4115(e) - Pharmacy technician license required	2%	1711 (d) -Quality assurance program finding shall be used to develop systems to prevent medication errors...	6%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	4%
4125/1711 - Pharmacy quality assurance program required/Quality assurance program	2%	1711(e) -Quality assurance program shall advance error prevention...	4%	4101 - Pharmacist-in-Charge, Exemptee: Termination of Employment; Notification to Board	4%

# Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There were nine office conferences held this quarter

Number of requests	137
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Number scheduled	137
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Number appeared	96
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Number Postponed	28**
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\*\*Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	8
Failed to appear	5

## Office Conference between July 1, 2007 and December 31, 2007

Total number of citations affirmed	44
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Decision	Total citations	Total dollar amount reduced
Modified	21	\$6,000.00
Dismissed	24	\$16,850.00
Reduced to Letter of Admonishment	1	\$0.00

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