



ENFORCEMENT COMMITTEE REPORT

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I. ENFORCEMENT MATTERS

- a. Discussion on the Preemption of California's e-Pedigree Requirements, as Required by California Business and Professions Code Section 4034.1 and Enacted HR 3204, the Federal Drug Quality and Security Act**

Attachment 1

On November 27, 2013, President Obama signed HR 3204, establishing a track and trace system for the US. This legislation contains language that immediately upon enactment preempts any state's track and trace systems. This exemption is:

“SEC. 585. UNIFORM NATIONAL POLICY

“(a) PRODUCT TRACING AND OTHER REQUIREMENTS.

—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with—

“(1) any waiver, exception, or exemption pursuant to section 581 or 582; or

(2) any restrictions specified in section 582.

In California's Business and Professions Code section 4034.1, there are additional provisions that preempt California's e-pedigree requirements should federal legislation be enacted. The law also requires that the board post action about the inactivation of California's standards with section 4034.1. Specifically, the law provides that:

4034.1. Enactment of Federal Pedigree Legislation

- (a) (1) Upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative.
(2) Within 90 days of the enactment of federal legislation or adoption of a regulation addressing pedigree or serialization measures for dangerous drugs, the board shall publish a notice that Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 are inoperative.
(3) Within 90 days of the enactment of federal legislation or adoption of a regulation that is inconsistent with any provision of California law governing the application of any pedigree or serialization requirement or standard, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.
- (b) (1) If the Food and Drug Administration (FDA) enacts any rule, standard, or takes any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, that provision of California law shall be inoperative.
(2) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall publish a notice that the provision is inoperative.
(3) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.
- (c) If the board fails to recognize the inoperation within 90 days pursuant to this section, nothing in this section shall preclude a party from filing an action in state or federal court for declaratory or injunctive relief as an alternative to filing a petition with the board.

At this meeting

The committee should consider recommending specific action to the board regarding California's e-pedigree law:

1. To provide and publish a notice of preemption to the public
2. To seek a legislative repeal of California's provisions via 2014 proposed legislation
3. Stop the adoption of and withdraw pending regulations to implement California's e-pedigree requirements.

Proposal 1: Provide and publish a notice of preemption to the public:

The board's staff has developed the following notice regarding preemption of California's e-pedigree requirements.

Pursuant to Business and Professions Code section 4034.1, which provides in pertinent part that "[u]pon the effective date of federal legislation . . . addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163(c) – (g), 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative," and which requires that within 90 days of the enactment of such legislation the board publish a notice regarding the invalidation of these statutes, the California State Board of Pharmacy is hereby publishing notice that federal legislation meeting the requirements of section 4034.1 has been enacted, and that Business and Professions Code sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative as of November 27, 2013.

The board's staff proposes to publish this notice in the California Regulation Notice Registry, include in a subscriber alert, and post on the board's website as a notice. It will also be included in a newsletter article to be published in the next *The Script*.

Proposal 2: Seek legislative repeal of California's e-pedigree provisions via 2014 board-sponsored legislation:

To provide for clear understanding to licensees and the public about components in California law, inactive/preemptive sections of law should be removed so that California Pharmacy Law contains only sections of law that are in effect. As such staff recommends that the board sponsor legislation to remove the inactive/preempted provisions dealing with e-pedigree in California law. Proposed text to do this is provided as **Attachment 1**.

Proposal 3: Stop the adoption of and withdraw pending regulations to implement California's e-pedigree provisions

There are currently two noticed rulemakings in progress regarding implementation of e-pedigree requirements. The staff recommends that the board withdraw and or stop action on the following two rulemakings:

1. Pedigree Requirements – Unique Identifier; Identification of 50 Percent of Product Serialized for Sale in California; Grandfathering – Adoption of sections 1747 -1747.1

Status: Disapproved by the Office of Administrative Law received on October 31, 2013 (the disapproval would have been corrected via addition of documents to the rulemaking file for 15 days)

2. Drop Shipment, add section 1747.2 to Title 16 California Code of Regulations

Status: Regulation noticed for 45 days of public comment, hearing held 10/29/13

Board adopted: 10/29/13

Again, the staff recommends that the board withdraw and or stop action on the following two rulemakings

b. Discussion on Federal Legislation that Eliminated Licensure of Third Party Logistics Providers as Wholesalers, Pursuant to the Enacted HR 3204, the Federal Drug Quality and Security Act

Attachment 2

The federal legislation enacted to eliminate California's e-pedigree requirements also contained provisions to establish national standards for wholesalers and establish specialized regulation of third party logistics providers (3PLs). The new federal law requires the FDA to establish regulation provisions regarding national standards for wholesalers and 3PLs over the next one to two years. If a state does not regulate wholesalers and 3PLs, the national registration will be required.

California has regulated wholesalers for more than 25 years. In recent years, the board has regulated 3PLs as wholesalers, in fact, California law defines 3PLs as a subdivision of wholesalers – specifically:

4045. Third-Party Logistics Provider or Reverse Third-Party Logistics Provider

"Third-party logistics provider" or "reverse third-party logistic provider" means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.

The federal provisions which took effect November 27, 2013, however, prohibit the regulation of 3PLs as wholesalers (which is exactly what California's current law does).

Specifically: Section 585(b)(2)

“(b) WHOLESALE DISTRIBUTOR AND THIRD -PARTY LOGISTICS PROVIDER STANDARDS.—

“(1) IN GENERAL.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

“(2) STATE REGULATION OF THIRD-PARTY LOGISTICS PROVIDERS.—No State shall regulate third-party logistics providers as wholesale distributors.

Consequently effective November 27, 2013, neither the state nor federal government is requiring registration of 3PLs until the federal requirements are put in place. Since 3PLs are vital members of the supply chain who store, select and ship prescription drugs, staff suggest that legislation be pursued by this board to restore licensure of 3PLs as a separate category of licensee, but to include them in California Pharmacy law everywhere wholesalers are mentioned. Proposed legislation to do this is provided as **Attachment 2**.

**c. Update on Implementation of AB 1136 (Levine) Chapter 304, Statutes of 2013
Regarding Warning Labels on Prescription Container Labels**

Attachment 3

Background

Existing law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug (1.) if the drug poses a substantial risk to the person consuming the drug, when taken in combination with alcohol, or if the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and (2.) the drug is determined by the Board of Pharmacy to be a drug or drug type for which the warning shall be given.

Assembly Bill 1136 (Levine), signed by the Governor on September 9, 2013, amends existing law to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel. The required label may be printed on an auxiliary label that is affixed to the prescription container.

Section 1744 provided the specific classes of drugs which trigger a pharmacist's verbal or written notice to patients where a patient's ability to operate a vehicle may be impaired. Section 1744 is also provided in **Attachment 3**.

At this meeting

The committee should consider if given the recent changes to CA Business and Professions Code section 4074, if the list of medication classes in regulation section 1744 are still current.

**d. Request for Comments from the D.E.A. on the Possible Scheduling of Tramadol into
Federal Schedule IV**

Background

Tramadol was approved for marketing as a non-controlled analgesic in 1995 based on information related to its low potential for abuse and very weak narcotic effect. Recent

data, however, indicates that tramadol produces effects, including adverse, analgesic, and other effects, similar to opioids in Scheduled III and IV.

Because of inadequate labeling due to its non-controlled status and lack of established potential abuse, many physicians felt tramadol was safe to prescribe. As a result, it has become one of the most prescribed opioids in the United States and numerous reports have surfaced regarding its misuse, abuse, and diversion.

As a result, on November 4, 2013, the Drug Enforcement Administration (DEA) published a notice of proposed rulemaking (NPR) to place tramadol in Schedule IV of the Controlled Substances Act. If tramadol is placed in schedule IV, entities that handle it, by the effective date of the final rule, will be subject to registration, security, labeling, packaging, inventory, recordkeeping, reporting, prescription, and import and export requirements required for substances placed in Schedule IV. Written comments on the NPR were due earlier this month.

A copy of the comments submitted by Executive Officer Herold and Board President Weisser will be provided at the meeting.

e. Request from Sharp Healthcare for a Waiver of 16 California Code of Regulations Section 1713(d) to Permit Expanded Use of Automated Prescription Dispensing Machines

Attachment 4

Background

Several years ago, the board promulgated regulations (16 California Code of Regulation section 1713) to allow for the use of automated delivery devices, which are markedly like vending machines, to permit the furnishing of refill medication in specified circumstances, to include the requirement that the patient must opt in to use the machine and that the medication to be refilled through the machine is appropriate. [A copy of the regulation is included in **Attachment 4**. The relevant section of the regulation is in bold.]

In recent years, the board has received several requests to use automated delivery devices in a variety of settings including workplace clinics, hospital lobbies, other areas on a hospital campus, and in employment locations. During each of these discussions, several concerns have been raised about whether the request would comply with current regulations and whether the board had the authority to approve the request without specific regulatory changes. To date the board has not approved any waivers since enactment of the regulation.

At the June 2013 committee meeting, representatives from Asteres and Sharp Healthcare requested a revision to section 1713 to allow three separate pilot studies on the campuses of Sharp, UCSD Health System and USC Hospital to expand the use of automated delivery devices. At the July 2013 board meeting, Mr. Burgess, representing Asteres reminded the board that section 1713(b) already allows the delivery of prescriptions to employees at their worksite. An excerpt of the minutes of this meeting have been provided in **Attachment 4**.

Mr. Burgess proposed to revise section 1713(d)(6) to allow for the placement of automated devices in a secure building controlled by a Board licensee at an alternate location readily accessible for Board inspection, but not adjacent to a secure pharmacy area.

At this meeting:

During this meeting the committee will have an opportunity to hear a brief presentation from representatives from Asteres and Sharp HealthCare as well as their formal proposal to request a waiver of the provisions of Section 1713 for purposes of conducting a study with UCSD to determine if use of the technology improves medication adherence in the targeted audience.

Provided in **Attachment 4** is a copy of CCR section 1713, an excerpt from the July 2013 board meeting, along with documentation very recently submitted by Asteres: Experimental Program/Research Study Proposal, Initial IRB Review Application and slides that will be presented during this committee meeting.

f. Request from MedAvail for a Waiver of 16 California Code of Regulations Section 1713(d) to Permit Expanded Use of Automated Prescription Dispensing Machines

Attachment 5

Related to the prior agenda item, board staff also received a request from MedAvail to provide a presentation to the committee on its technology for automated dispensing. During the meeting, the committee will receive a brief presentation that will include the existing use of the technology and possible use in California.

Attachment 5 includes a letter from MedAvail the opportunity to make a presentation and a copy of the presentation that will be provided during this meeting. There has been no formal waiver request for the committee to discuss during this meeting. The presentation is for informational purposes only.

g. Requests from Sharp Healthcare and Scripps Health San Diego for a Waiver of California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, California Business and Professions Code Section 4128 et seq.

Attachment 6

Background

In 2012 the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are bar coded. The specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012). Included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read.

The board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have on the reduction of medication errors that occur in hospitals. Specifically, the board's letter to the governor included the following:

“...Bar coding is important for patient safety. Before a medication is administered to a patient, by scanning the bar code on a medication, a patient's chart and a patient's wristband – the right medication, in the right dose will be ensured at the patient's bedside. This provides an important step forward to improve patient safety and decrease the rate of medication errors and potential adverse drug events...”

Recently board staff was advised that Scripps Health San Diego has limitations in its software that prohibit full compliance with the barcode requirements specified in Section 4128.4. Scripps Health system is requesting that the board interpret the meaning of those provisions more broadly to allow additional time following licensure to fully comply with the requirements.

In preparing for this meeting, board staff conferred with counsel on the applicability of such a waiver given the specificity of the language in B&PC 4118. This request is being brought to the committee for consideration and to provide direction to staff on the waiver request as well as interpretation and application of B&PC 4118.

Attachment 6 includes a copy of the waiver request, Scripps Centralized Pharmacy Case Study, AB 377, the board's support letter on AB 377 and B&PC 4118.

h. Request from K. Scott Guess, Pharm.D., to Present his Proposal for Safe, Effective Dispensing of Controlled Substances

At this meeting:

Dr. K. Scott Guess requested the opportunity to appear before the Enforcement Committee to discuss his proposal for safe, effective dispensing of controlled substances.

Dr. Guess will attend this meeting and make a power point presentation.

II. COMPOUNDING MATTERS

a. Update on Implementation of New California Sterile Compounding Laws: Senate Bill 294 (Emmerson) and Assembly Bill 1045 (Quirk-Silva)

Attachment 7

Background

Last year the board sponsored legislation following two large-scale public health emergencies in which contaminated products compounded by two out-of-state pharmacies were shipped nationwide. Senator Emmerson authored SB 294 for the board.

Senate Bill 294 (Chapter 565, Statutes of 2013) strengthens the board's ability to regulate and monitor pharmacies that compound sterile drug products. This law prohibits a pharmacy from compounding or dispensing to patients in this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy license. Such licensure must follow a board-performed inspection. The law also eliminates accreditation by designated agencies as an alternative to board licensure.

Assembly Member Quirk-Silva authored AB 1045 (Chapter 302, Statutes of 2013) that amends existing California law to revoke a nonresident pharmacy's license by operation of law if its pharmacy license is suspended or revoked in the pharmacy's home state. It also requires resident and nonresident pharmacies that issue a recall notice regarding a sterile compounded drug to contact the recipient pharmacy, prescriber or patient of the recalled drug and the board within 12 hours of the recall notice.

Since enactment board staff has been taken steps to implement the provisions of both measures including both education of our licensees revisions to application and renewal forms and advocating for the necessary staff and training resources. Board staff estimates that about 612 sterile compounding pharmacies will require inspection prior to July 1, 2014 when enactment of these provisions takes effect so as to not create a drug shortage. In addition staff estimates another 150 site will require inspection before the end of the calendar year. Inspections will be conducted on a random, unannounced basis and.

Attachment 7 includes the current proposed sterile compounding application. The law requires every location where sterile compounding is preformed to be licensed as a sterile compounding pharmacy. In the case of a hospital, the board may need to issue several sterile compounding licenses if a centralized model is not used. In such cases, it is the staff's intent to only require a single hospital license and link each separate sterile compounding location to the main hospital's pharmacy license.

b. Discussion Regarding Extension of Board Approval of Accreditation Agencies for Sterile Injectable Compounding Pharmacies Until July 1, 2014

Relevant Statutes

Business and Professions Code Sections 4127 – 4127.8 provides for the regulation of pharmacies that compound sterile injectable drug products in a pharmacy. Pharmacy law currently creates an exemption from the licensure requirements for a pharmacy that is accredited by a private accreditation agency approved by the board (B&PC 4127.1 (d) and 4127.2 (c).) This exemption will be repealed July 1, 2014 when the provisions of SB 294 take effect.

Background

There are currently five accreditation agencies approved by the board. As a matter of process, the board approved such entities for a specified period to allow for periodic review. Approval of four entities will expire in February 2014 unless the board grants an extension. Below is a list of the entities whose approval is set to expire.

1. Accreditation Commission for Health Care, Inc (ACHC) – 66 sites accredited
2. Community Health Accreditation Program (CHAP) – 51 sites accredited
3. Pharmacy Compounding Accreditation Board (PCAB) – 24 sites accredited
4. American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) – 5 sites accredited

Pharmacies that are currently performing sterile injectable compounding and sought accreditation in lieu of licensure will need to secure licensure with the board in advance of July 1, 2014. However, because the board's current approval of the above accreditations agencies expires in February the board needs to consider an extension in the approval term to June 30, 2014. The 5th accreditation agency's approval will expire June 30, 2014.

At this meeting

The committee will need to determine if a limited extension is appropriate for each of the above agencies to allow pharmacies to continue to perform sterile injectable compounding until the provisions of SB 294 take effect. In the interim, board staff will be contacting all of the accredited pharmacies and encouraging early submission of applications for licensure with the board.

c. Discussion on Compounding Provisions Enacted by HR 3204, The Federal Drug Quality and Security Act

Attachment 8

Background

Included as part of the federal Drug Quality and Security Act (HR 3204) are provisions that establish provisions for federal regulation and oversight of large scale drug compounding by “outsourcing facilities.” The federal law sets forth voluntary requirements for licensure and enforcement.

At this meeting

During the meeting counsel will provide a high level overview of the sterile compounding requirements of this new law for informational purposes only. It is important to note that California’s law is more restrictive than the federal law in several areas.

California will continue to require any pharmacy that is compounding sterile products for California residents or practitioners to possess licensure with our board and comply with CA requirements.

Attachment 8 includes the relevant compounding sections of HR3204.

d. Recalls of Compounded Drugs Throughout the United States

Attachment 9

Attachment 9 includes subscriber alerts sent regarding the recall of compounded drugs.

III. MEETING DATES FOR 2014

Meeting dates for the remainder of 2014 have been provided below.

- March 27, 2014
- June 26, 2014
- September 30, 2014
- December 17, 2014

IV. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

The public will have the opportunity to request agenda items for future meetings. The committee may not discuss or take action on these items during this meeting.

Attachment 1

E-Pedigree – Inoperative Statutes

CHAPTER 9. Pharmacy	4000-4426
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ARTICLE 1. Administration	4000-4013
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ARTICLE 2. Definitions	4015-4045
4034. – Inoperative / Repeal (E-Pedigree)	
4034.1. – Repeal	
4163. – Inoperative / Repeal (E-Pedigree) Reenact subdivisions (a) and (b) as 4163(a) and (b)	
4163.1. – Inoperative / Repeal (E-Pedigree)	
4163.2. – Inoperative / Repeal (E-Pedigree)	
4163.3. – Repeal.	
4163.4. – Inoperative / Repeal (E-Pedigree)	
4163.5. – Inoperative / Repeal (E-Pedigree)	

4034. - REPEAL

~~4034. (a) “Pedigree” means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, repackagers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.~~

~~(b) A pedigree shall include all of the following information:~~

~~(1) The source of the dangerous drug, including the name, the federal manufacturer’s registration number or a state license number as determined by the board, and principal address of the source.~~

~~(2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.~~

~~(3) The business name, address, and the federal manufacturer’s registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.~~

~~(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.~~

E-Pedigree - Inoperative Statutes

~~(5) The unique identification number described in subdivision (i).~~

~~(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number. Dangerous drugs that are repackaged shall be serialized by the repackager and a pedigree shall be provided that references the pedigree of the original package or packages provided by the manufacturer.~~

~~(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler or repackager, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug. For purposes of this section, the "smallest package or immediate container" of a dangerous drug shall include any dangerous drug package or container made available to a repackager, wholesaler, pharmacy, or other entity for repackaging or redistribution, as well as the smallest unit made by the manufacturer for sale to the pharmacy or other person furnishing, administering, or dispensing the drug.~~

~~(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.~~

~~(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.~~

~~(g) The following transactions are exempt from the pedigree requirement created by this section:~~

~~(1) An intracompany sale or transfer of a dangerous drug. For purposes of this section, "intracompany sale or transfer" means any transaction for any valid business purpose between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of the same corporate or legal entity.~~

~~(2) Dangerous drugs received by the state or a local government entity from a department or agency of the federal government or an agent of the federal government specifically authorized to deliver dangerous drugs to the state or local government entity.~~

~~(3) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.~~

E-Pedigree – Inoperative Statutes

~~(4) (A) A sale, trade, or transfer of a radioactive drug, as defined in Section 1708.3 of Title 16 of the California Code of Regulations, between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, the federal Nuclear Regulatory Commission, or an Agreement state.~~

~~(B) The exemption in this paragraph shall remain in effect unless the board, no earlier than the date that is two years after the compliance date for manufacturers set forth in subdivision (k) of Section 4034 or Section 4163.5, determines after consultation with the Radiologic Health Branch of the State Department of Public Health that the risk of counterfeiting or diversion of a radioactive drug is sufficient to require a pedigree. Two years following the date of any such determination, this paragraph shall become inoperative.~~

~~(5) The sale, trade, or transfer of a dangerous drug that is labeled by the manufacturer as “for veterinary use only.”~~

~~(6) The sale, trade, or transfer of compressed medical gas. For purposes of this section, “compressed medical gas” means any substance in its gaseous or cryogenic liquid form that meets medical purity standards and has application in a medical or homecare environment, including, but not limited to, oxygen and nitrous oxide.~~

~~(7) The sale, trade, or transfer of solutions. For purposes of this section, “solutions” means any of the following:~~

~~(A) Those intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.~~

~~(B) Those intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.~~

~~(C) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.~~

~~(8) Dangerous drugs that are placed in a sealed package with a medical device or medical supplies at the point of first shipment into commerce by the manufacturer and the package remains sealed until the drug and device are used, provided that the package is only used for surgical purposes.~~

~~(9) A product that meets either of the following criteria:~~

E-Pedigree – Inoperative Statutes

(A) A product comprised of two or more regulated components, such as a drug/device, biologic/device, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.

(B) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products or device and biological products.

(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

(i) “Interoperable electronic system” as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture and supplemented by a linked unique identification number in the event that drug is repackaged, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, repackagers, and pharmacies for the pedigree of a dangerous drug. No particular data carrier or other technology is mandated to accomplish the attachment of the unique identification number described in this subdivision.

(j) The application of the pedigree requirement shall be subject to review during the board’s evaluation pursuant to Section 473.4.

(k) This section shall become operative on January 1, 2015.

4034.1. – Repeal

(a) (1) Upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative.

(2) Within 90 days of the enactment of federal legislation or adoption of a regulation addressing pedigree or serialization measures for dangerous drugs, the board shall publish a notice that Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 are inoperative.

(3) Within 90 days of the enactment of federal legislation or adoption of a regulation that is inconsistent with any provision of California law governing the application of any pedigree or

E-Pedigree – Inoperative Statutes

serialization requirement or standard, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

~~(b) (1) If the Food and Drug Administration (FDA) enacts any rule, standard, or takes any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, that provision of California law shall be inoperative.~~

~~(2) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall publish a notice that the provision is inoperative.~~

~~(3) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.~~

~~(c) If the board fails to recognize the inoperation within 90 days pursuant to this section, nothing in this section shall preclude a party from filing an action in state or federal court for declaratory or injunctive relief as an alternative to filing a petition with the board.~~

~~*(Added by Stats. 2008, Ch. 713, Sec. 3. Effective January 1, 2009.)*~~

4163. – REPEAL

~~(a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.~~

~~(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.~~

~~(c) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.~~

~~(d) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not acquire a dangerous drug without receiving a pedigree.~~

E-Pedigree – Inoperative Statutes

~~(e) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.~~

~~(f) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not acquire a dangerous drug without receiving a pedigree.~~

~~(g) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy warehouse may not acquire a dangerous drug without receiving a pedigree. For purposes of this section and Section 4034, a “pharmacy warehouse” means a physical location licensed as a wholesaler for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of those drugs to a group of pharmacies under common ownership and control. (Amended by Stats. 2008, Ch. 713, Sec. 8. Effective January 1, 2009. Conditionally inoperative as prescribed in subd. (a) of Section 4034.1.)~~

4163 Add:

(a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

4163.1. – REPEAL

~~It is the intent of the Legislature that commencing on January 1, 2007, and continuing through the full implementation of the pedigree requirements specified by Section 4163, manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer’s specific relationships in the distribution of dangerous drugs with wholesalers.~~

E-Pedigree – Inoperative Statutes

(Added by Stats. 2006, Ch. 658, Sec. 68. Effective January 1, 2007. See same-numbered section added by Stats. 2008, Ch. 713.)

4163.1. – **REPEAL**

~~(a) For purposes of Sections 4034 and 4163, “drop shipment” means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:~~

~~(1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.~~

~~(2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.~~

~~(3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.~~

~~(b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.~~

(Added by Stats. 2008, Ch. 713, Sec. 9. Effective January 1, 2009. Conditionally inoperative as prescribed in subd. (a) of Section 4034.1. See same-numbered section added by Stats. 2006, Ch. 658.)

4163.2. – **REPEAL**

~~(a) (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.~~

~~(2) The written declaration shall include the National Drug Code Directory lot number for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.~~

E-Pedigree – Inoperative Statutes

~~(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. Information contained in these declarations shall be considered trade secrets and kept confidential by the board.~~

~~(b) Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.~~

(Added by Stats. 2008, Ch. 713, Sec. 10. Effective January 1, 2009. Conditionally inoperative as prescribed in subd. (a) of Section 4034.1.)

4163.3. – *repeal*

~~(a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, third-party logistics providers or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.~~

~~(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.~~

~~(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.~~

~~(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.~~

~~(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.~~

(Added by Stats. 2008, Ch. 713, Sec. 11. Effective January 1, 2009.)

E-Pedigree – Inoperative Statutes

4163.4. – REPEAL

~~(a) All units of dangerous drug in the possession of a wholesaler or pharmacy, for which the manufacturer does not hold legal title on the effective date of the pedigree requirement set forth in Section 4163.5, shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163. However, if any units of those drugs are subsequently returned to the manufacturer, they shall be subject to the pedigree requirements if the manufacturer distributes those units in California.~~

~~(b) All units of dangerous drug manufactured in California but distributed outside the state for dispensing outside the state shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163 at either the time of initial distribution or in the event that any of those units are subsequently returned to the manufacturer.~~

(Added by Stats. 2008, Ch. 713, Sec. 12. Effective January 1, 2009. Conditionally inoperative as prescribed in subd. (a) of Section 4034.1.)

4163.5. – REPEAL

~~(a) The Legislature hereby finds and declares that:~~

~~(1) The electronic pedigree system required by Sections 4034 and 4163 will provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end, all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.~~

~~(2) At the same time, it is recognized that the process of implementing serialized electronic pedigree for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, repackagers, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while participants implement these requirements.~~

~~(b) Before January 1, 2015, each manufacturer of a dangerous drug distributed in California shall designate those dangerous drugs representing a minimum of 50 percent of its drugs, generic or~~

E-Pedigree – Inoperative Statutes

~~single source, distributed in California, for which it is listed as the manufacturer by the federal Food and Drug Administration, which shall be the subject of its initial phase of compliance with the January 1, 2015, deadline of the state’s serialized electronic pedigree requirements set forth in Sections 4034 and 4163. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.~~

~~(c) Before January 1, 2016, each manufacturer of a dangerous drug distributed in California shall designate the final 50 percent of its drugs, generic or single source, distributed in California for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the state’s serialized electronic pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state’s serialized electronic pedigree requirement by January 1, 2016. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.~~

~~(d) For purposes of designating drugs to be serialized as required by subdivisions (b) and (c), manufacturers shall select from any of the following measures:~~

~~(1) Unit volume.~~

~~(2) Product package (SKU) type.~~

~~(3) Drug product family.~~

~~(e) Drugs not subject to compliance with the pedigree requirements set forth in Sections 4034 and 4163 under this section shall not be subject to the provisions of subdivisions (c), (d), (e), and (f) of Section 4163.~~

Attachment 2

3PL Oversight – Discussion Draft

ARTICLE 2. Definitions [4015 - 4045]

4022.5.

(a) “Designated representative” means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.

(b) “Designated representative-in-charge” means a designated representative or a pharmacist proposed by a ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the ~~wholesaler’s~~ wholesaler’s, third-party logistics provider’s or veterinary food-animal drug retailer’s compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

4040.5.

“Reverse distributor” means every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsalable dangerous drugs.

4043.

(a) “Wholesaler” means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

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

4045.

“Third-party logistics provider” or “reverse third-party logistic provider” means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which

3PL Oversight – Discussion Draft

there is no change of ownership in the dangerous drugs. For purposes of ~~Sections~~ Section 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.

Article 3. Scope of Practice and Exemptions. References to Wholesaler , designated rep, or pedigree:

4053. – Licensure of Designated Reps

(a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, warehousing, distribution and shipment of dangerous drugs and dangerous devices in the ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer.

(b) An individual that is at least 18 years of age may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development certificate equivalent.

(2) He or she shall have a minimum of one year of paid work experience in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

3PL Oversight – Discussion Draft

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages, and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

4060.

No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to either Section 4052.1 or 4052.2. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, third-party logistics provider, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer. Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

4066. – *WLS furnishing to first officer of a vessel*

(a) Notwithstanding Section 4059, a wholesaler or pharmacy may furnish dangerous drugs to the master or first officer of an ocean vessel, pursuant to a written prescription. The requisition shall

3PL Oversight – Discussion Draft

be on the vessel's official stationery, signed by the vessel's first officer. The drugs shall be maintained on board the vessel and dispensed from medicine chests, first aid packets, or dispensaries, pursuant to standardized procedures established by a registered medical officer.

(b) Dangerous drugs shall be furnished in a sealed container to the vessel's first officer, on proper identification, or delivered aboard the vessel.

(c) Wholesalers or pharmacies engaging in the activities authorized by this section shall give notice to the board within 30 days of undertaking the activity.

(d) Distribution of controlled substances shall be in accordance with federal requirements contained in Section 1301.28 of Title 21 of the Code of Federal Regulations.

Article 5 – Authority of Inspectors (Sections 4080-4086)

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, third-party logistics provider, 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.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider 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) The pharmacist-in-charge or designated 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 designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

3PL Oversight – Discussion Draft

Article 6. General Requirements (Sections 4100 – 4107)

4101.

(a) A pharmacist may take charge of and act as the pharmacist-in-charge of a pharmacy upon application by the pharmacy and approval by the board. Any pharmacist-in-charge who ceases to act as the pharmacist-in-charge of the pharmacy shall notify the board in writing within 30 days of the date of that change in status.

(b) A designated representative or a pharmacist may take charge of, and act as, the designated representative-in-charge of a ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer upon application by the ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer and approval by the board. Any designated representative-in-charge who ceases to act as the designated representative-in-charge at that entity shall notify the board in writing within 30 days of the date of that change in status.

4105.

(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug ~~retailer~~ retailer, wholesaler or ~~wholesaler~~ wholesaler, third-party logistics provider, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

3PL Oversight – Discussion Draft

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board’s authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

Article 7. Pharmacies (Sections 4110 – 4126.5)

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 or third-party logistics provider 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.

3PL Oversight – Discussion Draft

4126. [amend as below]

(d) A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license, or both a pharmacy and a third-party logistics provider license.

4126.

(a) Notwithstanding any other provision of law, a covered entity may contract with a pharmacy to provide pharmacy services to patients of the covered entity, as defined in Section 256b of Title 42 of the United States Code, including dispensing preferentially priced drugs obtained pursuant to Section 256b of Title 42 of the United States Code. Contracts between those covered entities and pharmacies shall comply with guidelines published by the Health Resources and Services Administration and shall be available for inspection by board staff during normal business hours.

(b) Drugs purchased pursuant to Section 256b of Title 42 of the United States Code and received by a pharmacy shall be segregated from the pharmacy's other drug stock by either physical or electronic means. All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records.

(c) Drugs obtained by a pharmacy to be dispensed to patients of a covered entity pursuant to Section 256b of Title 42 of the United States Code that cannot be distributed because of a change in circumstances for the covered entity or the pharmacy shall be returned to the distributor from which they were obtained. For the purposes of this section, a change in circumstances includes, but is not limited to, the termination or expiration of the contract between the pharmacy and the covered entity, the closure of a pharmacy, disciplinary action against the pharmacy, or closure of the covered entity.

(d) A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license, or both a pharmacy and a third-party logistics provider license.

3PL Oversight – Discussion Draft

(e) Neither a covered entity nor a pharmacy shall be required to obtain a license as a wholesaler or a third-party logistics provider based on acts reasonably necessary to fully participate in the drug purchase program established by Section 256b of Title 42 of the United States Code.

ARTICLE 11. ~~Wholesalers and Manufacturers~~ Wholesalers, Third-Party Logistics Providers and Manufacturers [4160 - 4169]

(Article 11 added by Stats. 1996, Ch. 890, Sec. 3.)

4160.

(a) A person may not act as a wholesaler or third party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a ~~wholesaler~~ wholesaler or third-party logistics provider. Each license shall be renewed annually and shall not be transferable.

(d) Every wholesaler or third party logistics provider shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's or third party logistics provider's compliance with state and federal laws governing ~~wholesalers.~~ wholesalers or third party logistics providers. As part of its initial application for a license, and for each renewal, each wholesaler or third party logistics provider shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license or third party logistics provider license without identification of an approved designated representative-in-charge for the ~~wholesaler.~~ wholesaler or third-party logistics provider.

(e) Every wholesaler or third party logistics provider shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to

3PL Oversight – Discussion Draft

approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(f) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(g) The board may issue a **temporary license**, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (f) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license. *(Amended by Stats. 2009, Ch. 307, Sec. 42. Effective January 1, 2010.)*

4161. – Add Nonresident 3PL provisions

(a) A person located outside this state that (1) ships, sells, mails, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, selling, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, or distributing dangerous drugs or devices within this state.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, or delivered to a site located in this state or sold, brokered, or distributed within this state. A license shall be renewed annually and shall not be transferable.

3PL Oversight – Discussion Draft

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler shall comply with all 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.

(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state or within this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars (\$550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a

3PL Oversight – Discussion Draft

temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(Amended by Stats. 2009, Ch. 308, Sec. 54. Effective January 1, 2010.)

4162.

(a) (1) An applicant, that is not a government owned and operated third-party logistics provider or wholesaler, for the issuance or renewal of a third-party logistics provider or wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the wholesaler or third-party logistics provider is ten million dollars (\$10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a third-party logistics provider or wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2) or (3), the board may require a bond up to one hundred thousand dollars (\$100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

3PL Oversight – Discussion Draft

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

4162.5. – Surety bonds for nonresident wholesalers – also for nonresident 3PLs = YES

(a) (1) An applicant for the issuance or renewal of a nonresident third-party logistics provider or wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the nonresident third-party logistics provider or wholesaler is ten million dollars (\$10,000,000) or less in which the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars (\$100,000) for any nonresident third-party logistics provider or wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident third-party logistics provider or wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

3PL Oversight – Discussion Draft

4164. – *Reporting sales of dangerous drugs and controlled substances*

(a) A wholesaler licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

(b) Each wholesaler shall develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. The system shall be capable of identifying purchases of any dangerous drug at preferential or contract prices by customers that vary significantly from prior ordering patterns for the same customer, including by identifying purchases in the preceding 12 calendar months by that customer or similar customers and identifying current purchases that exceed prior purchases by either that customer or similar customers by a factor of 20 percent. Each wholesaler shall have the tracking system required by this subdivision in place no later than January 1, 2006.

(c) Upon written, oral, or electronic request by the board, a wholesaler shall furnish data tracked pursuant to subdivision (b) to the board in written, hardcopy, or electronic form. The board shall specify the dangerous drugs, the customers, or both the dangerous drugs and customers for which data are to be furnished, and the wholesaler shall have 30 calendar days to comply with the request.

(d) As used in this section, “preferential or contract prices” means and refers to purchases by contract of dangerous drugs at prices below the market wholesale price for those drugs.

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

4165. – *Requirement to furnish the board with records upon request*

A wholesaler or third-party logistics provider licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.

(Amended by Stats. 2004, Ch. 857, Sec. 36. Effective January 1, 2005.)

3PL Oversight – Discussion Draft

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section ~~or of subdivision (c) or (d) of Section 4163~~ may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

Article 16 – Applications (Sections 4200 – 4209)

4201.

(a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) As used in this section, and subject to subdivision (c), the term “person beneficially interested” means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(c) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or

3PL Oversight – Discussion Draft

stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, third-party logistics provider or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, third-party logistics provider or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(f) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(g) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(h) Notwithstanding any other provision of law, the third-party logistics provider license shall authorize the holder to provide or coordinate warehousing, distribution or other similar services of dangerous drugs and devices. The license shall be renewed annually and shall not be transferable.

~~(h)~~ (i) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

~~(i)~~ (j) For licenses referred to in subdivisions (f), (g), ~~(h)~~ and ~~(i)~~, any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

3PL Oversight – Discussion Draft

(j) ~~This section shall become operative on July 1, 2001.~~

Article 19 – Disciplinary Proceedings (Sections 4300-4315)

Section 4301 – Amend to include 3PLs to Unprofessional Conduct

4305.5. – *Operating without a DRIC / grounds for discipline*

(a) A person who has obtained a license to conduct a ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of the designated representative-in-charge. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) A person who has obtained a license to conduct a ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of the designated representative-in-charge, and who continues to operate the licensee in the absence of the designated representative-in-charge for that location, shall be subject to summary suspension or revocation of his or her license to conduct a ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer.

(c) A designated representative-in-charge of a ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

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

4312. – *Cancel or Void a license*

(a) The board may cancel the license of a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall

3PL Oversight – Discussion Draft

file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) In the event that the license of a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer is cancelled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer is located, authorizing the board to enter the wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer.

(d) In the event that the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage

3PL Oversight – Discussion Draft

prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, “closed” means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

Article 20 – Prohibitions and Offenses (Sections 4320-4343)

4331.

(a) A person who is neither a pharmacist nor a designated representative and who takes charge of a third-party logistics provider, wholesaler or veterinary food-animal drug retailer or who coordinates the warehousing or distribution of dangerous drugs or devices, dispenses a prescription or furnishes dangerous devices except as otherwise provided in this chapter is guilty of a misdemeanor.

(b) A person who has obtained a license to conduct a veterinary food-animal drug retailer and who fails to place in charge of that veterinary food-animal drug retailer a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) A person who has obtained a license to conduct a wholesaler or third-party logistics provider and who fails to place in charge of that wholesaler or third-party logistics provider a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

3PL Oversight – Discussion Draft

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

Article 23 – Revenue and Renewal = Add references to 3PLs. Same license fee, nonresident 3PL license, temporary license fee, and DRIC fees as for a WLS or nonresident WLS

4400.

The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).

(d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(f) The fee for a **nongovernmental wholesaler** license and annual renewal shall be six hundred dollars (\$600), and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).

(h) (1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

3PL Oversight – Discussion Draft

(2) The fee for the annual renewal of a license as a **designated representative** shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(l) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

3PL Oversight – Discussion Draft

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(u) The fee for issuance or renewal of a nongovernmental license to compound sterile drug products shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

HR 3204

1 **SEC. 205. NATIONAL STANDARDS FOR THIRD-PARTY LOGIS-**
2 **TICS PROVIDERS; UNIFORM NATIONAL POL-**
3 **ICY.**

4 Subchapter H of chapter V, as amended by section
5 204, is further amended by adding at the end the fol-
6 lowing:

7 **“SEC. 584. NATIONAL STANDARDS FOR THIRD-PARTY LO-**
8 **GISTICS PROVIDERS.**

9 “(a) **REQUIREMENTS.**—No third-party logistics pro-
10 vider in any State may conduct activities in any State un-
11 less each facility of such third-party logistics provider—

12 “(1)(A) is licensed by the State from which the
13 drug is distributed by the third-party logistics pro-
14 vider, in accordance with the regulations promul-
15 gated under subsection (d); or

16 “(B) if the State from which the drug distrib-
17 uted by the third-party logistics provider has not es-
18 tablished a licensure requirement, is licensed by the
19 Secretary, in accordance with the regulations pro-
20 mulgated under subsection (d); and

21 “(2) if the drug is distributed interstate, is li-
22 censed by the State into which the drug is distrib-
23 uted by the third-party logistics provider if such
24 State licenses third-party logistics providers that dis-
25 tribute drugs into the State and the third-party lo-

1 logistics provider is not licensed by the Secretary as
2 described in paragraph (1)(B).

3 “(b) REPORTING.—Beginning 1 year after the date
4 of enactment of the Drug Supply Chain Security Act, a
5 facility of a third-party logistics provider shall report to
6 the Secretary, on an annual basis pursuant to a schedule
7 determined by the Secretary—

8 “(1) the State by which the facility is licensed
9 and the appropriate identification number of such li-
10 cense; and

11 “(2) the name and address of the facility and
12 all trade names under which such facility conducts
13 business.

14 “(c) COSTS.—

15 “(1) AUTHORIZED FEES OF SECRETARY.—If a
16 State does not establish a licensing program for a
17 third-party logistics provider, the Secretary shall li-
18 cense the third-party logistics provider located in
19 such State and may collect a reasonable fee in such
20 amount necessary to reimburse the Secretary for
21 costs associated with establishing and administering
22 the licensure program and conducting periodic in-
23 spections under this section. The Secretary shall ad-
24 just fee rates as needed on an annual basis to gen-
25 erate only the amount of revenue needed to perform

1 this service. Fees authorized under this paragraph
2 shall be collected and available for obligation only to
3 the extent and in the amount provided in advance in
4 appropriations Acts. Such fees are authorized to re-
5 main available until expended. Such sums as may be
6 necessary may be transferred from the Food and
7 Drug Administration salaries and expenses appro-
8 priation account without fiscal year limitation to
9 such appropriation account for salaries and expenses
10 with such fiscal year limitation.

11 “(2) STATE LICENSING FEES.—

12 “(A) STATE ESTABLISHED PROGRAM.—

13 Nothing in this Act shall prohibit a State that
14 has established a program to license a third-
15 party logistics provider from collecting fees
16 from a third-party logistics provider for such a
17 license.

18 “(B) NO STATE ESTABLISHED PRO-

19 GRAM.—A State that does not establish a pro-
20 gram to license a third-party logistics provider
21 in accordance with this section shall be prohib-
22 ited from collecting a State licensing fee from
23 a third-party logistics provider.

24 “(d) REGULATIONS.—

1 “(1) IN GENERAL.—Not later than 2 years
2 after the date of enactment of the Drug Supply
3 Chain Security Act, the Secretary shall issue regula-
4 tions regarding the standards for licensing under
5 subsection (a), including the revocation and
6 reissuance of such license, to third-party logistics
7 providers under this section.

8 “(2) CONTENT.—Such regulations shall—

9 “(A) establish a process by which a third-
10 party accreditation program approved by the
11 Secretary shall, upon request by a third-party
12 logistics provider, issue a license to each third-
13 party logistics provider that meets the require-
14 ments set forth in this section;

15 “(B) establish a process by which the Sec-
16 retary shall issue a license to each third-party
17 logistics provider that meets the requirements
18 set forth in this section if the Secretary is not
19 able to approve a third-party accreditation pro-
20 gram because no such program meets the Sec-
21 retary’s requirements necessary for approval of
22 such a third-party accreditation program;

23 “(C) require that the entity complies with
24 storage practices, as determined by the Sec-
25 retary for such facility, including—

1 “(i) maintaining access to warehouse
2 space of suitable size to facilitate safe op-
3 erations, including a suitable area to quar-
4 antine suspect product;

5 “(ii) maintaining adequate security;
6 and

7 “(iii) having written policies and pro-
8 cedures to—

9 “(I) address receipt, security,
10 storage, inventory, shipment, and dis-
11 tribution of a product;

12 “(II) identify, record, and report
13 confirmed losses or thefts in the
14 United States;

15 “(III) correct errors and inac-
16 curacies in inventories;

17 “(IV) provide support for manu-
18 facturer recalls;

19 “(V) prepare for, protect against,
20 and address any reasonably foresee-
21 able crisis that affects security or op-
22 eration at the facility, such as a
23 strike, fire, or flood;

24 “(VI) ensure that any expired
25 product is segregated from other

1 products and returned to the manu-
2 facturer or repackager or destroyed;

3 “(VII) maintain the capability to
4 trace the receipt and outbound dis-
5 tribution of a product, and supplies
6 and records of inventory; and

7 “(VIII) quarantine or destroy a
8 suspect product if directed to do so by
9 the respective manufacturer, wholesale
10 distributor, dispenser, or an author-
11 ized government agency;

12 “(D) provide for periodic inspection by the
13 licensing authority, as determined by the Sec-
14 retary, of such facility warehouse space to en-
15 sure compliance with this section;

16 “(E) prohibit a facility from having as a
17 manager or designated representative anyone
18 convicted of any felony violation of subsection
19 (i) or (k) of section 301 or any violation of sec-
20 tion 1365 of title 18, United States Code relat-
21 ing to product tampering;

22 “(F) provide for mandatory background
23 checks of a facility manager or a designated
24 representative of such manager;

1 “(G) require a third-party logistics pro-
2 vider to provide the applicable licensing author-
3 ity, upon a request by such authority, a list of
4 all product manufacturers, wholesale distribu-
5 tors, and dispensers for whom the third-party
6 logistics provider provides services at such facil-
7 ity; and

8 “(H) include procedures under which any
9 third-party logistics provider license—

10 “(i) expires on the date that is 3
11 years after issuance of the license; and

12 “(ii) may be renewed for additional 3-
13 year periods.

14 “(3) PROCEDURE.—In promulgating the regula-
15 tions under this subsection, the Secretary shall, not-
16 withstanding section 553 of title 5, United States
17 Code—

18 “(A) issue a notice of proposed rulemaking
19 that includes a copy of the proposed regulation;

20 “(B) provide a period of not less than 60
21 days for comments on the proposed regulation;
22 and

23 “(C) provide that the final regulation takes
24 effect upon the expiration of 1 year after the
25 date that such final regulation is issued.

1 “(e) VALIDITY.—A license issued under this section
2 shall remain valid as long as such third-party logistics pro-
3 vider remains licensed consistent with this section. If the
4 Secretary finds that the third-party accreditation program
5 demonstrates that all applicable requirements for licensure
6 under this section are met, the Secretary shall issue a li-
7 cense under this section to a third-party logistics provider
8 receiving accreditation, pursuant to subsection (d)(2)(A).

9 **“SEC. 585. UNIFORM NATIONAL POLICY.**

10 “(a) PRODUCT TRACING AND OTHER REQUIRE-
11 MENTS.—Beginning on the date of enactment of the Drug
12 Supply Chain Security Act, no State or political subdivi-
13 sion of a State may establish or continue in effect any
14 requirements for tracing products through the distribution
15 system (including any requirements with respect to state-
16 ments of distribution history, transaction history, trans-
17 action information, or transaction statement of a product
18 as such product changes ownership in the supply chain,
19 or verification, investigation, disposition, notification, or
20 recordkeeping relating to such systems, including paper or
21 electronic pedigree systems or for tracking and tracing
22 drugs throughout the distribution system) which are in-
23 consistent with, more stringent than, or in addition to, any
24 requirements applicable under section 503(e) (as amended

Attachment 3

Assembly Bill No. 1136

CHAPTER 304

An act to amend Section 4074 of the Business and Professions Code, relating to pharmacy.

[Approved by Governor September 9, 2013. Filed with Secretary of State September 9, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1136, Levine. Pharmacists: drug disclosures.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if a prescription drug poses a substantial risk to the person consuming the drug when taken in combination with alcohol or if the drug may impair a person's ability to drive a motor vehicle. This requirement applies when the board determines that the drug is a drug or drug type for which this warning shall be given. A violation of the Pharmacy Law is a crime.

This bill would additionally require, on and after July 1, 2014, a pharmacist to include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel if the pharmacist, in exercising his or her professional judgment, determines that the drug may impair a person's ability to operate a vehicle or vessel, as specified. Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program.

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

This bill would provide that no reimbursement is required by this act for a specified reason.

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

SECTION 1. Section 4074 of the Business and Professions Code is amended to read:

4074. (a) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if both of the following apply:

(1) The drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or the drug may impair a person's ability to drive a motor vehicle, whichever is applicable.

(2) The drug is determined by the board pursuant to subdivision (c) to be a drug or drug type for which this warning shall be given.

(b) In addition to the requirement described in subdivision (a), on and after July 1, 2014, if a pharmacist exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label required by this subdivision may be printed on an auxiliary label that is affixed to the prescription container.

(c) The board may by regulation require additional information or labeling.

(d) This section shall not apply to a drug furnished to a patient in conjunction with treatment or emergency services provided in a health facility or, except as provided in subdivision (e), to a drug furnished to a patient pursuant to subdivision (a) of Section 4056.

(e) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each drug given at the time of discharge and each drug given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other law shall be construed to require that only a pharmacist provide this consultation.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

CCR 1744

1744. Drug Warnings.

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) The following classes of drugs may impair a person's ability to drive a motor vehicle or operate machinery when taken alone or in combination with alcohol:

- (1) Muscle relaxants.
- (2) Analgesics with central nervous system depressant effects.
- (3) Antipsychotic drugs including phenothiazines.
- (4) Antidepressants.
- (5) Antihistamines, motion sickness agents, antipruritics, anti-nauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (6) All Schedule II, III, IV and V depressant or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.
- (7) Anticholinergic agents and other drugs which may impair vision.

(b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle.

- (1) Disulfiram and other drugs (e.g. chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
- (2) Mono amine oxidase inhibitors.
- (3) Nitrates.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022, 4055 and 4074, Business and Professions Code.

Attachment 4

1713 Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Initial IRB



Institutional Review Board
 8695 Spectrum Center Blvd
 San Diego, CA 92123
 (858) 499-4836 (phone) / (858) 499-3105 (fax)
<http://sharpnet/irb/> / www.sharp.com/research
 E-mail: research@sharp.com

For IRB Staff Use Only:
 IRB #: _____
 Principal Investigator: _____
 Meeting Agenda Date: _____
 Section: _____
 Date Submission Received: _____

INITIAL IRB REVIEW APPLICATION

Sponsor's protocol number (if applicable):	Sponsor's Name (if applicable):
Title (or Humanitarian Use Device name): Experimental Program/Research Study on Automated Delivery Systems (Asteres ScriptCenter Kiosk) in a Licensed Facility for Employee Prescriptions	
Indication: Other If "Other", Specify: Automated Delivery System at Sharp Memorial Hospital	

Local Investigative Site Information

Indicate local sites where subject recruitment, enrollment, and other activities will occur:

- | | | |
|--|---|---|
| <input type="checkbox"/> Coronado | <input type="checkbox"/> Mary Birch | <input type="checkbox"/> California Institute of Renal Research |
| <input type="checkbox"/> Chula Vista | <input checked="" type="checkbox"/> Memorial / OPP | <input type="checkbox"/> eStudySite |
| <input type="checkbox"/> Grossmont | <input type="checkbox"/> Mesa Vista | <input type="checkbox"/> San Diego Cardiac Center |
| <input checked="" type="checkbox"/> Rees-Stealy | | |
| <input type="checkbox"/> Medical Oncology Associates - San Diego | <input type="checkbox"/> Cancer Center Oncology Medical Group | |
| <input type="checkbox"/> South County Hematology/Oncology | <input type="checkbox"/> North County Oncology Medical Clinic, Inc. | |

Other – **Only complete the information below for local sites that are not selected above.** If more than one site is "Other," submit a separate sheet answering the questions below for each site listed. Complete the following only for sites listed as "Other".

Name of Study Location:
 Address: (street, city, state, postal code)

What type of facility is this site?
 If Other, specify: _____

What resources are available at this site to treat emergencies resulting from activity-related procedures? (check all that apply):

- ACLS trained personnel and crash cart
- Emergency drugs and supplies to stabilize subject until emergency personnel arrive
- Emergency response team within hospital
- Other - Specify: _____
- N/A

If your site is not a hospital, name the medical facility to be used in an emergency: _____ Or N/A

Does the PI or a sub-investigator have staff privileges at the facility to be used in an emergency?

Yes N/A

No (explain each of the following):

How will subjects be referred for hospitalization? _____ Or N/A

Have you made arrangements for a physician to attend to patients in an emergency? Yes No N/A

Have you taken measures to assure that attending physician(s) will communicate with the PI? Yes No N/A

Site Personnel

Submit each of the following for **all site personnel** listed on this application:

Completed, signed, dated Financial Disclosure Statements (FDS) (*sponsored activities only*)

Current Curriculum Vitae (CV) or resume (*if not previously submitted*)

Copy of current Medical License (*if not previously submitted*)

NIH training completion certificate or other research subject protection training program certificate (*to be completed within the past 24 months*)

Completed Demographic Form (DE) (*if not previously submitted or if person's information has changed*)

Has/have your site(s) and/or any site personnel been audited by the FDA, OHRP, sponsor, CRO and/or any other regulatory agencies?

Yes No

Has/have your site(s) and/or site personnel received a Form FDA 483, Warning Letter, and/or any other notification of regulatory issues?

Yes No

Have there been any professional disciplinary or legal actions involving your site(s) and/or site personnel?

Yes No

If yes to any of the above, provide copies of **all Form FDA 483s and/or correspondence** with application materials.

Attached Previously submitted (*The IRB may ask for additional information.*)

Principal Investigator (PI) Information

First Name: Sheila	Last Name: Alignay- Rivera	Degree: PharmD
If the PI is a student, resident or fellow, identify the site personnel responsible for oversight of PI:		
Is the PI a member of the Sharp HealthCare (SHC) Medical Staff or a SHC employee**?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>	
Specialty:	Pharmacy	
Company:	Sharp Rees Stealy Pharmacy	
Mailing Address:	2929 Health Center Drive	
City, State, Zip	San Diego, CA 92123	
E-mail address: sheila.rivera@sharp.com	Phone: 858.939.6586	Fax: 858.636.2999

Study Coordinator Information (*Will be primary contact for this activity.*)

Is there a designated study coordinator (other than the PI) for this activity?

No Yes - Complete the following:

First Name: Sheila	Last Name: Alignay-Rivera	Degree: PharmD
Is coordinator a member of the SHC Medical Staff or a SHC employee**?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
Specialty:	Pharmacy	
Company:	Sharp Rees Stealy Pharmacy	
Mailing Address:	2929 Health Center Drive	
City, State, Zip	San Diego, CA 92123	
E-mail address: sheila.rivera@sharp.com	Phone: 858-939-6586	Fax: 858-636-2999

Site Personnel

<u>First Name</u>	<u>Last Name</u>	<u>Degree</u>	<u>Role</u>	<u>SHC Medical Staff member or Employee? **</u>
-------------------	------------------	---------------	-------------	---

- b. Is there a CRO? No Yes Name: _____
- c. Does the Sponsor/CRO agree to cover subjects' costs for research related injuries?
 No Yes – Include in contract and consent.
- d. Does the Sponsor/CRO allow the Investigators to freely publish study results?
 Yes No - If no, describe any restrictions: _____
- e. ClinicalTrials.gov Identifier: _____ N/A - Sponsor's rationale: _____

Federally funded Research

Federal Agency: _____

Cooperative Group: _____ Or N/A

Foundation (*specify*):

Sharp HealthCare Foundation

Coronado Hospital Foundation

Grossmont Hospital Foundation

NOTE: If any one of the above is selected, the activity is considered "Sponsored" and individual FDS forms are required. Grant-funded activities also require individual FDS forms. In most cases, the selections below do not require Financial Disclosure Statements.

If none of the above, check all that apply below:

Investigator Initiated

Department Funded (*specify*): _____

No Support Required

Other: _____

Review Fees – Send check payable to Sharp HealthCare IRB to the address on page one of this application.

Initial Full Committee Review	\$3,000 (IRB and entity Administrative review)
Initial Expedited Review	\$1,000 (IRB and entity Administrative review)
Initial Humanitarian Use Device Review	\$1,000 (IRB and entity Administrative review)
System Antibiotic Review Committee Review	\$500 (SARC review fee is in addition to IRB and administrative review fees)

If internal Sharp HealthCare research site, provide SHC cost center number: _____

IRB and administrative review fees may be waived for unfunded research.

Site Personnel Financial Disclosure Statement

Is this sponsored research?

No - Skip to "Summary of Research Activity" section.

Yes - If any site personnel responded "Yes" to the corresponding questions on their individual FDS, select "Yes" below.

Financial Compensation from or Management Responsibilities in Related Businesses

No Yes

Equity Interest in Related Businesses

No Yes

Intellectual Property and Related Businesses

No Yes

Executive Relationship

No Yes

Business Ownership

No Yes

Other Relevant Financial Interests

No Yes

Summary of Research Activity

Is summary available in protocol, research narrative or study/project plan?

Yes – Page numbers _____ - Skip to “Expense to Subjects” and “Compensation to Subjects” sections.

No - Complete all Summary sections.

Explanation/Purpose:

Provide a brief description of the purpose of this activity and the hypotheses, or describe the purpose of the HUD. Specific aims may be used if they clearly define the purpose and intent of the activity.

Background and Significance:

Briefly describe the relevant background supporting the conduct of this activity or use of this HUD. Provide a summary of results obtained by others pertinent to this activity or HUD. Appropriate references should be included.

Design and Methods:

Describe the design and the procedures to be used to accomplish the specific aims of the activity. Define in clear terms exactly what will be done to the human subjects, source and types of data to be collected, and/or samples to be taken. Describe how the informed consent will be presented to potential subjects. Be sure to indicate which procedures are part of routine care, required for employment, and/or which procedures are experimental. Provide a precise description of the planned data collection, proposed analyses, and hypothesize activity results. This should include criteria for determining statistical significance and sample size.

Potential Risks:

Describe any potential or known risks - physical, psychological, social, legal or other - and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be available to the subjects.

Risk Management:

Describe the procedures for protecting against or minimizing potential risks. Where appropriate, discuss provisions for ensuring medical or professional intervention in the event of adverse effects to the subject. Also, where appropriate, discuss the provisions for monitoring the data collected to ensure the security of subjects' PHI.

Potential Benefits:

Benefits may be gained by:

- the individual subject: No Yes - Explain: **Increased access and medication adherence**
- society in general: No Yes - Explain: **Decreased healthcare costs**

Expense to Subject:

Does the research activity involve any added expense to subjects (e.g., longer hospitalization, additional tests, blood draws, travel, etc.)? No Yes - Explain:

Has the FDA authorized the drug or device sponsor to charge subjects or their insurance for the experimental drug, device, or intervention? No Yes (provide a copy of the authorization letter from the FDA with this application)

Will there be charges to subjects, or their third-party payers, for study-related procedures that are considered standard of care? No Yes - Explain:

Does the informed consent clearly outline the added expense to subjects?

No added expense Yes - provide page #:

Compensation to Subject:

Will subjects be compensated in any way?

No

Yes - Provide payment schedule or other compensation to be provided (include this information in the informed consent document(s) as well):

Subjects / Humanitarian Use Device (HUD) Recipients

Estimated number of subjects* to be enrolled at your site(s): **300**

(*Subjects = people (including HUD recipients), specimens, charts, etc.)

Is this a multi-center trial (or HUD)?

No Yes - Provide the total number of subjects to be enrolled at all sites: _____

Subjects will be (check all that apply):

Outpatients Inpatients Healthy Volunteers Employees/Medical Staff

Students Records Biological specimens

Will this activity involve subjects from the following "vulnerable" categories? No Yes - Check ***all*** that apply:

Pregnant women Neonates - {if neonates involved, choose from list}

Fetuses Placenta (after delivery)

Dead fetuses (after delivery) Fetal material (after delivery)

Prisoners Children - Ages: _____ to _____

Will this activity involve any of these other potentially vulnerable subjects? No Yes - Check ***all*** that apply:

Mentally ill Persons in detention Nursing home residents

Institutionalized Chronic condition Terminally ill

Hospitalized Limited literacy Limited English

Poor/uninsured Medical, pharmacy, dental or nursing students

Students of PI or study staff Students to be recruited in their educational setting, i.e. in class or at school

Employees directly supervised by PI or sub-investigator

Employees of Research Site or Sponsor

Cognitively or Decisionally Impaired

Others vulnerable to coercion (Specify) _____

Recruitment of Subjects

Explain how prospective subjects will be identified and/or pre-screened and/or recruited (check ***all*** that apply):

Personal contact (e.g., patients, students, employees)

Referrals

Medical Records

Database from which subjects have given prior permission to be contacted for research studies

Advertising (Submit all recruitment materials, including letters, posters, brochures, etc., with application materials)

Written or verbal pre-screening materials

Other (specify): _____

Are you using any written or verbal screening materials to screen subjects prior to enrollment in the research (e.g., telephone call scripts, written or web-based questionnaires or pre-screening forms)?

No Yes (Submit with application materials.)

Confidentiality of Protected Health Information (PHI) / HIPAA

What precautions will be used to maintain the confidentiality of identifiable subject information?

- Paper-based records will be kept in a secure location and accessible only to persons involved in the study.
- Computer-based files will be available only to persons involved in the study through the use of access privileges and passwords.
- Prior to accessing any PHI, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable health information.
- Whenever feasible, identifiers will be removed from study-related information.
- Other - *Specify*: _____

Coded - Provide example of code (*e.g., initials, relative's DOB, etc.*): **N/A**

Will there be a key that links the code to the subject? Yes No

Who will maintain the key? _____

Who will have access to the key? _____

How will the key be kept secure from improper use and disclosure? _____

Provide anticipated date when identifiers will be destroyed*? _____

(**To be done at earliest opportunity, unless there is a health or research justification for retaining the identifiers; or if such retention is otherwise required by law.*)

How long will data collected for this activity be stored at local site? **5** years after close of activity.

Does, or will, this research have a [Certificate of Confidentiality](#)? (*Issued by the National Institutes of Health (NIH) or other agencies for certain types of research.*) No Yes (*submit with application materials*)

Informed Consent / Assent

The Sharp HealthCare IRB expects that the subject consent / assent process will be conducted under the following conditions:

Will take place without undue influence or coercion.

Will allow subjects adequate time to consider the activity before signing.

Will be conducted in a private place and manner.

Will be conducted with words understandable to subjects (*goal is to have documents written at or below 8th grade reading level*).

The person obtaining consent will invite questions from the subject.

The subject will be allowed to take home an unsigned copy of the consent form to share with family and friends prior to enrollment.

If enrolled, the subject will be given a signed and dated copy of the consent form for their records.

Non-English speaking subjects will be provided with a certified translation of the approved consent form in the subject's first language. The translated document(s) are to be approved by the Sharp HealthCare IRB.

Indicate the **informed consent procedure(s)** to be used for this activity (*check all that apply*):

- The consent process will meet all of the above conditions. (*Separate PHI Authorization may be needed.*)

And/Or

- The consent process will **take place in emergency situations** and will therefore not satisfy all of the above conditions. Briefly explain the proposed consent process and complete the Emergency Research Section of the application:

And/Or

- Short form written consent** will be presented orally to some or all potential subjects, or their legally authorized representative.

Requirements when this method is used (45 CFR 46.117(b)(2)):

- Impartial witness to the oral presentation.
- Submit written summary to IRB of what is to be said to the potential subject or their representative. At minimum, the summary shall include the elements of informed consent described in the beginning of this section.
- Short form itself is to be signed by the subject or the representative.
- Impartial witness shall sign both the short form and a copy of the summary.

- Person actually obtaining consent shall sign a copy of the summary.
- A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

And/Or

Request for **waiver** of **signed** informed consent may be allowed **if at least one** of the following conditions are met (*separate PHI Authorization may be needed*):

- The only record linking the subject and this activity would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; and/or
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

And/Or

Request to **alter***, or not include, some required elements of informed consent (*separate PHI Authorization may be needed.*)

And/Or

Request for **complete waiver*** of the requirement to obtain informed consent.

***Complete waiver and/or Alteration of informed consent** may be allowed if **all** of the following conditions are met.

Explain:

- Why the activity will not adversely affect the rights and welfare of the subjects, and will involve no more than minimal risk to the subjects: _____
- Why the activity cannot be conducted without the waiver or alteration: _____
- Whether or not the subjects will be provided with additional pertinent information after participation.
 - No
 - Yes - Explain the plan for providing information to subjects: _____

Who will conduct the consent / assent interview? (**check all that apply**)

Principal Investigator Co-Investigator(s) or Sub-Investigator(s) Coordinator *Or* N/A

Will consent be obtained from, and/or other decisions made by, some form of substitute decision-maker?

No Yes - Describe the categories of people from whom you will accept substituted consent.

If any of the subjects will be cognitively impaired, describe how capacity for consent will be determined:

- Capacity assessment by _____
- Other (*specify*): _____

Describe how the consent process will be conducted with cognitively impaired subjects:

Or

Provide a copy of your Standard Operating Procedure for consenting subjects with these vulnerabilities:

Attached Previously submitted (*The IRB may ask for additional information.*)

NOTE: *If the consent form will be read to the subject, an impartial witness not affiliated with the research or study doctor (or treating physician in the case of HUD recipients) to be present for the consent discussion and shall sign the consent document.*

Complete this section if this activity involves children (< 18 years of age).

Describe the assent plan for children (*check all that apply*):

- Children will be capable of providing assent. Describe the assent plan:
 - Separate assent to be signed by the minor; or
 - Assent collected by minor signing the parents' permission form; or
 - Other - *Specify*: _____

Children are not capable of providing assent.

Waiver of assent is requested (*specify*):

- Capability of minor is limited therefore they cannot reasonably be consulted; and/or
- Activity holds out a prospect of direct benefit that is important to the health or well-being of the child, and is available only in the context of the activity.

Drug(s) or Biologic(s)

Does this study involve any drugs or biologics? No Yes - Complete the following information:

Phase of research: **[choose from list]**

Investigational Drug or Biologic name(s) and/or number(s): _____ **or** N/A

Investigational New Drug (IND) number(s): _____

Sponsor of the IND: _____

If an IND is not available, explain why not:

List the names of any drugs or other agents required for the study that do not require an IND. Submit current Prescribing Information or Package Insert(s) with application materials.

Describe who will be responsible for storage, monitoring and dispensing of study drug(s):

Device(s) (Excluding Humanitarian Use Devices (HUDs))

Does this study involve the use of any devices? No Yes - Complete the following information:

Is the device to be used in this study FDA-approved? No Yes

Investigational device name(s): Device not an IDE (see below)

Manufacturer(s) of the device(s): _____

Investigational Device Exemption (IDE) number: _____ (*Submit FDA letter granting an IDE for the proposed use.*)

IDE Sponsor(s):

Or

510(k) number: _____ (*Submit FDA letter granting 510(k) and designation of substantial equivalence for the proposed use.*)

Categorization of the device (*check one of the following*):

Significant risk (SR)

Per 21 CFR 812.3(m), an SR device is an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Non-significant risk (NSR); Does not meet the definition for an SR device study.

List the names of any devices required for the study that do not require an IDE. Submit current Instructions for Use or User Manual(s) with application materials.

Automated Delivery System (Asteres ScriptCenter Kiosk)

Describe the inventory control procedures for storage, monitoring and dispensing of study devices:

The Asteres ScriptCenter kiosk uses barcode technology to track and monitor finished prescriptions. The device knows at all times where any given prescription is located. ScriptCenter also takes a photo and signature of each patient during their prescription pick up. These reports are available real-time through a web based application called AsteresCentral®. Pharmacy staff is given role specific access to ScriptCenter reports on AsteresCentral. For examples of ScriptCenter reports, see "Asteres User Guide" and

"Asteres Policies and Procedures". **See attached** " Asteres User Guide"

Describe the training procedures for personnel to ensure the safe handling of the study devices:

Pharmacy personnel is trained by Asteres staff before the go-live of the ScriptCenter kiosk. They are provided the Asteres Policies and Procedures document that is kept available at the pharmacy at all times. Asteres also provides a toll free customer care number where pharmacy staff can call for additional help or questions. For more on staff training, see "Asteres Policies and Procedures"

If an IDE is not available and the device is not approved, provide one of the following:

Letter from sponsor stating that the study is a non-significant risk device study and fulfilling the abbreviated requirements under 21 CFR 812.2(b)

Or

Letter from sponsor explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c)

Humanitarian Use Device (HUD)

Is this a request for use of a Humanitarian Use Device? No Yes - Complete the following information:

Name of the device: _____

Manufacturer of the device: _____

Humanitarian Device Exemption (HDE) number: _____

Submit:

- FDA approval order(s) granting HDE for the proposed use
- Summary of Safety and Probable Benefit
- Patient labeling and informed consent
- Professional labeling
- Any other consumer information

Describe the inventory control procedures for storage, monitoring and dispensing of HUD:

Describe the training procedures for personnel to ensure the safe handling of the HUD:

Emergency Research

Is this Emergency Research (21 CFR 50.24) which involves the following?

- An Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) is required,
- Subjects who have a life-threatening medical condition (*for which available treatments are unproven or unsatisfactory*),
- Subjects who, because of their condition (*e.g., unconsciousness*) cannot give informed consent,

And

- To be effective, the intervention must be administered before informed consent from the subjects' legally authorized representative is feasible.

No (*if fewer than four of the above are checked*) Yes (*if all four of the above are checked*) – Complete the following:

What additional protections will be provided to subjects in this emergency research?

(check all to confirm and provide explanation of how conditions will be met for each):

- Consultation (*including, where appropriate, consultation carried out by the IRB*) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn:

Provide explanation:

- Public disclosure of plans for the investigation and its associated risks and benefits to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation:

Provide explanation:

- Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results:

Provide explanation:

- Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation:

Provide explanation:

And

- If obtaining informed consent is not feasible within the therapeutic window, and a legally authorized representative is not reasonably available, the investigator will attempt to contact subject's family member to ask whether he or she objects to the subject's participation in the clinical investigation:

Provide explanation:

NOTE: *Studies involving an exception from the informed consent requirements may proceed only after a sponsor has received prior written authorization from FDA. The IRB shall find and document that these specific conditions have been met. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.*

List of Items Submitted

List the items submitted exactly as they are to be listed on the approval letter. For example, "Protocol (Version 1.0; Dated: 09Jul2010)".

NOTE: Please do not list site personnel information in this section as these items will not be listed on the approval letter.

Name of person who prepared this submission: **Sheila Alignav- Rivera**

Phone #: **858-939-6586** e-mail address: **sheila.rivera@sharp.com**



Your time is valuable and a complete application packet helps avoid delays!

**A complete application package includes
the completed application and all required attachments.**

Use the checklist on the following page to make sure that your application packet is complete before submitting.

INITIAL IRB REVIEW APPLICATION CHECKLIST

IRB forms are designed to be completed electronically (typed). Please submit completed forms electronically, in the same format forms were provided to you (.doc or .docx). Documents that require signatures (e.g., PI Attestation, FDS) should be scanned and submitted electronically (or faxed to (858) 499-3105 if you don't have access to a scanner).	Are the items below complete & ready for submission?		
IRB SUBMISSION	Yes	No	N/A
Application Form - All sections are complete and Principal Investigator has reviewed before submitting.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principal Investigator's (PI) Attestation – To be signed and dated by the PI.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Site Personnel Information – Submit the following for all site personnel listed on this application: Completed, signed and dated Financial Disclosure Statements (FDS) (<i>sponsored activities only</i>) Current Curriculum Vitae (CV) or resume (<i>if not previously submitted</i>) Copy of current Medical License (<i>if not previously submitted</i>) NIH training completion certificate or other research subject protection training program certificate (<i>to be completed within the past 24 months</i>) Completed Demographic Form (DF) (<i>if not previously submitted or if person's information has changed</i>). Any Form FDA 483s, Warning Letters, and/or any other notification of regulatory issues for site or site personnel (<i>if not previously submitted</i>)	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
Completed, signed, dated Form FDA 1571 (for investigator-initiated studies, treatment IND, or treatment protocol using investigational drug(s))	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Completed, signed, dated Form FDA 1572 (for Phase I, II, or III studies of investigational drugs only)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Study Protocol (Drug or Device studies), Research Narrative or Study Plan (<i>if not imbedded in application</i>) <i>Or</i> Summary of Probable Risks and Benefits (Humanitarian Use Devices only)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Grant Application (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Investigator's Brochure (Investigational Drugs) <i>And/or</i> Package Insert(s) (FDA-Approved Drugs) <i>And/or</i> User's Manual (Investigational or FDA-Approved Devices) <i>And/or</i> Instructions for Use (Investigational or FDA-Approved Devices)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
Other supporting documents, including but not limited to the following: Informed Consent / Assent, PHI (HIPAA) Authorization, Informed consent letter, Case Report Forms, data collection forms, surveys, questionnaires, measures, and any other documents/tools/forms to be used to carry out the study.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FINANCE AND ADMINISTRATIVE REVIEW			
Review Fees – Send check payable to Sharp HealthCare IRB to the address on page one of this application. Initial Full Committee Review - \$3,000 (IRB and entity Administrative review) Initial Expedited Review - \$1,000 (IRB and entity Administrative review) Initial Humanitarian Use Device Review - \$1,000 (IRB and entity Administrative review) System Antibiotic Review Committee Review - \$500 (in addition to IRB and Administrative review fees)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Service Agreement - Call 858-499-4830 for assistance in determining whether a Service Agreement is needed.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Sharp Medicare Coverage Analysis Form – Submit completed form to clinicaltrials@sharp.com to determine when a trial is considered qualified to bill Medicare.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Contract Contact Sharp's Legal Secretary, Jenna Haynes at jenna.haynes@sharp.com or (858) 499-4023 to determine if a contract is needed.			
Review by Hospital/Medical Group Administration IRB Office staff will submit the application packet to representative(s) of Administration at each Sharp entity where this project is to be conducted. Please see "Required Approvals for Research Activities" for more information.			

SUBMIT COMPLETE APPLICATION PACKET ELECTRONICALLY TO Research@Sharp.com

Proposal

**Experimental Program/Research Study on an Automated
Delivery Device (Asteres ScriptCenter[®]) in a Licensed
Facility for Employee Prescriptions**

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E. McPherson, Pharm.D. Candidate, D. Laufer, Pharm.D., H. Morales, Pharm.D.**

**Sharp Rees Stealy Pharmacy
UCSD School of Pharmacy
Sharp Memorial Hospital**

2013-2014

Table of Contents

Table of Contents.....	2
Introduction	3
Hypothesis	3
Background and Significance.....	3
The problem and the solution	Error! Bookmark not defined.
Study aims	4
Stages of the study	5
Study design	5
Statistical Analysis Plan	7
Conflict of interest	8
Conclusion	8
Appendix	Error! Bookmark not defined.
Questionnaire.....	Error! Bookmark not defined.
References	8

Introduction

This study examines the effectiveness and safety of an automated prescription delivery device (Asteres ScriptCenter[®]) as a new method for picking up finished prescriptions. ScriptCenter is an approach to simplify prescription pick up to improve medication adherence.

We postulate that if prescription medications are available for pick up at all times, even when the pharmacy is closed, patients' compliance with their treatment plan will improve and potential medical complications will decrease.

Hypothesis

Does better access lead to better adherence? We predict that the presence of an automated delivery device, available 24 hours a day, 7 days a week, for Sharp Memorial Hospital (SMH) employees will be advantageous for picking up prescriptions at any time with the same level of access to a pharmacist for consultation, which ultimately will lead to better adherence.

Background and Significance

In the past ten years, pharmacy has incorporated automation technology¹. Automation includes barcoding for filling, restocking, returns and dispensing in order to improve efficiency, safety and accuracy².

In 2005 and 2006, the California State Board of Pharmacy granted a waiver to allow the use of automated delivery devices in pharmacies to deliver refill medications even after the pharmacy has closed³. Regulation 1713 section D has since been written to allow for these types of devices in California pharmacies⁴.

In addition, states such as Arizona⁵ and Illinois⁶ have adopted their own regulations to allow for the delivery of not only previously dispensed prescriptions but also new prescriptions after appropriate counseling has taken place and the placement of these devices away from the pharmacy.

Researches indicate that low or non-adherence to medication therapy is a major healthcare cost and quality problem. One method to measure success of pharmacy automation is medication adherence. It is important to understand factors that lead to low adherence but also effectively evaluate clinical and economical outcomes⁷. The cost of non-adherence to the U.S healthcare system is estimated at \$100- \$300 billion annually⁸.

The problem and the solution

Sharp HealthCare recognizes that managing employees' health and wellness is important in maximizing workforce productivity⁹. Today only 5% only of Sharp HealthCare employees are using the Sharp Rees Stealy Pharmacy. Sharp Rees Stealy (SRS) Pharmacy can improve prescription medication adherence of Sharp employees at the workplace by providing improved access to prescriptions. This effort would improve employee health, productivity and control overall healthcare cost.

Studies show that patients have difficulty filling prescriptions due to the following barriers; lack of transportation, difficulty affording medications, and long wait times at the pharmacy¹⁰.

Therefore, the emerging technology will improve access to employees' prescriptions.

Approximately 5.7% of all prescriptions filled at Sharp Rees Stealy Pharmacy are never picked up by the patient. In a small sample of patients who failed to pick up their prescriptions, failure of communication was the primary reason cited and convenience of location was the secondary reason¹¹. By providing a secure and convenient method of prescription pick up for Sharp employees, they will have better access to their prescription without leaving the workplace, therefore decreasing the number of prescriptions returned to stock (RTS) for patients utilizing the automated delivery device.

Prescriptions not picked up are returned to stock by the pharmacy. We chose Sharp Rees Stealy Outpatient Pharmacy one of Sharp HealthCare's seven pharmacies as our study site. The automated delivery device will be used to deliver finished prescriptions to Sharp Memorial Hospital employees. Employees working at SMH do not currently have convenient 24/7 access to their prescriptions, therefore, by providing a secure and convenient prescription pick up method for employees, they will have better access to their prescriptions without having to leave work.

All new prescriptions will receive mandatory counseling before the medication is released from ScriptCenter. All refill prescriptions will have access to a pharmacy consultation 24 hours a day, seven days a week. In addition, the filling pharmacist will use their professional judgment and ensure that any refill prescription will receive a pharmacist consult if appropriate.

Asteres ScriptCenter has successfully delivered over 750,000 prescriptions to date without one known break-in or delivery error.

Study aims

Primary Aim: To measure medication adherence by determining changes during a six month period after kiosk implementation in number of new patients to the pharmacy and return to stock (RTS) numbers at Sharp Rees Stealy (SRS) Outpatient Pharmacy which services employees at Sharp Memorial Hospital.

Secondary Aim: To measure the number of patients, in a six month period, who called the consultation service line at Scriptcenter as a means to show non-inferiority of the kiosk to the traditional method of prescription pick up. Measurement of the new technology will not affect the ability to provide healthcare information and pharmacist expertise on medications. Furthermore, will increase SHS employees' utilization to

Stages of the study

Stage 1: Approval from the California Board of Pharmacy and project planning. 2-3 months.

Stage 2: Implementing ScriptCenter free of charge in SMH. 4-6 months.

Stage 3: Experimental study including measuring patient satisfaction. 6 months.

Study Design and Methods

Method

This will be an observational experiment, using a questionnaire type of survey as tool for data collection.

Questionnaire development

Because the subjects of this study are Sharp Memorial Hospital employees, it is assumed that they have a basic level of comprehension and understanding. Therefore, the questionnaire was developed and presented to be suitable for employee knowledge.

Study procedures

The study will distribute a pre-implementation questionnaire targeting Sharp Memorial Hospital employees to measure whether better access to patient prescriptions leads to better adherence. The study will also include a second questionnaire after implementation to evaluate employee satisfaction rate.

Data collection will be six months in duration.

Sample size

2610 employee of SMH employee population.

Sample recruitment procedures

Questionnaires will be distributed to Sharp employees with a brief description of the automated delivery device and will provide a Sharp Rees Stealy Pharmacy phone number to contact for further information.

Informed Consent Process

The following reasons support the waiver of informed consent: minimal risk of harm to subjects and the lack of medical procedures involved.

Protected Health Information

Protected Health Information (PHI) is removed and reports are de-identified to protect privacy of SRS patients per HIPAA regulations. Data will be kept on a password protected database and will be linked only with a study identification number for this research. There are no patient identifiers. All data will be entered into a computer that is password protected.

Potential Risks

Potential risk for this study may include possible loss of participant confidentiality. To prevent this, PHI will be removed and reports will be de-identified. This study presents minimal risk to the privacy of individuals.

Risk Management/Confidentiality

This study involves the analysis of survey reports that have been de-identified. Data will be prepared with privacy, and all research staff will have completed the human research training module and HIPAA module that provides training in regards to HIPAA regulations, research ethics, investigators responsibilities, IRB role etc. Data will be kept confidential and stored in the study investigator's locked cabinets, archived, and saved in password-protected electronic files that are backed up daily. Data will be maintained for a minimum of five years after the completion of the study. There will be no patient identifiers used or linked to any data for analysis or publications.

Potential Benefits:

SRS Pharmacy anticipates learning that the placement of an automated delivery device at Sharp Memorial Hospital will increase access to prescription medications for employees and their dependents, which could potentially increase adherence and lead to better outcomes.

Data and results from this study will enable SRS pharmacy to effectively and efficiently utilize information with the end goals of ensuring patient safety and delivering optimal health outcome for patients. The anticipated benefits for learning whether the effectiveness and safety of automated delivery devices would deliver these prescriptions with convenient access at SRS outweigh the potential risk of loss of confidentiality.

Security and Safety

ScriptCenter weighs more than 1,300 lbs and is bolted to the floor. It is equipped with a camera and collects a signature and photo for every pick up. The device includes reporting capabilities to track inventory and system access (both patient and pharmacy).

Study Timeline

The questionnaire will be delivered online using Survey Monkey (an online survey technology provider) through employees' email. The survey will launch on in the first quarter of 2014. A series of three reminder messages will be sent by e-mail to those who do not respond to the initial request to complete the survey. The survey will close after one month. A final thank you e-mail will be sent to all respondents at the end.

Statistical Analysis Plan

Aim of the study	Tool	Before Kiosk Implementation	After Kiosk Implementation
Primary Aim: To measure prescription medication adherence	Return to Stock (RTS) numbers at Sharp Rees Stealy (SRS) Outpatient Pharmacy	RTS% mean for 12 month period	Anticipate RTS% numbers to decrease at the kiosk compared with the Rx counter
Secondary Aim: To show non-inferiority of the kiosk to the traditional method of prescription pick up*	To track the number of patients who called the consultation service line at the kiosk	Numbers of patients who declined counseling by pharmacist	Anticipate numbers to be the same or show non-inferiority

Conflict of interest

The ScriptCenter kiosk will be loaned to the SRS Pharmacy at no cost for the duration of the study and no third party funding will be received. This research study will be conducted by SRS Pharmacy and the UCSD Skaggs School of Pharmacy and Pharmaceutical Science. No aspect of the relationship between the research participants and Asteres may be considered an apparent conflict of interest.

Conclusion

Sharp employees would benefit from an automated delivery device located at the Sharp Memorial Hospital. Sharp employees would pick up their medications at their workplace improving accessibility, patient care and medication adherence.

References

- 1- Novek J (2000). *Hospital pharmacy automation: collective mobility or collective control?* Social Science & Medicine. 51(4):491–503.
- 2- Shack, J., Tulloch, S. (2008), *Integrated pharmacy automation systems lead to increases in patient safety and significant reductions in medication inventory costs* [Shore Memorial Hospital] (Case Study). Fairport, NY: Shack & Tulloch, Inc
- 3- State Board Of Pharmacy Department Of Consumer Affairs Enforcement Committee Meeting Minutes Date: June 4, 2013.
- 4- California Code of Regulations
- 5- The Arizona State Board Of Pharmacy, Minutes Of A Regular Meeting Held On November 14, 2012.
- 6- *Section 1330.510 Telepharmacy: Automated Pharmacy Systems; “Kiosk” To Go Into Effect* 2014 Illinois Register, 2009.33(39):12904-13571
- 7- Methods for evaluation of medication adherence and persistence using automated databases. By Andrade.S, et.al. *Pharmacoepidemiology and Drug Safety*,2006. 15(8):565–574
- 8- Improving Prescription Medicine Adherence Is Key To Better Health Care. Taking Medicines as Prescribed Can Lower Costs and Improve Health Outcomes [PDF document]. The Pharmaceutical Research and Manufacturers of America (PhRMA). Jan 2011.
- 9- B Hall, R Hunt, D Ratcliffe. Working Well: What’s next for wellness? Highlights and implications of the 5th Global Wellness Survey [PDF document].Buck Consultants.
- 10- *Medication Adherence: WHO Cares?* By Marie T. Brown and Jennifer K. Bussell. Mayo Clin Proc. 2011 April; 86(4): 304–314
- 11- Sharp Rees-Stealy (SRS) Survey Data Sharp Employee the value in a pharmacy.2009.

Appendix

Questionnaire

Pre-Implementation emailed to Sharp employees

1. Do you use the Sharp Rees Stealy pharmacy for your prescriptions?

1. Yes
2. No

2. If no, what pharmacy do you use?

1. Mail order
2. Another pharmacy
3. I don't take any prescription medications

3. The ability to pick up prescriptions for you and your family at Sharp Memorial Hospital would be beneficial to you.

1. Strongly agree
2. Agree
3. Neutral
4. Disagree
5. Strongly disagree

4. Easier access to your prescriptions would lead to an increase in your adherence to your medications.

1. Strongly agree
2. Agree
3. Neutral
4. Disagree
5. Strongly disagree

5. Location or limited hours of the pharmacy is a barrier to picking up your prescriptions.

1. Strongly agree
2. Agree
3. Neutral
4. Disagree
5. Strongly disagree

Post – Implementation at the kiosk

1. How satisfied are you with the kiosk?

1. Strongly Satisfied
2. Satisfied
3. Neutral
4. Unsatisfied
5. Strongly unsatisfied

2. How important is it to have 24/7 access to your prescriptions?

1. Very important
2. Important
3. Neutral
4. Unimportant
5. Very unimportant

3. If this kiosk was not available would you still use Sharp Rees Stealy Pharmacy?

1. Yes
2. No

Characteristic	Population		Surveyed		Respondents		Non respondents	
	n	%	n	%	n	%	n	%
Sharp Memorial Hospital Employees	2800	100	2610	93.2				

From the Respondents:

	Yes		No	
	n	%	n	%
Do you use the Sharp Rees Stealy pharmacy for your prescriptions?				

	Mail order		Another pharmacy		I don't take any prescription medications	
	n	%	n	%	n	%
If no, what pharmacy do you use?						

	Strongly agree		Agree		Neutral		Disagree		Strongly disagree	
	n	%	n	%	n	%	n	%	n	%
The ability to pick up prescriptions for you and your family at Sharp Memorial Hospital would be beneficial to you.										
Easier access to your prescriptions would lead to an increase in your adherence to your medications.										
Location or limited hours of the pharmacy is a barrier to picking up your prescriptions?										

Presentation

Thank you for giving us the opportunity to discuss
Automated Pick Up Solutions



SHARP[®]

January 10, 2014

COMPANY CONFIDENTIAL



Timeline

Date	Motion	Vote
June 4, 2013 Enforcement Committee	Present proposal to Board to install ScriptCenter at Sharp corporate building serviced by Sharp Rees-Stealy	✓
July 31, 2013 Board of Pharmacy Meeting	Install ScriptCenter pilot in Sharp corporate office serviced by Sharp Rees-Stealy*	4-5 ✗
July 31, 2013 Board of Pharmacy Meeting	License Sharp corporate office and install ScriptCenter serviced by Sharp Rees-Stealy* <i>(This was later deemed impossible without legislation changes; AstereS to pursue).</i>	8-1 ✓
January 10, 2014 Enforcement Committee	Present proposal and study outline to install ScriptCenter pilot in Sharp Memorial Hospital (licensed facility) serviced by Sharp Rees-Stealy	?



* It was made clear a study outline from UCSD needed to be presented to the Board in order to receive final approval to move forward with pilot.

Sharp Memorial Hospital – San Diego, CA

Location	Sharp Memorial Hospital 7901 Frost Street, San Diego, CA 92123
Number of employees	2,600+ employees
ScriptCenter benefits	<ul style="list-style-type: none"> • Allow convenient pick-up of employee & dependent prescriptions • Ability to stock OTC items • Provide employees access to their medications without leaving work • Increase medication adherence and compliance, supporting Sharp's Employee Wellness Program • Patient/employee centered, offers a solution that fits their need • In line with Sharp's vision to provide alternative care models (eg patient portal).
Servicing pharmacy	Sharp Rees-Stealy, 2929 Health Center Dr., San Diego, CA (0.2 mi.) Service the kiosk daily, Monday-Friday



Sharp Memorial Hospital – San Diego, CA



Kiosk placed in employee entrance hallway of licensed facility within close proximity of information desk and telephone.

Study – UCSD

Access > Adherence > Better Outcomes

- UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences
- Dean's letter (1706.5)
- Study outline
- 6 month pilot



Experience



ScriptCenter has successfully delivered over **750,000** prescriptions without one reported delivery error!



Thank you!



Reference Materials



Secure Enrollment with Opt-In

ScriptCenter®

LOG IN

ENROLL

SINGLE PRESCRIPTION ACCESS

Convenient.
Secure.
Private.

Refills available 24/7.

ESPAÑOL

< BACK

ScriptCenter®

QUIT

Scan Your Fingerprint 4 Times

1. Press your finger on the scanner.
2. Remove when image appears.
3. Repeat 4 times with the same finger.

We suggest you use your index finger.



	Scan 2	Scan 3	Scan 4
			

Press your finger firmly on the scanner



NEXT >

< BACK

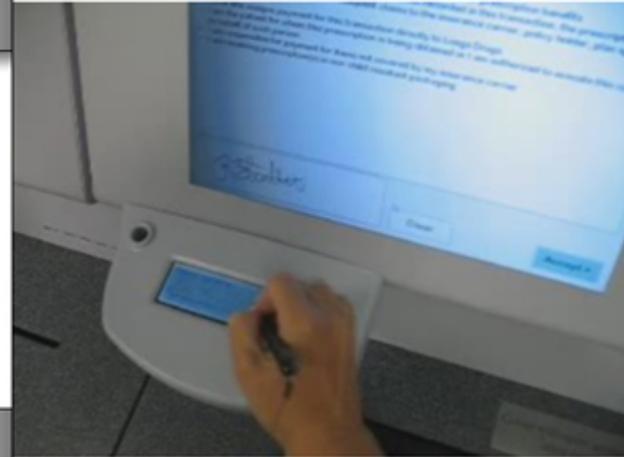
ScriptCenter®

QUIT

Sign to Authorize Enrollment

By Signing below I acknowledge that:

- My eligible prescriptions will be put in ScriptCenter.
- Anyone with my ID and PIN may have access to my prescriptions.



Sign on the pad below



CLEAR

ACCEPT >

Pharmacy ScriptLink® and Secure Loading

MMC Outpatient Pharmacy
1800 Coffee Rd. Ste 110 Modesto, CA. 95355
Refills: (209) 572-7167 Main: (209) 572-7132

Rx# 7854369 U Dr. TEST, THOMAS M.
TEST PATIENT 03/02/11 JK
LISINOPRIL/HCTZ Generic for :
10-12.5MG TAB (LP) #90 ZESTORETIC
TAKE ONE TABLET BY MOUTH DAILY

SC: Y

prohibits the transfer of this drug to any patient for whom it was prescribed.



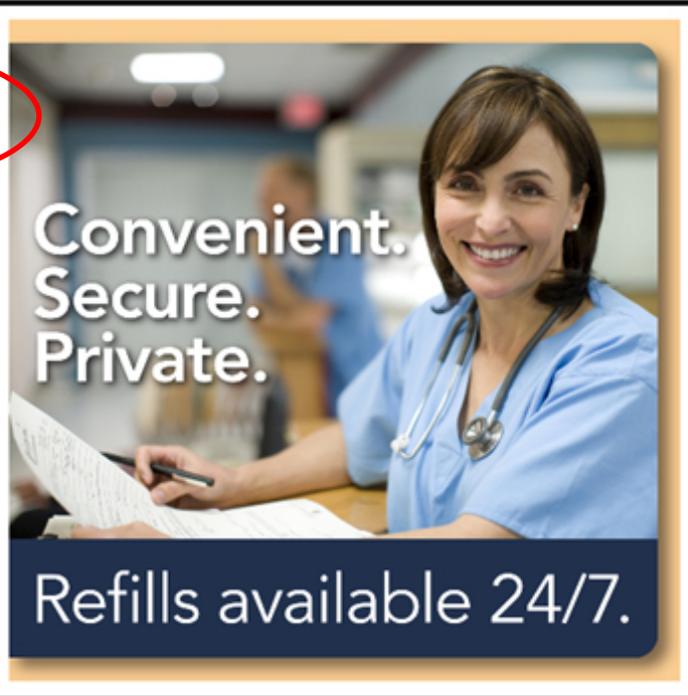
Secure Login and Delivery

ScriptCenter®

LOG IN

ENROLL

SINGLE PRESCRIPTION ACCESS



ESPAÑOL

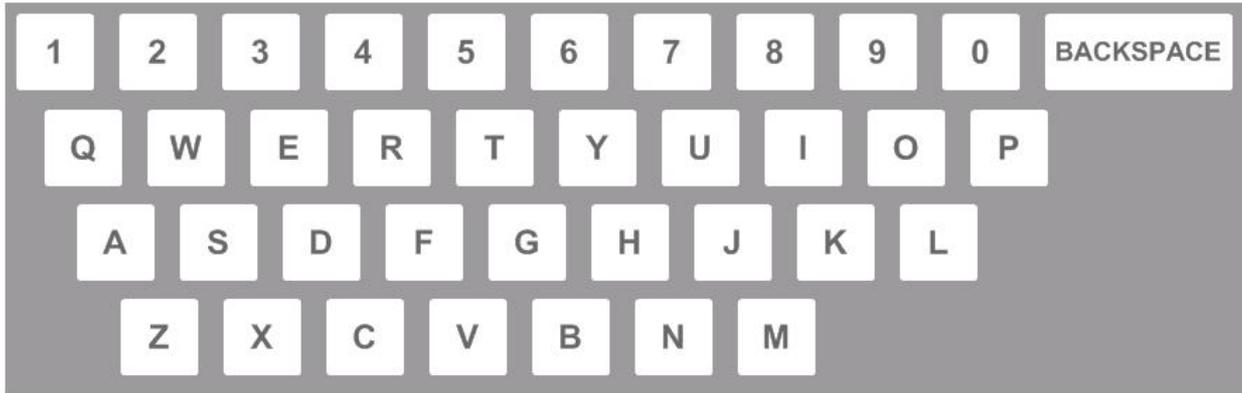
Scan Your Fingerprint or Enter Your User ID



User ID:

NEXT >

FORGOT ID?



< BACK

ScriptCenter[®]

QUIT

Enter Your PIN

User ID: **marge1**

PIN:

NEXT >

FORGOT PIN?

1	2	3	BACKSPACE
4	5	6	
7	8	9	
	0		

My Shopping Cart

MARGARET CASTANEDA

Name	Item	Rx #	Price	Pick up
MARGARET CASTANEDA	DYNACIRC CR 10MG TABLET SA #30	2500490-015	See Pharmacy Staff	
ELVIRA CASTANEDA	FORTEO 750MCG/3ML PEN #3	2500327-003	\$10.00	<input checked="" type="checkbox"/>

Total: \$10.00 1 Item(s)

PERSONAL CARE STORE

MY SETTINGS

NEXT >

Would you like to speak with a pharmacist
about these medications?

YES

NO

Directions for Pharmacy Consultation

1. Finish picking up your prescription here.
2. Please go to the counter and ask to speak to a Pharmacist.
3. If the pharmacy is closed:
Call 444-333-2222 or for assistance.

OK

Read and Acknowledge

Name	Item	Rx #	Child Safety Cap
ELVIRA CASTANEDA	FORTEO 750MCG/3ML PEN #3	2500327-003	No

- I am picking up these prescriptions.
- I am receiving prescription(s) in non child resistant packaging.

Margaret Castaneda

CLEAR

ACCEPT >

ScriptCenter®

1. Remove your items
2. Take your receipt
3. Verify your items before leaving

 The bin will close in 4 seconds



Secure Login and Delivery

Welcome staff | Dashboard | Logoff

AsteresCentral® 3.4.0.6310 (30QA 9/11/11)

Dashboard Reports **Patients** ScriptLink™ Access Product Link Holds

Patient: **FIGUEROA, ELISA**

Birthdate: **7/8/1980** Home Phone: **4760717950** User ID **ELFIGU** Clear Registration
Post Code: **74130** Mobile Phone: **Not Provided** Fingerprint: **Not On File**
Email:

Prescriptions Pick Up Lists Edit Patient Data

Hold	Select	Rx #	Fill	Location	Container	Medication	Status
Hold	<input type="checkbox"/>	4471455	004	7-2-6	000000182	LEXAPRO 20MG TABLET	Deliverable
Release	<input type="checkbox"/>	1010303	006	7-2-5	000000181	SYNTHROID 150MCG TABLET	Deliverable

Retrieve Items Light Trays and Unlock Now

Back

Inventory Reconciliation – Receipt printed from kiosk compared to activity report by pharmacist

Activity

10 Transactions

Filter: "Today"

Purchased: 0	Returned: 0	Loaded: 0
Delivered: 0	Retrieved: 0	Unloaded: 0
Linked: 10	Unlinked: 0	Deposit: 0
Hold: 0	Hold Removed: 0.00	

Date and Time	Container No.	Rx Number	Fill	Trans. Type	User / Shopper	Patient
12/17/2013 11:38:26A	002001031	2500475	001	Linked	LEBOWITZ, RYAN [RYANL]	AGUILERA, ANA
12/17/2013 11:38:55A	002001032	2500476	001	Linked	LEBOWITZ, RYAN [RYANL]	KELLEY, STEVEN
12/17/2013 11:39:22A	002001021	2500449	001	Linked	LEBOWITZ, RYAN [RYANL]	DAILEY, BETTE JO
12/17/2013 11:39:55A	002001055	2500583	001	Linked	LEBOWITZ, RYAN [RYANL]	LIMON, WENDY
12/17/2013 11:40:20A	002001071	2500271	001	Linked	LEBOWITZ, RYAN [RYANL]	WHITTEN, PATRICIA
12/17/2013 11:40:38A	0003096307	2500373	001	Linked	LEBOWITZ, RYAN [RYANL]	BAKER, MILTON
12/17/2013 11:41:07A	002001038	2500493	001	Linked	LEBOWITZ, RYAN [RYANL]	CHRISTENSEN, FRANKIE
12/17/2013 11:41:40A	002001046	25000444	001	Linked	LEBOWITZ, RYAN [RYANL]	PINNEY, LINDA
12/17/2013 11:42:07A	002001019	2500443	001	Linked	LEBOWITZ, RYAN [RYANL]	PEREZ, MARIA E
12/17/2013 11:42:25A	002001057	2500585	001	Linked	LEBOWITZ, RYAN [RYANL]	ISEL, JOHN

ScriptCenter Inventory Status

Total Packages:	184
New Packages Loaded*:	10
Packages Unloaded*:	0
Ready to Unload:	0
Unknown:	0
Incomplete Orders:	0

Trays to Inspect:	0
Missing Trays:	0

*Since 12/17/2013 11:35 AM.

Run by ryan lebowitz at 12:10 PM on
12/17/2013.

100% Audit Trail

Asteres Activity

48 Transactions

Filter: "Today"

Date and Time	Transaction Type	Container No.	Rx Number	Fill	User / Shopper	Patient / Product
08/10/10 09:57:24	UNLINKED	002001095	3500502	002	LAKE, SARA	VANCE, WARREN
08/10/10 09:56:42	UNLOADED	002001095	3500502	002	LAKE, SARA	VANCE, WARREN
The package was moved from location 6/4/10 to the holding area.						
08/10/10 09:55:43	SERVICE_REQUEST				Unknown LAKE, SARA	
[sara] Sara Lake issued a request to unlock the back door by Bio ID.						
08/10/10 09:50:26	DELIVERED	002001028	2500469	002	GODINEZ, LUPE	GODINEZ, LUPE
The package at location 4/3/5 was delivered.						
08/10/10 09:48:47	UNLOADED	002001053	2500581	001	LAKE, SARA	JOHNSON, GARY C
The package was moved from location 6/5/6 to the holding area.						
08/10/10 09:48:46	ACCESSED	002001052	2500580	001	LAKE, SARA	LIMON, STACEY
The package at location 6/5/1 was accessed.						
08/10/10 09:48:45	ACCESSED	002001192	2500673	001	LAKE, SARA	HEUPEL, SANDRA
The package at location 6/5/5 was accessed.						
08/10/10 09:48:41	LOADED	002001095	3500502	002	LAKE, SARA	VANCE, WARREN
The package was moved from the holding area to location 6/4/10.						
08/10/10 09:48:23	ACCESSED	002248974	OTC		LAKE, SARA	Schick Quattro
The package at location 5/2/8 was accessed.						
08/10/10 09:48:23	ACCESSED	002248973	OTC		LAKE, SARA	Schick Quattro
The package at location 5/2/7 was accessed.						
08/10/10 09:48:23	ACCESSED	002248948	OTC		LAKE, SARA	Gillette MACH3 Turbo
The package at location 5/2/5 was accessed.						
08/10/10 09:47:53	DOOR_CLOSED				Unknown	
Back door was closed.						
08/10/10 09:47:31	DOOR_OPENED				Unknown	
Back door was opened.						
08/10/10 09:47:16	SERVICE_REQUEST				Unknown LAKE, SARA	
[sara] Sara Lake issued a request to unlock the back door by Bio ID.						
08/10/10 09:46:57	LINKED	002001095	3500502	002	LAKE, SARA	VANCE, WARREN
08/10/10 09:44:13	MOVED	002001031	2500475	001	Unknown	AGUILERA, ANA
The package was moved within ScriptCenter from location 4/5/6 to location 4/4/3.						
08/10/10 09:43:45	MOVED	002001018	2500439	001	Unknown	KELLEY, TIM
The package was moved within ScriptCenter from location 5/4/2 to location 5/6/7.						
08/10/10 09:41:15	ACCESSED	002010063	2500326	001	DEYSHER, CHERYL	GAXIOLA, HILDA
The package at location 1/3/6 was accessed.						
08/10/10 09:41:14	ACCESSED	002010069	2500339	001	DEYSHER, CHERYL	NEAL, CHARLES
The package at location 1/3/5 was accessed.						
08/10/10 09:41:14	ACCESSED	002010075	2500354	001	DEYSHER, CHERYL	JUSTICE, FRANCES

Asteres Activity - Mira Main Street

August 10, 2010

9:58 am

Photo Capture Log

Filter: Date Signed is between '6/25/2009' and '6/26/2009'

RX #	Fill	Date Signed	Time	Medi-Cal Relationship	Third Party	Co-Pay	Credit/Debit Card	POS ID	Photo
2500302	1	6/25/2009	1:32:52PM		SBHA	\$20.00			 SARA LAKE
2500228	1	6/26/2009	9:27:18AM			\$10.00			 Stacey Limon
2500302	2	6/26/2009	9:46:09AM		SBHA	\$10.00			 Gary Johnson
2500301	1	6/26/2009	9:47:36AM		CRK	\$15.00			 Sandra Heupel
2500306	1	6/26/2009	10:04:31AM		PACS	\$10.00			 Tim Kelley

Photo Capture Log - Mira Demo Room

June 26, 2009

1:40 pm

July 2013 Meeting Excerpt

b. Request from Sharp Healthcare on a Waiver of 16 California Code of Regulations Section 1713(d) to Permit Expanded Use of Automated Prescription Dispensing Machines

Relevant Regulation

California Code of Regulations Section 1713 establishes the requirements for use of an automated prescription delivery device and provides the condition under which it can be used. Under the current regulation the device can be used to furnish refill medications in specified circumstances. These circumstances include, that the patient must opt in to use the machine, the medication to be refilled through the machine is appropriate.

California Code of Regulations Section 1706.5 allows the board to waive particular regulation requirements to allow for experimental plans or programs for drug handling, teaching, and research or to develop better methods involving the ethical practice of pharmacy.

Background and Previous Committee Discussion

In 2009-10, Pharmacist Consultant Philip Burgess, on behalf of a manufacturer of one of these machines (Asteres), sought an exemption to permit the use of these machines in areas away from adjacent to the licensed pharmacy premises. The board did not approve the request, and requested more information about how and where the kiosks would be used. One concern was that the board considered that it lacked the ability to provide the exemption sought (which would have required a regulation change). There was no further interest pursued by Asteres after the January 2010 meeting.

Further, at the Committee's March 14, 2013 meeting, Al Carter, representing Walgreens, discussed a request that would allow for Walgreens to place kiosks in workplace clinics. Mr. Carter provided an overview of the types of services that are provided at the clinic and how Walgreens would provide medication. Mr. Carter highlighted that the kiosk would not be stored in the clinic, but would be housed across the street in a separate building. The board did not approve the request, indicating there was insufficient evidence to act.

During the committee meeting, the committee heard a presentation from representatives from Asteres and Sharp HealthCare discussing the need to revise CCR section 1713 to expand the use of automated delivery devices. The presentation included a request to allow three separate pilot studies on the campuses of Sharp, UCSD Health System and USC Hospital to review the use of automated delivery devices. The committee was reminded that section 1713(b) already allows the delivery of prescriptions to employees at their worksite.

Specifically the proposal would revise section 1713(d)(6) to allow for the placement of automated devices in a secure building controlled by a board licensee at an alternate location readily accessible for board inspection, but not adjacent to a secure pharmacy area.

In response to questions by the committee members about the location of the devices, members were advised that the devices would not have to be on the premises of a licensee but could be at corporate offices, for example, a non-licensed facility.

In addition, the proposal seeks to revise section 1713(d) to also allow the dispensing of new prescriptions delivered from automated devices as the delivery system allows the ability to load filled prescriptions in the device. This would only occur after a pharmacist provided consultation, and proper documentation has been reviewed and saved. The prescriptions would not be released to the patients until the patients had been counseled by a pharmacist via telephone (adjacent to the device).

The committee heard information on the uses of these devices and was provided pictures. It was noted that in one location employee utilization of the device had grown from 13 percent to 44 percent.

The committee was provided information about the security measures for the device including a camera which takes a photo of every patient as well as the requirement to collect signatures of the patient. The device also weighs over 1,350 pounds and is bolted to the ground. The committee was advised that more than 700,000 prescriptions have been delivered without incident in other states.

The committee was provided with information about Sharp's current structure including seven hospitals, seven retail pharmacies and 22 clinics in San Diego serving 200,000 patients. Representatives stated that use of the automated devices align with their vision of providing patient/employee-centered care to the 3000 employees who work in their corporate offices and noted that although their pharmacy is only two miles away, getting to the pharmacy can be difficult due to work schedules and heavy traffic. The committee was provided photos of the proposed location of the device and advised that that the building in which the device would be placed has 24-hour security and requires a badge for entry.

The committee discussed the logistics from the patient's perspective including that a patient could drop off a paper prescription through a slot in the device which would subsequently be picked up and delivered to the pharmacy the following day when the device is serviced.

Counsel discussed whether the board could act on the request because current law does not allow for the storage of dangerous drugs at a location not licensed by the Board. In response proponents of the proposal argued that current law allows for the delivery of prescription medications to a patient at his or her office and that the Board should focus on delivery of medications as opposed to the storage of medications.

In response to committee questions, the committee was advised that Sharp planned to have only one pharmacy responsible for filling and delivering prescriptions to an automated device.

The committee heard a second proposal in which Sharp would use the same pharmacy to deliver prescriptions to an automated device located at Sharp Memorial Hospital Campus to dispense discharge medications. Sharp envisions a patient being counseled by a pharmacist at the bedside or over the phone, receiving an access code, then being discharged and obtaining their prescriptions from the automated device. The device allows for the use of a credit or debit card for payment. The committee was advised that Sharp does provide next-day home delivery via mails, but prefers delivery via an automated device because the device is secure in that it allows for the tracking of who picks up their medications and who does not.

The committee was advised that delivery transaction date is kept forever and there is no purge criteria. Further, the committee was advised that the data includes a full audit trail which includes a photo of the person picking up the prescription and the signature log.

The presenters were advised to create a formal proposal for the board to review including specifying some parameters from the school explaining parts such as what measurements they would take and how long the pilot study would last. It was also suggested that two separate proposals may be appropriate based on the proposed locations being licensed.

The committee was reminded that the board has limited authority to waive a regulation based on an experimental program pursuant to the requirements listed in section CCR 1706.5. The results of the experimental program would have to demonstrate to the board that the automated device is safe and that a regulation revision would be advantageous.

Included in the meeting materials were the relevant regulations as well as the written proposal and supporting materials submitted by Asteres, Sharp HealthCare and UCSD as well as information on prior board discussion on the use of these machines.

Discussion at Board Meeting

Phil Burgess, consultant for Asteres, Kim Allen, Sharp Health Care, and Sara Lake, Asteres, provided a formal presentation on the waiver request to allow for new prescriptions to be delivered from an automated kiosk location in a non-pharmacy location. The presentation and related documents were provided in the meeting materials.

Dr. Gutierrez asked if the proposal would include new prescriptions for employees being dispensed at the machine. Mr. Burgess confirmed that it would.

Ms. Veale asked where the phone that would be used if a patient needed to talk to a pharmacist. Ms. Lake answered that no phone would be attached to the machine, an alert would appear on the machine providing the phone number for someone to call and the prescription would be placed on hold until the call was made.

Dr. Castellblanch asked if controlled substances would be dispensed. Mr. Burgess answered that they would. Ms. Allen provided that at this time controlled substances would not be dispensed.

Mr. Law asked if refrigerated medications would be dispensed. Mr. Burgess responded that no refrigerated items would be dispensed at the machine.

Mr. Burgess clarified that this system is “opt-in” and the patient is told what will and will not be dispensed from the machine.

Ms. Allen reported that Sharps feels the machine will offer easier access to their medications.

President Weisser and Dr. Castellblanch expressed concern that anyone with a Sharps employee badge could get to the machine and get medication for someone other than themselves. Mr. Burgess clarified that there is 24/7 security on site and you need a pin number and thumb print to be dispensed your medication from the machine.

Dr. Wong asked if there was a cost saving for the patients to use the machine. Ms. Allen responded that there is no incentive, except convenience, to use the machine.

Chairperson Gutierrez asked what the physical pharmacy hours are and what would happen if a patient needed a consultation after hours. Ms. Allen reported that they are 8:30am-5:30pm Monday through Friday and a pharmacist would be on call for after hour needs.

Mr. Burgess commented that increased access to medications improves patient health, and that is the goal of the machine.

Dr. Castellblanch asked if patient health would be measured in the study. Ms. Lake responded that a survey would be on the machine, but it would focus on satisfaction with the machine, not improvement in health.

Mr. Zee asked council to clarify if the board had the authority to grant the waiver. Ms. Shellans expressed her opinion that the board does not have the authority to allow drugs to be stored or dispensed from a location not associated with a licensed pharmacy because it is a statutory requirement in 1410 and 1437. She also commented that she is concerned about how the study is being conducted, in that a private corporate entity is running the experiment while the school is simply monitoring and reporting.

Mr. Burgess disagreed with counsel’s opinion that the location of the machine would need to be licensed as a pharmacy as the drugs are being kept there solely for patient pick-up. He explained that in his opinion using the same logic, drug delivery companies like UPS would have to be licensed with the board.

Mr. Room asked if Sharps would be willing to become licensed as it may address some of the board’s concerns. Ms. Allen responded that they would be willing to consider it.

Dr. Wong asked if the board approved the waiver then any pharmacy would be able to use a machine. Mr. Burgess responded that the request was only for a 6 month pilot of one machine and at the end of the 6 months the board could review the results and deny the request for the program to continue.

Dr. Castellblanch expressed his concern that the study proposal does not meet academic standards. Ms. Lake commented that in order for UCSD and Sharp to fully get behind the study they need indication from the board that the project could move forward.

Ms. Herold commented that she feels the board needs to recognize that council has advised that the board does not have the authority because they are asking to waive a statute not a regulation. She agreed that the study needs to be more robust.

Mr. Burgess provided that they are willing to work on the issues raised by the board and come before the board again prior to beginning the study to ensure that the issues have been resolved to the board's satisfaction.

Ms. Veale asked if Sharps chooses to get licensed as a pharmacy if they would have to meet all the requirements required for a pharmacy (sinks, bathrooms, etc.). Ms. Herold commented that the board could waive some of these requirements.

Dr. Castellblanch asked counsel what the board's liability would be if they vote to violate a statute. Mr. Room responded that he did not think the board would have any liability; however, Ms. Shellans expressed her opinion that they could be held criminally liable.

Mr. Law commented that new technology is a good way to give patients more access; however, he is concerned about the possibility of language barriers being a problem with the use of the machines.

Ms. Herold asked who would be at fault if there was an error in the dispensing at the machine. Mr. Burgess commented that the pharmacist-in-charge would be responsible.

Elizabeth Shitaki, registered nurse, commented that she feels there are too many uncertainties for the board to approve the waiver and added that taking away direct contact with a pharmacist will harm the patient.

Dr. Steve Grey, Kaiser Permanente, commented that current law allows for the delivery of medications to a patient's place of employment and the use of technology will make this already existing practice safer.

Allison Fuller, pharmacist-in-charge, expressed her concern with the use of these machines in retail pharmacies.

Dennis McAllister, Arizona Board of Pharmacy, commented that this is not new technology and he does not feel that a study is needed.

Motion: Waive California Code of Regulations Section 1713(b) and allow Asteres to install one automated dispensing machine in Sharp Headquarters for a period of 6 months. As a provision of the waiver Asteres must provide a more substantive research report and draft an agreement giving the board unlimited access to the location and study data.

M/S: Zee/Veale

Support: 4

Oppose: 5

Abstain: 0

Ms. Veale and Chairperson Gutierrez asked if adding the requirement for the location to become licensed as a pharmacy would change the board's decision.

Motion: Waive California Code of Regulations Section 1706.5 and allow Asteres to install one automated dispensing machine in Sharp Headquarters for a period of 6 month. As a provision of the waiver Asteres must provide a more substantive research report (meeting academic standards and approved by the board) and draft an agreement giving the board unlimited access to the location and study data. In addition the location at Sharps Headquarters must become licensed as a pharmacy subject to waivers of certain conditions (i.e. bathrooms, skinks ect.)

M/s: Zee/Veale

Support: 8

Oppose: 1

Abstain: 0

Attachment 5

August 26, 2013

VIA EMAIL AND FEDEX

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834
e. Virginia.Herold@dca.ca.gov

Re: Board of Pharmacy meeting - October 29-30, 2013

Dear Ms. Herold,

Further to our correspondence of August 15, we were advised by Ms. Sodergren that the Enforcement Committee agenda for September is fully committed. As such, with this letter I am respectfully requesting that MedAvail be given an opportunity to present before the Board of Pharmacy at its upcoming meeting in Sacramento on October 29 or 30.

As you know from our August 15 letter, MedAvail is a US-owned business that has developed a pharmacist-centered remote dispensing telepharmacy technology that is unique in the world. I had the pleasure of addressing the **Legislation** and Regulation Committee at its recent meetings held in Sacramento on July 29, where I offered comments in support of Senate Bill 306, and in particular the proposed expansion of the range of California clinics in which Automated Drug Dispensing Devices could be deployed. We firmly believe, based on strong empirical evidence, that increasing access to medications at or near the point of care, promotes stronger medication adherence, better patient outcomes and decreased healthcare costs.

We would appreciate an opportunity to present our solution to the California Board of Pharmacy at its scheduled meeting on October 29 - 30 - at this meeting, we would like to present our pharmacist - controlled, patient facing technology, and review with the Committee the various safety, privacy and security features which we believe allow pharmacists to increase patient access and enhance patient care by harmonizing world leading automation and technology with the traditional role of the pharmacist. Our technology, known as the MedAvail MedCenter™, allows a pharmacist to interact with and dispense medications to a patient remotely through a live, two-way audio and video connection.

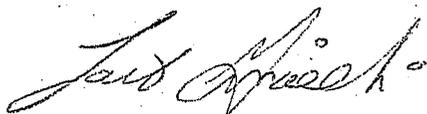
In our submission to the Legislative Committee on July 29, we stated our position that the pharmacist plays a fundamental and critically important role in health care, and he/she must play an integral role in the dispensing of prescription medication. We also cited several studies in support of the notion that providing access to pharmacy services at the point of care improves patient outcomes, given the positive correlation with higher medication adherence and compliance. This access however, must be combined with pharmacist consultation.

In the current California Business and Professions Code, Automated Drug Delivery Systems are permitted for use in specified clinics under section 4186. MedAvail will be seeking to review with the Board our specific plans to deploy our MedCenter technology within the existing rules - as well, we may be seeking a waiver and approval for a Pilot deployment project in early 2014 to be based on a proposed study to be conducted in conjunction with a California based institution.

We at MedAvail would greatly appreciate an opportunity to present our technology to the California Board of Pharmacy and answer any questions or concerns. We would have every intention of delivering a specific agenda of topics, as well as background materials, in advance for the Board's prior consideration.

Thank you - we await your kind reply.

Sincerely,



Loreto Grimaldi
COO General Counsel & Regulatory
c. 416 540 3601
e. lgrimaldi@medavail.com

cc: Sunny Lalli, RPH - Director of Pharmacy and Regulatory Affairs - MedAvail
cc: Anne Sodergren - Assistant Executive Officer (via email)
cc: Ed Rickert - Krieg DeVault LLP (via email)

MedAvail Presentation

MedAvail MedCenter™ Presentation

California Board of Pharmacy

January 10th 2014

Agenda

- (1) Product Introduction / Role of MedAvail (Video)
- (2) Deployment Opportunities
- (3) Deployment History
- (3) Current California Regulations
- (4) Overview of the MedAvail MedCenter™
 - Achieving High Standards of Care

Product Introduction Role of MedAvail Video

January 10th 2014

The MedAvail MedCenter™ Video Introduction

<https://www.youtube.com/watch?v=BFqCrv1tZnQ>

Product Introduction

- The MedAvail MedCenter™ is a first fill, patient-facing *pharmacist*-controlled and administered remote dispensing solution for Rx and OTC medications
- The MedAvail MedCenter™ provides private, confidential, real-time professional advice and counselling via a 2 way audio/video link.
- Safety and accuracy are ensured as the system requires the pharmacist to verify each item at several stages during dispense (i.e. inventory retrieval, labelling, dispense to patient)
- The pharmacist must approve every dispense of prescription medications to a patient and all transaction information is retained

The MedAvail MedCenter™ System

- The MedAvail MedCenter™ is a networked device that leverages the Pharmacy Management System (PMS) of the deploying Pharmacy – operationally, it is similar to a bricks and mortar pharmacy
- Prescription adjudication, co-pay, balance owing and other practice related issues are managed through the PMS by the call center Pharmacist in a manner similar to retail pharmacy
- Staffing decisions, patient wait times and other business decisions are controlled by the deploying Pharmacy – **i.e. higher call center Pharmacy availability = shorter wait times**

The MedCenter extends reach of traditional pharmacy via technology

MedCenter Technology – Where does it fit In?

- Enhances access to Pharmacy services in 3 ways:
 - (i) After Hours Dispensing
 - (ii) Pharmacy access in rural / underserviced areas
 - (iii) “Point of Care” dispensing
 - IMS data reports that up to 50% of prescriptions are never filled
 - MedCenter improves access to a pharmacist by facilitating safe, secure and timely dispensing – often at the point of care

The MedAvail MedCenter™ integrates 21st century technology with the important role of the Pharmacist in Rx dispensing

Deployment Opportunities

January 10th 2014

Main Deployment Opportunities (Channels)

- **Hospitals** – access to medications for patients discharged from the hospital or emergency department allows patients to receive their medication before going home – improves adherence
- **Clinic** – Access to medications at clinics helps to ensure that patients have received their medication and have been educated about their medication in a timely manner
- **Retail** – Provide access to pharmacy services in pharmacy and non pharmacy retail environments
- **Other** – Large employer sites (adjacent to other healthcare), Long-Term Care facilities

All Deployments of the MedCenter offer opportunities for greater access to pharmacy services.

MedCenter Deployment Potential

- MedCenter system can be deployed within a pharmacy as an extension of the pharmacy for after hour service.
- Can be deployed in a non-pharmacy retail space
- Hospital Emergency Room and Clinics
- Employer worksites
- College and university health centers
- In each scenario, pharmacist controlled, patient centered pharmacist care is brought to the patient
 - Home Pharmacy acquires and deploys the MedCenter
 - Home Pharmacy – overall responsibility for the care and control of the MedCenter (answers to CA BOP)
 - MedAvail – technology (Hardware/Software) Vendor; handles field service and maintenance

Deployment History

January 10th 2014

Deployment History – US and Canada

Greater Toronto Area	Illinois
Ontario Board of Pharmacy – enacted rules permitting MedCenter deployments in mid 2011 – approved in all deployment channels	Regulations passed by Illinois DFPR in 2008 – approved in all deployment channels
16 Deployments including doctors and specialists clinics, hospital waiting rooms and EDs, and remote Native Reserves	Current deployments – large employer site (no on-site pharmacy) and large private urban clinic that also serves 340B patients (Chicagoland Area)
Early data pointed to enjoyable user experience, high customer satisfaction and accuracy in dispensing (no misfills)	Current model includes centralized out of State (Florida) call center (audio video) for patient receipt and info verification, prescription entry into PMS, required DURs, patient counseling, final check and approval of patient dispense (all functions of community pharmacy)
Currently finalizing pilot deployment with large Canadian pharmacy retailer (proposed hospital deployment)	Q1 deployment at Chicago – Mercy Hospital – Comprehensive Pharmacy Services (CPS) is the pharmacy partner

Current California Regulations

January 10th 2014

California Regulatory

- Telepharmacy is presently permitted for deployment in certain licensed clinic settings in order to promote access to pharmacy services. Cal. B&P Code 4180.
- Legislative efforts have been made to expand 4180 to expand the range of settings in which remote dispensing technology can be deployed. SB 306.
- MedCenter deployment would not require new legislation.

California Regulation 1713(d)(4)

- 16 California Code of Regulations section 1713(d) states that a pharmacy may use an automated delivery device to delivery previously dispensed prescription medications provided certain requirements are met:
 - ***The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counselling as set forth in section 1707.2(a)(2).***
- The MedCenter provides the ability to review a paper prescription document as well as receive e-prescriptions while in consultation with the patient. The system therefore allows the pharmacy to fill new prescription orders as a brick-and-mortar pharmacy would.
 - ***Patient interaction with the pharmacist occurs with every dispense!***
- Previous filled limitation is therefore not needed to protect the public.
- A waiver would be requested prior to deployment.

California Regulation 1713(d)(6)

- 16 California Code of Regulations section 1713(d) also requires the device to be located “adjacent to the secure pharmacy area”.
- The MedAvail MedCenter™ is equipped with robust security systems and internet connectivity which requires connection with the pharmacy at all times. This would allow the system to be deployed remotely from a brick and mortar pharmacy and maintain the ability to connect with the pharmacist at all times.
- Prior to deployment, a waiver from this requirement would be requested.

MedAvail MedCenter Achieving High Standards of Care

January 10th 2014

MedCenter Dispensing Process – How it Works



1 Patient provides proof of ID

2 Patient submits or requests their prescription

- Paper prescription inserted into scanner, OR
- Technician pulls up e-Rx/refill

3 Pharmacists and Technicians communicate with Patient

- Live 2 way Audio and Video connection
- Pharmacists provide medication counseling and verify prescriptions before dispensing.

4 Accuracy and Accountability

- Pharmacy Management System utilized for prescription processing/adjudication
- Fully tracked and auditable (all order entry, drug selection and verifications are recorded and these records maintained)
- Bar code identification of product by unit
- RPh performs final visual verification of Rx package/label before dispense.

MedCenter: Exterior At a Glance



PROTECTIVE GLASS

Robust glass bezel protects display screens and camera

AUDIO

Hi-fidelity hands free stereo audio system tuned and optimized for privacy.
Handset option for additional privacy.

BENEFIT CARDS & ID

Versatile card scanner for ID and benefits card

SCRIPT SCANNING

Duplex scanner with multi-size and multi-page document handling

2-WAY VIDEO

2-way video (w/audio) is presented on the upper screen and with the integrated camera

TOUCH SCREEN

Touchscreen user interface can be software branded and customized

DISPENSE BAY

Secure dispense bay delivers medication and printouts at completion of transaction

PAYMENT

Payment support with card reader and PIN pad for credit, debit and loyalty cards

MedAvail MedCenter™ Achieving High Standards of Care

- The MedAvail MedCenter system incorporates many elements of pharmacy practice that are already approved in many States:
 - Remote Order Entry and Adjudication
 - Central Call Center
 - Out of State Supply and Delivery of Rx (mail order)
 - Pharmacist counselling and supervision via electronic means
 - Contracted pharmacy services with local and remote entities

Achieving High Standards of Care: Prescription Interpretation and Data Entry



- The MedCenter accepts both eRx and paper prescriptions.
- When a paper prescription is inserted, the RPh/Technician sees a high resolution scan and can zoom for enhanced viewing.
- A RPh is ultimately responsible for all prescriptions dispensed.
- **The same standard for RPh accountability and technician entry of information (including video review of prescriptions) is permitted in Hospital, Retail and Mail Order practices today**

Achieving High Standards of Care: Prescription Verification

Order ID: 44142467-9222-42a0-9f1a-fead28429919
00:02:05 Connected HMI: Item-sc017y

Ready
Get Rx from user
Receive Rx details from Call Center
Confirm Payment Amount And Select Type
Receive Payment
Print Medication Info Forms
Dispensing Medication
Releasing Medication
Open Release Door
Close Release Door
Print Receipt
Aborting
Returning Rx Document
Voiding Transaction
Printing Void Payment Receipt
Discarding Medication
Capturing Rx Document
Done!

Queued Item Status
SILVER SULFADIAZINE CREA... QTY: 400 GM
LPC12 305910810467 1 of 1
Awaiting Verification

Inventory Item Serialization Info

Label Name: Silver Sulfadiazine 1% Cream Quantity in Pack: 400 GM
Generic Name: Silver Sulfadiazine Package Code: LPC12: 305910810467
Drug Code: NDC: 00591081046 Manufacturer: WATSON Regulatory Class: RX Length: 115.7 mm
Inventory ID: 0007C3E34K5644A Lot: 1 Expiry Date: 12/31/2018 Width: 63.1 mm
Height: 63.1 mm

Item Ready For Pharmacist Approval

Item Picked Label Printed on Package Post Labeling Image Pre-Release Image

	Expected	Actual		
Label Sequence Check	1234	1234	Passed	✓
Product Check	305910810467	305910810467	Passed	✓
Expiry Date		31-Dec-2018		?
Lot		1		?

Release Drug
Discard & Repick

Cancel Transaction Patient Lift Phone

- MedCenter allows the RPh/Technician to process a patient's Rx while viewing their Rx history
- The RPh can use built in interaction checks in the PMS and through adjudication
- The RPh verifies the medication and compares it with electronic checks
- Expiration date is checked and RPh approves the Rx for dispensing

Achieving High Standards of Care: Drug Selection and Labeling

- Following patient verification, prescriptions are processed and a Rx number is generated
- Medication is selected via robotics using barcode technology and then labelled
- No items are dispensed until the RPh does a final product check and provides approval
- RPh visually verifies the filled prescription (product and label) before release to the patient



Achieving High Standards of Care: Patient Counseling

- The RPh counsels the patient via a 2 way audio/visual communication
- The RPh can counsel on all new Rx items or require a consult if they deem it necessary
- All required patient education and documentation is printed and dispensed along with the medication
- Patient privacy is protected with privacy panels and an optional handset



Questions? Next Steps

January 10th 2014

Attachment 6

Assembly Bill No. 377

CHAPTER 687

An act to amend Section 4029 of, and to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

[Approved by Governor September 28, 2012. Filed with
Secretary of State September 28, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 377, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant.

This bill would authorize a centralized hospital packaging pharmacy to prepare medications, by performing specified functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership, as defined, and within a 75-mile radius of each other. The bill would require a centralized hospital packaging pharmacy to obtain a specialty license from the board, and the bill would make these licenses subject to annual renewal. The bill would condition both the issuance and renewal of a specialty license on a board inspection of the centralized hospital packaging pharmacy to ensure that the pharmacy is in compliance with the bill's provisions and regulations established by the board. The bill would impose specified issuance and annual renewal fees for a specialty license, and because these fees would be deposited into the Pharmacy Board Contingent Fund, a continuously appropriated fund, the bill would make an appropriation.

The bill would authorize a centralized hospital packaging pharmacy to prepare and store a limited quantity of specified unit dose drugs in advance of receipt of a patient-specific prescription in a specified quantity. The bill would impose various requirements on centralized hospital packaging pharmacies, including, but not limited to, that medications be barcoded to be readable at the inpatient's bedside and that medication labels contain

specified information. The bill would make these pharmacies and pharmacists responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the packaging pharmacy. Because a knowing violation of these provisions would be a crime, the bill would impose a state-mandated local program.

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

This bill would provide that no reimbursement is required by this act for a specified reason.

Appropriation: yes.

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

SECTION 1. Section 4029 of the Business and Professions Code is amended to read:

4029. (a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy also includes a pharmacy that may be located outside of the hospital in another physical plant that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

SEC. 2. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.6. Centralized Hospital Packaging Pharmacies

4128. (a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

(1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.

(2) Preparing compounded unit dose drugs for parenteral therapy for administration to inpatients, if each compounded unit dose drug is barcoded to contain at least the information required by Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.

(b) For purposes of this article, “common ownership” means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

4128.2. (a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.

(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.

(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.

(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.

(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.

(h) The fee for issuance or annual renewal of a centralized hospital packaging pharmacy license shall be six hundred dollars (\$600) and may be increased by the board to eight hundred dollars (\$800).

4128.3. A centralized hospital packaging pharmacy may prepare and store a limited quantity of the unit dose drugs authorized by Section 4128 in advance of receipt of a patient-specific prescription in a quantity as is necessary to ensure continuity of care for an identified population of inpatients of the general acute care hospital based on a documented history of prescriptions for that patient population.

4128.4. Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient’s bedside. Upon reading the barcode, the following information shall be retrievable:

- (a) The date the medication was prepared.
- (b) The components used in the drug product.
- (c) The lot number or control number.
- (d) The expiration date.
- (e) The National Drug Code Directory number.
- (f) The name of the centralized hospital packaging pharmacy.

4128.5. The label for each unit dose medication produced by a centralized hospital packaging pharmacy shall contain all of the following:

- (a) The expiration date.
- (b) The established name of the drug.
- (c) The quantity of the active ingredient.
- (d) Special storage or handling requirements.

4128.6. All compounding and packaging functions specified in Section 4128 shall be performed only in the licensed centralized hospital packaging pharmacy and that pharmacy shall comply with all applicable federal and state statutes and regulations, including, but not limited to, regulations regarding compounding and, when appropriate, sterile injectable compounding.

4128.7. A centralized hospital packaging pharmacy and the pharmacists working in the pharmacy shall be responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Support Letter



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

September 13, 2012

The Honorable Edmund G. Brown Jr.
Governor
State of California
State Capitol
Sacramento, CA 95814

RE: Assembly Bill 377 (Solorio) - Enrolled

Dear Governor Brown:

The California State Board of Pharmacy respectfully requests your signature on **Assembly Bill 377** (Solorio). This bill would allow a hospital chain under common ownership to prepare consolidated packaging operations to prepare single dose medications that are bar coded. The unit medications would be delivered to any of multiple campuses of the general acute care hospitals under the same ownership for patient administration. Such operations would be done in a specialty pharmacy licensed and regulated by the board. The FDA has determined that a pharmacy performing such packaging is not “manufacturing.”

Currently a hospital may package such unit dose medication for administration to patients solely within the same hospital’s premises. Assembly Bill 377 would require a specialty license that would result in bar coding of all unit dose medications produced. Hospitals would still be required to maintain existing pharmacies to evaluate, prepare, compound and dispense medication ordered for patients that are not fulfilled by the centralized packaging pharmacy. Further, under AB 377, the new packaging pharmacies would be subject to annual inspections by this board before issuance or renewal of the specialty pharmacy permit.

The board strongly supports this consolidation of specific pharmacy operations to prepare unit dose medication for patients of the same hospital chain. This would facilitate the use of costly, specialized equipment that would affix bar codes to every dose of medication packaged. Bar coding is important for patient safety. Before a medication is administered to a patient, by scanning the bar code on a medication, a patient’s chart and a patient’s wristband – the right medication, in the right dose will be ensured at the patient’s bedside. This provides an important step forward to improve patient safety and decrease the rate of medication errors and potential adverse drug events.

Published examples of how bar coding would benefit patients include:

- Medication errors in hospitals are common, and dispensing errors made in the pharmacy contribute considerably to these errors. Overall, dispensing error rates are relatively low, but because of the high volume of medications dispensed, more than 100 undetected dispensing errors may occur in a busy hospital pharmacy every day.

Because only about one third of these dispensing errors are intercepted by nurses before medication administration, many errors reach hospitalized patients. Therefore, dispensing errors are an important target for patient safety interventions. Bar code technology has been touted as a promising strategy to prevent medication errors. (Poon, et al., 2006)

- Medications are the most frequent cause of adverse events. More than a million injuries and nearly 100,000 deaths are attributable to medical errors annually. (Maviglia, et al., 2009)

Under the regulation of the Board of Pharmacy, packaging pharmacies would repackage three principal forms of medication: pill or other solid dosage forms, compounded medication and injectable compounded medication. Existing law allows pharmacies to compound medication for administration to patients either pursuant to a prescription or in advance of a prescription, based on normal usage or needs. Further, California law allows pharmacies to compound for future furnishing for their use or for use by physicians.

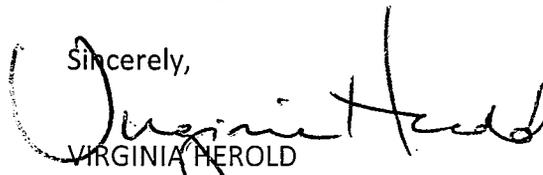
Compounding in such a manner is the practice of pharmacy – not manufacturing. Pursuant to the Compliance Policy Guide Section 460.100, the US FDA provides, in part, the following:

“We interpret Section 510 of the Federal Food, Drug, and Cosmetic Act as not requiring registration by the hospital pharmacy that compounds medication for inpatient dispensing, outpatient dispensing (sale or free), mailing to a patient within the State or out of the State, or for transferral to another unit of the same hospital (within the State or in another State) for dispensing by that unit of the hospital.”

In 2010, Board of Pharmacy regulations took effect to ensure the safety of medication compounded for administration or injection pursuant to a patient-specific prescription or in advance of receipt of a prescription. These are encompassing regulations that require efficacy assays, staff training, specialized equipment, specific processes and detailed recordkeeping to ensure the quality of medication compounded by pharmacies. These regulations and the pharmacy self-assessments that pharmacies that compound must complete periodically ensure the public safety.

Permitting hospital pharmacies under common ownership to repackage into unit doses if they bar code the medication will aid hospitals in improving patient safety. Annual inspections by the board will ensure these pharmacies are following all requirements. The Board of Pharmacy supports this measure and respectfully requests that you sign Assembly Bill 377.

Sincerely,



VIRGINIA HEROLD
Executive Officer

cc: Assembly Member Solorio

B&PC 4118

4118. Waiving of Minimum Requirements by Board

(a) When, in the opinion of the board, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a pharmacy that does not meet all of the requirements for licensure as a pharmacy, the board may waive any licensing requirements.

(b) When, in the opinion of the board, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a hospital pharmacy, as defined by subdivision (a) of Section 4029, that does not meet all of the requirements for licensure as a hospital pharmacy, the board may waive any licensing requirements. However, when a waiver of any requirements is granted by the board, the pharmaceutical services to be rendered by this pharmacy shall be limited to patients registered for treatment in the hospital, whether or not they are actually staying in the hospital, or to emergency cases under treatment in the hospital.

Waiver Request

Request by Scripps Health for an Interpretation/Waiver for B & PC, Article 7.6, Section 4128.4 by Board of Pharmacy Enforcement Committee

EXECUTIVE SUMMARY

Pursuant to AB 377, Scripps Health has built a central pharmacy production center to improve patient safety by supporting Bedside Bar Code Medication Administration (BBCMA), by using an optimal production environment and personnel skills and by decreasing reliance on OUTsourcing. The Scripps Health BBCMA system currently being developed is consistent with the industry standard for Bedside verification of the right drug for the right patient by instantly matching the patient's wrist-band barcode with the unit dose barcode per the patient's drug orders. Scripps Health further submits the system being developed is consistent with B&P Section 4128.4's requirement for "retrievable" information, i.e. that through each unit dose package's barcode all of the information (see below*) can be retrieved for quality control and investigation purposes, as was the intent of AB 377. Scripps Health wishes no further delays on implementation of this patient-safety system and asks for acknowledgement of either the systems compliance with the B&P Code or an immediate waiver, as suggested by Board staff, of an interpretation that all the information* must be instantly human readable at the bedside. In essence, "retrievable" is not meant to be *"human readable at the bedside"*, but does mean that the information is human readable upon follow-up investigation as needed.

** "4128.4 (a) The date the medication was prepared. (b) The components used in the drug product. (c) The lot number or control number. (d) The expiration date. (e) The National Drug Code Directory number. (f) The name of the centralized hospital packaging pharmacy."*

BACKGROUND

Scripps Health has built a central pharmacy production center at a location centrally located to the five Scripps Hospitals to provide IV compounding and unit dose packaging and distribution services for the hospitals. The purpose of this central pharmacy is:

- To improve patient safety at the hospitals by producing and distributing the drugs in a state-of-the-art facility properly laid out and equipped, with workflows designed to minimize errors and systems and practices that assure a controlled production environment, an environment that cannot be duplicated at any of our hospitals;
- To decrease reliance on outsourced compounding and repackaging vendors;
- To support the bedside bar code medication administration (BBCMA) system being developed at Scripps by utilizing technology that can apply a barcode to every product that can be read at the bedside.

We have invested in developing this facility, with the expectation that AB377 would be signed into law and when completed the facility could be appropriately licensed by the Board of Pharmacy. It was planned to bring this facility on-line in parallel with the development of our BBCMA system, thereby assuring that the central production operation would be stabilized by the time the barcoded products were needed. We also expected that, since current BBCMA technology does not support inclusion and parsing of all of the elements called for in AB377, we could meet this

requirement through being able to retrieve these elements from our batch record once the bar coded lot number was read at the bedside.

All of the policies and procedures, equipment and systems are in place in the Central Pharmacy to provide high quality production that meets or exceeds all applicable compounding and drug preparation requirements. We have submitted applications for licensure as a Hospital Pharmacy, under one of our system Hospitals, as a Centralized Hospital Packaging Pharmacy and as a Sterile Injectable Compounding Pharmacy.

After contacting the Board of Pharmacy office to request pre-licensure inspection we were contacted by the assigned enforcement officer to discuss inspection readiness. During this discussion and in subsequent discussion with the Supervising Inspector and Board Executive, we became aware that the section 4128.4 phrase "Upon reading the barcode, the following information shall be retrievable:" was interpreted as requiring some immediate electronic provision of the information elements rather than subsequent retrieval from the product batch record. We then submitted our IV compounding workflows as requested. Subsequent to review of provided workflows detailing the bar coding processes associated with our production and labeling, we were told by the Supervising Inspector that we were not in compliance with the requirements. The Supervising Inspector suggested that if we believed we are in compliance or wish to obtain a waiver as provided for in B&P 4118 we should plan on presenting the case at the Enforcement Committee meeting on 1/10/14 in Sacramento.

INTENT OF THE AB377 LEGISLATION

It is our understanding that the intent of the AB377 legislation was to improve patient safety by allowing health systems in California to establish centralized pharmacies that could compound and repackage drugs in a more controlled, closely monitored environment, using better work flow processes and automated/robotic devices requiring less human intervention than is possible in most individual hospitals. These features of the centralized pharmacy would improve the reliability, consistency and quality of the products produced and thereby, patient safety. It was also the intent to improve the information available to the nurse at the bedside, administering the drug produced by the centralized pharmacy, in order to reduce medication errors and improve follow-up investigation of medication issues.

The Scripps centralized pharmacy incorporates the following improvements over compounding and packaging operations in our individual hospitals:

1. A state-of-the art cleanroom with adequate working space for safe operation.
2. Robotic compounding and packaging devices that minimize human intervention in the processes and use barcodes and scales to assure accuracy.
3. Consistent staffing with well-trained individuals whose primary focus is pharmacy compounding and production.
4. 24/7/365 environmental monitoring for particles, differential pressures, temperature and humidity with text and e-mail message out-of range alarm notices to managers
5. Policies and standard operating procedures that meet and exceed all applicable USP 797 standards and sterile injectable compounding pharmacy requirements.
6. A quality management system that incorporates standard process auditing, variance reporting and CAPA (corrective action/preventive action) follow-up on deviations.

7. Contracted routine cleaning, by a professional cleanroom cleaning service, to supplement daily cleaning by staff.
8. Workflows that keep raw product and ingredients separated from finished product.
9. An automated, tightly controlled inventory management system.
10. A full security system with motion sensors, glass break sensors and multiple CTV cameras.
11. Carousel drug storage that improves security and the accuracy of distribution by utilizing barcode scanning.
12. A document control system that assures proper document management, storage and retrieval.
13. Barcodes on all compounded and repackaged products that allow retrieval of the product batch record, including components, expiration dates, lot numbers and beyond use dates.

All of these features improve product reliability, quality and patient safety.

THE LEGISLATION IS AHEAD OF THE TECHNOLOGY

Although the several elements of information required to be retrievable at the bedside by B&PC, Article 7.6, Section 4128.4 can be placed in a single bar code, current BBCMA systems are not programmed to read, parse out and present this information. Since pharmaceutical manufacturers are not required to include this information in the bar codes on their products, BBCMA system vendors have not been requested to build this functionality into their programs. Making changes like this to their programs that have already been certified and tested is a lengthy process. They have very limited incentive to make these program changes a priority since they are needed only by an extremely small subset of their clients nationwide.

Scripps extensively evaluated several BBCMA systems prior to selection of a vendor. None of these systems could provide the functionality called for by section 4128.4. We are not aware of any hospital or healthcare system that has a fully implemented BBCMA system that can provide this functionality.

THE STATUS OF THE SCRIPPS BBCMA SYSTEM IMPLEMENTATION

The Scripps BBCMA system is expected to be implemented between October 2014 and April 2015. We have made our vendor aware of the requirement for the mentioned functionality. Since the BBCMA software for our system has already been tested and certified in order to meet the Meaningful Use requirements, additional software changes to fully integrate the 4128.4 functionality cannot be made until after this initial implementation. We are working on approaches that would make this information electronically available to the nurse at the bedside, not as an integral part of the BBCMA system, at an earlier date.

THE CASE FOR LICENSURE WITHOUT FULL COMPLIANCE WITH SECTION 4128.4

The information elements required by Section 4128.4 are all present on the product label for products produced by the Scripps Centralized Hospital Packaging Pharmacy and are fully readable by the nurse. The practical value of immediate electronic retrieval of this same information is limited. In the case of a problem with the product or product outcome, the full

details, including and beyond these six elements, for the preparation of the product can be quickly retrieved from the batch record as referenced by the printed lot number.

Operationalization of the Scripps Central Pharmacy, through licensure, will provide the thirteen quality and patient safety improvements detailed above. Implementation of the Central Pharmacy will also allow discontinuation of purchases from outsourced compounders, improving control, quality and reliability.

Scripps has made a significant capital and personnel investment to achieve these improvements. It would be a disservice to our patients and patient safety in general to delay implementation.

OUR REQUEST

We believe that the Board of Pharmacy has the discretionary authority to both interpret the options for bedside retrieval of this information more broadly and to allow additional time following licensure to fully comply with the requirement as currently interpreted. This would allow us to significantly improve patient safety within the Scripps Health system while we work with our vendors to provide electronic retrievability of the required information elements at the bedside. We respectfully request a temporary stay on the strict interpretation of this requirement and issuance of our Central Hospital Packaging Pharmacy license while we attempt to reach full compliance. We also request that the Board submit the appropriate request for change in the language of the law to make the barcoding requirement compatible with currently available BBCMA technology.

Case Study

CENTRALIZED PHARMACY

COMPOUNDING AND REPACKAGING



Creating a Centralized Compounding Pharmacy within a Health System

Amy Benner, PharmD
Director of Central Pharmacy
and Shared Services
Scripps Health

Robert Miller, MS
Pharmacy Quality Manager
Scripps Health

Ensuring the production of accurate and safe sterile compounded medications for our patients spurred our investigation to identify the ideal approach for creating a centralized compounding pharmacy. To create a cutting edge facility that consistently and efficiently delivers safe and effective medications required us

to embrace automation. It became clear as we investigated our options that establishing a centralized production facility to provide medications throughout our health system would allow us to justify the purchase of innovative technologies and construct a facility that would operate under an advanced workflow.

Scripps Health System consists of five, commonly owned hospitals, all located within a 50-mile radius. These facilities are of various sizes, ranging from 170 beds up to 400+ beds. A notable difference among the facilities was the different approaches taken to compounding. Much of this variability resulted from the variety of equipment and cleanrooms that had

been installed at different points in time. As a result, each of our hospitals had achieved various levels of USP <797> compliance; we did not have consistent compounding practices or facilities.

Drivers for Creating a Centralized Compounding Pharmacy

Three years ago, we began the process of creating a new, centralized facility to provide sterile compounded and repackaged medications to the five hospitals in our health system. Our goal was to create a single facility to centrally produce sterile IV products for all of our facilities in an efficient and cost-effective manner.

Having made the commitment to implement BCMA in our health system, it was obvious that our compounded and repackaged products also required a comprehensive bar coding process. An intrinsic component of the automation in our central compounding pharmacy is the software that consistently creates bar code labeled products to support BCMA. Our final product bar codes ultimately provide the batch lot number for each product, allowing us to retrieve the necessary information for each component used in a given product.

Building a new, USP <797>-compliant facility gave us the opportunity to ensure that both the facility and standard operating procedures (SOPs) would meet or exceed standards. By centralizing operations we also were able to take advantage of economies of scale to justify the purchase of cutting edge technology. This allowed us to create efficiency and safety through automation while avoiding the problems inherent with space constraints in our existing facilities. For example, we have sufficient space within the new cleanroom for three IV compounding robots, a refrigerated carousel connected to the cleanroom for product transfer and storage, as well as a high-speed oral solid packager and a liquid packaging machine.

CENTRALIZED PHARMACY

COMPOUNDING AND REPACKAGING

After reviewing various locations to house the central compounding facility, we ultimately chose to locate it in a stand-alone space centrally located between our multiple hospitals; approximately 3500 square feet are dedicated to the operation including a 1570 square foot cleanroom. One unexpected benefit of the standalone space is the ease of shipping and receiving activities, as we are not constrained by a busy hospital shipping dock. Utilizing batch production in this centralized facility will help us create economies of scale in our compounding processes, which will positively impact pharmacy's bottom line.

Meeting Regulatory Requirements

At the time that we began exploring the possibility of creating a centralized compounding pharmacy, the state regulations in California did not permit batch compounding from a central location even within facilities under the same ownership. As such, we approached the state board of pharmacy and worked with them to develop the necessary state legislation that was eventually enacted (Assembly Bill 377) to permit a centralized pharmacy to provide medications to commonly owned facilities within a 70-mile radius. Key to the success of this legislation was emphasizing the improved safety we could provide our patients via robotic equipment and

compounding automation—technology that might prove unaffordable for a single hospital. Under the new legislation, a central compounding facility must pass a state board of pharmacy inspection prior to opening, and undergo regular inspections thereafter.

During our planning process uncertainty continued to define the interpretation of federal regulations as applied to centralized hospital pharmacy operations. Thus, we chose to create SOPs that would meet the strictest regulatory guidelines; the design of our SOPs is based on FDA's current good manufacturing practices (cGMPs) to ensure that our practice will deliver products defined by safety and that we will be prepared to meet new regulations as they develop. For example, in addition to providing in depth training on our SOPs and requiring meticulous process documentation, we will ensure our procedures are followed through consistent, routine auditing. Should a discrepancy be identified, a Corrective Action/Preventive Action (CAPA) approach is undertaken as prescribed in the cGMPs. Discrepancies are documented, root causes are investigated, and the corrective action to prevent a recurrence of the problem is implemented along with a plan for follow-up. This rigorous approach helps avert the risk of developing poor practices.

Designing the New Space

Advanced technology drives the efficiency that makes a centralized compounding pharmacy practical. Therefore, robotic compounding will facilitate much of our compounding production. Two IV robots as well as a robot for preparing sterile syringes complement our modular cleanroom. In addition, IV workflow and inventory management software programs support the process, while a refrigerated carousel ensures appropriate product management and storage. A high-speed oral solid packager and liquid packager round out the automation.

The first decisions in the build process revolved around the cleanroom. Rather than have our contractor build the cleanroom, we chose to install a modular cleanroom built by experts who specialize exclusively in cleanroom construction. The decision to go with Grifols was obvious as they not only provided a highly detailed proposal that included cleanroom design and workflow diagrams, but they also have extensive experience designing and building cleanrooms for their own manufacturing facilities. The storage and inventory management system for all compounded products is also automated and includes hardware tools such as our Grifols-SencorpWhite CleanRoom Connect carousel. The refrigerated carousel offers a pass-through design with automatic, interlocked doors to prevent cross contamination when moving products

VALIDATION ROOM VIEW



BUFFER GENERAL IV ROOM VIEW



With the Grifols-SencorpWhite CleanRoom Connect carousel, products are easily moved into and out of the cleanroom via the automatic doors.

BUFFER GENERAL IV ROOM



BUFFER GENERAL IV ROOM



WIPE DOWN & STORAGE ROOM



Robot production takes place within the Misterium modular cleanroom and the pass-through refrigerator improves product accessibility.

into and out of the cleanroom. We also chose to install our robots and oral solid packaging equipment within the cleanroom. While it is not required that this equipment be located within an ISO-controlled area, we felt this placement would ensure the highest levels of cleanliness and sterility for our operation.

Planning the layout required significant expertise. We benefited from Grifols' extensive experience in cleanroom design and construction, and also worked with an expert consultant to fill in our knowledge gaps. Taking a team approach to the design and construction phases allows you to take full advantage of in-house expertise. Our facilities department managed the construction phase, which freed pharmacy to work on SOPs and workflow design. It is important to engage the facilities department early in the process and to support the allocation of adequate resources to oversee construction.

The IS department was equally integral to our success. In any highly automated operation, all of the new systems and devices need to be vetted to ensure interoperability and network compatibility. Keep in mind, the technology vetting process can take as long as the construction process, so advanced planning is required. Finally, during the actual installations, the IS department is invaluable to the complex configuration and testing processes.

Workflow

By design, our centralized compounding pharmacy will only produce products from FDA approved sterile ingredients; no high-risk or hazardous compounding will be conducted in this facility in the interests of product safety. Our plan is to begin on a small scale, develop expertise, and then expand our practice. The first products we compound will be those that are commonly used throughout our facilities and often outsourced to outside, large-scale sterile compounding pharmacies. An important component of our layout and workflow design is to prevent any process overlap between raw ingredients and final products. As such, the complete production process for each product is mapped out as part of our SOPs.

Just as the centralized approach allows us to take advantage of cutting edge cleanroom equipment, we also enjoy the benefits of process standardization that are only possible on this larger scale. For example, we have a dedicated validation area where all pharmacist checks are completed. Our automated workflow technology tracks and documents each production stage including compounding, pharmacist check, sterility testing, and product releases (ie, sterility testing passed), which provides significant peace of mind. The software also allows for batch number and expiration date management,

making it easier to manage out of date or recalled products. Additional control is delivered through the cleanroom carousel's inventory management system, which allows or denies access to products based on their current status (eg, sterility testing, product release). Another area that benefits from standardization is sterility testing. As we conduct batch production, every batch assigned a beyond use date (BUD) exceeding USP <797> microbial contamination risk levels will undergo a USP <71> sterility test.

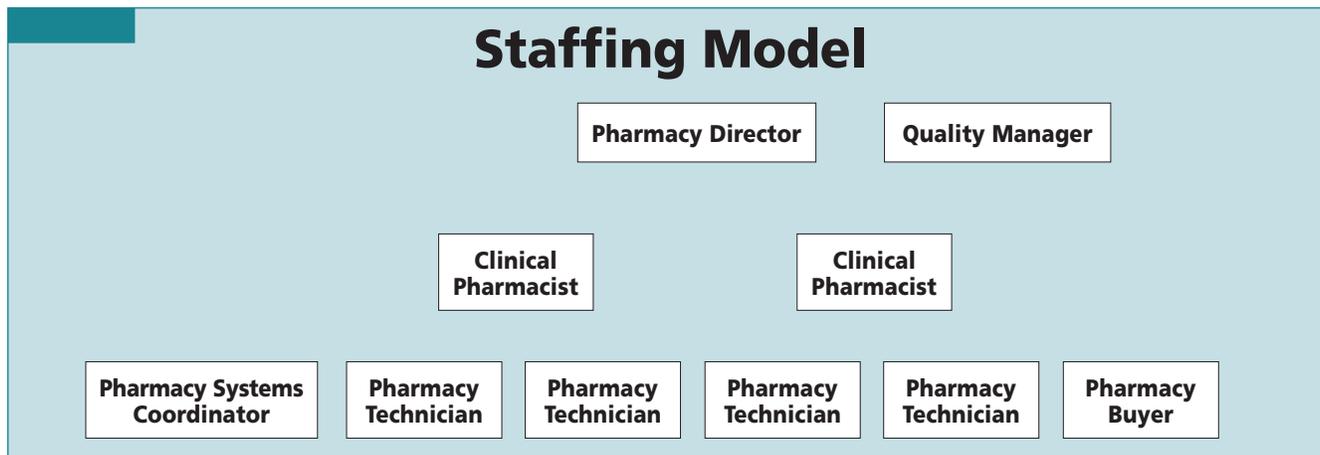
Because compounded products are only as good as the environment in which they are prepared, environmental monitoring becomes a key component of the process. We installed the Grifols/CIMScan environmental monitoring system, which includes sensors to monitor temperature, humidity, differential pressure, and particle counts. CIMScan monitors these parameters and alerts designated individuals if pre-established alert values are exceeded. By automating the environmental monitoring, data is collected regularly and reliably, while staff is free to focus on other areas. Because, the data is collected continuously, it is easy to document our compliance.

Quality Control Drives Long-term Success

The key building blocks of a centralized pharmacy operation are creating an

CENTRALIZED PHARMACY

COMPOUNDING AND REPACKAGING



The initial staffing model will support a single shift, 5 day a week compounding program. All staff reports to the Pharmacy Director, with the exception of the Quality Manager. While the Quality Manager works closely with the Pharmacy Director, this role reports to the Executive Director of Pharmacy Services to ensure the independence of this position. The Pharmacy Systems Coordinator is a technician position that manages the automated equipment and interfaces with the IS department and the technology vendors.

environment that is capable of consistently providing USP <797>-compliant compounded products for multiple facilities and establishing SOPs that ensure consistency. However, ongoing quality control measures are imperative to ensuring that the benefits of those initial efforts are maintained over time. Comprehensive training is the first step to ensuring high proficiency

among staff members. Initial efforts should focus on training a limited number of staff members and expand only when the core group has demonstrated sustained proficiency through regular practice. Because our initial operations will commence with just one shift, we will utilize 10 employees at the outset (see Figure 1). Given the realities of vacations and unexpected absences, appropriately trained back-up staff must be available to step in, possibly on short notice. Again, our training will focus on a core group of inpatient pharmacy staff to serve in back-up roles. By keeping this number small we will be able to provide the extensive training that is necessary to develop expertise among both groups.

Considering how easy it is for the best of intentions to be lost in practice drift, or the gradual shift away from precise practices into bad habits, establishing a dedicated quality control position underscores management's commitment to the consistent application of quality as well as affords a bulwark against this inevitable drift. Providing a separate reporting structure for this position is necessary to maintain independence. Key responsibilities for this role include scheduling regular times to observe staff in

action, paying particular attention to aseptic technique, cleaning and disinfecting, hand hygiene and garbing, equipment operation, policy and procedure adherence, and environmental sampling competency.

In addition to keeping a record of training conducted, quality management requires that deviations and incidents be tracked, and corrective actions documented. Implementing quality management software simplifies this process and makes survey preparation and data trend reporting painless.

Conclusion

As the centralized compounding pharmacy project has developed, additional opportunities for delivering cost-effective, safe, efficient centralized services have also evolved. We began with a plan at the outset to provide certain high volume compounded products to our health system facilities, but we now plan to expand to providing centralized automated dispensing cabinet (ADC) and code cart drug tray replenishment as well. Once the safety, efficiency, and cost effectiveness of the centralized model are established, the opportunities for expanding the utility of such a progressive operation abound.



The automated workflow software tracks and documents each stage in the compounding process.

Sharp Healthcare Waiver Request

**Sharp HealthCare
Request for Waiver of
California B&P Code Sections 4128(a)(2) and 4128.4
Presented to the California Board of Pharmacy Enforcement Committee on
January 10, 2014**

EXECUTIVE SUMMARY

SITUATION

- The California Board of Pharmacy (the Board) has directed Sharp HealthCare (Sharp) to immediately cease centralized hospital packaging pharmacy (CHPP) operations.
- This order is based, in part, upon the Board's interpretation of Sections 4128(a)(2) and 4128.4 of the California Business & Professions (CA B&P) Code as requiring barcodes to directly incorporate six enumerated elements.
- Compliant technology does not exist.

BACKGROUND

- Sharp operates six hospitals in the San Diego area comprising 2110 inpatient beds, and cared for 84,000 inpatients during 2013.
- Sharp has worked with the Board since 2007 on the construction of a CHPP and has completed a 10,000 ft² facility with a 1800 ft² USP<797> compliant clean room, for which Sharp has been seeking licensure since February of 2013.
- Construction of this unit incorporated several complementary medication-safety technologies; the unit has demonstrated its safety, quality, and efficiency value in multiple ways, including (see Tabs 1-6 for further detail):
 - Control of product and label design in ways still not available commercially.
 - Barcoding allowing retrieval of the product NDC batch record, including components, expiration dates, lot numbers and beyond use dates in human readable script.
 - Exceeding the quality assurance principles of USP<797>.
 - Standardizing and implementing safety best practices across all sites.
 - Minimizing manual processes in production and the use of auxiliary labels.
 - Minimizing the impact of drug shortages.
- CA B&P Sections 4128(a)(2) and 4128.4 are designed to ensure that information about drug produced by CHPP's is available at bedside.
- CA B&P Section 4118 permits the Board to authorize alternate methods by which a CHPP operation can still demonstrate "a high standard of patient safety, consistent with good patient care."

ASSESSMENT

- No vendors associated with Sharp has a solution for presenting the data elements required by CA B&P 4128(a)(2) and 4128.4 within a barcode.
- Required elements beyond those already included in Sharp's barcoding solution are not as useful to nurses focused on medication administration and may cause the current barcode technology to malfunction.
- Sharp could manually apply secondary barcode labels solely to meet the Board's interpretation of the law, but many risks are inherent to this approach.
- Sharp believes it is possible for the Board to interpret the statutory requirements differently, or in the alternative, to grant a waiver until technology catches up to the full scope of the requirements and permit an interim solution with some data elements readable by humans instead of included in barcodes.

RECOMMENDATION

Sharp requests the Board please consider alternate methods of presenting the required information to bedside caregivers, in order to secure the benefits of CHPP operation to California hospitals more quickly.

DISCUSSION

SITUATION

On December 20, 2013, Sharp HealthCare (Sharp) received formal notice that it must immediately cease operations at Sharp's centralized hospital packaging pharmacy (CHPP). This notice, and ensuing discussion between Sharp pharmacists and representatives of the the California Board of Pharmacy (Board) indicated that the order was partly based on the Board's interpretation of Sections 4128(a)(2) and 4128.4 of the California Business & Professions (CA B&P) Code as requiring that six enumerated items of information be hard-coded into the barcoded labels accompanying all drug produced at a CHPP.

BACKGROUND

Sharp is an integrated health care system serving the San Diego area. The system includes six hospitals, totaling 2110 inpatient beds, and cared for approximately 84,000 inpatients during 2013. In 2007, and in consultation with the Board, Sharp built a 10,000 square foot CHPP production center, which includes an 1800 square foot USP<797> compliant cleanroom. This centralized production center has allowed Sharp Healthcare to maximize the use of robotic technology (Intellifill), improve standardized processes, and improve quality throughout the Sharp system. Technology implemented in the same timeframe, partly driven by California's developing requirements for centralized hospital packaging pharmacies, include bedside medication administration barcoding (BCMA) technology, automated admixture, routing and tracking software (Dose Edge), computerized physician order entry (CPOE), automated dispensing management (Pyxis and A-System Pyxis), automated labeling software (Codonics, BarTender, MediDose, NiceLabel), and an electronic health record with an electronic medication administration record.

Sharp has been exploring operational possibilities at its CHPP since at least the time of its application for CHPP licensure was submitted in February of 2013, and has already gathered substantial data in support of the benefits of operating a CHPP. CHPP operations at Sharp have demonstrated their value, in terms of safety, quality and efficiency, by reducing the recurrence of errors and permitting Sharp to impose controls and design labels against common human error factors in ways not available commercially. In general, successes include the following (see Tabs 1-6 for further detail):

- Minimizing the impact of drug shortages through batching as unit dose products.
- Standardized production.
- Minimizing the use of manually-applied auxiliary labels.
- Validating extended beyond use dating
- Decreased outsourcing and dependence upon third party vendors
- Exceeding the quality assurance principles of USP<797> by incorporating a more stringent cleaning schedule than required
- Staffing with consistent and well-trained individuals whose primary focus is pharmacy compounding and production.
- Barcoding all compounded and repackaged products to conform with the requirements of BCMA software and scanning equipment at the patients bedside, allowing retrieval of the product NDC batch record, including components, expiration dates, lot numbers and beyond use dates in human readable script.

ASSESSMENT

Our understanding of the AB377 legislation was that California, and the Board, wished to encourage hospitals to improve patient safety by exploring the gains that could be realized by incorporating standardized, controlled CHPPs into hospital systems. The centralized nature of these operations permit hospitals to focus resources, time and attention in ways that are not otherwise possible for most hospitals, both at the pharmacy and at bedside. Sharp employs approximately 5,000 nurses among which up to 30% are neophytes, floaters, agency, etc. Sharp has accordingly standardized many key medication processes across sites, e.g., Cerner EMR design, Alaris smart pump datasets, IV medication guidelines, and many medication related policies and procedures. As with all systems, process flow and synchronization are important. Here, barcoding enters the discussion, as a mechanism for linking the

work of the pharmacy, through its various steps, to the work of administering drug according to the electronic and human confirmation of the “six rights.”¹

The workflow of bedside barcoding as applied to medication administration is geared towards the identification of these key aspects. The additional information requirements of Sections 4128(a)(2) and 4128.4, although useful to pharmacy, are not necessarily as useful to nurses focused on the safety parameters of medication administration. The additional information may cause the current barcode technology to malfunction, nullifying the safety associated with BCMA if embedded in the barcode.

Although the intent of the requirement is ideal, current bedside technology does not permit such parsing of data. Pharmaceutical manufacturers are not currently required to include this information in their bar codes on their products, leaving little incentive for barcode solution providers to make these program changes a priority. Currently, no vendors associated with Sharp, and in particular it's established electronic medical record, provide barcode-enabled medication administration technologies that can meet all of the requirements of Sections 4128(a)(2) and 4128.4.

To meet the intent of the Board's current interpretation, Sharp does have a way to manually type in the information so it will embed into another barcode. This will require the manual addition of an ancillary barcode to each label and will add an additional barcode for nursing to scan. This moves away from the safety incentive of using a single Barcode. Adding an additional barcode can lead to increased human error in choosing which barcode to scan, affecting documentation of medication administration in the electronic medical record. If this redundant step is determined by the Board to be necessary, then we will comply. However, with our experience in implementing BCMA, we fear that it is not in the best interest of patient care nor adds any value to do so and suggest that the board take a more practical interpretation of Sections 4128(a)(2) and 4128.4.

CA B&P Section 4128(a)(2) permits a CHPP to perform non-patient specific batching of drug with anticipated inpatient use, if certain criteria are met. With respect to the product itself, the requirements state that each unit dose or dose package must be “barcoded to contain at least the information required by Section 4128.4.”² CA B&P Section 4128.4 goes on to state that any “unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient's bedside.” The statute further provides that upon “reading the barcode, the following information shall be retrievable” and supplies a list of six data elements.³ Little guidance exists on exactly what was meant by these specific statements. Legislative history shows that these quoted passages concerning barcoding remained unchanged between the enrollment of these statutes and the original introduction of Assembly Bill 377 in February of 2011. The language of the two statutory statements, taken together, appears partially contradictory. One way to read them is to have CA B&P Section 4128(a)(2) commanding that all elements of information specified in CA B&P Section 4128.4 be directly contained in the barcode generated for each product, and to likewise have CA B&P Section 4128.4 commanding that the data elements it lists must be directly translatable from the machine-readable barcoding itself.

Sharp believes there is an alternate way to read these statutes, based on the following observations concerning barcoding. The intent of applying barcode technology to the bedside medication administration workflow is to provide the safety net of automating the review of the 6 rights. Combined with the manual review of the 6 rights, patient safety is greatly enhanced. This combination is more potent when the information provided through the barcode also correlates closely with the required fields in other software used during the process of delivering drug to patients, including the electronic medication administration record. Additional information can be embedded in the barcode, but can easily disrupt the established workflow by causing mechanical scanning failures. This degrades the safety enhancement of including barcoding in the workflow. Sharp believes it is possible to read CA B&P Section 4128.4 as

¹ These are: right patient, right drug, right dose, right time, right route, and right rationale.

² CA B&P §4128 at (a)(1), (a)(2) and (a)(3).

³ CA B&P §4128.4, at (a) through (f), requires: the date the medication was prepared, the components used in the drug product, the lot number or control number, the expiration date, the National Drug Code Directory number, the name of the centralized hospital packaging pharmacy.

requiring that the elements be available or retrievable at the bedside, if needed. This will permit end users to focus on the information already prompted by their workflows, as well as permitting them to extract the additional elements in the situations where that is indicated. In other words, so long as the information is available to end users in some form (with the barcode expediting the process, to the extent information is not already present on a human-readable label), it would meet the intent of the safety requirement of the Board. Sharp believes that its current methodology meets this standard. Currently Sharp Central Pharmacy embeds the NDC number in the barcode, which meets the needs of the BCMA software. All other elements are in human readable form on the label. This provides Sharp staff, at any time when a barcode would be scanned, with all data required under CAP B&P Section 4128.4.

RECOMMENDATION

Rather than deny our patients the other, immediately-realizable benefits of CHPP processing, and without incurring any greater risk, Sharp hopes the Board will consider alternate methods of presenting the full set of required information to bedside caregivers, whether through computer networking or human readable script, until such time as a broader solution can be effected.

Sharp would prefer that the waiver embrace Sharp's current methodology of encoding only limited information in the actual product barcodes. Again, if the Board determines that it is necessary for Sharp to use the alternative method mentioned previously, Sharp will comply. In the absence of the Board adopting this alternate reading of the relevant statutes, Sharp instead requests a temporary waiver of the strict enforcement of the Board's current reading so as to permit Sharp to continue enjoying the quality and safety benefits it has already secured from its CHPP, and to permit time for Sharp to come into full compliance with the Board's requirements. Sharp has searched diligently, and cannot find any commercially-available BCMA technology that supports the conversion of all the elements listed in CA B&P Section 4128.4 within the printed symbology of a barcode into a human-readable script at the bedside. Vendors contacted by Sharp are currently examining the problem, but have not yet commented on possible solutions, much less committed to any sort of implementation schedule.

Sharp believes the Board has the authority to grant such a waiver. CA B&P Section 4118 provides that when "a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a pharmacy that does not meet all of the requirements for licensure as a pharmacy, the board may waive any licensing requirements." As currently designed, Sharp's CHPP records all of the information required by CA B&P Section 4128.4 for every product, and shares it with end users in the human-readable portion of the label, rather than in the barcode. While the mechanism differs from having the information already encoded into a barcode, the end result is substantially similar in terms of safety and quality of care. Encoding the missing elements would not add to the safety of the medication administration itself, and could partly degrade the effectiveness of the current methodology. Incorporating another set of barcoded information, at this time and using currently-available tools, would cause confusion to the approximately 5,000 Sharp staff administering medication regularly, and would lead to increased errors and decreased compliance with the use of barcoding.

Sharp Healthcare Presentation

**Sharp HealthCare
Request for Waiver of
California B&P Code Sections
4128(a)(2) and 4128.4**

**Presentation for the California Board
of Pharmacy Enforcement Committee
January 10, 2014**

What we will cover:

- Scope
- The quality gains and patient safety aspects of hospital central pharmacy compounding
- Examples of patient safety gains
- The barcode conundrum

Scope: The patients we serve annually:

- 84,000 inpatients
 - 216,000 emergency cases
 - 36,000 surgeries
 - 15,000 births
 - 811,000 outpatients
-
- 70% of the IV compounded admixtures they receive are made by Sharp

Quality Gains of Sharp's hospital central pharmacy compounding center

- Standardized products with clear labeling
 - Use of TALL MAN lettering (HYDRORmorphone)
 - concentrations defined as (1x), (5X)
- Minimizing the impact of drug shortages
- Validating extended beyond use dating
 - Allows placement of product in Pyxis, greatly decreasing time from physician order to administration

Quality Gains of Sharp's hospital central pharmacy compounding center

- Decreasing outsourcing and dependence upon third party vendors
- Staffing with consistent and well-trained individuals whose primary focus is pharmacy compounding and production

Documented patient safety

IV PCA Errors

Single 1x vs 5x concentrations

- Multiple errors over three quarters.
- No errors over the last seven consecutive quarters since making changes to labeling

Commercially Available PCA

This is 1x morphine



This is 5x HYDROmorphine



This is 1x HYDROmorphine



And this is... 5x, UNDILUTED fentaNYL!!



Requested Pharmedium wrap-around labeling

Morphine
1 mg/ml...

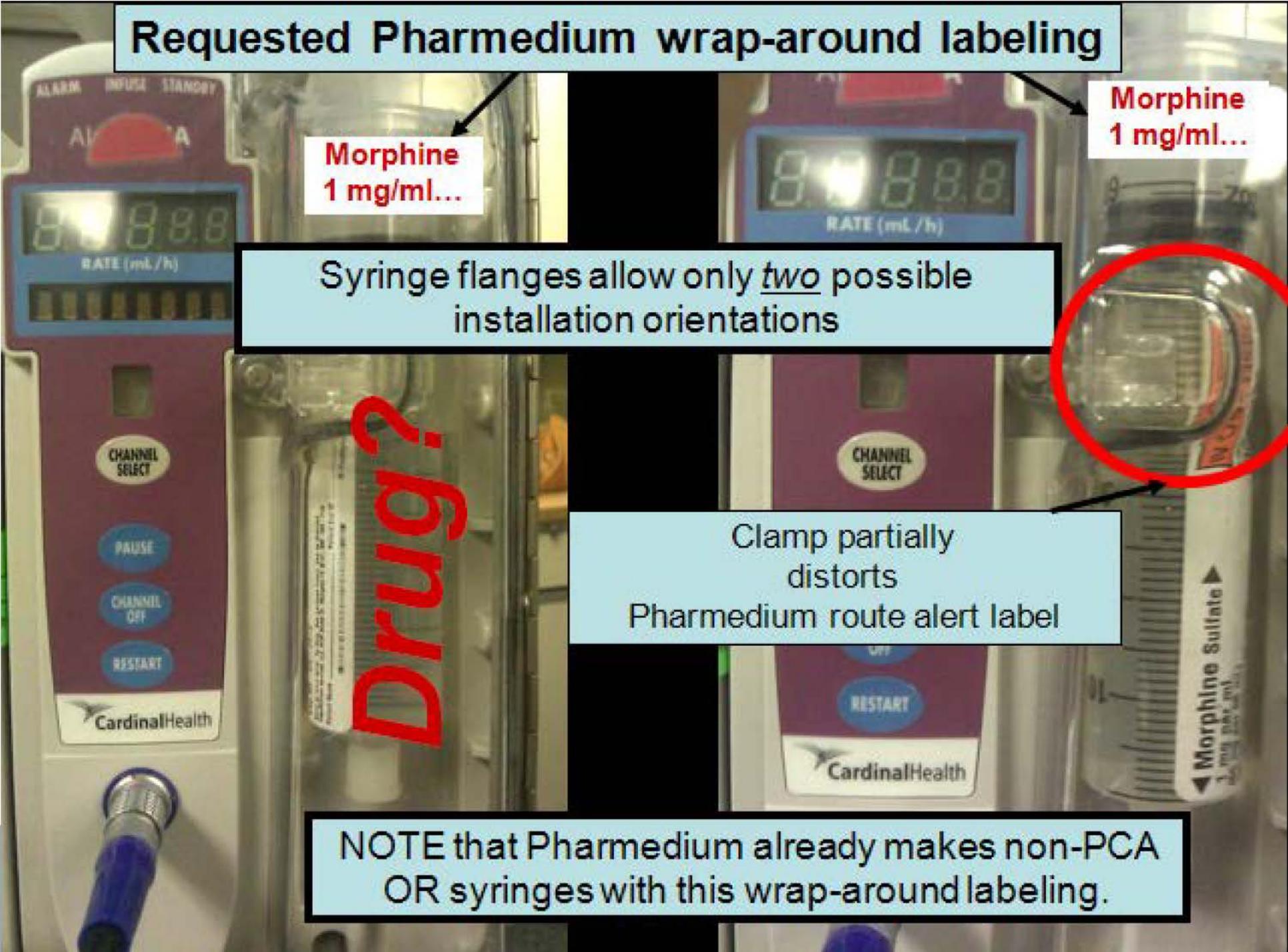
Morphine
1 mg/ml...

Syringe flanges allow only two possible installation orientations

Drug?

Clamp partially distorts Pharmedium route alert label

NOTE that Pharmedium already makes non-PCA OR syringes with this wrap-around labeling.



Our PCA Syringes:

NURSE customer - **Administration:**

Horizontal banner includes root library name, with strength (1x, 5x), matching the brain and module screens. Concentration included for confirmation. Visible in either of two possible installed positions (due to flanges).

PHARMACY customer – **Preparation, Dispensing:**

Non-clinical Pharmacy name, address, etc., are behind the clamp & case bubble, not visible during clinical use.

NURSE customer - **Administration:**

Label's clinically relevant text remains undistorted by the plastic case during clinical use. Text is consistent with the horizontal banner, brain, and module.

NURSE customer - **Wastage:**

Barrel graduations are visible when needed during wasting after removal from the pump, *not* during clinical use (pump very accurately measures and displays volume).

NEW

Hydromorphone (1X)
0.2mg/ml

fentanYL (1X)
10mcg/ml

morphine (1X)
1mg/ml

Lot: 12/2011
S HARE
3558 Ruffe

Expiry Date: 02/29/2012
Pharmacy Services
San Diego, CA 92123

Temperature
Expires: 02/29/2012
Pharmacy Services
San Diego, CA 92123

HYDROMORPHONE (1X)
0.2mg/ml NS 55ml syringe

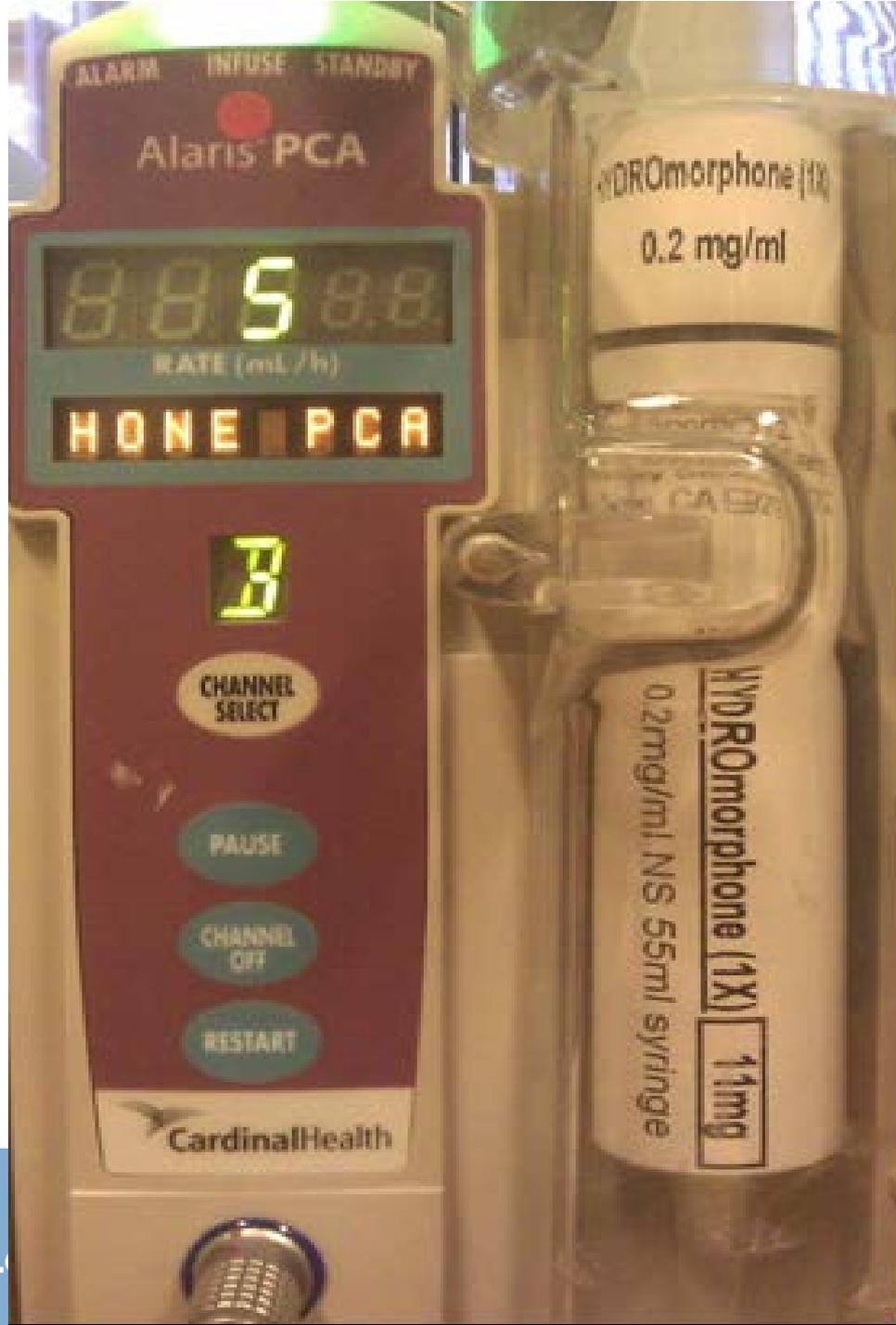
11mg

fentanYL (1X)
10mcg/ml 50ml syringe

500mcg

morphine (1X)
1mg/ml NS 55ml syringe

55mg



Our Epidural Syringe Experience

- IV MS given epidurally to 9 OB patients
- NO recurrences x 4 years since going to PCEA yellow label, horizontal banner
 - Label contents same as Alaris screens
 - Drug & concentration 100% visible regardless of how the syringe is installed in the PCA pump.
 - Eliminated the vendor product.

Vendor Epidural Syringe



Fentanyl Citrate
5 mcg per mL
(275 mcg per 55 mL)
and Bupivacaine HCl
0.0825%
55 mL total volume in a 60 mL BD Syringe
in Sodium Chloride 0.9%

Epidural Use Only

1511700NC1011700NC1011700NC
BD
NDC 61863-136-12 CU
Exp 07-28-2010
Service Code 278136 Lot# 1011700NC

B-D
20Z

NEW SHC FentaNYL/Bupivacaine PCEA SYRINGE 1/2011



Top, wrap around label makes drug names visible regardless of orientation in the Alaris PCA module.

Yellow label is unique to premade epidural syringes. IV remains white.

Graduations remain visible for accurate wasting.



The Barcode Conundrum

- Upon reading the barcode, the following information shall be **retrievable**:
 - (a) The date the medication was prepared.
 - (b) The components used in the drug product.
 - (c) The lot number or control number.
 - (d) The expiration date.
 - (e) The National Drug Code Directory number.
 - (f) The name of the centralized hospital packaging pharmacy.

The Barcode Conundrum

- We feel the legislature got it right. The intent of the language is ideal.
- But... the technology to retrieve all of the defined data with the barcode at the bedside does not yet exist

The Barcode Conundrum

- All of the data elements are retrievable via:
 - Barcode (NDC plus expiration date)
 - Plus Human readable script on the label
 - Retrievable data stored at our compounding center

A Waiver or Different Interpretation

- We would like to continue to use an appropriately licensed hospital central pharmacy compounding service to be able to provide the safest products for our patients.

A Waiver or Different Interpretation

- We believe it is reasonable to interpret the definition of “retrievable” to mean the use of the product barcode and other information sources or
- Provide Sharp HealthCare a waiver of 4128(a)(2) and 4128.4 until the technology catches up with the language of the regulation.

Attachment 7

Assembly Bill No. 1045

CHAPTER 302

An act to amend Section 4303 of, and to add Section 4127.9 to, the Business and Professions Code, relating to pharmacy.

[Approved by Governor September 9, 2013. Filed with Secretary of State September 9, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1045, Quirk-Silva. Sterile compounding and nonresident pharmacies.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies in this state by the California State Board of Pharmacy. A violation of these provisions is a crime.

Existing law provides that a 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. Existing law prohibits a person from acting as a nonresident pharmacy unless he or she has obtained a license from the board, and authorizes the board to register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed. The law also prohibits a resident or nonresident pharmacy from compounding injectable sterile drug products for shipment into this state without a license issued by the board, and authorizes a license to compound injectable sterile drug products to be issued only for a location that is licensed as a resident or nonresident pharmacy.

This bill would require a resident or a nonresident pharmacy that issues a recall notice regarding a sterile compounded drug to contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if use of or exposure to the recalled drug may cause serious adverse health consequences or death and if the recalled drug was dispensed or is intended for use in this state. Because a violation of these requirements would be a crime, the bill would impose a state-mandated local program.

The bill would also provide that if the home state pharmacy license of a nonresident pharmacy is canceled, revoked, or suspended for any reason, any license issued pursuant to the provisions governing the licensing and registration of nonresident pharmacies or authorizing a nonresident pharmacy to compound injectable sterile drug products shall be immediately canceled, revoked, or suspended by operation of law.

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

This bill would provide that no reimbursement is required by this act for a specified reason.

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

SECTION 1. Section 4127.9 is added to the Business and Professions Code, to read:

4127.9. (a) A pharmacy licensed pursuant to Section 4127.1 or 4127.2, including a pharmacy that is exempt from licensure pursuant to subdivision (d) of Section 4127.1 and subdivision (c) of Section 4127.2, that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.

(2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.

(3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, who shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

SEC. 2. Section 4303 of the Business and Professions Code is amended to read:

4303. (a) The board may report any violation by a nonresident pharmacy of the laws and regulations of this state, any other state, or of the United States, including, but not limited to, any violation of this chapter or of the regulations established by the board, to any appropriate state or federal regulatory or licensing agency, including, but not limited to, the regulatory or licensing agency of the state in which the nonresident pharmacy is a resident or in which the pharmacist is licensed.

(b) The board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.

(c) If the home state pharmacy license of a nonresident pharmacy is canceled, revoked, or suspended for any reason, any license issued pursuant

to Section 4112 or 4127.2 shall be immediately canceled, revoked, or suspended by operation of law.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SB 294

Senate Bill No. 294

CHAPTER 565

An act to amend the heading of Article 7.5 (commencing with Section 4127) of Chapter 9 of Division 2 of, and to amend, repeal, and add Sections 4127, 4127.1, 4127.2, and 4400 of, the Business and Professions Code, relating to pharmacy.

[Approved by Governor October 4, 2013. Filed with
Secretary of State October 4, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

SB 294, Emmerson. Sterile drug products.

(1) The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. Existing law requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Existing law requires pharmacies to obtain a license from the board, subject to annual renewal, in order to compound injectable sterile drug products. A similar licensing requirement applies to nonresident pharmacies compounding injectable sterile drug products for shipment into California. A violation of the Pharmacy Law is a crime.

This bill, commencing July 1, 2014, would expand these provisions to prohibit a pharmacy from compounding or dispensing, and a nonresident pharmacy from compounding for shipment into this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy license from the board. The bill, commencing July 1, 2014, would specify requirements for the board for the issuance or renewal of a license, and requirements for the pharmacy as a licensee. The bill would require the board to adopt regulations to implement these provisions, and, on and after July 1, 2014, to review formal revisions to specified national standards relating to the compounding of sterile preparations to determine whether amendments to those regulations are necessary, as specified. By adding additional requirements to the Pharmacy Law concerning sterile drug products, the violation of which is a crime, the bill would impose a state-mandated local program.

(2) Existing law specifies the fee for issuance or renewal of a nongovernmental license to compound sterile drug products.

This bill, commencing July 1, 2014, would establish the fee for the issuance or renewal of a nonresident sterile compounding pharmacy license in the amount of \$780 and would require the applicant to deposit a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing an inspection of the nonresident pharmacy location, as specified.

(3) The bill would also require the board to report to the Legislature, on or before January 1, 2018, regarding the regulation of nonresident pharmacies, including, among other things, a detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

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

This bill would provide that no reimbursement is required by this act for a specified reason.

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

SECTION 1. The heading of Article 7.5 (commencing with Section 4127) of Chapter 9 of Division 2 of the Business and Professions Code is amended to read:

Article 7.5. Sterile Drug Products

SEC. 2. Section 4127 of the Business and Professions Code is amended to read:

4127. (a) The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

(b) The board shall adopt emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to initially implement the provisions of this article that become operative on July 1, 2014. The initial adoption, amendment, or repeal of a regulation authorized by this section is deemed to address an emergency for purposes of Sections 11346.1 and 11346.6 of the Government Code, and the board is hereby exempted for that purpose from the requirements of subdivision (b) of Section 11346.1 of the Government Code. After the initial adoption, amendment, or repeal of an emergency regulation pursuant to this section, the board may request approval from the Office of Administrative Law to readopt the regulation as an emergency regulation pursuant to Section 11346.1 of the Government Code.

(c) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 3. Section 4127 is added to the Business and Professions Code, to read:

4127. (a) A pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation shall possess a sterile compounding pharmacy license as provided in this article.

(b) The board shall adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(c) The board shall review any formal revision to General Chapter 797 of the United States Pharmacopeia and The National Formulary (USP–NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary for the regulations adopted by the board pursuant to subdivision (b).

(d) This section shall become operative on July 1, 2014.

SEC. 4. Section 4127.1 of the Business and Professions Code is amended to read:

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 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 requirements 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 inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 5. Section 4127.1 is added to the Business and Professions Code, to read:

4127.1. (a) A pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from

the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy and shall be issued only to the owner of the pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the pharmacy's policies and procedures for sterile compounding.

(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Is provided with copies of all inspection reports conducted of the pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the pharmacy's operations.

(4) Receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

(e) A pharmacy licensed pursuant to this section shall do all of the following:

(1) Provide to the board a copy of any disciplinary or other action taken by another state within 10 days of the action.

(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

(g) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following requirements 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.

(h) This section shall become operative on July 1, 2014.

SEC. 6. Section 4127.2 of the Business and Professions Code is amended to read:

4127.2. (a) A nonresident pharmacy shall not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued

to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:

(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.

(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and 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.

(d) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

(2) The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations, or orders under consideration by the federal Food and Drug Administration or other appropriate federal agency, and cases pending before the courts.

(3) If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

(e) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 7. Section 4127.2 is added to the Business and Professions Code, to read:

4127.2. (a) A nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a nonresident pharmacy and shall be issued only to the owner of the nonresident pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident

pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.

(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the nonresident pharmacy's policies and procedures for sterile compounding.

(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Is provided with copies of all inspection reports conducted of the nonresident pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the nonresident pharmacy's operations.

(4) Receives a list of all sterile drug products compounded by the pharmacy within the prior 12 months.

(e) A pharmacy licensed pursuant to this section shall do all of the following:

(1) Provide to the board a copy of any disciplinary or other action taken by its state of residence or another state within 10 days of the action.

(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

(4) Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.

(f) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

(g) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

(2) Whether fee revenue collected pursuant to subdivision (v) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of this section provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident pharmacies.

(3) The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations, or orders under consideration by the federal Food and Drug Administration or other appropriate federal agency, and cases pending before the courts.

(4) If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

(h) The requirement for submitting a report imposed under subdivision (g) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.

(i) This section shall become operative on July 1, 2014.

SEC. 8. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).

(d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(f) The fee for a nongovernmental wholesaler license and annual renewal shall be six hundred dollars (\$600), and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).

(h) (1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(l) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty

dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(u) The fee for issuance or renewal of a nongovernmental license to compound sterile drug products shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(v) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 9. Section 4400 is added to the Business and Professions Code, to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).

(d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(f) The fee for a nongovernmental wholesaler license and annual renewal shall be six hundred dollars (\$600), and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).

(h) (1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(l) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(u) The fee for issuance or renewal of a nongovernmental sterile compounding pharmacy license shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(v) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars (\$780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board.

If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) This section shall become operative on July 1, 2014.

SEC. 10. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Non-Resident Sterile Compounding Application



California State Board of Pharmacy
 1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
 Phone (916) 574-7900
 Fax (916) 574-8618
 www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

APPLICATION FOR NON-RESIDENT STERILE COMPOUNDING PHARMACY LICENSE

Please print or type ALL BLANKS MUST BE COMPLETED; IF NOT APPLICABLE, ENTER N/A

Name of Pharmacy:		Pharmacy License Number		
Pharmacy Telephone Number:		Sterile Compounding Telephone Number: (if different)		
Address of Pharmacy:	Street and Number	City	State	Zip Code
Pharmacy License Number in home state: _____ Attach a copy of licensure verification from the home state licensing authority.				

Indicate type of ownership:	<input type="checkbox"/> Individual	<input type="checkbox"/> Partnership	<input type="checkbox"/> Corporation
	<input type="checkbox"/> Not-for-profit corporation	<input type="checkbox"/> Government Owned	<input type="checkbox"/> Limited Liability Company (LLC)

Types of compounding performed: <input type="checkbox"/> Non-sterile to sterile <input type="checkbox"/> Sterile to sterile <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Radiopharmacy	Type of Products to be compounded: <input type="checkbox"/> Injectable <input type="checkbox"/> Inhalation <input type="checkbox"/> Ophthalmics
--	--

Indicate the types of ISO environments and the number of each environment. Attach the most recent certifications for ALL ISO environments.	
Hoods _____ (number)	
Rooms _____ (number)	
Will you compound for prescribers or other pharmacies, attach a list of all entities.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Will you perform non-patient specific compounding? If yes, attach a list of all pharmacies and prescribers for whom you will provide this service.	Yes <input type="checkbox"/> No <input type="checkbox"/>

FOR OFFICE USE ONLY		
STAFF REVIEW	CASHIER LOG	
<input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ Referred for inspection: _____ Inspection Completed: _____	Approved _____ Denied _____ Date _____	Cashier # _____ Date _____ Amount of fee _____

Indicate whether this application for a Sterile Compounding License is for:		
<input type="checkbox"/> New License	<input type="checkbox"/> Change of Location	<input type="checkbox"/> Change of Ownership

If this is a **change of location** or **change of ownership**? If yes, enter previous name, address and license number below.

Name:	Address:	License Number:
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Pharmacist in Charge

Name of pharmacist-in-charge of licensed pharmacy:		Pharmacist license number	
Residence address:	Street and Number	City	State Zip Code

I certify that the policies and procedures of the sterile compounding for this pharmacy are consistent with California Code of Regulations Title 16, section 1735 et seq and 1751 et seq. I further certify that the submitted self-assessment for sterile compounding is consistent with California Code of Regulations, Title 16, section 1735.5.

(A copy of the pharmacy's proposed policies and procedures for sterile compounding and the sterile compounding self-assessment must accompany the application.)

Signature of Pharmacist-in-Charge

Name (please print)

Date

Ownership Information

A license to compound sterile drug products may only be issued to the owner of a licensed pharmacy at the licensed location.

If a Sole Ownership:			
Name of Sole Owner		*Social Security Number	Telephone Number
Address	number and street	City	State Zip Code

If a Partnership: (attach additional sheets, if needed)			
Name of Partner		*FEIN Number	Telephone Number
Address	number and street	City	State Zip Code
Name of Partner		*FEIN Number	Telephone Number
Address	number and street	City	State Zip Code

If a Corporation: (attach additional sheets, if needed)

Name of Corporation (If applicable)	Telephone Number
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Address	number and street	City	State	Zip Code
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Print below the name, title, address and license number of all the pharmacy owners. This includes the individual owner, all partners, corporate officers. Under the heading "Licensed as" list any state professional or vocational licenses held; e.g., pharmacist, physician, podiatrist, dentist or veterinarian etc., and license number. Non-profit organizations must list the names and titles of persons holding corporate positions. Attach additional sheets if necessary.

Title	Name	Residence Address	*Social Security Number	Licensed as and license number

*Disclosure of your social security number (or federal employer identification number ("FEIN"), if you are a partnership) is mandatory. Section 30 of the Business and Professions Code and Public Law 94-455 (42 USCA 405(c)(2)(C)) authorize collection of your social security number. Your social security number or FEIN will be used exclusively for tax enforcement purposes or compliance with any judgment or order for family support in accordance with section 17520 of the Family Code. If you fail to disclose your social security number or your FEIN, your application for initial or renewal license will not be processed AND you may be reported to the Franchise Tax Board, which may assess a \$100 penalty against you.

NOTICE: Effective July 1, 2012, the State Board of Equalization and the Franchise Tax Board may share individual taxpayer information with the board. You are obligated to pay your state tax obligation. This application may be denied or your license may be suspended if the state tax obligation is not paid.

Sterile Compounding Application



California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

APPLICATION FOR STERILE COMPOUNDING PHARMACY LICENSE

Please print or type ALL BLANKS MUST BE COMPLETED; IF NOT APPLICABLE, ENTER N/A

Name of Pharmacy:		Pharmacy License Number		
Pharmacy Telephone Number:		Sterile Compounding Telephone Number: (if different)		
Address of Pharmacy:	Street and Number	City	State	Zip Code

Indicate type of ownership:	<input type="checkbox"/> Individual	<input type="checkbox"/> Partnership	<input type="checkbox"/> Corporation
	<input type="checkbox"/> Not-for-profit corporation	<input type="checkbox"/> Government Owned	<input type="checkbox"/> Limited Liability Company (LLC)

Types of compounding performed: <input type="checkbox"/> Non-sterile to sterile <input type="checkbox"/> Sterile to sterile <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Radiopharmacy	Type of Products to be compounded: <input type="checkbox"/> Injectable <input type="checkbox"/> Inhalation <input type="checkbox"/> Ophthalmics
--	--

Indicate the types of ISO environments and the number of each environment. Attach the most recent certifications for ALL ISO environments.

Hoods _____
(number)

Rooms _____
(number)

Will you compound for prescribers or other pharmacies, attach a list of all entities.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Will you perform non-patient specific compounding? If yes, attach a list of all pharmacies and prescribers for whom you will provide this service.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Do you have satellite pharmacies where compounding is done? If yes, attach a list of all locations where sterile compounding is performed.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Do you perform centralized packaging for unit dose packaging? If yes, provide the license number for the centralized hospital packaging location.	Yes <input type="checkbox"/> No <input type="checkbox"/>

FOR OFFICE USE ONLY		
STAFF REVIEW	CASHIER LOG	
<input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ Referred for inspection: _____ Inspection Completed: _____	Approved _____ Denied _____ Date _____	Cashier # _____ Date _____ Amount of fee _____

If a Corporation: (attach additional sheets, if needed)

Name of Corporation (If applicable)	Telephone Number
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Address number and street	City	State	Zip Code
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Print below the name, title, address and license number of all the pharmacy owners. This includes the individual owner, all partners, corporate officers. Under the heading "Licensed as" list any state professional or vocational licenses held; e.g., pharmacist, physician, podiatrist, dentist or veterinarian etc., and license number. Non-profit organizations must list the names and titles of persons holding corporate positions. Attach additional sheets if necessary.

Title	Name	Residence Address	Social Security Number	Licensed as and license number

*Disclosure of your social security number (or federal employer identification number ("FEIN"), if you are a partnership) is mandatory. Section 30 of the Business and Professions Code and Public Law 94-455 (42 USCA 405(c)(2)(C)) authorize collection of your social security number. Your social security number or FEIN will be used exclusively for tax enforcement purposes or compliance with any judgment or order for family support in accordance with section 17520 of the Family Code. If you fail to disclose your social security number or your FEIN, your application for initial or renewal license will not be processed AND you may be reported to the Franchise Tax Board, which may assess a \$100 penalty against you.

NOTICE: Effective July 1, 2012, the State Board of Equalization and the Franchise Tax Board may share individual taxpayer information with the board. You are obligated to pay your state tax obligation. This application may be denied or your license may be suspended if the state tax obligation is not paid.

Attachment 8

Calendar No. 236

113TH CONGRESS
1ST SESSION

H. R. 3204

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 30, 2013

Received

NOVEMBER 4, 2013

Read the first time

NOVEMBER 5, 2013

Read the second time and placed on the calendar

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Drug Quality and Se-
5 curity Act”.

1 **SEC. 2. REFERENCES IN ACT; TABLE OF CONTENTS.**

2 (a) REFERENCES IN ACT.—Except as otherwise spec-
 3 ified, amendments made by this Act to a section or other
 4 provision of law are amendments to such section or other
 5 provision of the Federal Food, Drug, and Cosmetic Act
 6 (21 U.S.C. 301 et seq.).

7 (b) TABLE OF CONTENTS.—The table of contents of
 8 this Act is as follows:

Sec. 1. Short title.
 Sec. 2. References in Act; table of contents.

TITLE I—DRUG COMPOUNDING

Sec. 101. Short title.
 Sec. 102. Voluntary outsourcing facilities.
 Sec. 103. Penalties.
 Sec. 104. Regulations.
 Sec. 105. Enhanced communication.
 Sec. 106. Severability.
 Sec. 107. GAO study.

TITLE II—DRUG SUPPLY CHAIN SECURITY

Sec. 201. Short title.
 Sec. 202. Pharmaceutical distribution supply chain.
 Sec. 203. Enhanced drug distribution security.
 Sec. 204. National standards for prescription drug wholesale distributors.
 Sec. 205. National standards for third-party logistics providers; uniform na-
 tional policy.
 Sec. 206. Penalties.
 Sec. 207. Conforming amendment.
 Sec. 208. Savings clause.

9 **TITLE I—DRUG COMPOUNDING**

10 **SEC. 101. SHORT TITLE.**

11 This Act may be cited as the “Compounding Quality
 12 Act”.

13 **SEC. 102. VOLUNTARY OUTSOURCING FACILITIES.**

14 (a) IN GENERAL.—Subchapter A of chapter V (21
 15 U.S.C. 351 et seq.) is amended—

1 (1) by redesignating section 503B as section
2 503C; and

3 (2) by inserting after section 503A the fol-
4 lowing new section:

5 **“SEC. 503B. OUTSOURCING FACILITIES.**

6 “(a) IN GENERAL.—Sections 502(f)(1), 505, and 582
7 shall not apply to a drug compounded by or under the
8 direct supervision of a licensed pharmacist in a facility
9 that elects to register as an outsourcing facility if each
10 of the following conditions is met:

11 “(1) REGISTRATION AND REPORTING.—The
12 drug is compounded in an outsourcing facility that
13 is in compliance with the requirements of subsection
14 (b).

15 “(2) BULK DRUG SUBSTANCES.—The drug is
16 compounded in an outsourcing facility that does not
17 compound using bulk drug substances (as defined in
18 section 207.3(a)(4) of title 21, Code of Federal Reg-
19 ulations (or any successor regulation)), unless—

20 “(A)(i) the bulk drug substance appears on
21 a list established by the Secretary identifying
22 bulk drug substances for which there is a clin-
23 ical need, by—

24 “(I) publishing a notice in the Federal
25 Register proposing bulk drug substances to

1 be included on the list, including the ra-
2 tionale for such proposal;

3 “(II) providing a period of not less
4 than 60 calendar days for comment on the
5 notice; and

6 “(III) publishing a notice in the Fed-
7 eral Register designating bulk drug sub-
8 stances for inclusion on the list; or

9 “(ii) the drug compounded from such bulk
10 drug substance appears on the drug shortage
11 list in effect under section 506E at the time of
12 compounding, distribution, and dispensing;

13 “(B) if an applicable monograph exists
14 under the United States Pharmacopeia, the Na-
15 tional Formulary, or another compendium or
16 pharmacopeia recognized by the Secretary for
17 purposes of this paragraph, the bulk drug sub-
18 stances each comply with the monograph;

19 “(C) the bulk drug substances are each
20 manufactured by an establishment that is reg-
21 istered under section 510 (including a foreign
22 establishment that is registered under section
23 510(i)); and

24 “(D) the bulk drug substances are each ac-
25 companied by a valid certificate of analysis.

1 “(3) INGREDIENTS (OTHER THAN BULK DRUG
2 SUBSTANCES).—If any ingredients (other than bulk
3 drug substances) are used in compounding the drug,
4 such ingredients comply with the standards of the
5 applicable United States Pharmacopeia or National
6 Formulary monograph, if such monograph exists, or
7 of another compendium or pharmacopeia recognized
8 by the Secretary for purposes of this paragraph if
9 any.

10 “(4) DRUGS WITHDRAWN OR REMOVED BE-
11 CAUSE UNSAFE OR NOT EFFECTIVE.—The drug does
12 not appear on a list published by the Secretary of
13 drugs that have been withdrawn or removed from
14 the market because such drugs or components of
15 such drugs have been found to be unsafe or not ef-
16 fective.

17 “(5) ESSENTIALLY A COPY OF AN APPROVED
18 DRUG.—The drug is not essentially a copy of one or
19 more approved drugs.

20 “(6) DRUGS PRESENTING DEMONSTRABLE DIF-
21 FICULTIES FOR COMPOUNDING.—The drug—

22 “(A) is not identified (directly or as part
23 of a category of drugs) on a list published by
24 the Secretary, through the process described in
25 subsection (c), of drugs or categories of drugs

1 that present demonstrable difficulties for
2 compounding that are reasonably likely to lead
3 to an adverse effect on the safety or effective-
4 ness of the drug or category of drugs, taking
5 into account the risks and benefits to patients;
6 or

7 “(B) is compounded in accordance with all
8 applicable conditions identified on the list de-
9 scribed in subparagraph (A) as conditions that
10 are necessary to prevent the drug or category of
11 drugs from presenting the demonstrable dif-
12 ficulties described in subparagraph (A).

13 “(7) ELEMENTS TO ASSURE SAFE USE.—In the
14 case of a drug that is compounded from a drug that
15 is the subject of a risk evaluation and mitigation
16 strategy approved with elements to assure safe use
17 pursuant to section 505–1, or from a bulk drug sub-
18 stance that is a component of such drug, the out-
19 sourcing facility demonstrates to the Secretary prior
20 to beginning compounding that such facility will uti-
21 lize controls comparable to the controls applicable
22 under the relevant risk evaluation and mitigation
23 strategy.

24 “(8) PROHIBITION ON WHOLESALING.—The
25 drug will not be sold or transferred by an entity

1 other than the outsourcing facility that compounded
2 such drug. This paragraph does not prohibit admin-
3 istration of a drug in a health care setting or dis-
4 pensing a drug pursuant to a prescription executed
5 in accordance with section 503(b)(1).

6 “(9) FEES.—The drug is compounded in an
7 outsourcing facility that has paid all fees owed by
8 such facility pursuant to section 744K.

9 “(10) LABELING OF DRUGS.—

10 “(A) LABEL.—The label of the drug in-
11 cludes—

12 “(i) the statement ‘This is a com-
13 pounded drug.’ or a reasonable comparable
14 alternative statement (as specified by the
15 Secretary) that prominently identifies the
16 drug as a compounded drug;

17 “(ii) the name, address, and phone
18 number of the applicable outsourcing facil-
19 ity; and

20 “(iii) with respect to the drug—

21 “(I) the lot or batch number;

22 “(II) the established name of the
23 drug;

24 “(III) the dosage form and
25 strength;

1 “(IV) the statement of quantity
2 or volume, as appropriate;

3 “(V) the date that the drug was
4 compounded;

5 “(VI) the expiration date;

6 “(VII) storage and handling in-
7 structions;

8 “(VIII) the National Drug Code
9 number, if available;

10 “(IX) the statement ‘Not for re-
11 sale’, and, if the drug is dispensed or
12 distributed other than pursuant to a
13 prescription for an individual identi-
14 fied patient, the statement ‘Office Use
15 Only’; and

16 “(X) subject to subparagraph
17 (B)(i), a list of active and inactive in-
18 gredients, identified by established
19 name and the quantity or proportion
20 of each ingredient.

21 “(B) CONTAINER.—The container from
22 which the individual units of the drug are re-
23 moved for dispensing or for administration
24 (such as a plastic bag containing individual
25 product syringes) shall include—

1 “(i) the information described under
2 subparagraph (A)(iii)(X), if there is not
3 space on the label for such information;

4 “(ii) the following information to fa-
5 cilitate adverse event reporting:
6 www.fda.gov/medwatch and 1-800-FDA-
7 1088 (or any successor Internet Web site
8 or phone number); and

9 “(iii) directions for use, including, as
10 appropriate, dosage and administration.

11 “(C) ADDITIONAL INFORMATION.—The
12 label and labeling of the drug shall include any
13 other information as determined necessary and
14 specified in regulations promulgated by the Sec-
15 retary.

16 “(11) OUTSOURCING FACILITY REQUIRE-
17 MENT.—The drug is compounded in an outsourcing
18 facility in which the compounding of drugs occurs
19 only in accordance with this section.

20 “(b) REGISTRATION OF OUTSOURCING FACILITIES
21 AND REPORTING OF DRUGS.—

22 “(1) REGISTRATION OF OUTSOURCING FACILI-
23 TIES.—

24 “(A) ANNUAL REGISTRATION.—Upon
25 electing and in order to become an outsourcing

1 facility, and during the period beginning on Oc-
2 tober 1 and ending on December 31 of each
3 year thereafter, a facility—

4 “(i) shall register with the Secretary
5 its name, place of business, and unique fa-
6 cility identifier (which shall conform to the
7 requirements for the unique facility identi-
8 fier established under section 510), and a
9 point of contact email address; and

10 “(ii) shall indicate whether the out-
11 sourcing facility intends to compound a
12 drug that appears on the list in effect
13 under section 506E during the subsequent
14 calendar year.

15 “(B) AVAILABILITY OF REGISTRATION FOR
16 INSPECTION; LIST.—

17 “(i) REGISTRATIONS.—The Secretary
18 shall make available for inspection, to any
19 person so requesting, any registration filed
20 pursuant to this paragraph.

21 “(ii) LIST.—The Secretary shall make
22 available on the public Internet Web site of
23 the Food and Drug Administration a list
24 of the name of each facility registered
25 under this subsection as an outsourcing fa-

1 cility, the State in which each such facility
2 is located, whether the facility compounds
3 from bulk drug substances, and whether
4 any such compounding from bulk drug
5 substances is for sterile or nonsterile
6 drugs.

7 “(2) DRUG REPORTING BY OUTSOURCING FA-
8 CILITIES.—

9 “(A) IN GENERAL.—Upon initially reg-
10 istering as an outsourcing facility, once during
11 the month of June of each year, and once dur-
12 ing the month of December of each year, each
13 outsourcing facility that registers with the Sec-
14 retary under paragraph (1) shall submit to the
15 Secretary a report—

16 “(i) identifying the drugs compounded
17 by such outsourcing facility during the pre-
18 vious 6-month period; and

19 “(ii) with respect to each drug identi-
20 fied under clause (i), providing the active
21 ingredient, the source of such active ingre-
22 dient, the National Drug Code number of
23 the source drug or bulk active ingredient,
24 if available, the strength of the active in-
25 gredient per unit, the dosage form and

1 route of administration, the package de-
2 scription, the number of individual units
3 produced, and the National Drug Code
4 number of the final product, if assigned.

5 “(B) FORM.—Each report under subpara-
6 graph (A) shall be prepared in such form and
7 manner as the Secretary may prescribe by regu-
8 lation or guidance.

9 “(C) CONFIDENTIALITY.—Reports sub-
10 mitted under this paragraph shall be exempt
11 from inspection under paragraph (1)(B)(i), un-
12 less the Secretary finds that such an exemption
13 would be inconsistent with the protection of the
14 public health.

15 “(3) ELECTRONIC REGISTRATION AND REPORT-
16 ING.—Registrations and drug reporting under this
17 subsection (including the submission of updated in-
18 formation) shall be submitted to the Secretary by
19 electronic means unless the Secretary grants a re-
20 quest for waiver of such requirement because use of
21 electronic means is not reasonable for the person re-
22 questing waiver.

23 “(4) RISK-BASED INSPECTION FREQUENCY.—

24 “(A) IN GENERAL.—Outsourcing facili-
25 ties—

1 “(i) shall be subject to inspection pur-
2 suant to section 704; and

3 “(ii) shall not be eligible for the ex-
4 emption under section 704(a)(2)(A).

5 “(B) RISK-BASED SCHEDULE.—The Sec-
6 retary, acting through one or more officers or
7 employees duly designated by the Secretary,
8 shall inspect outsourcing facilities in accordance
9 with a risk-based schedule established by the
10 Secretary.

11 “(C) RISK FACTORS.—In establishing the
12 risk-based schedule, the Secretary shall inspect
13 outsourcing facilities according to the known
14 safety risks of such outsourcing facilities, which
15 shall be based on the following factors:

16 “(i) The compliance history of the
17 outsourcing facility.

18 “(ii) The record, history, and nature
19 of recalls linked to the outsourcing facility.

20 “(iii) The inherent risk of the drugs
21 compounded at the outsourcing facility.

22 “(iv) The inspection frequency and
23 history of the outsourcing facility, includ-
24 ing whether the outsourcing facility has

1 been inspected pursuant to section 704
2 within the last 4 years.

3 “(v) Whether the outsourcing facility
4 has registered under this paragraph as an
5 entity that intends to compound a drug
6 that appears on the list in effect under sec-
7 tion 506E.

8 “(vi) Any other criteria deemed nec-
9 essary and appropriate by the Secretary
10 for purposes of allocating inspection re-
11 sources.

12 “(5) ADVERSE EVENT REPORTING.—Outsourc-
13 ing facilities shall submit adverse event reports to
14 the Secretary in accordance with the content and
15 format requirements established through guidance or
16 regulation under section 310.305 of title 21, Code of
17 Federal Regulations (or any successor regulations).

18 “(c) REGULATIONS.—

19 “(1) IN GENERAL.—The Secretary shall imple-
20 ment the list described in subsection (a)(6) through
21 regulations.

22 “(2) ADVISORY COMMITTEE ON
23 COMPOUNDING.—Before issuing regulations to im-
24 plement subsection (a)(6), the Secretary shall con-
25 vene and consult an advisory committee on

1 compounding. The advisory committee shall include
2 representatives from the National Association of
3 Boards of Pharmacy, the United States Pharma-
4 copeia, pharmacists with current experience and ex-
5 pertise in compounding, physicians with background
6 and knowledge in compounding, and patient and
7 public health advocacy organizations.

8 “(3) INTERIM LIST.—

9 “(A) IN GENERAL.—Before the effective
10 date of the regulations finalized to implement
11 subsection (a)(6), the Secretary may designate
12 drugs, categories of drugs, or conditions as de-
13 scribed such subsection by—

14 “(i) publishing a notice of such sub-
15 stances, drugs, categories of drugs, or con-
16 ditions proposed for designation, including
17 the rationale for such designation, in the
18 Federal Register;

19 “(ii) providing a period of not less
20 than 60 calendar days for comment on the
21 notice; and

22 “(iii) publishing a notice in the Fed-
23 eral Register designating such drugs, cat-
24 egories of drugs, or conditions.

1 “(B) SUNSET OF NOTICE.—Any notice
2 provided under subparagraph (A) shall not be
3 effective after the earlier of—

4 “(i) the date that is 5 years after the
5 date of enactment of the Compounding
6 Quality Act; or

7 “(ii) the effective date of the final reg-
8 ulations issued to implement subsection
9 (a)(6).

10 “(4) UPDATES.—The Secretary shall review,
11 and update as necessary, the regulations containing
12 the lists of drugs, categories of drugs, or conditions
13 described in subsection (a)(6) regularly, but not less
14 than once every 4 years. Nothing in the previous
15 sentence prohibits submissions to the Secretary, be-
16 fore or during any 4-year period described in such
17 sentence, requesting updates to such lists.

18 “(d) DEFINITIONS.—In this section:

19 “(1) The term ‘compounding’ includes the com-
20 bining, admixing, mixing, diluting, pooling, reconsti-
21 tuting, or otherwise altering of a drug or bulk drug
22 substance to create a drug.

23 “(2) The term ‘essentially a copy of an ap-
24 proved drug’ means—

1 “(A) a drug that is identical or nearly
2 identical to an approved drug, or a marketed
3 drug not subject to section 503(b) and not sub-
4 ject to approval in an application submitted
5 under section 505, unless, in the case of an ap-
6 proved drug, the drug appears on the drug
7 shortage list in effect under section 506E at the
8 time of compounding, distribution, and dis-
9 pensing; or

10 “(B) a drug, a component of which is a
11 bulk drug substance that is a component of an
12 approved drug or a marketed drug that is not
13 subject to section 503(b) and not subject to ap-
14 proval in an application submitted under sec-
15 tion 505, unless there is a change that produces
16 for an individual patient a clinical difference, as
17 determined by the prescribing practitioner, be-
18 tween the compounded drug and the com-
19 parable approved drug.

20 “(3) The term ‘approved drug’ means a drug
21 that is approved under section 505 and does not ap-
22 pear on the list described in subsection (a)(4) of
23 drugs that have been withdrawn or removed from
24 the market because such drugs or components of

1 such drugs have been found to be unsafe or not ef-
2 fective.

3 “(4)(A) The term ‘outsourcing facility’ means a
4 facility at one geographic location or address that—

5 “(i) is engaged in the compounding of ster-
6 ile drugs;

7 “(ii) has elected to register as an outsource-
8 ing facility; and

9 “(iii) complies with all of the requirements
10 of this section.

11 “(B) An outsourcing facility is not required to
12 be a licensed pharmacy.

13 “(C) An outsourcing facility may or may not
14 obtain prescriptions for identified individual pa-
15 tients.

16 “(5) The term ‘sterile drug’ means a drug that
17 is intended for parenteral administration, an oph-
18 thalmic or oral inhalation drug in aqueous format,
19 or a drug that is required to be sterile under Federal
20 or State law.”.

21 “(d) OBLIGATION TO PAY FEES.—Payment of the fee
22 under section 744K, as described in subsection (a)(9),
23 shall not relieve an outsourcing facility that is licensed as
24 a pharmacy in any State that requires pharmacy licensing
25 fees of its obligation to pay such State fees.”.

1 (b) FEES.—Subchapter C of chapter VII (21 U.S.C.
2 379f et seq.) is amended by adding at the end the fol-
3 lowing:

4 **“PART 9—FEES RELATING TO OUTSOURCING**
5 **FACILITIES**

6 **“SEC. 744J. DEFINITIONS.**

7 “In this part:

8 “(1) The term ‘affiliate’ has the meaning given
9 such term in section 735(11).

10 “(2) The term ‘gross annual sales’ means the
11 total worldwide gross annual sales, in United States
12 dollars, for an outsourcing facility, including the
13 sales of all the affiliates of the outsourcing facility.

14 “(3) The term ‘outsourcing facility’ has the
15 meaning given to such term in section 503B(d)(4).

16 “(4) The term ‘reinspection’ means, with re-
17 spect to an outsourcing facility, 1 or more inspec-
18 tions conducted under section 704 subsequent to an
19 inspection conducted under such provision which
20 identified noncompliance materially related to an ap-
21 plicable requirement of this Act, specifically to deter-
22 mine whether compliance has been achieved to the
23 Secretary’s satisfaction.

1 **“SEC. 744K. AUTHORITY TO ASSESS AND USE OUTSOURC-**
2 **ING FACILITY FEES.**

3 “(a) ESTABLISHMENT AND REINSPECTION FEES.—

4 “(1) IN GENERAL.—For fiscal year 2015 and
5 each subsequent fiscal year, the Secretary shall, in
6 accordance with this subsection, assess and collect—

7 “(A) an annual establishment fee from
8 each outsourcing facility; and

9 “(B) a reinspection fee from each out-
10 sourcing facility subject to a reinspection in
11 such fiscal year.

12 “(2) MULTIPLE REINSPECTIONS.—An outsource-
13 ing facility subject to multiple reinspections in a fis-
14 cal year shall be subject to a reinspection fee for
15 each reinspection.

16 “(b) ESTABLISHMENT AND REINSPECTION FEE SET-
17 TING.—The Secretary shall—

18 “(1) establish the amount of the establishment
19 fee and reinspection fee to be collected under this
20 section for each fiscal year based on the method-
21 ology described in subsection (c); and

22 “(2) publish such fee amounts in a Federal
23 Register notice not later than 60 calendar days be-
24 fore the start of each such year.

25 “(c) AMOUNT OF ESTABLISHMENT FEE AND REIN-
26 SPECTION FEE.—

1 “(1) IN GENERAL.—For each outsourcing facil-
2 ity in a fiscal year—

3 “(A) except as provided in paragraph (4),
4 the amount of the annual establishment fee
5 under subsection (b) shall be equal to the sum
6 of—

7 “(i) \$15,000, multiplied by the infla-
8 tion adjustment factor described in para-
9 graph (2); plus

10 “(ii) the small business adjustment
11 factor described in paragraph (3); and

12 “(B) the amount of any reinspection fee (if
13 applicable) under subsection (b) shall be equal
14 to \$15,000, multiplied by the inflation adjust-
15 ment factor described in paragraph (2).

16 “(2) INFLATION ADJUSTMENT FACTOR.—

17 “(A) IN GENERAL.—For fiscal year 2015
18 and subsequent fiscal years, the fee amounts es-
19 tablished in paragraph (1) shall be adjusted by
20 the Secretary by notice, published in the Fed-
21 eral Register, for a fiscal year by the amount
22 equal to the sum of—

23 “(i) 1;

24 “(ii) the average annual percent
25 change in the cost, per full-time equivalent

1 position of the Food and Drug Administra-
2 tion, of all personnel compensation and
3 benefits paid with respect to such positions
4 for the first 3 years of the preceding 4 fis-
5 cal years, multiplied by the proportion of
6 personnel compensation and benefits costs
7 to total costs of an average full-time equiv-
8 alent position of the Food and Drug Ad-
9 ministration for the first 3 years of the
10 preceding 4 fiscal years; plus

11 “(iii) the average annual percent
12 change that occurred in the Consumer
13 Price Index for urban consumers (U.S.
14 City Average; Not Seasonally Adjusted; All
15 items; Annual Index) for the first 3 years
16 of the preceding 4 years of available data
17 multiplied by the proportion of all costs
18 other than personnel compensation and
19 benefits costs to total costs of an average
20 full-time equivalent position of the Food
21 and Drug Administration for the first 3
22 years of the preceding 4 fiscal years.

23 “(B) COMPOUNDED BASIS.—The adjust-
24 ment made each fiscal year under subparagraph
25 (A) shall be added on a compounded basis to

1 the sum of all adjustments made each fiscal
2 year after fiscal year 2014 under subparagraph
3 (A).

4 “(3) SMALL BUSINESS ADJUSTMENT FACTOR.—
5 The small business adjustment factor described in
6 this paragraph shall be an amount established by
7 the Secretary for each fiscal year based on the Sec-
8 retary’s estimate of—

9 “(A) the number of small businesses that
10 will pay a reduced establishment fee for such
11 fiscal year; and

12 “(B) the adjustment to the establishment
13 fee necessary to achieve total fees equaling the
14 total fees that the Secretary would have col-
15 lected if no entity qualified for the small busi-
16 ness exception in paragraph (4).

17 “(4) EXCEPTION FOR SMALL BUSINESSES.—

18 “(A) IN GENERAL.—In the case of an out-
19 sourcing facility with gross annual sales of
20 \$1,000,000 or less in the 12 months ending
21 April 1 of the fiscal year immediately preceding
22 the fiscal year in which the fees under this sec-
23 tion are assessed, the amount of the establish-
24 ment fee under subsection (b) for a fiscal year

1 shall be equal to $\frac{1}{3}$ of the amount calculated
2 under paragraph (1)(A)(i) for such fiscal year.

3 “(B) APPLICATION.—To qualify for the ex-
4 ception under this paragraph, a small business
5 shall submit to the Secretary a written request
6 for such exception, in a format specified by the
7 Secretary in guidance, certifying its gross an-
8 nual sales for the 12 months ending April 1 of
9 the fiscal year immediately preceding the fiscal
10 year in which fees under this subsection are as-
11 sessed. Any such application shall be submitted
12 to the Secretary not later than April 30 of such
13 immediately preceding fiscal year.

14 “(5) CREDITING OF FEES.—In establishing the
15 small business adjustment factor under paragraph
16 (3) for a fiscal year, the Secretary shall—

17 “(A) provide for the crediting of fees from
18 the previous year to the next year if the Sec-
19 retary overestimated the amount of the small
20 business adjustment factor for such previous
21 fiscal year; and

22 “(B) consider the need to account for any
23 adjustment of fees and such other factors as
24 the Secretary determines appropriate.

1 “(d) USE OF FEES.—The Secretary shall make all
2 of the fees collected pursuant to subparagraphs (A) and
3 (B) of subsection (a)(1) available solely to pay for the
4 costs of oversight of outsourcing facilities.

5 “(e) SUPPLEMENT NOT SUPPLANT.—Funds received
6 by the Secretary pursuant to this section shall be used
7 to supplement and not supplant any other Federal funds
8 available to carry out the activities described in this sec-
9 tion.

10 “(f) CREDITING AND AVAILABILITY OF FEES.—Fees
11 authorized under this section shall be collected and avail-
12 able for obligation only to the extent and in the amount
13 provided in advance in appropriations Acts. Such fees are
14 authorized to remain available until expended. Such sums
15 as may be necessary may be transferred from the Food
16 and Drug Administration salaries and expenses appropria-
17 tion account without fiscal year limitation to such appro-
18 priation account for salaries and expenses with such fiscal
19 year limitation. The sums transferred shall be available
20 solely for the purpose of paying the costs of oversight of
21 outsourcing facilities.

22 “(g) COLLECTION OF FEES.—

23 “(1) ESTABLISHMENT FEE.—An outsourcing
24 facility shall remit the establishment fee due under
25 this section in a fiscal year when submitting a reg-

1 istration pursuant to section 503B(b) for such fiscal
2 year.

3 “(2) REINSPECTION FEE.—The Secretary shall
4 specify in the Federal Register notice described in
5 subsection (b)(2) the manner in which reinspection
6 fees assessed under this section shall be collected
7 and the timeline for payment of such fees. Such a
8 fee shall be collected after the Secretary has con-
9 ducted a reinspection of the outsourcing facility in-
10 volved.

11 “(3) EFFECT OF FAILURE TO PAY FEES.—

12 “(A) REGISTRATION.—An outsourcing fa-
13 cility shall not be considered registered under
14 section 503B(b) in a fiscal year until the date
15 that the outsourcing facility remits the estab-
16 lishment fee under this subsection for such fis-
17 cal year.

18 “(B) MISBRANDING.—All drugs manufac-
19 tured, prepared, propagated, compounded, or
20 processed by an outsourcing facility for which
21 any establishment fee or reinspection fee has
22 not been paid, as required by this section, shall
23 be deemed misbranded under section 502 until
24 the fees owed for such outsourcing facility
25 under this section have been paid.

1 “(4) COLLECTION OF UNPAID FEES.—In any
2 case where the Secretary does not receive payment
3 of a fee assessed under this section within 30 cal-
4 endar days after it is due, such fee shall be treated
5 as a claim of the United States Government subject
6 to provisions of subchapter II of chapter 37 of title
7 31, United States Code.

8 “(h) ANNUAL REPORT TO CONGRESS.—Not later
9 than 120 calendar days after each fiscal year in which fees
10 are assessed and collected under this section, the Sec-
11 retary shall submit a report to the Committee on Health,
12 Education, Labor, and Pensions of the Senate and the
13 Committee on Energy and Commerce of the House of
14 Representatives, to include a description of fees assessed
15 and collected for such year, a summary description of enti-
16 ties paying the fees, a description of the hiring and place-
17 ment of new staff, a description of the use of fee resources
18 to support inspecting outsourcing facilities, and the num-
19 ber of inspections and reinspections of such facilities per-
20 formed each year.

21 “(i) AUTHORIZATION OF APPROPRIATIONS.—For fis-
22 cal year 2014 and each subsequent fiscal year, there is
23 authorized to be appropriated for fees under this section
24 an amount equivalent to the total amount of fees assessed
25 for such fiscal year under this section.”.

1 **SEC. 103. PENALTIES.**

2 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.
3 331) is amended by adding at the end the following:

4 “(ccc)(1) The resale of a compounded drug that is
5 labeled ‘not for resale’ in accordance with section 503B.

6 “(2) With respect to a drug to be compounded pursu-
7 ant to section 503A or 503B, the intentional falsification
8 of a prescription, as applicable.

9 “(3) The failure to report drugs or adverse events
10 by an entity that is registered in accordance with sub-
11 section (b) of section 503B.”.

12 (b) MISBRANDED DRUGS.—Section 502 (21 U.S.C.
13 352) is amended by adding at the end the following:

14 “(bb) If the advertising or promotion of a com-
15 pounded drug is false or misleading in any particular.”.

16 **SEC. 104. REGULATIONS.**

17 In promulgating any regulations to implement this
18 title (and the amendments made by this title), the Sec-
19 retary of Health and Human Services shall—

20 (1) issue a notice of proposed rulemaking that
21 includes the proposed regulation;

22 (2) provide a period of not less than 60 cal-
23 endar days for comments on the proposed regula-
24 tion; and

25 (3) publish the final regulation not more than
26 18 months following publication of the proposed rule

1 and not less than 30 calendar days before the effective date of such final regulation.

3 **SEC. 105. ENHANCED COMMUNICATION.**

4 (a) SUBMISSIONS FROM STATE BOARDS OF PHARMACY.—In a manner specified by the Secretary of Health
5 and Human Services (referred to in this section as the
6 “Secretary”), the Secretary shall receive submissions from
7 State boards of pharmacy—

9 (1) describing actions taken against
10 compounding pharmacies, as described in subsection
11 (b); or

12 (2) expressing concerns that a compounding
13 pharmacy may be acting contrary to section 503A of
14 the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 353a).

16 (b) CONTENT OF SUBMISSIONS FROM STATE
17 BOARDS OF PHARMACY.—An action referred to in sub-
18 section (a)(1) is, with respect to a pharmacy that com-
19 pounds drugs, any of the following:

20 (1) The issuance of a warning letter, or the im-
21 position of sanctions or penalties, by a State for vio-
22 lations of a State’s pharmacy regulations pertaining
23 to compounding.

24 (2) The suspension or revocation of a State-
25 issued pharmacy license or registration for violations

1 of a State’s pharmacy regulations pertaining to
2 compounding.

3 (3) The recall of a compounded drug due to
4 concerns relating to the quality or purity of such
5 drug.

6 (c) CONSULTATION.—The Secretary shall implement
7 subsection (a) in consultation with the National Associa-
8 tion of Boards of Pharmacy.

9 (d) NOTIFYING STATE BOARDS OF PHARMACY.—The
10 Secretary shall immediately notify State boards of phar-
11 macy when—

12 (1) the Secretary receives a submission under
13 subsection (a)(1); or

14 (2) the Secretary makes a determination that a
15 pharmacy is acting contrary to section 503A of the
16 Federal Food, Drug, and Cosmetic Act.

17 **SEC. 106. SEVERABILITY.**

18 (a) IN GENERAL.—Section 503A (21 U.S.C. 353a)
19 is amended —

20 (1) in subsection (a), in the matter preceding
21 paragraph (1), by striking “unsolicited”;

22 (2) by striking subsection (c);

23 (3) by redesignating subsections (d) through (f)
24 as subsections (c) through (e), respectively; and

1 (4) in subsection (b)(1)(A)(i)(III), by striking
2 “subsection (d)” and inserting “subsection (e)”.

3 (b) SEVERABILITY.—If any provision of this Act (in-
4 cluding the amendments made by this Act) is declared un-
5 constitutional, or the applicability of this Act (including
6 the amendments made by this Act) to any person or cir-
7 cumstance is held invalid, the constitutionality of the re-
8 mainder of this Act (including the amendments made by
9 this Act) and the applicability thereof to other persons and
10 circumstances shall not be affected.

11 **SEC. 107. GAO STUDY.**

12 (a) STUDY.—Not later than 36 months after the date
13 of the enactment of this Act, the Comptroller General of
14 the United States shall submit to Congress a report on
15 pharmacy compounding and the adequacy of State and
16 Federal efforts to assure the safety of compounded drugs.

17 (b) CONTENTS.—The report required under this sec-
18 tion shall include—

19 (1) a review of pharmacy compounding in each
20 State, and the settings in which such compounding
21 occurs;

22 (2) a review of the State laws and policies gov-
23 erning pharmacy compounding, including enforce-
24 ment of State laws and policies;

1 (3) an assessment of the available tools to per-
2 mit purchasers of compounded drugs to determine
3 the safety and quality of such drugs;

4 (4) an evaluation of the effectiveness of the
5 communication among States and between States
6 and the Food and Drug Administration regarding
7 compounding; and

8 (5) an evaluation of the Food and Drug Admin-
9 istration’s implementation of sections 503A and
10 503B of the Federal Food, Drug, and Cosmetic Act.

11 **TITLE II—DRUG SUPPLY CHAIN**
12 **SECURITY**

13 **SEC. 201. SHORT TITLE.**

14 This title may be cited as the “Drug Supply Chain
15 Security Act”.

16 **SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY**
17 **CHAIN.**

18 Chapter V (21 U.S.C. 351 et seq.) is amended by
19 adding at the end the following:

20 **“Subchapter H—Pharmaceutical Distribution**
21 **Supply Chain**

22 **“SEC. 581. DEFINITIONS.**

23 “In this subchapter:

Attachment 9

Sodergren, Anne@DCA

From: Pharmacy_Subscriberlist@DCA
Sent: Thursday, December 19, 2013 2:08 PM
To: PHARM-GENERAL@LISTSERV.DCA.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - Abrams Royal Pharmacy

Abrams Royal Pharmacy is recalling all unexpired lots of sterile products dispensed nationwide due to concerns of lack of sterility assurance. Sterile products are injectable medications, IVs, eye drops, pellet implants, nasal sprays, inhalation solutions, and eye ointments.

All recalled products have a label that includes Abrams Royal Pharmacy's name and phone as well as a lot number. While not every label contains an expiration date, consumers can call the pharmacy with the lot number and learn the expiration date.

The recall was issued after a single, isolated report of an adverse event involving a patient in California who received a compounded medication from the pharmacy. Out of an abundance of caution, Abrams Royal is recalling all sterile products within expiry. If there is microbial contamination in products intended to be sterile, patients are at risk for serious, potentially life-threatening infections.

The recalled products were distributed to health care facilities, physicians, and patients from June 17, 2013 through December 17, 2013.

To return product or request assistance related to this recall, users should contact Abrams Royal at 214-349-8000, Monday through Friday, between 9:00 a.m. and 7:00 p.m. CST, and on Saturday between 9:00 a.m. and 3:00 p.m. CST.

Customers that have product which is being recalled should stop using it and contact the pharmacy to arrange for return of unused product. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using these products. Adverse reactions may be reported to the FDA's MedWatch program via:

Online: www.fda.gov/medwatch/report.htm

Mail: use postage-paid, pre-addressed Form FDA 3500 found at www.fda.gov/MedWatch/getforms.htm.

Fax: 1-800-FDA-0178

Buckner, Rob@DCA

From: Pharmacy_Subscriberlist@DCA
Sent: Monday, September 09, 2013 12:21 PM
To: PHARM-GENERAL@LISTSERV.DCA.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - Medaus Pharmacy

Birmingham, Alabama, Medaus Pharmacy is recalling certain sterile compounded consumer products (see table) due to our inability to confirm that the quality control testing performed on these specific lots by an independent, third party laboratory was conducted in a manner consistent with the highest standards of excellence we demand from ourselves and on behalf of our patients. Though Medaus received test results indicating that these lots met all safety standards, they are being recalled because the independent testing lab's sterility testing practices as applied to these lots indicate that the product's sterility cannot be confirmed. Therefore, Medaus decided to conduct this voluntary recall out of an abundance of caution.

The use of a non-sterile injectable product exposes patients to the risk of contracting serious life-threatening infections. Medaus has not received any reports of adverse events related to the products affected by this recall to date. In fact, Medaus has never in its history experienced a single adverse patient reaction attributable to a failure of Medaus safety standards or quality control.

Product Name	Lot #	Expiry
Testosterone CYP 200 mg/mL	130508-1	11/16/2013
Lipo injection with lidocaine	130510-26	11/16/2013
Lipo injection with lidocaine	130610-24	12/7/2013
Taurine 50 mg/mL PF	130618-64	12/15/2013
L-Glutathione 200 mg/mL	130617-10	12/14/2013
Pyridoxine HCl 100 mg/mL NS PF	130531-31	11/27/2013
Magnesium CHI 200 mg/mL	130307-60	9/3/2013
Sodium ascorbate 500 mg/mL PF	130702-1	12/29/2013
Lipo injection with lidocaine	130709-68	1/5/2014
Sodium ascorbate 500 mg/mL non- corn PF	130613-8	12/10/2013

These products were dispensed between March 12 and July 22nd, 2013 nationwide throughout the United States. We are contacting all patients and doctors offices that received these lots by phone to recall any unused medications from these lots.

Medaus is notifying its customers by telephone and email, and is arranging for return of affected products. Health care facilities and customers that have products which are being recalled should stop using the product and call Medaus at 800-526-9183 for instructions on returning the product for a full refund.

To return medication or request assistance related to this recall, patients and physicians should contact Medaus Pharmacy at (800) 526-9183 , Monday through Friday, between 9 a.m. and 5 p.m. CDT.

Adverse reactions or quality problems experienced with the use of these products may be reported to FDA's MedWatch Adverse Event Reporting program either online, by regular mail or fax.

- **Online:** <http://www.fda.gov/MedWatch/report.htm>
- **Mail:** use postage-paid, pre-addressed Form FDA 3500 at <http://www.fda.gov/MedWatch/getforms.htm>
- **Fax:** 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Buckner, Rob@DCA

From: Pharmacy_Subscriberlist@DCA
Sent: Monday, September 09, 2013 3:33 PM
To: PHARM-GENERAL@LISTSERV.DCA.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - Avella Specialty Pharmacy

FOR IMMEDIATE RELEASE – September 9, 2013 – Avella Specialty Pharmacy is recalling two compounded sterile medications. The recall is a result of concerns of sterility assurance with the specialty pharmacy’s independent testing laboratory, Front Range Laboratories. Avella is recalling the following medications:

Product	Lot Number	Expiry
Bevacizumab 1.25 mg/0.05 mL PF	12-20130508@179	11/3/2013
Vancomycin PF (BSS) 1%	12-20130508@181	10/4/2013

Avella was notified that in a recent inspection of Front Range Labs, FDA investigators observed methods used to assess sterility and other qualities (e.g. strength and stability) which may have resulted in Avella receiving inaccurate laboratory test results on the specified lots. FDA has raised concerns that test results obtained from Front Range Labs may not be reliable. Therefore, Avella decided to conduct this voluntary recall out of an abundance of caution. Avella has discontinued its relationship with Front Range Labs as a result of this issue.

If microbial contamination occurs in medications intended to be sterile, patients are at risk of serious infections that may be life threatening. To date, Avella has not received **any** reports of adverse events related to the recall. The recalled products were dispensed directly to healthcare providers nationwide. The medications can be identified based on product label and corresponding medication name and lot number.

Avella Specialty Pharmacy is notifying customers of the voluntary recall by phone and mail. Customers that have any of the medications that are being recalled should immediately discontinue use and return the unused portion to Avella.

Patients and healthcare providers with questions regarding this recall can contact Avella at (877) 738-0797 Monday through Friday between 6am and 6pm Pacific Standard Time or via e-mail at QA@avella.com. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular mail: use postage-paid, pre-addressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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