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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE
MINUTES

DATE: December 3, 2009

LOCATION: Samuel Greenberg Board Meeting Room
Los Angeles International Airport
1 World Way
Los Angeles, California 90045

COMMITTEE MEMBERS PRESENT: Stanley C. Weisser, RPh, Chair
Randy Kajioka, PharmD

COMMITTEE MEMBERS NOT PRESENT: Ramón Castellblanch, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Kristy Schieldge, DCA Staff Counsel (via conference call)
Tessa Fraga, Staff Analyst

Call to Order

Chair Stanley Weisser called the meeting to order at 12:33 a.m.

1. Emergency and Disaster Response Planning: Update on the H1N1 Emergency Response Activities in California

Chair Weisser provided that for more than one year, health care providers, policy makers and governments worldwide have been dealing with the H1N1 flu worldwide pandemic.

Chair Weisser provided that board staff continue to work closely with the Department of Public Health to assist in ways that will benefit the public.

Chair Weisser provided that in order to ensure that the board can act quickly to activate the board's emergency response policy in response to a sudden declared crisis, at the October 2009 Board Meeting, the board voted that:

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

Public Comment

Stanley Goldenberg provided comment on the availability of the H1N1 vaccine. He explained that there is a lot of questions and fear regarding the vaccine among patients, especially pregnant women.

Dr. Steve Gray, representing Kaiser Permanente, provided that H1N1 vaccine availability is limited. He provided comment on the confusion surrounding the vaccine and the occurrence of price gouging. Dr. Gray recommended that the board encourage pharmacists to provide the vaccine to those who have been identified as "high risk."

Executive Officer Virginia Herold provided comment on the price gouging and displacement within the marketplace.

Discussion continued regarding the availability of the H1N1 vaccine.

There was no additional committee discussion or public comment.

2. Impact on Patient Care Caused by Diverse Supply Issues Impacting the Availability of Medication to Hospitals: Presentation by Chad Signorelli, PharmD, Assistant Director of Pharmacy Services, Lompoc Valley Medical Center

Presentation – Dr. Chad Signorelli, Lompoc Valley Medical Center

Dr. Chad Signorelli, representing Lompoc Valley Medical Center, provided an overview on diverse supply issues affecting hospital pharmacies. He expressed concern regarding the abundance of medications that are unavailable due to various manufacturer supply issues. Dr. Signorelli offered possible solutions to this supply issue including pedigree laws, enforce/clarify price gouging laws, conscience clauses, and forewarning of supply issues.

Committee Discussion

Ms. Herold provided that pedigree laws will help to alleviate this issue. She explained that currently it is illegal for pharmacies to sell drugs to a wholesaler other than the original wholesaler from which it purchased the drugs. She encouraged Dr. Signorelli to file a complaint in the event he is aware of such activity.

Public Comment

Stanley Goldenberg sought clarification with regards to compounding and this issue.

Dr. Steve Gray, representing Kaiser Permanente, provided comment on supply shortages and compounding. He discussed “just-in-time inventories” and contractual agreements between suppliers and hospitals.

Ms. Herold sought clarification regarding recourse if a supplier does not provide drugs during a shortage.

Dr. Gray referenced to good business practices. He recommended that education be provided on supply chain management.

Dr. Randy Kajioka asked if there are any guidelines that prohibit specialty wholesalers from having a specified percentage of “shortage-list drugs.”

Ms. Herold provided that a substantial portion of the secondary market specializes in specialized and hard-to-find products.

Bill Young, representing the California Pharmacists Association (CPhA), provided comment on the current drug shortage. He encouraged education or initiatives regarding alternative manufacturing sources.

There was no additional committee discussion or public comment.

3. Request to Modify Title 16 California Code of Regulations Section 1713(d) Regarding the Requirement that Automated Dispensing Machines Be Adjacent to the Secure Pharmacy Area

Chair Weisser provided that in 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. He stated that this was a use of emerging technology and several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with afterhours access (as well as access during times when the pharmacy was open) to refills. Chair Weisser explained that a patient could pick up refill medication, if approved by the pharmacy, from a vending-like machine using a credit card for payment and not specifically deal with the pharmacy staff. He indicated that the machine was to be located near – specifically adjacent -- to the physical area of the pharmacy.

Chair Weisser provided that in 2006 the board carefully crafted the placement of the machine to be very near the pharmacy for a number of reasons – for added security, so that the pharmacy could readily refill it, so that patient could be near the pharmacy, and to ensure it was not placed outside a store.

Chair Weisser provided that this regulation was promulgated cautiously. He stated that throughout 2006, the board modified and adopted the regulation now in effect as section 1713. Chair Weisser advised that in January 2007, the regulation actually took effect.

Chair Weisser referenced to section 1713 (d):

> (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).

Presentation – Phil Burgess, Asteres

Phil Burgess, representing Asteres, requested that the board amend regulation section 1713 (d)(6) regarding the placement of automated medication dispensing machines in hospitals. He provided an overview of a 24/7 automated pharmacy prescription pick-up machine.

Committee Discussion

Chair Weisser sought clarification regarding where the machines will be located.

Mr. Burgess provided that the machines will be located in a secure area that is readily accessible for the patient. He added that a telephone will be placed adjacent to the machine for patients to ask questions of a pharmacist.

Discussion continued regarding the capabilities of the machine. A variety of safety features were identified that help to prevent fraud. It was clarified that the machine dispenses refill prescriptions only.

Chair Weisser asked if this request is relevant to section 1713 (b) or (d), as Mr. Burgess indicated.

Ms. Herold stated that this issue will be taken to the board. She stated that subdivision (b) is broader than subdivision (d) and deals with the delivery of any prescription without the controls that are required under subdivision (d).

Kristy Schieldge, DCA Staff Counsel, expressed concern regarding whether a pharmacy license would allow for this request.

Mr. Burgess referenced to section 4119.1(d) regarding an automated drug delivery system.

Ms. Schieldge expressed concern regarding a pharmacy's responsibility for drugs that are not immediately accessible.

Dr. Steve Gray, representing Kaiser Permanente, offered support for the request being made. He stated that this technology represents another avenue for pharmacy delivery. Dr. Gray encouraged the board to look at this as an evolving process.

Dr. Paul Norris, representing Loma Linda University, clarified that the pharmacy would be responsible for the medication being dispensed by the machine.

Dr. John Cronin, speaking at the request of the California Pharmacists Association (CPhA), provided comment on how this request does not reflect the mission of the California Board of Pharmacy and the emphasis on pharmacist's care. He provided background on this issue. Dr. Cronin recommended that the board consider this request carefully.

Chair Weisser asked whether all 3 applicants for this request are acute facilities.

Mr. Burgess provided that the applicants are all hospitals.

Ms. Herold encouraged the committee to direct board staff to develop some possible options to offer to the board. She encouraged Mr. Burgess to submit a written request on the behalf of the 3 applicants.

There was no additional committee discussion or public comment.

4. Final Comments on Best Practices for Recalls in Hospitals

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

Chair Weisser provided that the recall system is not working. He stated that over the last year, the board convened a two-board member task force to work with relevant associations, regulators, hospitals, wholesalers and patient advocates on ways to improve recalls, and other changes needed to provide for improved drug distribution and control within a hospital. Chair Weisser indicated that three meetings were held, and at the last meeting in September, a draft Best Practices

document was refined. He advised that the Best Practices for Hospital Recalls document is one major outcome of these meetings.

Chair Weisser provided that the document will be presented to the board at the January 2010 Board Meeting for adoption and future publication in the board's newsletter.

Committee Discussion

Ms. Herold provided that the California Society of Health-System Pharmacists (CSHP) very recently submitted proposed language and comments for the guidelines. She requested some time to review and refine these comments with the guidelines. Ms. Herold advised that she will bring a revised draft to the January 2010 Board Meeting.

Public Comment

Philip Swanger, representing the California Society of Health-System Pharmacists (CSHP), thanked the committee for the opportunity to submit comments.

There was no additional committee discussion or public comment.

5. Presentation of a Drug Distribution Model Proposed by Medco Health Solutions, Using Two Pharmacies, Each with Specialized Functions

Chair Weisser provided that this presentation was cancelled.

No committee discussion or public comment was provided.

6. State of California's Right Care Initiative

Chair Weisser provided that during the late summer the Department of Managed Health Care convened a meeting to describe its development of a Right Care Initiative (RCI), which seeks to improve patient care related to blood pressure, diabetes, and lipid control.

Chair Weisser provided that the Pharmacy Foundation of California led the California Pharmacy Council in providing comments in support of a pharmacist's role in medication therapy management. He advised that the board is a member of the California Pharmacy Council.

Chair Weisser referenced to the copy of the California's Pharmacy Council's letter to the Department of Managed Health Care, signed by all members of the council that is contained within the committee packet.

Committee Discussion

Ms. Schieldge asked the committee to consider ratifying the executive officer's decision to sign this letter.

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

MOTION: To make the necessary ratifications to the executive officer's signature to the letter.

M/S: Kajioka/Weisser

Approve: 2 Oppose: 0 Abstain: 0

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

Chair Weisser provided that during the April 2009 Board Meeting, the board voted to direct staff to take the necessary steps to secure a vendor to complete the necessary psychometric assessments of the Pharmacy Technician Certification Board (PTCB) and Exam for the Certification of Pharmacy Technicians (ExCPT). He stated that the psychometric assessment of the examination is needed to ensure for compliance with Section 139 of the Business and Professions Code. Chair Weisser provided that board staff initiated the process; however, because of an Executive Order signed by the Governor, we were unable to proceed.

Chair Weisser provided that the results of the review would ensure that these applicants who qualify for licensure as a pharmacy technician have passed a validated exam.

Chair Weisser provided that board staff has discussed contracting options with the department to determine possible avenues to facilitate this review and are hopeful that the Office of Professional Examination Services will have staff available to perform these services for the board.

Committee Discussion

Assistant Executive Officer Anne Sodergren provided that a formal request has been submitted.

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

8. Discussion of the Reporting and Accounting of Intern Hours for California Pharmacy School Students

Chair Weisser provided that under current law, an intern must possess 1,500 hours of intern experience under the supervision of a pharmacist before he or she can be made eligible to take the pharmacist licensure examinations in California.

Chair Weisser stated that board regulations specify that a minimum of 900 hours of pharmacy experience must be earned under the supervision of a pharmacist in a pharmacy. He stated that the remaining 600 hours can be granted for experience under the supervision of a pharmacist substantially related to the practice of pharmacy, but not specifically earned within a pharmacy. Chair Weisser advised that California pharmacy students typically earn the 600 "discretionary" hours for school-related experiential training (clinical clerkship).

Chair Weisser provided that during the October 2009 Board Meeting, the board discussed the reporting and accounting of intern hours. He stated that at that time, staff advised the board of some problems encountered by students and board staff. Chair Weisser explained that for students who earn their experience in other states, it is virtually impossible to determine where an intern has gained experience as the board accepts intern hours verified by the state board in the state where the hours were earned. He indicated that additionally, the distinction upon whether these hours have been earned in a pharmacy under the supervision of a pharmacist cannot be discerned. Chair Weisser provided that some states have specific requirements for their respective jurisdictions that are not consistent with our requirements. He stated that board staff was recently advised that New York will no longer verify intern hours.

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

Chair Weisser provided that given the changes surrounding the intern hours requirements as well as the disparity in how the board accepts hours from various jurisdictions, staff recommended during the October 2009 Board Meeting that the intern hours requirements remain unchanged, but that the method by which staff confirm this information be contingent upon one of the following:

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

Chair Weisser provided that based on further review of the statutory requirements detailed in pharmacy law, such a change would require statutory amendment. Chair Weisser indicated that the following statement will be placed on the board's web site to respond to questions from students and schools of pharmacy regarding the change.

> Recently the Board of Pharmacy considered changes to the application process for pharmacist licensure. This change was in response to the fact that some states no longer verify intern hours to other states.
>
> Please note that the intern hours requirements in California remain unchanged. All applicants for the pharmacist licensure examination must earn 1,500 hours of internship (or have been licensed as a pharmacist in another stated for one year.) For states that do not validate or transfer intern hours, applicants must submit proof of their intern experience on board affidavits (form 17A-29) as part of their exam application.
>
> Likewise, the board will continue to require submission of intern hours on board affidavits (form 17A-29) as part of the application process for the exam.

Committee Discussion

Ms. Herold provided that the deans from each of the California schools of pharmacy have been notified about this issue.

Kathleen Hill Besinque, representing the University of Southern California (USC), proposed that the board create a form that schools can use to certify that their students have fulfilled the intern hour requirements.

Ms. Schieldge provided that verification would require a legislative change.

Dr. Kajioka discussed the creation of a form that would verify the hours obtained by out-of-state students.

Ms. Sodergren clarified that out-of-students would be able to use the same form as proposed by Ms. Hill Besinque. She clarified that the form would need to be certified by a pharmacist under whose supervision the experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience, as required by section 4209(b). Ms. Sodergren provided that clarification is needed from board counsel regarding whether or not the proposed form would satisfy this requirement.

Eric Mack, representing Loma Linda University, provided that students are receiving unclear messages from board staff regarding these requirements. He expressed concern regarding experiential education requirements.

Ms. Sodergren reviewed the statement that will be released on the board's Web site. She stated that outreach could be provided to schools to clarify the requirements.

Discussion continued regarding the certification of intern hours.

Dr. Steve Gray, representing Kaiser Permanente, expressed concern regarding pharmacy experience obtained by graduates. He provided that the person signing the form should have appropriate knowledge regarding the actual experience obtained.

Ms. Herold provided comment on the benefit of schools certifying intern hours.

Fred Wiseman, representing the University of Southern California (USC), provided comment regarding a school's responsibility when signing the proposed form.

Paul Norris, representing Loma Linda University, provided that experiential directors from Loma Linda University visit their students on-site to ensure that they are receiving the necessary experience.

Mr. Mack provided that it is recommended that the requirement for 300 hours for introductory pharmacy practice experience be split evenly between institutional and community practice. He provided an overview of how this requirement is met at Loma Linda University.

Discussion continued regarding fulfillment of the intern hours requirement.

Ms. Schieldge reviewed the options for verification of intern hours based on the current requirements in pharmacy law. She reiterated that any changes to the requirements require legislative change.

Ms. Herold referenced to the statement that will be released on the board's Web site. She indicated that this will help to alleviate confusion and provide clarification for applicants.

There was no additional committee discussion or public comment.

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

Ms. Sodergren provided that the board is continuing to perform its key licensing functions. She stated that the current processing times for pharmacy technician applications is about 90 days and is about 60 – 75 days for all other application types. Ms. Sodergren explained that there has been a significant increase in the number of applications received. She indicated that despite this increase in workload, the board has not received an augment in the number of staff.

Ms. Sodergren provided that status inquiries are to be submitted via e-mail. She stated that this method of request allows the board to research and respond to such inquiries more a more efficient manner. (The board receives over 600 telephone status inquiries from pharmacy technician applicants on a monthly basis.)

Ms. Sodergren provided that executive staff and managers continue to be available to address immediate or urgent applicant concerns from callers**.**

Committee Discussion

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

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

10. Competency Committee Report and Job Analysis for the CPJE Initiates in December 2009

Chair Weisser provided that each Competency Committee workgroup met this fall and focused on examination development and item writing. He advised that additional workgroup meetings are scheduled throughout 2010.

Chair Weisser provided that the committee also developed a job survey to be used to complete an occupational analysis with the board's contracted psychometric firm. He stated that pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically (typically every five years) which serves as the framework for the

examination. Chair Weisser explained that the information learned from this survey will determine if changes are necessary to the content outline of the CPJE.

Committee Discussion

Ms. Herold provided an overview on the job analysis and the random sample solicited to participate. She stated that the board mailed 4,000 postcards to encourage licensees to participate in the job analysis. Ms. Herold advised that participants will receive 3 hours of continuing education credit. She encouraged all interested licensees to participate.

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

11. Public Comment for Items Not on the Agenda

Stanley Goldenberg, representing Bravo Pharmacy, shared a story of a 12-year-old patient who had achieved improvement in her blood pressure with the help of her pharmacist. He underscored the importance of pharmacists and their ability to change a life.

Dr. Steve Gray, speaking on his own behalf, provided comment regarding the misinformation to licensees regarding what their licenses entitle them to do. He recommended that the board consider holding a future discussion to provide clarification on this issue.

Eric Mac, representing the California Pharmacists Association (CPhA), expressed concern that there is not a requirement for a post-secondary degree for a pharmacy technician. He stated that CPhA is recommending that the committee establish standards for pharmacy technicians.

Phil Burgess provided that a resolution will be presented at the May 2010 National Association of Boards of Pharmacy (NABP) Meeting to encourage the standardization of technician training.

There was no additional public comment.

The meeting was adjourned at 2:38 p.m.

Diverse Supply Issues and Hospital Pharmacy

LOMPOC VALLEY MEDICAL CENTER
Lompoc Healthcare District

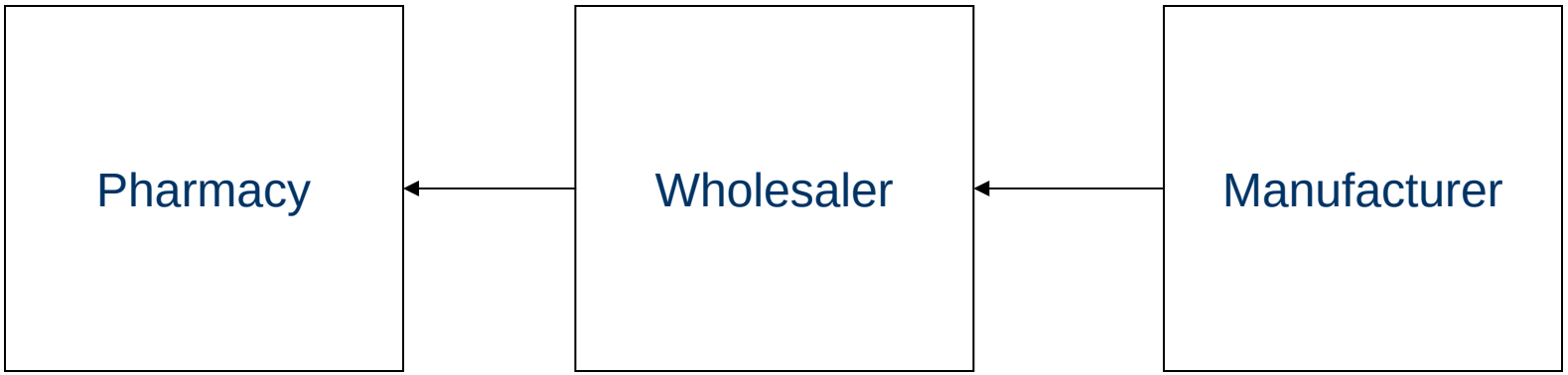
Medication Shortages

- ASHP Drug Shortage Management Center
  - Over 100 current shortages
- Medications with little or no alternatives
  - Erythromycin Ophthalmic Ointment
  - Propofol Injection
  - Seasonal Flu Vaccine
  - Vancomycin Injectable
- Estimated 30 to 99 million national economic impact of medication shortages (2002).

Ref: http://www.ashp.org/DrugShortages/Current/, accessed 11/2009.

Baumer AM, Clark AM, Witmer DR, Geize SB, et al. National Survey of the Impact of Drug Shortages in Acute Care Hospitals. 2004; 61:19.

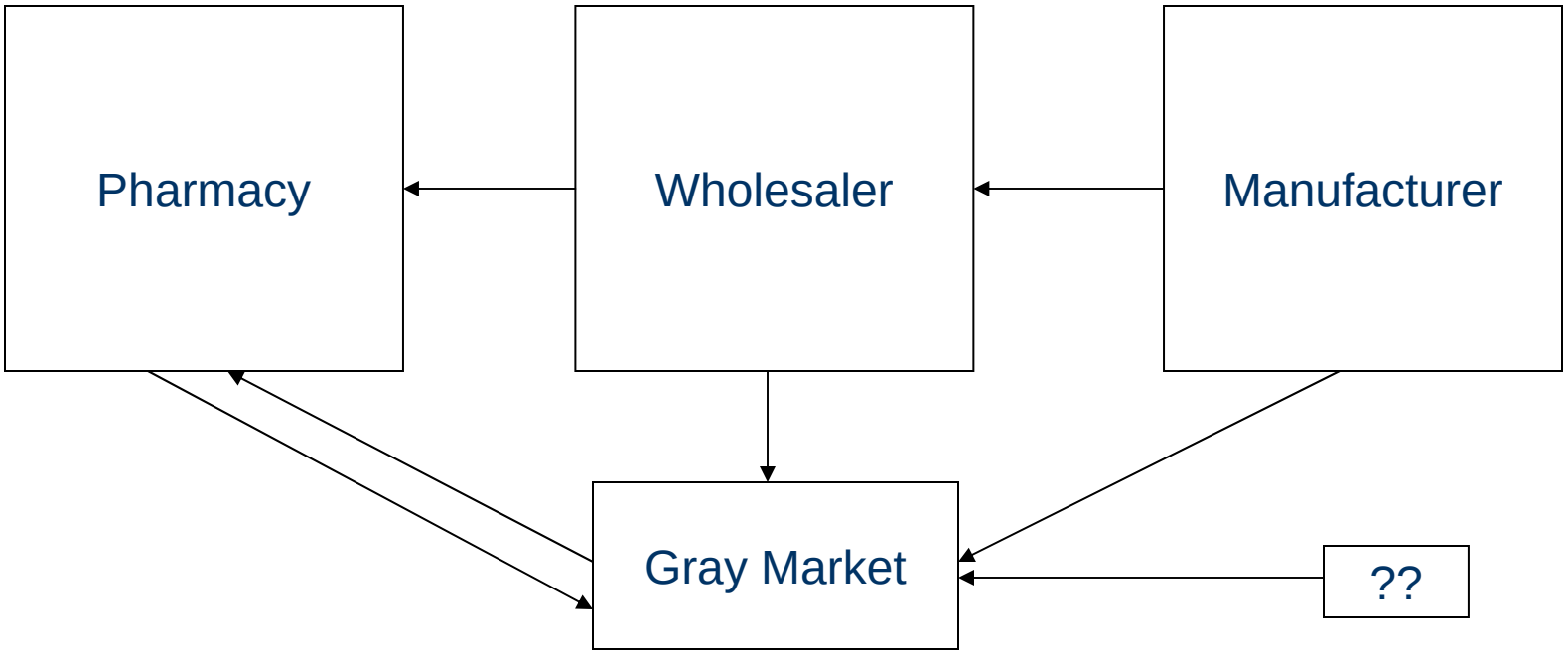
Supply Chain



Gray Market

- An alternate source of difficult to find drug products outside the normal supply chain

Supply Chain



Gray Market

- An alternate source of difficult to find drug products outside the normal supply chain
- Pharmacy Practice News, 2008
  - 85% of pharmacy directors had concerns
  - 43% still purchased in last year (avg. 9x/year)

Ref: D'Arrigo T. Uneasily, Pharmacy Directors Turn to Gray Market Medicine. Pharmacy Practice News. 2008; 35:04.

Necessity

- Necessity breeds opportunity
- Products move to open market
  - Price follows demand

Supply Cost Examples (Oct/Nov 2009)

- Erythromycin Ophthalmic Eye Ointment
  - Prevents infection that may cause blindness in newborns
  - $849.00 - 3032% markup
- Seasonal Influenza Vaccine
  - $275.00 to 550.00 – 491 to 982% markup
- Propofol Injection
  - Used for sedation in ventilated patients
  - $775.00 – 1123% markup

Solutions

- Pedigree Laws
  - Remove the uncertainty of supply sources
- Enforce/clarify price gouging laws, conscience clauses
- Forewarning of Supply Issues
  - Prevents stockpiling
- Other??

Questions??

CALIFORNIA STATE BOARD OF PHARMACY

We need your help

On behalf of the California State Board of Pharmacy, I am requesting your assistance with completing a job analysis survey concerning the duties you perform as a pharmacist. The board's examination committee will develop examination items based on the information collected from the survey responses. Such surveys enable examination items to reflect current technologies, methods, and practices performed, and are required by California law.

You may access the survey at http://www.goamp.com/CABOPsurvey. Please submit your responses by **January 3, 2010**. If you have trouble with the survey, contact Jennifer Benavente at Applied Measurement Professionals, Inc. at CABOP@goAMP.com. All information obtained, including your survey responses, will remain confidential. We only use this information for purposes of the study.

You will be credited for 3-hours of continuing education via completion of the final page of the survey. If you have any questions about this survey, please contact Debbie Anderson at (916) 574-7935. Thank you for your cooperation and assistance in this process.

Truly,

Virginia Herold, Executive Officer

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