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
LEGISLATION AND REGULATION COMMITTEE
MINUTES

DATE: October 21, 2009

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

COMMITTEE MEMBERS PRESENT:
Greg Lippe, Public Member, Chair
Stanley C. Weisser, RPh, Treasurer
Robert Swart, PharmD
Shirley Wheat, Public Member

COMMITTEE MEMBERS NOT PRESENT: Ryan Brooks, Public Member

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

Call to Order

Chair Greg Lippe called the meeting to order at 3:25 a.m.

A. LEGISLATIVE REPORT

1. Board Sponsored Legislation

a. **SB 819** (Senate Business, Professions & Economic Development Committee) – Omnibus Provisions (formerly contained in the enrolled version of SB 1779 [2008], vetoed).

As of 10/11/2009

Last Amendment: 9/12/09

Status: Signed by the Governor - - Chapter 308, Statutes of 2009

Chair Lippe provided that at the October 2008 Board Meeting, the board voted to pursue all of the omnibus provisions approved for sponsorship in 2008. He stated that many of these provisions were included in (2007-08) SB 1779 (Senate Committee on Business, Professions and Economic Development) which was vetoed by the Governor.

Chair Lippe indicated that this year, the Senate Committee on Business, Professions & Economic Development sponsored SB 819, which contained many of the same provisions formerly contained in last session's SB 1779.

Chair Lippe provided that the following four types of changes are addressed in SB 819:

1. Use of mobile pharmacies.
2. Changes resulting in a comprehensive legal review by board staff and counsel on the legal requirements surrounding the Pharmacist-in-Charge and Designated Representative-in-Charge.
3. General omnibus provisions.
4. Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.

Chair Lippe provided a summary of the following changes by category and section:

Use of Mobile Pharmacies

Section 4062 Furnishing Dangerous Drugs During an Emergency
This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

Section 4110 License Required, Temporary Permit Upon Transfer of Ownership
This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

Pharmacist-in-Charge and Designated Representative-in-Charge

Chair Lippe provided that consistent with the board's strategic objective 3.3, board staff and counsel completed a comprehensive review of the legal requirements surrounding the requirements of a pharmacist-in-charge (PIC) as well as a designated representative-in-charge (DRIC). He stated that as a result of this review, several omnibus changes were recommended to include some technical changes as well as refine the definitions of the pharmacist-in-charge and designated representative-in-charge and clarify the reporting requirements when a change of PIC or DRIC occurs.

Chair Lippe provided a list of the following specific recommended changes as well as a brief statement about the specific proposed changes.

Section 4022.5 – Designated Representative; Designated Representative-in-Charge
This section requires amendment to clarify the definition of "designated representative-in-charge" as well as the responsibilities of a licensee serving as such.

Section 4036.5 – Pharmacist-in-Charge
A new section is needed to define the term "pharmacist-in-charge" as well as the responsibilities a pharmacist serving as such.

Section 4161 – Non-Resident Wholesaler; Requirements
This section requires amendment to further clarify the duties that constitute a business operating as a non-resident wholesaler. This definition is already provided in B&PC 4043.

Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
This section requires amendment to specify that failure to meet notification requirements will constitute grounds for disciplinary action.

Section 4329 – Nonpharmacists; Prohibited Acts
This section requires amendment to include the prohibition of a nonpharmacist from acting as a supervisor or pharmacist-in-charge.

Section 4330 – Proprietors; Prohibited Acts
This section requires amendment to clarify that any pharmacy owner that subverts or tends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

General Omnibus Provisions

Chair Lippe provided that in addition to the changes listed above all of the following proposals were also approved as omnibus provisions for 2008*.*

Section 4059.5 - Who May order Dangerous Drugs or Devices, Exceptions.
A technical change to this section is necessary to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

Section 4081 – Records of Dangerous Drugs or Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
This section requires amendment to replace the term representative-in-charge with "designated representative-in-charge."

Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy
This section requires amendment to clarify specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
This section requires amendment to expand the board's authority to also include the board's ability to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal, fails to provide proof either as part of an audit or investigation initiated by the board.

H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature
This section requires amendment to require that a clinic that dispensed schedule III and schedule IV controlled substances must report to CURES*.*

Omnibus Provisions Resulting from Recodification of Business and Professions Code §4052.

Chair Lippe provided that in 2006 Business and Professions Code section 4052 was recodified into four sections. He stated that as a result, the following B&PC sections and H&SC section reference 4052 and require technical updates.

- Section 733 – Dispensing Prescription Drugs and Devices
- Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling

- Section 4111 – Restrictions on Prescriber Ownership
- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

No committee discussion or public comment was provided.

b. **SB 821** (Senate Business, Professions & Economic Development Committee) – New Ombibus Provisions specific to PIC and DRC Requirements

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Last Amendment: 8/17/09

Status: Signed by the Governor - - Chapter 307, Statutes of 2009

Chair Lippe provided that the remaining omnibus provisions in SB 821 remain unchanged from the prior version.

Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.
This section requires amendment to clarify when a pharmacist-in-charge or designated representative-in-charge must notify the board that he or she ceased to serve in such a capacity

Amend Section 4112 – Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
This section requires amendment to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the state.

Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications
This section requires amendment to clarify the procedures to be followed by a pharmacy when identifying a pharmacist-in-charge as well as the procedures to notify the board when a change in pharmacist-in-charge has occurred.

Section 4160 – Wholesaler Licenses
This section requires amendment to clarify the procedures to be followed by a wholesaler when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked
This section requires amendment to clarify the procedures to be followed by a veterinary food-animal drug retailer when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Section 4200.3 – Examination Process to be Reviewed Regularly
This section requires amendment to clarify that the examination process schall meet the standards and guidelines set forth in the Standards for Educational and Psycholgical Testing and the Federal Uniform Guidelines for Employee Selection Procedures.

Section 4200.4 – Retaking the National Examination After Failure
This section requires amendment to clarify that an applicant who fails the national examination may not retake the examination for at least 90 days or for a period established by regulations adopted by the board in consultation with the Office of Professional Examination Services of the department.

No committee discussion or public comment was provided.

c. **SB 470** (Corbett) – "Purpose" bill. Proposal to amend B&P §4040 and §4076 re: prescription labeling.

As of: October 11, 2009

Last Amendment: 4/30/09

Status: Signed by the Governor - - Chapter 590, Statutes of 2009

Background

At the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the "condition" for which a medicine is prescribed, with the "purpose" for which the medicine is prescribed.

Senator Corbett authored SB 470 on behalf of the board to amend Business and Professions Code §4040 and §4076 to include the "condition or purpose" for which a medicine is prescribed. (In 2007, Senator Corbett authored SB 472, Chapter 470, and Statutes of 2007, requiring the board to standardize the prescription label to make them patient-centered.)

As introduced, the California Medical Association issued a "Support if Amended" letter and offered amendments which were accepted by the author (resulting in a 4/27/09 amendment).

*The current version of the bill (4/30/09) amends the definition of "Prescription" in §4040(a)(E) to include the condition **or purpose** for which the drug was prescribed, if requested by the patient or patients. §4076(a)(10) is amended to include the condition **or purpose** for which the drug was prescribed if the condition or purpose is indicated on the prescription."*

While board staff has worked to establish a broad base of support for this proposal, it was necessary to make the "condition or purpose" permissive so as to remove opposition and keep the bill moving through policy committee.

Committee Discussion

Chair Lippe provided an overview of the bill.

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

d. **AB 977** (Skinner) – Pharmacists: Immunization Administration. Proposal to amend B&PC §4052 and §4052.8

As of 6/30/09

Last Amendment: 4/23/09

Status: AB 977 did not move out of policy committee by the statutory deadline

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Background

The board's immunization proposal, AB 977, is authored by Assembly Member Skinner. This measure, as introduced, proposed amendments to Business and Professions Code section 4052 and added 4052.8 to authorize a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP). However, the President of the Board approved amendments to allow a pharmacist to administer influenza and pneumococcal vaccinations or any other immunization pursuant to a protocol with a prescriber. Unfortunately the California Medical Association (CMA) continues to oppose the measure, even with the proposed amendments.

The most recent amendment (4/23/09) provides intent language (only) which requests that the California Pharmacists Association provide information to the respective chairpersons of the Assembly Committees on Business and Professions and Health; and to the Senate Committees on Business, Professions and Economic Development, and Health on the status of immunization protocols between independent pharmacists and physicians.

CPhA is developing a survey to disseminate regarding immunization protocols. The results of the survey will be provided at a future meeting.

Committee Discussion

Chair Lippe provided an overview of the bill. He advised that the bill did not move out of policy committee by the statutory deadline.

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

e. **AB 1071** (Emmerson) Pharmacy Fees. Proposal to Amend B&PC §4110, §4127.8, §4160, §4400, and §4127.5

As of: October 11, 2009

Introduced: September 2, 2009

Status: Signed by the Governor - - Chapter 270, Statutes of 2009

Background

AB 1071 (Emmerson), as introduced 2/27/09, adjusts application and renewal fees to ensure that the Board of Pharmacy has sufficient funds to fulfill all of its statutory obligations as a consumer protection agency. This bill also builds in a cap to increase future fees by no more than 30 percent.

In early September this bill was amended to extend the board's sunset date to 2013 as well as to extend the sunset date for several other DCA boards.

Committee Discussion

Chair Lippe provided an overview of the bill. He advised that this bill has been signed by the Governor.

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

2. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction Enrolled or Chaptered

a. **AB 830** (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia recognized by the Centers of Medicare and Medicaid

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Board Position: Opposition removed after amendments
Status: Signed by the Governor - - Chapter 479, Statutes of 2009

Committee Discussion

Chair Lippe provided that AB 830 replaces USP references in Pharmacy Law with "various drug compendia references with compendia approved by the federal Centers for Medicare and Medicaid Services." He stated that the amended version of the bill is expected to be in print next week.

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

b. **AB 931** (Fletcher) Emergency Supplies – Doses stored in an emergency supplies container

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Board Position: None
Status: Signed by the Governor - - Chapter 491, Statutes of 2009

Committee Discussion

Chair Lippe provided that AB 931 would increase the number of oral dosage form and suppository dosage form drugs for storage within an emergency supplies container to a limit of 48. He indicated that the current limit is 24. Chair LIppe stated that recent amendments (6/17/09) provide limitations to psychotherapeutic drugs contained in that e-kit, as specified.

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

c. **SB 762** (Aanestad) Professions and Vocations; Healing Arts

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Board Position: Support
Status: Signed by the Governor - - Chapter 16, Statutes of 2009

Committee Discussion

Chair Lippe stated that SB 762 provides that no city, county or city and county shall prohibit a person, authorized by one of the agencies in the Department of Consumer Affairs from engaging in the business for which the license was obtained.

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

3. Legislation That Failed Passage Deadline, May Become Two Year Bill

Chair Lippe referenced to the following bills:

a. **AB 418** (Emmerson) Pharmacy Technicians – Education and CE Requirements

This bill would alter the requirements for licensure as a pharmacy technician as well as establish continuing education requirements as a condition of renewal. This measure was last amended on 4/13/09, but failed to pass policy committee before the statutory deadline.

Board Position: Support (4/30/09)

b. **AB 484** (Eng) Licensees not in compliance with judgment or order; enforcement; action on a license

Current law requires every board to provide the Franchise Tax Board (FTB) with specified information upon request from the FTB. This measure, instead, requires that governmental entities who issue professional licenses provide specific information to the Franchise Tax Board for every licensee. The bill further requires, that if a licensee fails to pay taxes for which a state lien has been recorded, to send a notice of suspension to the applicable governmental agency and the licensee. Administrative remedies now available to licensees remain. The sponsor (FTB) asserts that current state law lacks an effective method to collect from a tax debtor who is an individual licensed to engege in an occupation or profession operating on a cash basis. This measure is an attempt to suspend one's licensing status because of unpaid tax liabilities. This measure failed to

pass policy committee and did not meet the deadline for bills to be passed out of the house of origin (J.R. 61(a)(8)).

Board Position: Support

c. **AB 583** (Hayashi) Health Care Practitioners: Disclosure of Education and Office Hours

Existing law (BPC 680) requires a health care practitioner to disclose his or her name, license on a name tag in 18-point type. AB 583 as amended 7/8/09 further requires a health care practitioner to provide their license type and the highest level of academic degree he or she holds on either a name tag, in writing to a patient as specified, or on a prominent display in his or her office. The measure provides specified exceptions for those licensed under BPC 2700, makes additional requirements to those licensed under Chapter 5 or under the Osteopathic Act, and makes further requirements of physicians and surgeons who supervise locations outside of their primary office. The measure excepts from some of the requirements those who work in a facility licensed under HSC 1250 or in a clinical laboratory licensed under HSC 1265. The latest version passed the Senate but was then placed on the Inactive File at the request of the author.

The board has not taken a position on this measure.

d. **AB 877** (Emmerson) (*Intent language*) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice

This bill would require the Department of Consumer Affairs to appoint a scope of practice committee of five members, as specified, to perform occupational analyses and prepare written reports on bills seeking to substantively expand the scope of a healing arts practice. The bill would require that the reasonable cost of analysis and report be paid by the affected licensing board. The bill was placed on suspense and subsequently held under submission.

The board has not taken a position on this measure.

e. **AB 1458** (Davis) Drugs: Adverse Effects Reposting

This bill requires health professionals, as defined, to report serious adverse drug events, as defined, to the federal Food and Drug Administration and would exempt violations from related criminal provisions. The measure was placed on the Assembly Appropriations suspense file 5/5/09.

The board has taken a "Support" position on the 5/5/09 version of the bill, stating"[the board] strongly believes that MedWatch provides an important consolidation point for collecting drug related misadventures, but reporting to this system on a voluntary basis has not resulted in adequate reporting."

f. **SB 26** (Simitian) Home-Generated Pharmaceutical Waste

The board has closely monitored this measure for drug take-back. Amendments to sections 4040.5, 41266.5, and 4081 have been offered to the author to clarify the role of reverse distributors; define "dispenses" for purposes of drug take-back; specify that a pharmacy may furnish dangerous drugs to a integrated waste hauler, as defined, for the sole purpose of waste disposal of pharmaceutical waste returned to a pharmacy; and to specify the recordkeeping requirements of those drugs returned to a wholesaler or reverse distributor. The measure was placed on the Senate Appropriations Suspense File.

g. **SB 238** (Calderon) Prescription Drugs

SB 238 amends the Confidentiality of Medical Information Act to allow a pharmacy, without the patient's authorization, to mail specified written materials to a patient regarding a prescribed course of treatment, only as specified. The latest amendment authorizes health care service enrollees to receive a 90-day supply of medication when so indicated on a prescription; and makes corresponding amendments to the Insurance Code related to the coverage of that 90-day supply. This measure failed passage from its first policy committee and is now a 2-year bill.

The board has not taken a position on this bill.

h. **SB 341** (DeSaulnier) California Department of Public Health. CDPH to contract with UC to study/evaluate the safety and effectiveness of prescription Drugs

This bill would require the California Department of Public Health (CDPH) to make every effort to enter into a contract with the University of California to establish a program to evaluate scientific literature related to the safety and effectiveness of prescription drugs and to communicate that information to consumers and prescribers. The bill did not pass out of the house of origin by deadline.

The board has not taken a position on this measure.

i. **SB 389** (Negrete McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus

The bill would require applicants for a license and, commencing January 1, 2011, licensees who have not previously submitted fingerprints, who petition for reinstatement of a revoked, surrendered or canceled license, or for whom a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information search, as specified. The bill would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she has been convicted, as defined, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued. SB 389 failed passage in the Assembly Committee on Public Safety, but was granted reconsideration.

At its July 2009 Board Meeting, and to be consistent with the board's public protection mandate, the board voted to "Support" the latest version (6/1/09) of the bill.

j. **SB 484** (Wright) Ephedrine Products / Schedule V

The California Office of the Attorney General sponsored SB 484 to place greater restrictions on the sale and reporting of sales of ephedrine / pseudoephedrine for the purpose of combating the manufacture and sale of methamphetamine in California, including the requirement that a prescription would be required for ephedrine and pseudoephedrine. The bill amends the Health & Safety Code to require that transactions, as specified, be reported to DOJ / CURES. The bill exempts from these reporting requirements any manufacture or wholesaler licensed by the board, as specified. The bill specifies criminal penalties for a person obtaining such substances without a prescription.

The board held a Support if Amended position of the 5/5/09 version, suggesting that ephedrine and pseudoephedrine be placed in controlled substance schedules III or IV. At its July 2009 Board Meeting, and to be consistent with the board's public protection mandate, the board voted to "Support" the latest version (5/12/09) of the bill.

k. **SB 638** (Negrete McLeod) DCA regulatory boards; sunset reviews; operations; report requirements

This bill would redefine the sunset review process. The bill was held in Senate Rules and did not meet the deadline for bills to be passed out of the house of origin. The board's Executive Officer worked with the Senate Business, Professions and Economic Development committee to identify options to secure

an extension of the board's sunset date. Following discussion, the committee voted to recommend that the board authorize the Executive Officer to have the Board of Pharmacy's sunset provisions addressed through a different legislative measure in order to extend the board's sunset date. Through those efforts, and through the amendment of the board's fee bill, AB 1071, the Board of Pharmacy's sunset provisions were extended to 2013.

Staff will continue to monitor SB 638 when the Legislature reconvenes in January.

B. Proposal to Allow a Board Licensed Hospital Pharmacy to Package Unit Dose Medication and Compound for Inpatients of Hospitals with Common Ownership

1. Presentation by Scripps and Sharp Hospitals – Elaine Levy (Sharp Healthcare – San Diego) and Robert Miller (Scripps Health – San Diego)

Robert Miller, representing Scripps Health, provided that Scripps and Sharp Hospitals are seeking to ensure that all intermittent parenteral drug doses are labeled to include a dose specific barcode. He proposed support for barcode checked distribution and bedside barcode based administration.

Elaine Levy, representing Sharp Healthcare (San Diego), provided an overview of intermittent parenteral dose preparation at Scripps and Sharp Hospitals. She proposed the establishment of a licensed Central Pharmacy Operation to service the "production" needs of the five Scripps hospitals and to maximize the use of the established Central Pharmacy Operation for the Sharp hospitals. Ms. Levy introduced Intellifill, an automated, high speed parenteral preparation syringe filling robotic system.

Committee Discussion

Dr. Robert Swart sought clarification regarding the doses that will be used.

Ms. Levy provided that both regular and patient specific doses will be used and will be replenished daily to the hospitals. She indicated that there will be appropriate oversight, checking, and quality control and documentation as specified by the board in the proposed sterile compounding regulations. Ms. Levy stated that Sharp will utilize its own courier system.

Mr. Miller discussed oral solid packaging and checking procedures. He stated that barcode processes are more consistent, controlled and safe than current processes.

Stan Weisser sought clarification regarding the bedside administration process.

Mr. Miller provided that bedside technology can be used when a drug is labeled with a barcode. It was indicated that Scripps and Sharp Hospitals are currently implementing barcode processes for both employees and patients.

Dr. Swart sought asked whether the policies and procedures for "barcoding" are developed by the facilities individually or the manufacture of the equipment.

Mr. Miller provided that the policies and procedures are developed by the facilities.

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

2. Demonstration by Intelifill for Use in Preparing Hospital Medications – Dennis Tuhll (For Health Technologies, Inc.)

Dennis Tublh, representing For Health Technologies, Inc., provided an overview of IntelliFill i.v. He stated that the product provides automated checks and verifications during the preparation of medications which enables hospital pharmacies to dramatically reduce the likelihood of errors. Mr. Tublh presented a video demonstration of the Intellifill i.v. device. He indicated that as a medical device, the Intellifill i.v. is managed as a pharmacy compounding device under U.S. Food and Drug Adminsitration (FDA) control.

Committee Discussion

Mr. Weisser sought clarification regarding the maintenance of the device.

Mr. Tublh provided that maintenance is included in the contract for the device including monthly, quarterly, semiannual and annual preventive maintenances.

Mr. Lippe sought clarification regarding the availability of replacement parts.

Mr. Tublh provided that replacement parts are available at UPS depots across the country. He added that field service engineers are also available for assistance.

Mr. Weisser asked about the sterility of the device.

Mr. Tublh provided an overview of the sterility components and maintenance of the device.

Executive Officer Virginia Herold asked how many devices are in use in the U.S.

Mr. Tublh provided that 30 devices are currently in use in facilities in the U.S. He stated that the smallest facility has 250 beds and the largest has 800 beds. Mr. Tublh clarified that the Intellifill i.v. is a pharmacy compounding device/

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

3. Demonstration by Amerisource Bergen on TrakRx System – Joel Weber and Kartik Joneja (Amerisource Bergen)

Joel Weber provided an overview of the TrakRx, a dispensing system. He stated that a Scripps pharmacist will validate the product to ensure that it was dispensed correctly.

Committee Discussion

Dr. Swart questioned how many medications the system is setup for.

Mr. Weber discussed the various medications that can be dispensed.

Mr. Herold provided that board staff will discuss this system with its counsel to determine any legislation changes that may be needed.

Joshua Room, Deputy Attorney General, provided that a transfer between pharmacies may be needed to allow for this system.

The committee provided support for pursuing the implementation of this system.

Mr. Weisser sought clarification regarding ownership of the drugs.

Mr. Weber provided that Scripps own the drugs during the entire process.

Ms. Herold clarified that the pharmacist will be held accountable for any error made by the system.

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

C. REGULATIONS REPORT

Chair Lippe referenced to the following regulations:

1. **Board Adopted Regulations – Recently Approved by OAL**
   Title 16 CCR Amend §1773 and Adopt §1773.5 – Establishment of an Ethics Course as an Optional Enforcement Component for Discipline

   Amendments to 16 CCR §1773 and §1773.5 became effective on September 3, 2009.

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

   The board determined the requirements as necessary, based on testimony received during the October 2007 Board Meeting. During the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethics course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of IMQ, the board's proposal also incorporates an additional 8 hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post-course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

   During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. At the conclusion, the board directed staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: change the word "medicine" to "pharmacy" at proposed §1773.5(a)(5)(B). If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with this modified text.

   No comments were received during the 15-day comment period. At the end of the 15-day comment period, board staff compiled the rulemaking and transmitted it to the Office of Administrative Law. The Office of Administrative Law approved

the regulatory action on August 4, 2009, and the new regulations became effective on September 3, 2009.

2. Board Adopted Regulations – Undergoing Review by the Administration
Title 16 CCR Repeal §1716.1 and §1716.2, Amend and Adopt sections 1751 through 1751.8 and Adopt sections 1735 through 1735.8 – Pharmacies that Compound

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

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

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

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

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

Staff compiled the final regulatory proposal and submitted it to the department. On August 20, 2009, the Director of the Department of Consumer Affairs pursuant to Business and Professions Code section 313.1(e)(1) extended the length of the notice period, and the regulatory proposal is currently under review by the department.

3. Board Approved Regulations – Awaiting Notice

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

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

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting and, subsequently, was approved by the board at the October 2007 Board Meeting.

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

b. Title 16 CCR Sections 1721 and 1723.1 – Dishonest Conduct During a Pharmacist's Licensure Examination / Confidentiality

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

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

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

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies. The proposed language was approved by the board at its July 2007 Board Meeting.

This regulation will specify the process and criteria that will be utilized to approve accreditation agencies for pharmacies that compound injectable sterile drug products.

4. Regulations Under Development

a. Title 16 CCR Section 1780 – Update the USP Standards Reference Material

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

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

President Schell may wish to consider filling the subcommittee vacancy created when former board member Jim Burgard's term concluded. This subcommittee has not held any meetings.

b. Title 16 CCR Section 1732.2 – Continuing Education for Competency Committee Members

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

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

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

One of the core functions of this committee is to complete an on-line review of all test questions prior to administration. As the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically, committee members are not compensated for their time to complete this function. If a committee member is seeking reimbursement for this time, however, continuing education will not be awarded.)

Current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- *Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05),*
- *Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), and/or*
- *By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).*

Additionally, the board will award CE for:

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

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

5. Proposed Regulations to Implement Recently Enrolled Legislation

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

Chapter 270, Statutes of 2009

Assembly Member Emmerson authored AB 1071 to update the board's fee schedule. The board approved an increase in fees in January 2009, following consideration of the results of an independent fee audit and to ensure the solvency of the board.

In September, the bill was amended to include provisions to extend the sunset date of the Board of Pharmacy and other specified boards within the Department. Following passage and concurrence of the amendments, the bill was enrolled and ultimately signed by the Governor on October 11, 2009.

Staff has drafted proposed text to update the board's fee schedule to implement the new fee schedule, which is effective January 1, 2010.

Committee Discussion

Ms. Herold provided that there may be a potential conflict between statutory fees and fees in the regulation. She stated that because statutory requirements take precedence over regulation requirements, the committee does not need to act today to conform the regulations to the new statute.

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

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

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

M/S: Weisser/Swart

Approve: 4 Oppose: 0

D. Request for Legislative and Regulation Changes Submitted by the Public or Staff

Public Requests

Chair Lippe reviewed the following statements, recommendations, information and/or proposals that have been provided to the board for consideration:

1. Richard Sakai, PharmD, FASHP, FCSHP, Children's Hospital Central California Legislative and/or Regulatory suggestions to improve drug distribution in hospitals.

    A. Nursing Unit Checks – a suggestion to consider the utilization of pharmacy technicians in the checking for outdated medications on nursing units and emergency medication carts/kits/trays/boxes, etc.

    B. Nursing Unit Checks – monthly check of emergency medication carts/trays/boxes/kits/etc.

    C. Bar Code with Lot Numbers – consider mandating the insertion of lot numbers in the bar codes on all medications that the State of California will allow into the state.

    D. Disciplinary Guidelines – consider amending the guidelines/regulations to hold a PIC accountable for the operations and compliance to regulations, but not on a personal basis.

    E. State Board of Pharmacy Members – members should spend a minimum of 40 hours annually visiting a pharmacy within the State of California with a minimum of five different types of practice settings.

    F. Joint meetings between the State Board of Pharmacy and CDPH

    G. Responsiveness of the State Board of Pharmacy – length of time to get a response from the board.

    H. Article reference: ASHP Section of Pharmacy Informatics and Technology Executive Committee. *Technology-enabled practice: A vision statement by the ASHP Section of Pharmacy Informatics and Technology, Am J Health-Syst Pharm, 66:1573-1577, September 1, 2009.*

Committee Discussion

Mr. Herold provided that these suggestions were generated at a Subcommittee to Evaluate Drug Distribution in Hospitals Meeting.

The committee discussed the merits of the submitted regulation changes.

Ms. Herold provided that board staff will review the suggestions and bring them back to the Licensing Committee.

2. Douglas Barcon, PharmD

Dr. Barcon reviewed Business and Professions Code, Chapter 9, Division 2, Article 20 Regulation 4330(b). He recommended that the board work with the Office of the California Attorney General and draft an amendment to the regulation that extends the jurisdiction of the board to include any corporate officers, administrators, supervisors, managers, or licensees of other California regulatory boards, such as the Board of Registered Nursing.

Mr. Room provided that the board has no ability to compel any other licensing agency to take action based on the board's laws.

Staff Requests

Carolyn Klein, Legislation and Regulation Manager, provided an overview of staff recommendations for revisions to Pharmacy Law for the second half of the 2009-2010 Legislative session.

The committee reviewed each of the following staff legislative proposals:

1. §4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, sought clarification with the term "inspector" with regards to a board inspector or any authorized officer of the law. He recommended that the section be revised to include "authorized representatives of the board."

There was no additional public comment.

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

M/S: Wheat/Swart

Approve: 4 Oppose: 0

2. §4104 – Licensed Employee, Theft or Impairment: Pharmacy Procedure

Public Comment

Dr. Steve Gray suggested the availability of an extension to allow for the time necessary to conduct an audit as required.

Mr. Room clarified that the 14 day deadline is enforced after the completion of the audit.

There was no additional public comment.

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

M/S: Swart/Weisser

Approve: 4 Oppose: 0

3. §4112 – Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

Committee Discussion

The committee discussed the board's ability to monitor this provision. It was clarified that the burden will be placed on the employing state to verify their employee's ability to service any California patient.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, expressed concern regarding possible retaliation by other boards of pharmacy and the ability of a pharmacist whose license has been revoked by California to seek employment.

The committee discussed the implications of allowing a pharmacist whose license has been revoked by California to service California patients.

Kristy Schieldge, DCA Staff Counsel, clarified that under current law it is already a requirement that a nonresident pharmacy disclose to the board all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to California residents.

Dr. Gray expressed concern regarding the enforcement of this requirement.

There was no additional committee discussion or public comment.

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

M/S: Weisser/Swart

Approve: 4 Oppose: 0

4. §4120 – Nonresident Pharmacy: Registration Required

Committee Discussion

Mr. Room provided that board staff has identified this section to be entirely duplicative of §4112.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided that subdivision (d) of this provision is not duplicative. He recommended that this subdivision be moved to §4112.

There was no additional committee discussion or public comment.

MOTION: To repeal §4120.

M/S: Swart/Weisser

The committee discussed the proposed repeal of §4120, and tabled this item to allow further research and consideration of those provisions which may not be duplicative of other Pharmacy Law provisions.

5. §4200.1 – Retaking Examinations; Limits; Requirements

Committee Discussion

Ms. Klein provided that this statutory provision becomes inoperative on January 1, 2010. She stated that §4200.1 is being added to reinstate the provision.

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

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

M/S: Weisser/Wheat

Approve: 4 Oppose: 0

6. §4301 - Revocation and Suspension: Authority; Conditions; Issuance of Probationary License; Application of Administrative Procedure Act; Judicial Review

Committee Discussion

Chair Lippe reviewed the proposed amendments.

The committee discussed revisions to be made to subdivision (g) of the proposal.

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

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

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

M/S: Wheat/Weisser

Approve: 4 Oppose: 0

7. §4301.1 – Pharmacist License; Suspension; Felony Conviction

Committee Discussion

Chair Lippe reviewed the proposal to add §4301.1 to allow the board to suspend the license of a pharmacist or pharmacist intern for a felony conviction for a crime of unprofessional conduct as specified in §4301.

Mr. Room provided that counsel would like some revision of language in this section.

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

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

Chair Proposal

Chair Lippe provided that a test conducted by the L.A. City Attorney produced results indicating that medical marijuana has 600 times the safe amount of pesticides. He proposed the creation of legislation to set standards and to establish enforcement to protect patients from receiving contaminated medical marijuana.

Committee Discussion

Ms. Schieldge provided that this proposal may be beyond the scope of the board.

The committee discussed possible obstacles the board may encounter in the event it pursued this proposal. Concern was expressed about the board's jurisdiction as it relates to medical marijuana.

Mr. Room provided that the board has the ability to develop guidelines for this issue.

Chair Lippe provided that he will help to develop guidelines that can be discussed at a future committee meeting.

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

E. Strategic Plan Update for the Legislation and Regulation Committee for 2009-10

Chair Lippe referenced to the Strategic Plan Update for the Legislation and Regulation Committee for 2009-2010.

F. Public Comment for Items Not On the Agenda

Dr. Darlene Fujimoto, representing the University of California San Diego (UCSD), discussed the requirement for a pharmacist to stock automated drug delivery systems. She expressed concern regarding the intent of this requirement.

Ms. Herold provided an overview of relevant code sections relating to automation in pharmacies. She offered to bring this issue to the Licensing Committee.

Dr. Steve Gray, representing Kaiser Permanente, discussed the establishment of automation in pharmacies. He suggested that clarification be provided regarding who is responsible for stocking pyxis machines. Dr. Gray encouraged the board to consider a statute to overrule Title 22.

There was no additional public comment.

The meeting was adjourned at 5:31 p.m.

Legislation and Regulation Committee

DATE: October 21, 2009

TO: Legislation and Regulation Committee

FROM: Staff

The following statements, recommendations, information and/or proposals are provided to the board for consideration:

1. Richard Sakai, PharmD, FASHP, FCSHP, Children's Hospital Central California Legislative and/or Regulatory suggestions to improve drug distribution in hospitals.

   A. Nursing Unit Checks – a suggestion to consider the utilization of pharmacy technicians in the checking for outdated medications on nursing units and emergency medication carts/kits/trays/boxes, etc.

   B. Nursing Unit Checks – monthly check of emergency medication carts/trays/boxes/kits/etc.

   C. Bar Code with Lot Numbers – consider mandating the insertion of lot numbers in the bar codes on all medications that the State of California will allow into the state.

   D. Disciplinary Guidelines – consider amending the guidelines / regulations to hold a PIC accountable for the operations and compliance to regulations, but <u>not</u> on a personal basis.

   E. State Board of Pharmacy Members – members should spend a minimum of 40 hours annually visiting a pharmacy within the State of California with a minimum of five different types of practice settings.

   F. Joint meetings between the State Board of Pharmacy and CDPH

   G. Responsiveness of the State Board of Pharmacy – length of time to get a response from the board.

   H. Article reference: ASHP Section of Pharmacy Informatics and Technology Executive Committee. *Technology-enabled practice: A vision statement by the ASHP Section of Pharmacy Informatics and Technology, Am J Health-Syst Pharm, 66:1573-1577, September 1, 2009.*

2. Douglas Barcon, PharmD

   Request to address the Board of Pharmacy regarding Business and Professions Code, Chapter 9, Division 2, Article 20 Regulation 4330(b) as an agenda item.

Leg

Douglas Barcon, Pharm.D.

California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

October 1, 2009

Re: October 2009 Board of Pharmacy Meeting

Gentlemen,

I wish to address the Board of Pharmacy regarding Business & Professions Code, Chapter 9, Division 2, Article 20 Regulation 4330(b) as an agenda item:

4330. Misdemeanor: Non-Pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist-in-Charge
(a) Any person who has obtained a license to conduct a pharmacy, who fails to place in charge of the pharmacy a pharmacist, or any person, who by himself or herself, or by any other person, permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs, in his or her pharmacy, except by a pharmacist, or as otherwise provided in this chapter, is guilty of a misdemeanor.
(b) Any non-pharmacist owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor.

Apparently regulation 4330(b) is not enforceable, unless the violator is a licensee of the Board of Pharmacy, yet it specifically addresses "any non-pharmacist owner," which seems straight forward, except by omission it excludes corporate officers, hospital administrators, and others that are not specifically listed on the application for a pharmacy permit. For example, a hospital's Chief Nursing Officer or Administrator can be the supervisor over the Pharmacy Department and the Pharmacist-in-Charge and can interfere with the pharmacist-in-charge in meeting regulatory requirements. Regulation 4330(b) does not apply to nurses or the Chief Nursing Officer, because these individuals are not under the jurisdiction of the Board of Pharmacy regardless of whether they are considered to be an officer of the corporation and thus an owner that holds the pharmacy permit. Consequently, violators may not be charged.

I recommend that the California State Board of Pharmacy work with the Office of the California Attorney General and draft an amendment to Pharmacy Regulation 4330(b) that extends the jurisdiction of the Board of Pharmacy to include any corporate officers, administrators, supervisors, managers, or licensees of other California regulatory boards, such as the Board of Registered Nursing. A further amendment should enable the Board of Pharmacy to forward complaints addressing violations of Pharmacy Regulation 4330(b) to the licensing board of the violator for further action. At first glance, the change included in SB 819 (Yee) addresses other

pharmacy owners regarding regulation 4330(b) and improves on the current regulation, but it does not address whether regulation 4330(b) is enforceable. Regardless of the change, the regulation would remain unenforceable.

Sincerely,

Douglas Barcon, Pharm.D.
RPH 36419
(909) 860-2494

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

DATE: October 21, 2009

TO: Legislation and Regulation Committee

FROM: Staff

RE: 2009-2010 Staff Legislative Proposals (2nd Year)

Staff recommends the following revisions to Pharmacy Law for the second half of the 2009-2010 Legislative session. Unless otherwise specified, all section numbers are within the Business and Professions Code.

Updates to Pharmacy Law

§4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions (separate document)

§4081 Amend Business and Professions Code to specify a time frame in which records requested by an inspector shall be provided to the board and allow an extension if requested in writing and approved by the board; and to strike the operative date (subdivision d)

§4104 Licensed Employee, Theft or Impairment: Pharmacy Procedures

Amend §4104(c) to specify that a pharmacy shall provide to the board within 30 days the information specified in subsections (1) through (6).

Amend §4104(c)(4) to specify that the evidence that demonstrates theft, diversion, or self-use of dangerous drugs by a licensed individual, include an audit that determines the loss to the pharmacy, if any.

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

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

§4120 Nonresident Pharmacy: Registration Required [repeal]

§4200.1 Retaking Examinations; Limits; Requirements

Add 4200.1.

§4301 Revocation and Suspension: Authority; Conditions; Issuance of Probationary License; Application of Administrative Procedure Act; Judicial Review

Amend subdivision (g) to clarify that "unprofessional conduct" includes a license holder who furnishes false, misleading or incomplete information to the board, or who fails to furnish information requested or required.

Amend subdivision (q) to clarify that "unprofessional conduct" includes a license holder who engages in any conduct that subverts or attempts to *impede* an investigation of the board.

Strike subdivision (t) – the date the section became operative.

§4301.1 Pharmacist License; Suspension; Felony Conviction

Add §4301.1 to specify that the board shall suspend the license of a pharmacist or a pharmacist intern who is convicted of a felony for a crime of unprofessional conduct, as defined in §4301; that the board may decline to impose or may set aside the suspension when it appears to be in the interest of justice to do so; and that the issue of penalty shall be heard by an administrative law judge, or a committee of the board with an ALJ, or the board sitting with an ALJ, at the discretion of the board. The section would allow a pharmacist or pharmacist intern to request a hearing within a specified timeframe; and that if an accusation for permanent discipline is not filed within 90 days of the suspension that the suspension shall terminate.

Update References to the State Department of *Public Health* (not Health Services)

§4127.1 License to Compound Injectable Sterile Drug Products Required

§4425 Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Services Utilization Review and Monitoring

§4426 Department of Health Services to Study Reimbursement Rates

Medically Indigent Patients

As discussed by the Enforcement Committee at its meeting last month, the Los Angeles County Department of Health Services is seeking the ability for pharmacies serving medically indigent patients to better use the drug benefits of drug manufacturers' patient assistance programs.

A copy of the staff memo provided to the Enforcement Committee summarizing the request and suggestions from Los Angeles County is provided for the committee's discussion.

Through the implementation of such a program, as proposed, the Los Angeles County Department of Health Services may realize a savings of up to $8 million.

Staff will work with the Los Angeles County Department of Health Services to develop language, and staff will bring a recommendation back to the board in January 2010.

§4059 (See separate document provided)

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

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

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

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

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

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

§4104

Licensed Employee, Theft or Impairment: Pharmacy Procedures

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

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

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

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.
(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.
(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual. As part of this evidence, the pharmacy shall conduct an audit to determine the loss, if any, from the pharmacy. A certified copy of the audit and results shall be provided
(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

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

§4112

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

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

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

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

(d) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the California State Board of Pharmacy to manufacture, compound, furnish, sell, dispense, initiate the prescription of any dangerous drug or dangerous device, or provide any pharmacy-related service to any patient in California.

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

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

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

a label affixed to each container of drugs dispensed to patients in this state.

~~(g)~~ (h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

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

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

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

§4120. **Nonresident Pharmacy: Registration Required**

~~4120. (a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler pursuant to this chapter without registering as a nonresident pharmacy.~~

~~(b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.~~

~~(c) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.~~

~~(d) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state~~

§4200.1 **Retaking Examinations; Limits; Requirements**

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

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

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

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

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

§4301.1 **Pharmacist License; Suspension; Felony Conviction**

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

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

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

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

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

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

(g) Furnishing false, misleading, or incomplete information to the board, or the failure to furnish information requested by the board or required by this chapter.

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

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

§4301 *(Continued)*

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs. (k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States **Code** regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal **Code** allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

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

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

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

§4301 *(Continued)*

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

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

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

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

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

§4301.1

Pharmacist or Pharmacist Intern License; Suspension; Felony Conviction

(a) The board shall suspend the license of a pharmacist or pharmacist intern convicted of a felony for a crime of unprofessional conduct as specified in section 4301. The board shall notify the pharmacist or pharmacist intern of the license suspension and of his or her right to have the issue of penalty heard as provided in this article.

(b) Upon its own motion or for good cause shown, the board may decline to impose or may set aside the suspension when it appears to be in the interest of justice to do so, with due regard to maintaining the integrity of and confidence in the pharmacy profession.

(c) If an accusation for permanent discipline is not filed within 90 days of the suspension imposed pursuant to this section, the suspension shall automatically terminate.

References to the State Department of Public Health

§4127.1 **License to Compound Injectable Sterile Drug Products Required**

4127.1. (a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the **State Department of Public Health** ~~Services~~ and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(f) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

References to the State Department of Public Health

Article 24. Prescription Rates for Medicare Beneficiaries

§4425 and §4426

4425. (a) As a condition for the participation of a pharmacy in the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000) of Division 9 of the Welfare and Institutions **Code**, the pharmacy, upon presentation of a valid prescription for the patient and the patient's Medicare card, shall charge Medicare beneficiaries a price that does not exceed the Medi-Cal reimbursement rate for prescription medicines, and an amount, as set by the State Department of Public Health ~~Services~~ to cover electronic transmission charges. However, Medicare beneficiaries shall not be allowed to use the Medi-Cal reimbursement rate for over-the-counter medications or compounded prescriptions.

(b) The State Department of Public Health ~~Services~~ shall provide a mechanism to calculate and transmit the price to the pharmacy, but shall not apply the Medi-Cal drug utilization review process for purposes of this section.

(c) The State Department of Public Health ~~Services~~ shall monitor pharmacy participation with the requirements of subdivision (a).

(d) The State Department of Public Health ~~Services~~ shall conduct an outreach program to inform Medicare beneficiaries of their right to participate in the program described in subdivision (a), including, but not limited to, the following:

(1) Including on its Internet Web site the Medi-Cal reimbursement rate for, at minimum, 200 of the most commonly prescribed medicines and updating this information monthly.

(2) Providing a sign to participating pharmacies that the pharmacies shall prominently display at the point of service and at the point of sale, reminding the Medicare beneficiaries to ask that the charge for their prescription be the same amount as the Medi-Cal reimbursement rate and providing the department's telephone number, e-mail address, and Internet Web site address to access information about the program.

(e) If prescription drugs are added to the scope of benefits available under the federal Medicare program, the Senate Office of Research shall report that fact to the appropriate committees of the Legislature. It is the intent of the Legislature to evaluate the need to continue the implementation of this article under those circumstances.

(f) This section shall not apply to a prescription that is covered by insurance.

4426. The State Department of Public Health ~~Services~~ shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services.

Scripps SHARP

Intermittent Parenteral Dose Preparation
At Scripps Health and Sharp Healthcare (San Diego)

Current Situation

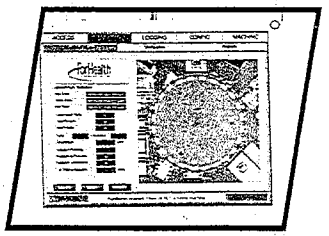
- Scripps Health owns and operates five hospitals in San Diego; Sharp Healthcare owns and operates six hospitals in San Diego.
- Each hospital has a separately licensed Pharmacy.
- Intermittent parenteral doses of medication are supplied in various forms including IV piggybacks, batched syringes, IV bags with vial connection system, etc.
- The majority of these doses are prepared manually; some are prepared using a semi-automated process (e.g. Baxa Repeater Syringe Pump).
- Some intermittent doses are purchased pre-made from the manufactures.
- At Scripps the doses are prepared at each hospital in the IV room; at Sharp batch doses are prepared at the Central Pharmacy facility.
- All doses are checked by a pharmacist before release.
- Current processes for intermittent dose preparation add both product and labor cost.
- The labels placed on these doses are not bar coded.
- Due to lack of bar-coding, the doses cannot be picked from stock for placement in automated drug cabinets (ADCs) using bar code checking, nor can they be placed in the ADC using this safety technology.
- The intermittent parenteral doses, without individual dose bar coding, cannot be checked at administration using bedside barcode technology.

Desired Situation

- Processes support meeting new proposed compounding regulations by capturing all necessary information for immediate drug recall should it be necessary.
- All intermittent parenteral drug doses are labeled to include a dose specific barcode, supporting bar code checked distribution and bedside barcode based administration.
- Preparation and documentation is automated, whenever possible, and supply and labor efficient.
- Preparation is done in an anticipatory manner, when possible, assuring a more controlled process and immediate availability for patient care when needed.
- Preparation does not add significantly to the cost of drug doses.
- Preparation is done centrally for all Health System hospitals to make maximum use of automated preparation equipment; avoid the need for underutilized, duplicated equipment at each hospital; and assure a consistent, well controlled process involving a minimum number of trained staff.
- The central preparation location is well designed for the purpose and licensed as a Pharmacy.
- Processes are more consistent, controlled and safe than current processes.

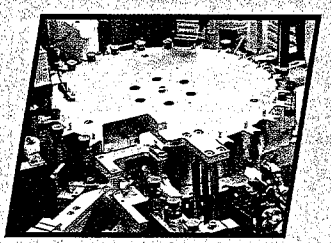
Proposed Solution

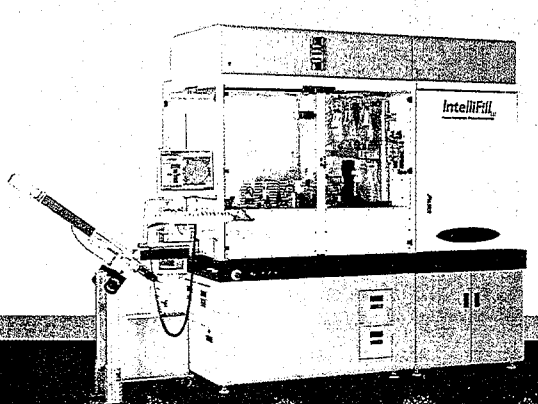
- Establish a licensed Central Pharmacy Operation to service the "production" needs of the five Scripps hospitals; maximize the use of the established Central Pharmacy Operation for the Sharp hospitals.
- Install automated, high speed parenteral preparation equipment (e.g. Baxa Intellifill-IV syringe filling robotic system).
- At Scripps the Intellifill unit would be installed in a licensed central pharmacy location, not in a clean room environment (this is compatible with Intellifill's self contained ISO Class 5 environment and meets USP 797 guidelines); at Sharp the Intellifill would be placed in the clean room at the Central Pharmacy.
- Assure appropriate pharmacist oversight and checking, quality control and documentation as specified by the Board of Pharmacy in the proposed sterile compounding regulations.
- Deliver prepared drugs on a daily basis via secure carrier to the hospitals, within the System.
- These drugs would be provided only to the System owned facilities of each organization and at the cost of production.
- Save up to a minimum $600,000/year through centralized, automated preparation.



IntelliFill® i.v.

Human Intelligence, Robotic Performance





High Speed, Automated I.V. Preparation

ForHealth® TECHNOLOGIES, INC.

IntelliFill i.v.

Modes of Compounding

Filling from vials

- Patient-specific batch doses
- Non-patient-specific batch doses
- Stat or new-order, patient-specific doses
- Both liquid and powder forms

Filling from reservoir

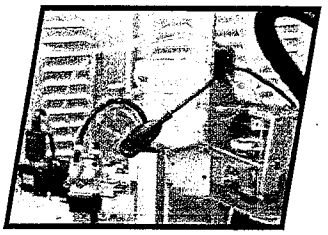
- Batch doses from pre-filled bulk bags

Vial reconstitution

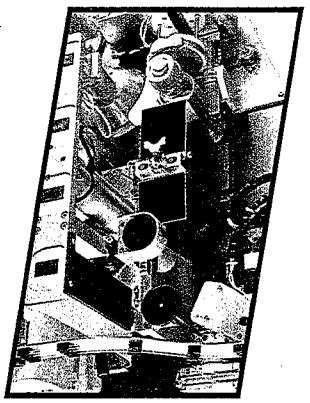
- Prepares vials for later use by IntelliFill i.v. or by hand

Dilution

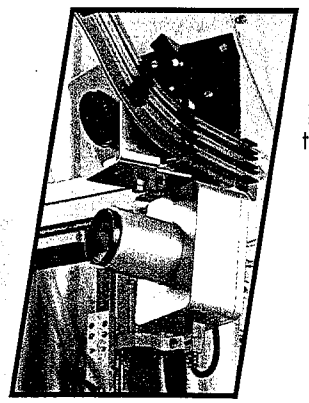
- Prepares custom dilutions in syringes and vials

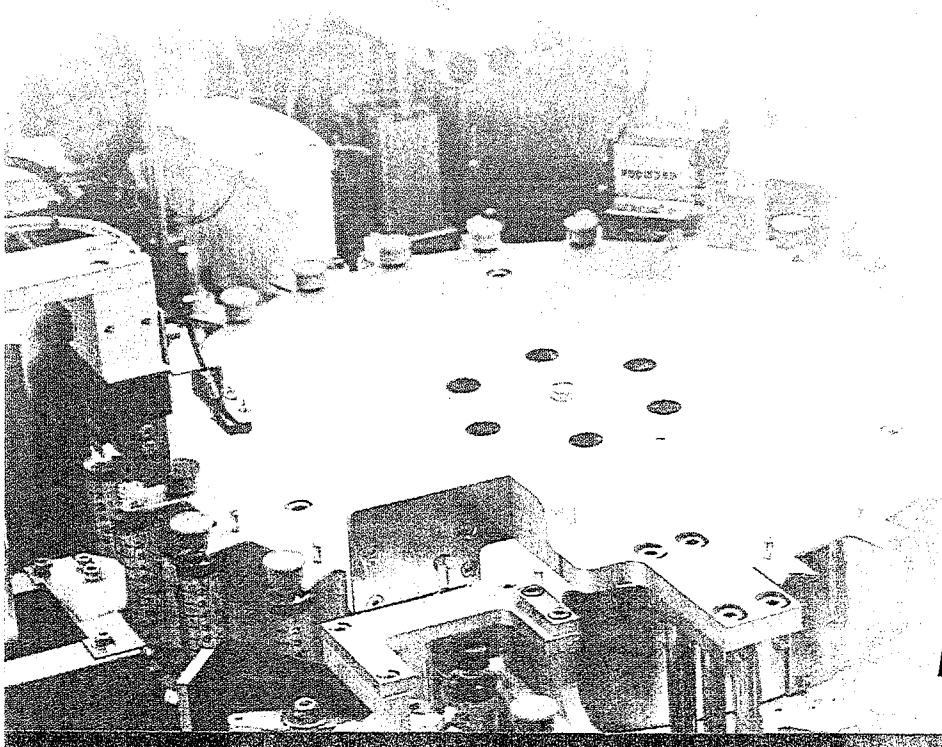


IntelliFill i.v.'s multiple checks and verifications, during preparation of medications, enable hospital pharmacies to dramatically reduce the likelihood of errors:



- Remote camera option enables field service personnel to send real-time images of IntelliFill i.v. station status for efficient troubleshooting
- Automated dosage-preparation trail for each dose reduces time and labor required to manually check doses for accuracy
- Weight confirmation is performed for each dose for accuracy and patient safety
- Drug selection is verified by barcodes at multiple locations for accuracy and safety
- Barcoded labels help facilitate patient safety at the bedside when used with bedside scanning technology
- IntelliFill i.v. knows the amount of time particular vials can be safely used, once opened and reconstituted, and keeps them stored in its ISO Class 4 environment until expired or removed by a user
- Delivers routine reporting and automatic emailing of significant data to designated users
- IntelliFill i.v. gathers and retains significant amounts of data about each dose, including actual pictures of vials used to prepare doses





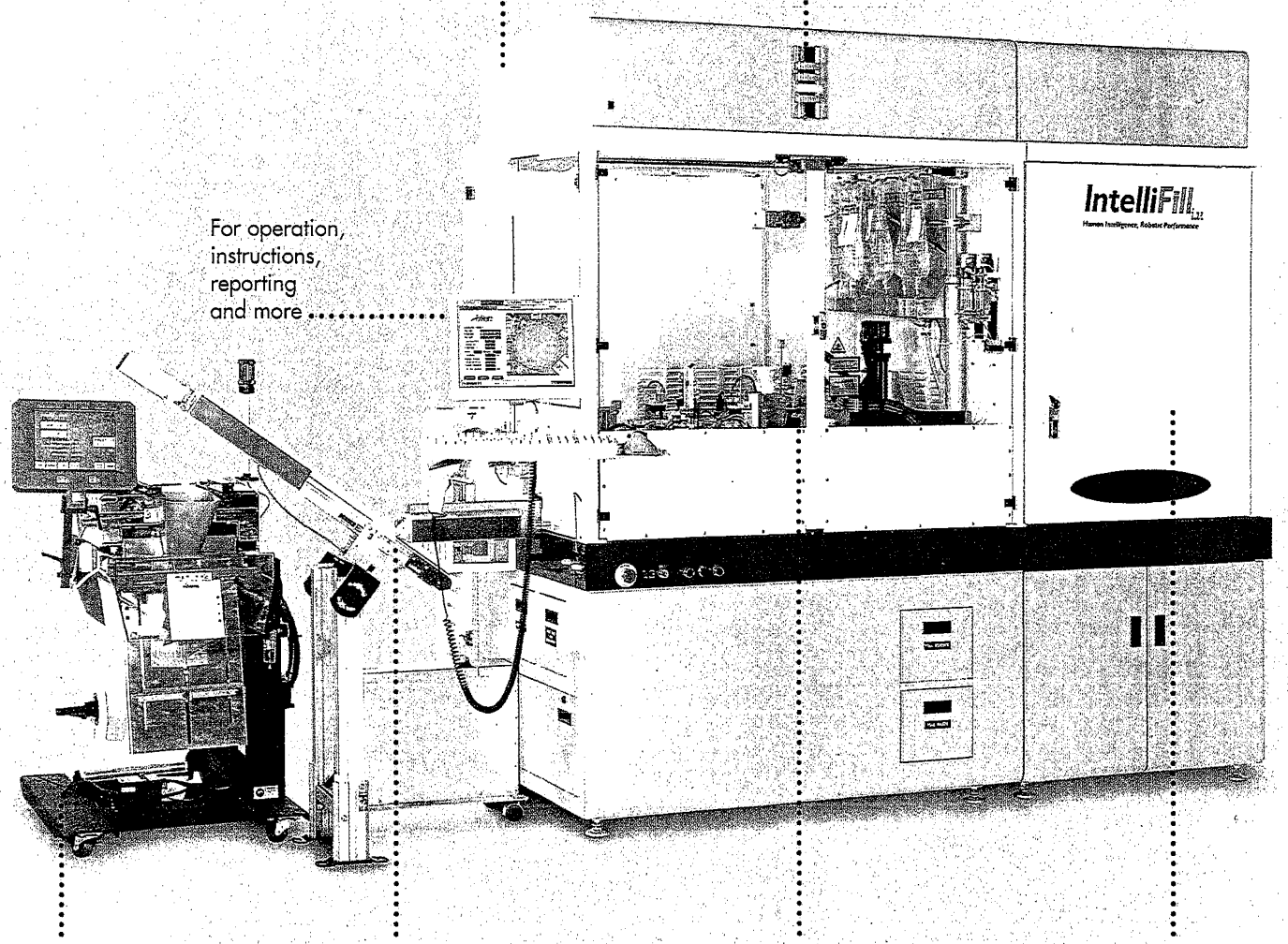
IntelliFill® i.v.

Human Intelligence, Robotic Performance

Eliminates particulates and helps create ISO Class 4 environment

Facilitates ease of determining system status; optional remote pager sends indicator to operator outside the immediate vicinity of the robot

For operation, instructions, reporting and more

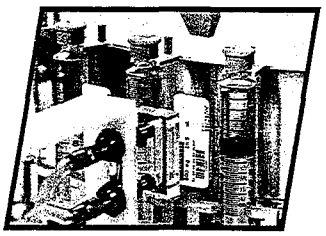


Optional

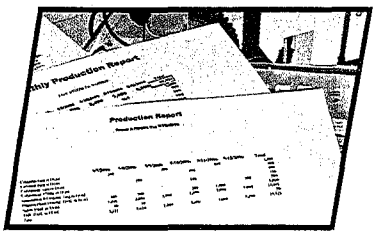
For high-throughput batch syringe production; conveyor is configurable for maximum use of optional, automated bagger

Provides numerous process controls and an ISO Class 4 environment

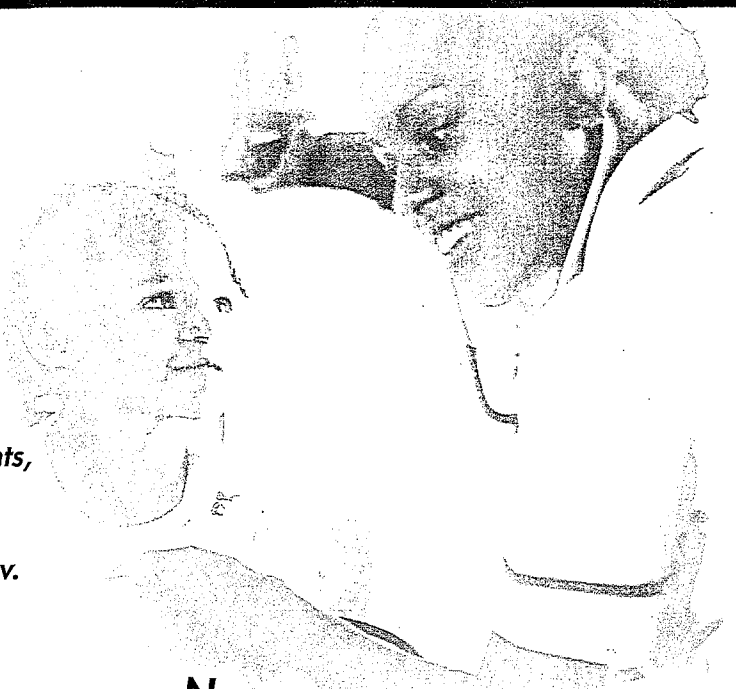
Stores 50 different types of drugs and multiple days inventory



Motivated to improve the safety of their patients, while continually focusing on their institution's financial well being, hospital decision-makers are choosing ForHealth Technologies' IntelliFill i.v. as a means of fulfilling their goals.



Because IntelliFill i.v. delivers a rare blend of cutting-edge technology with a proven track record, hospitals across the country recognize IntelliFill i.v. as the cornerstone of their i.v. admixture programs.



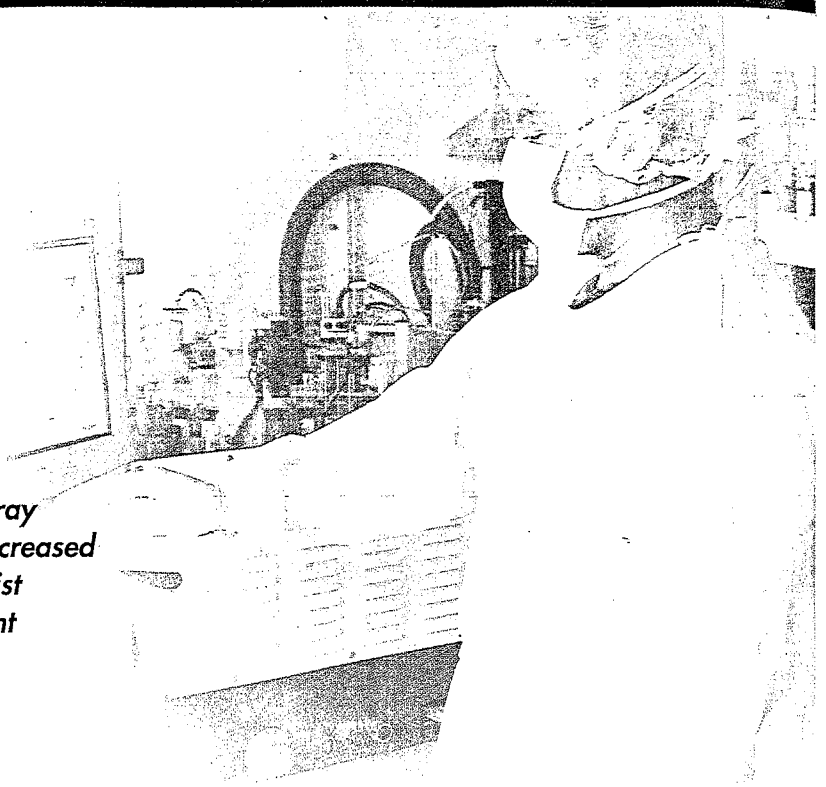
Nurses

Free to focus on what they do best – Patient Care

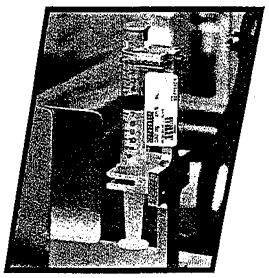
IntelliFill i.v. puts the preparation of injectable medications in the pharmacy, so nurses can spend their precious time caring for patients through direct interaction, assessment, and education.

With IntelliFill i.v. nurses receive ready-to-administer syringes, thereby facilitating consistency and cost-effectiveness with:

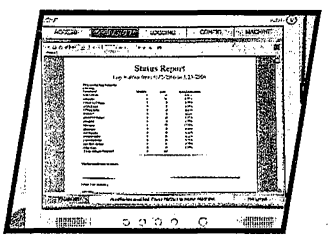
- Customized labeling of syringes, allowing the hospital to control information provided, type size, order of information and more
- Unobstructed views of syringe barrels for ease of verifying dosage-increment markings, medication color and precipitation
- Elimination of risks associated with decentralized preparation of flush and i.v.-push syringes (e.g., unlabeled syringes and sterility)
- Elimination of errors caused by failures to activate unreconstituted medication bags
- Enhanced control over the amount of fluid introduced to pediatric, critical-care and oncology patients



Healthcare providers face a daunting array of challenges – critical staff shortages, increased rates of patient acuity, an ever-growing list of new and complex medications, stringent regulatory standards and requirements, and intense pressure to control costs.



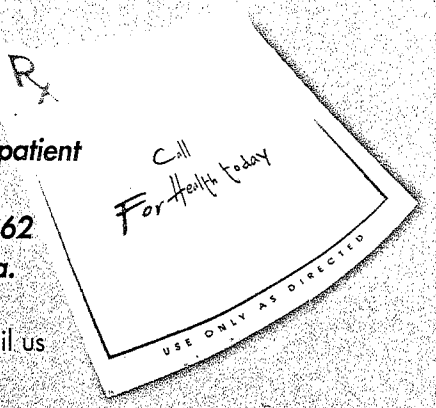
IntelliFill i.v. is the first robotic technology to automate i.v. compounding with speed and accuracy often not possible using manual processes.



IntelliFill i.v. facilitates the optimum union of human intelligence and robotic performance, thereby helping hospitals across the country realize:

- Patient safety and medication quality goals
- Reductions in the risks of touch contamination during i.v. compounding
- Significant medication-acquisition cost reductions
- Reduced medication inventories
- Increases in time pharmacists and nurses are able to devote to direct patient care and quality assurance activities

Founded in 1998, ForHealth Technologies is firmly committed to increasing patient safety and reducing operating costs by delivering innovative and reliable pharmacy automation and unmatched customer service.



Take the first step toward achieving your patient safety, operational and regulatory goals. Call ForHealth Technologies at 888-434-8462 and ask for the Sales Manager in your area.

Visit us at www.fhtinc.com. For information, email us at info@fhtinc.com

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