California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Contact Person: Patricia Harris
(916) 445-5014

ENFORCEMENT COMMITTEE MEETING

December 15, 2004
9:30 a.m. – 12:30 p.m.

Department of Consumer Affairs
400 R Street
1st Floor Hearing Room – Suite 1030
Sacramento, CA 95814

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item. Members of the board who are not on the committee may attend and comment during the meeting.

AGENDA

CALL TO ORDER **9:30 a.m.**

A. Discussion Regarding the Importation of Prescription Drugs

B. Request from Safeway Inc. for Waiver of California Code of Regulations, title 16, section 1717(e) to Use an Automated Dispensing Device for Refill Prescriptions at its Safeway and Vons Pharmacies

C. Proposed Regulation Change to Delete California Code of Regulation, title 16, section 1717(e) and to Add California Code of Regulation, title 16, section 1713 to Authorize the Use of Drop Boxes for Prescriptions and to Authorize the Use an Automated Dispensing Device for Refill Prescription Medications

D. Request from Advanced Pharmacy Solutions for Waiver of California Code of Regulations, title 16, section 1717(e) to Allow the delivery of Prescription Medications to a Licensed Home Health Agency

E. Proposed Amendment to Business and Professions Code section 4104 – Mandatory Reporting to the Board of Pharmacy of Impaired Licensed Individuals

F. Discussion Regarding the Implementation of SB 151 (Chapter 406, Statutes of 2003) – Requirements for Controlled Substance Prescriptions to Become Effective January 1, 2005
   - Proposed Amendments from Department of Justice and Recommended Amendments from Board Staff

G. Implementation of SB 1307 (Senator Figueroa) Relating to Wholesalers

- Presentation by T3Ci on their Technology Solution to the Counterfeit, Diversion and Pedigree Issues

H. Pharmacist-in-Charge (PC) Certification Program at the College of Pharmacy, Western University of Health Sciences – Presentation by Sam Shimomura, Associate Dean Professional and Student Affairs

I. New Statutory Changes Effective January 1, 2005

J. Proposed Meeting Dates for 2005

K. Adjournment 12:30 p.m.

Committee materials will be available on the board's website by December 8, 2004

AGENDA ITEM A

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: December 7, 2004

From: Patricia F. Harris
Executive Officer

Subject: **Importation of Prescription Drugs**

Attached is a copy of SB 19 that was introduced by Senator Ortiz on December 6, 2004. The purpose of the bill is to establish the California Rx Program, to be administered by the Department of Health Services. The bill would authorize the department to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under this program. The bill also establishes eligibility criteria and application procedures for California residents to participate in the program.

The bill would also require the Department of Consumer Affairs to implement, as part of the California Rx Program, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering their prescription drug costs. The Web site shall include information about public and private drug coverage and drug discount programs that are available to California seniors and other consumers and tips for cutting costs on medications, including guidance concerning generic drugs.

In addition, the Web site shall include information about ordering prescription drugs from Canada and other countries. The Web site is to include a list of pharmacies that the Board of Pharmacy has determined meet pharmacy management practices required of pharmacies licensed to operate in California and the United States and a list of medications that can be ordered through the Web site from licensed pharmacies in Canada and other countries.

The department may either provide a direct link for consumers to pharmacies in Canada and other countries or provide a link for consumers to other Web sites if the Board of Pharmacy determines that the pharmacies listed in those other Web sites meet pharmacy management requirements that apply to California licensed pharmacies.

The other attachment is a press release issued by the Federal FDA regarding action it took against a company for the importation of prescription drugs into the U.S.

SENATE BILL No. 19

Introduced by Senator Ortiz

December 6, 2004

An act to add Division 113 (commencing with Section 130600) to the Health and Safety Code, relating to prescription drugs, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 19, as introduced, Ortiz. California Rx Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter in to contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufactures are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Program, to be administered by the department. The bill would authorize the department to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under the program. The bill would establish eligibility criteria and application procedures for California residents to participate in the program.

The bill would establish the California Rx Program Fund, as a continuously appropriated fund, into which all payments directly received under the program would be deposited.

The bill would appropriate $3,000,000 from the State Treasury to the department to fund staff and contract costs for the program.

The Pharmacy Law is administered by the California State Board of Pharmacy in the Department of Consumer Affairs.

This bill would require the Department of Consumer Affairs to implement, as a part of the California Rx Program that would be established under the bill, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering prescription drug costs.

Vote: ⅔. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

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

1 SECTION 1. Division 113 (commencing with Section
2 130600) is added to the Health and Safety Code, to read:
3
4 DIVISION 113. CALIFORNIA RX PROGRAM
5
6 CHAPTER 1. GENERAL PROVISIONS
7
8 130600. (a) This division shall be known, and may be cited,
9 as the California Rx Program.
10 (b) For the purposes of this division, the following definitions
11 shall apply:
12 (1) "Department" means the State Department of Health
13 Services.
14 (2) "Fund" means the California Rx Program Fund.
15 (3) "Prescription drug" means any drug that bears the legend:
16 "Caution: federal law prohibits dispensing without prescription,"
17 "Rx only," or words of similar import.
18 (4) "Private discount drug program" means a prescription drug
19 discount card or manufacturer patient assistance program that
20 provides discounted or free drugs to eligible individuals. For
21 purposes of this division, a private discount drug program is not
22 considered an insurance or a third-party payer program.
23 (5) "Program" means the California Rx Program.
24 (6) "Recipient" means a resident that has completed an
25 application and has been determined to be eligible for the
26 program.
27 (7) "Resident" means a California resident pursuant to Section
28 17014 of the Revenue and Taxation Code.
29 130602. (a) There is hereby established the California Rx
30 Program.

(b) Any California resident may enroll in the program if determined eligible pursuant to Section 130605.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCEDURES

130605. (a) To be eligible for the program, an individual shall meet all of the following requirements at the time of application and reapplication for the program:

(1) Be a resident.

(2) Have family income, as reported pursuant to Section 130606, that does not exceed 400 percent of the federal poverty guidelines, as revised annually by the United States Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902), as amended, or be a resident whose family incurs unreimbursed expenses for prescription drugs equal to or greater than 5 percent of family income, or be a resident whose family incurs unreimbursed medical expenses equal to or greater than 15 percent of family income.

(3) Not have or be eligible for outpatient prescription drug coverage paid for in whole or in part by any of the following:

(A) The Medi-Cal program.

(B) The children's health insurance program.

(C) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any other provision of this division to the contrary, an individual enrolled in Medicare may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare.

(b) Application and a simple annual reapplication for the program shall be made pursuant to subdivision (d) of Section 130606. An applicant may apply or reapply on behalf of the applicant and the applicant's spouse and children. The guardian or custodian of an applicant may apply or reapply on behalf of the applicant.

130606. (a) The department shall develop an application form for the determination of a resident's eligibility for the program.

(b) The application, at a minimum, shall do all of the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application about the applicant.

(2) Require that the applicant attest that the information the applicant provides in the application is accurate to the best knowledge and belief of the applicant.

(3) Specify that the application fee is due upon application submission. The application fee shall be ten dollars ($10) for the initial enrollment. The initial application may be made at participating pharmacies or through a private third-party vendor.

(c) In assessing the income requirement for program eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) Application and annual reapplication may be made at any pharmacy participating in the program. The pharmacy completing the application shall keep the application fee as reimbursement for its cost of processing the application. If it is determined the applicant is already enrolled in the program, the pharmacy shall return the fee to the applicant and inform the applicant of his or her current status as a recipient.

(e) The department may provide for a secure electronic application process that can be used by pharmacies to enroll applicants in the program.

(f) During normal hours, the department shall make a determination of eligibility within four hours of receipt of the application. The department shall mail the recipient an identification card no later than four days after eligibility has been determined.

(g) For applications submitted through a pharmacy, the department may issue a recipient identification number for eligible applicants to the pharmacy for immediate access to the program.

130607. (a) The department shall execute agreements with private discount drug programs to provide a simple point of entry for eligibility determination and claims processing for drugs available in those private discount drug programs.

(b) (1) An applicant may be required to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.

(2) An applicant shall not be, under any circumstances, required to participate in, or to disclose information that would determine the applicant's eligibility to participate in, these private discount drug programs in order to participate in the program provided for in this division.

(c) For those drugs available pursuant to subdivision (a), the department shall develop a system that provides a recipient with the best prescription drug discounts that are available to them through the program or through private discount drug programs.

(d) The recipient identification card issued pursuant to subdivision (f) of Section 130606 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a health benefit card.

CHAPTER 3. ADMINISTRATION AND SCOPE

130615. The department shall conduct outreach programs to inform residents about this program. No outreach material shall contain the name or likeness of a drug or the likeness of an elected state official.

130616. (a) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program provided for under this division.

(b) Any drug manufacturer may participate in the program provided for under this division.

130617. (a) The amount a recipient pays for a drug within the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the specific drug or an average discount for a group of drugs or all drugs covered by the program.

(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the drug's manufacturer and the state's share of the discount.

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

(d) The department shall provide a claims processing system that complies with all of the following requirements:

(1) Provides for the price that meets the requirements of subdivision (b).

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides a single point of entry for access to private discount drug programs pursuant to Section 130607.

(4) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8(g)).

(e) The department shall pay a participating pharmacy the discount provided to recipients pursuant to subdivision (b) by a date that is not later than two weeks after the claim is received by the department.

130618. (a) The department shall negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts.

(b) The drug rebate agreements shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

(6) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(7) Require the manufacturer to provide, upon the request of the department, documentation that the department can use to

validate that the per unit rebate provided complies with paragraph (4).

(8) Permit a drug manufacturer to audit claims for the drugs the manufacturer provides under the program. Claims information made available to a manufacturer pursuant to this paragraph shall comply with all federal and state privacy statutes to protect a recipient's individual health information.

(9) Develop a program to prevent the occurrence of fraud in the program.

(10) Develop a mechanism for recipients to report problems or complaints regarding the program.

(c) If the department receives a determination that the California Rx Program is a state pharmaceutical assistance program for purposes of federal law pursuant to Section 130621, the department shall seek to contract for drug rebates that result in a net price equal to the lowest price paid for the drug by the federal government.

(d) To obtain the most favorable discounts, the department may limit the number of drugs available within the program, including through development of a formulary or preferred drug list.

(e) No less than 95 percent of the drug rebates negotiated pursuant to this section shall go to reducing the cost to participants in the program of purchasing drugs. The Legislature shall annually appropriate an amount to cover the state's share of the discount provided by this section.

(f) The department may collect prospective rebates from drug manufacturers for payment to pharmacies pursuant to subdivision (e) of Section 130617. The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to this section.

(g) The names of manufacturers and labelers who do and do not enter into rebate agreements pursuant to this division are public information. The department shall release the information to health care providers and the public. The department may impose prior authorization requirements in the Medi-Cal program, as permitted by law, on the drugs of any manufacturer or labeler that either does not agree to provide rebates pursuant to this section or does not agree to provide rebates that result in drug prices that are equal to the lowest price paid for its drugs by

the federal government. A prior authorization requirement imposed pursuant to this subdivision shall be consistent with the goals of the California Rx Program and the requirements of Title XIX of the federal Social Security Act (42 U.S.C. Sec. 1396 et seq).

130619. (a) The department shall deposit all payments the department directly receives pursuant to Section 130618 and any other provision of this division into the California Rx Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, the fund is hereby appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130617 and for defraying the costs of administering this division. Notwithstanding any other law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

130620. (a) The department may hire any staff needed for the implementation and oversight of the program established under this division.

(b) The department may contract with one or more public or private entities, such as pharmacy benefit management companies, to implement or administer the program completely or in part.

(c) (1) Drug rebate contracts negotiated by a third-party vendor shall be subject to review by the department.

(2) The department shall not enter into a contract, and may cancel a contract, negotiated by a third-party vendor pursuant to paragraph (1) that it finds not to be in the best interest of the state or the recipients of the program.

(3) The third-party vendor may directly collect rebates from manufacturers in order to facilitate payment to pharmacies pursuant to subdivision (f) of Section 136017.

(4) The department shall develop a system to prevent diversion of funds collected by the third-party vendor.

(d) Any entity with whom the department is contracting pursuant to subdivision (b) shall issue a monthly report to the department that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) The information provided in paragraphs (1), (2), and (3), at the national drug code level.

(5) A summary of the problems or complaints reported regarding the program.

(e) Payment of fees to entities contracting pursuant to subdivision (b) shall be from the fund.

(f) (1) The department shall require any pharmacy benefits manager that it contracts with to pass on to the department any revenues, rebates, or discounts that it receives from pharmaceutical manufacturers and labelers or other entities in connection with prescription drug benefits specific to the program.

(2) The department shall prohibit the disclosure or sale of enrollee utilization data by the pharmacy benefits manager to any person or entity other than the department.

130621. The department shall seek and obtain confirmation from the federal Centers for Medicare and Medicaid that the program established pursuant to this division complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) and that discounts provided under the program are exempt from the Medicaid best price.

130622. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code, the director may implement this article, in whole or in part, by means of a provider bulletin, or other similar instructions, without taking regulatory action.

CHAPTER 4. PRESCRIPTION DRUG RESOURCE CENTER

130630. (a) The Department of Consumer Affairs shall implement a Prescription Drug Resource Center Web site to educate California consumers about options for lowering their prescription drug costs.

(b) The Web site shall include information about public and private drug coverage and drug discount programs that are available to California seniors and other consumers and tips for

1 cutting costs on medications, including guidance concerning
2 generic drugs.
3 (c) (1)The Web site shall also include information about
4 ordering prescription drugs from Canada and other countries.
5 (2) Subject to paragraph (3), this information shall include a
6 list of pharmacies that the California State Board of Pharmacy
7 has determined meet pharmacy management practices required of
8 pharmacies licensed to operate in California and United States
9 and a list of medications that can be ordered through the Web site
10 from licensed pharmacies in Canada and other countries.
11 (3) For purposes of paragraph (2), the department may either
12 provide a direct link for consumers to pharmacies in Canada and
13 other countries or provide a link for consumers to other Web sites
14 if the California State Board of Pharmacy determines that the
15 pharmacies listed in those other Web sites meet pharmacy
16 management requirements that apply to California licensed
17 pharmacies.
18 SEC. 2. The sum of three million dollars ($3,000,000) is
19 hereby appropriated from the State Treasury to the State
20 Department of Health Services, to fund staff and contract costs
21 for the California Rx Program established pursuant to Division
22 113 (commencing with Section 130600) of the Health and Safety
23 Code.

O

U.S. Food and Drug Administration

FDA News

FOR IMMEDIATE RELEASE
P04-108
December 1, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-F

FDA Takes Action Against Company for Illegal Importation of Unapproved, Potentially Unsafe Drugs

The U.S. Attorney's Office, Southern District of New York, has on behalf of the Food and Drug Administration (FDA), filed a civil complaint against Canada Care Drugs, Inc. (Canada Care), Claire Ruggiero, and Christine Ruggiero for the illegal importation of prescription drugs into the U.S.

Canada Care was previously affiliated with Rx Depot, Inc., a company that was engaged in the illegal importation of prescription drugs until November 6, 2003, when the United States District Court for the Northern District of Oklahoma entered an order of preliminary injunction against the company and its affiliates to stop their illegal activity.

"By continuing to illegally import unapproved drugs, Canada Care is putting at risk the health of patients who are expecting to improve their health," said Dr. Lester M. Crawford, Acting FDA Commissioner.

According to the complaint filed in the Southern District of New York on Monday, following the preliminary injunction order against Rx Depot and its affiliates, which was made permanent with the entering of a consent decree on August 20, 2004, Canada Care severed its relationship with Rx Depot, but continued illegal activity in violation of the Food, Drug and Cosmetic Act (FDCA).

As is alleged in the complaint, FDA's investigation of Canada Care's illegal importation operations has revealed several products that pose a risk to the public health. In February and August 2004, FDA made two undercover purchases of the FDA-approved drugs Sporanox and Neurontin through Canada Care.

Instead of Neurontin, FDA received unapproved drugs called APO-Gabapentin and Novo-Gabapentin. The unapproved drugs purchased through the defendants pose a public health threat because, as alleged in the complaint, FDA cannot assure the safety and efficacy of unapproved drugs. Because unapproved drugs are not subject to the FDA's oversight, the FDA has no knowledge how unapproved drugs are made, what patient information is included with the drug, or what the side effects of the drugs are, and as a result they are more likely to be contaminated, counterfeit, inherently ineffective, or contain different amounts of the active ingredients from similar drugs that have been reviewed and approved by the FDA.

In addition, as alleged in the complaint, the manner in which the Sporanox shipment was sent by the foreign pharmacy posed a potentially serious health threat to the patients who received it. Patients should take it in treatment "pulses" of one week, and then wait three weeks before resuming another pulse treatment. Between treatments, patients should consult their doctors to determine whether the treatment should be terminated either

because it is no longer necessary or because they are experiencing liver or heart side effects. Because the foreign pharmacy sent three packages of Sporanox at one time, patients receiving the drugs could have taken all 84 tablets without consulting their doctor in between "pulse" treatments - an action that could have exposed them to serious and even fatal side effects.

The complaint was filed in the United States District Court in the Southern District of New York and seeks to enjoin Canada Care from directly or indirectly importing or causing the importation of U.S.-manufactured and unapproved, foreign-manufactured prescription drugs into the U.S. in violation of the FDCA. The government will also seek preliminary injunctive relief and monetary relief in the form of restitution, disgorgement, or both.

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AGENDA ITEM B

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: December 6, 2004

From: Patricia F. Harris
Executive Officer

Subject: **Request from Safeway Inc. for Waiver of California Code of Regulations section 1717(e) to Install and Use An Automated Dispensing Device**

At its October meeting, the Board of Pharmacy granted to Longs Drug Stores its request for a waiver of 1717(e) to install and utilize a self-service dispensing unit, such as the Asters ScriptCenter, at various Long Drug Stores in California.

The board granted to Longs Drug Stores a waiver of the prohibition(s) stated by that section to permit the use of an automated dispensing device that allows a patient to access his/her filled prescriptions under the following specified conditions:

- The automated dispensing device is used for refill prescriptions only.
- It is the patient's choice to use the automated dispensing device.
- The device is located in reasonable proximity to the licensed pharmacy premises.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the device.
- A pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires counseling pursuant to CCR, title 16, sec. 1707.2(a)(2).

The Board of Pharmacy has received a second request for waiver of California Code of Regulations section 1717(e) to install and utilize a self-service dispensing unit. This waiver request is from Safeway Inc. to use the dispensing units at its various Safeway and /or Vons Pharmacies in California.

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

December 6, 2004

Michael Cantrell, RPh, Esq.
Vice President Professional Services
Longs Drug Stores
P.O. Box 5222
Walnut Creek, CA 94596

Dear Mr. Cantrell:

Pursuant to its authority to do so granted by California Code of Regulations, title 16, section 1717, subdivision (e), the Board of Pharmacy hereby grants Longs Drug Stores a waiver of the prohibition(s) stated by that section to permit the use of an automated dispensing device that allows a patient to access his/her filled prescriptions under the following specified conditions:

- The automated dispensing device is used for refill prescriptions only.
- It is the patient's choice to use the automated dispensing device.
- The device is located in reasonable proximity to the licensed pharmacy premises.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the device.
- A pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires counseling pursuant to CCR, title 16, sec. 1707.2(a)(2).

This waiver is temporary and given without guarantee or promise of continuance or renewal. This waiver may be rescinded at any time by the board, with or without cause, with or without notice, and without regard to any reliance or injury claimed by Longs Drug Stores. No rights shall accrue to Longs Drug Stores by way of this temporary waiver.

Please complete the information on the following page and return it to my attention.

Sincerely,

P. F. Harris

Patricia F. Harris
Executive Officer

I, _____(Name and Title), am authorized to execute this waiver acceptance on behalf of Longs Drug Stores. By my signature hereon, I acknowledge on behalf of Longs Drug Stores that the waiver is temporary, is given without guarantee or promise of continuance or renewal, may be rescinded at any time with or without cause or notice and without regard to any reliance or injury by Longs Drug Stores, and causes no rights to accrue to Longs Drug Stores.

_____ Date:

Signature

SAFEWAY INC.
5918 STONERIDGE MALL ROAD
PLEASANTON, CA 94588-3229

RECEIVED BY CALIF. BOARD OF PHARMACY
2004 NOV -3 AM 10: 44

October 31, 2004

Patricia Harris, Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Re: REQUEST FOR WAIVER- CCR 1717(e)

Dear Ms. Harris:

Safeway Inc. is requesting a waiver to install and utilize self service prescription dispensing units, such as the Asteres ScriptCenter, at various Safeway and/or Vons pharmacies located within the state of California.

The Asteres ScriptCenter, that would be featured as the unit for our pilot test, is an automated, self-contained unit that allows patients to access their refilled prescriptions for which no consultation is required. To facilitate a test environment, the units would be installed adjacent or in close proximity to the pharmacy area. In addition, a few units may be placed away from the pharmacy toward the front of the store to evaluate patient acceptance and usage especially for those patients that are ambulatory impaired. These units may be accessed by a patient during pharmacy hours or during those times when the main store is open but the pharmacy is closed, to improve patient therapeutic compliance.

Prescriptions would be filled, then checked by a pharmacist using the same safeguards currently in place. The filled prescriptions would be placed into the unit under the supervision of a pharmacist. As medications are placed into the unit, security measures are used to ensure accurate dispensing. The manufacturer of the Asteres Unit has previously provided the Board with additional information, specifically illustrating the unit's numerous privacy and security features.

California Code of Regulations, Section 1717(e) places limitations as to how a patient may receive his/her prescription, but also allows the Board to waive this section for good cause. Accordingly, Safeway Inc is requesting a waiver for California Code of Regulations, Section 1717(e) to install and utilize self service dispensing units at its pharmacies throughout the state. Please place this request in the agenda of the Board's next Enforcement meeting and also in the agenda for the next full Board meeting.

Please contact me at the address above listed or directly by phone (925) 469-7747 with any questions or comments.

Sincerely,

Ron Bingaman

Ron Bingaman, R.Ph.
Corporate Pharmacy Director
Safeway Inc.

Cc: Dave Fong, Corporate Vice Pres. Pharmacy
File

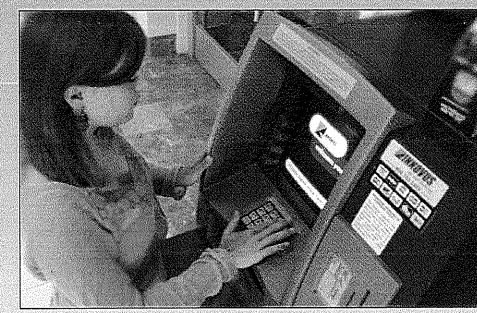
Recycled Paper

Board of Pharmacy Waiver Request (CCR 1717e) - Safeway

Agenda

- Description of focused use of remote Rx refill dispensing
- Benefits
- Description and specifications of proposed remote Rx refill dispenser

Remote Rx Refill Dispensing – Focused Use

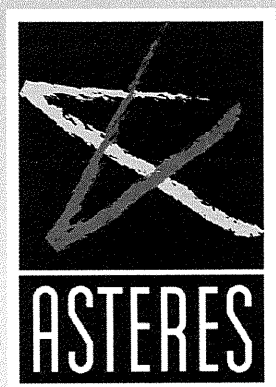


- Facilitates:
  - Busy lifestyle
  - More convenient access to Rx refills
- May only be used:
  - Upon patient request - “opt in”
  - Only for Rx refills when the pharmacist determines no consultation or other intervention is required
  - When Patients are comfortable using with ATM type units

Benefits

- Enhances availability of Rx refills that improves patient medication compliance
- Shifts routine Rx refill pick up away from pharmacy register resulting in better access for patients who wish to talk with their pharmacist
- Provides value add services to help keep patients using their local pharmacy and not shift to mail order services

Asteres ScriptCenter™



A secure, self-service prescription refill dispensing unit to be used by Safeway

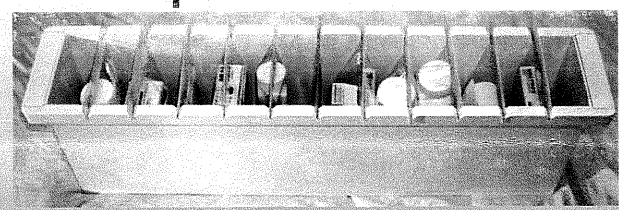
ScriptCenter Functions

- Automates the storage and purchase of finished prescription refills that do not require any pharmacist consultation or intervention
- Allows pharmacy patients to pick up and pay for finished prescriptions
- Provides patients access to their prescription refills when store is open but the pharmacy closed

ASTERES

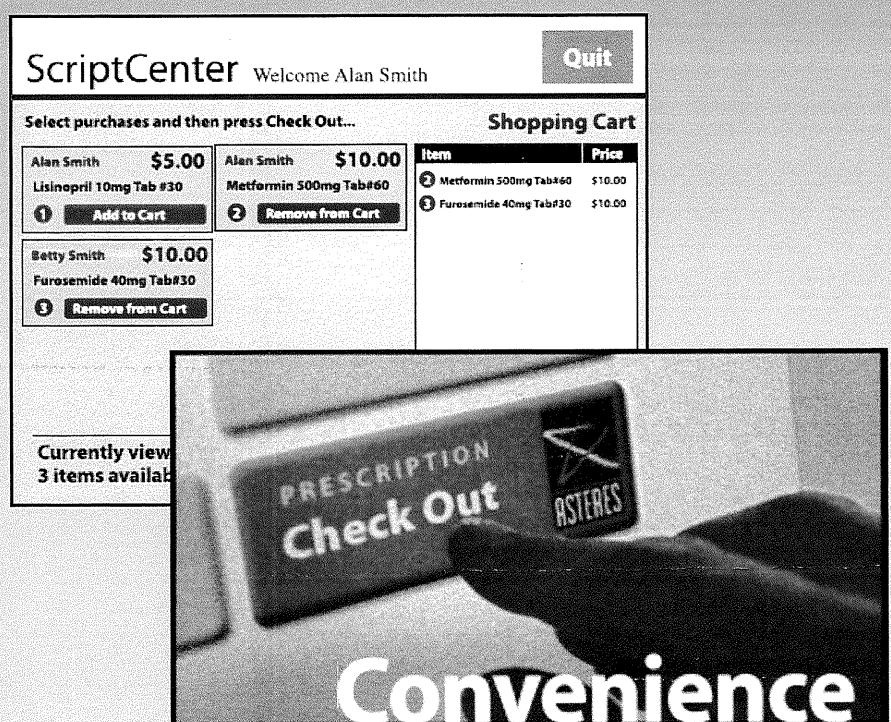
ScriptCenter Procedures
Fill → Load → Pay

- Fill prescriptions using established work flow with final check by the pharmacist
- Patient requests refilled prescription be available via ScriptCenter dispensing unit
- Place checked prescription refills in dispensing bags
- Link bar-coded bags to prescriptions
- Load bags into trays
- Load trays into ScriptCenter
- Customers purchase from ScriptCenter



ASTERES

How do pharmacy patients access their Rx refills from ScriptCenter?



- Login
- Select prescriptions
- Sign and acknowledge
- Pay
- Remove from bin
- Take receipt

ASTERES

Security Features

- One prescription per bag
- Bar code assures patient/RX match
- Electronic signature and photo log
- Equipped with floor bolts & door locks
- Privacy screen for confidentiality

ASTERES

Pharmacy Patient Satisfaction

- Easy to use
- Shorter lines
- More flexibility
- Private transaction environment
- Added convenience

ASTERES

Initial Pharmacy Patient Feedback:

Nov. 4-21, 2003

Retail drug store - San Diego, CA

- 450 surveys collected
- 99% - easy to use
- 92% - likely to use
- 31% - requested email notification

ASTERES

AGENDA ITEM C

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: December 6, 2004

From: Patricia F. Harris
Executive Officer

Subject: Proposed Regulation Change to Delete California Code of Regulations section 1717(e) and Add section 1713

At its October meeting, the Board of Pharmacy approved two waivers of California Code of Regulations section 1717(e). The first waiver allowed Longs Drug Stores to use a secure drop box for receiving prescription orders from patients. The second waiver authorized the use of a self-serve, automated dispensing device for patients to pick-up their refilled prescriptions.

Based on this action, the board then approved a proposed regulation change to allow these practices without a waiver. The proposal relocates existing provision 1717(e) into new section 1713 and provides the authorization for both the drop boxes and self-service automated dispensing devices.

The proposed language authorizes a patient to deposit a prescription in a secure container that is at the same address or adjoining the licensed premises and the pharmacy is responsible for the security and confidentiality of the prescriptions deposited in the container. The proposed regulation also allows a patient to access his/her filled prescriptions from an automated dispensing device under the following specified conditions:

- The automated dispensing device is used for refill prescriptions only.
- It is the patient's choice to use the automated dispensing device.
- The device is located in reasonable proximity to the licensed pharmacy premises.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the device.
- A pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires counseling pursuant to CCR, title 16, sec. 1707.2(a)(2).

While the board approved the regulation change, it has not been noticed for a regulation hearing. President Goldenberg also directed that this proposal be placed on the December Enforcement Committee agenda.

Add Section 1713

§1713 Receipt and Delivery of Prescriptions

(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.[1]
(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.[2]
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address or adjoining the licensed premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d)A pharmacy may use a device to dispense refilled prescriptions provided:

(1) The patient chooses to use the device .
(2) The device is located in reasonable proximity to the licensed premises.
(3) The device has a means to identify the patient and only release that patient's prescriptions.
(4) The device is secure from access by unauthorized individuals.
(5) The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
(6) The pharmacy is responsible for the prescriptions stored in the device.

§1717. ~~Pharmaceutical~~ Pharmacy Practice.

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

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

(b) In addition to the requirements of Business and Professions Code Section 4040 ~~4036, Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the

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[1] Moved from 1717 (e).
[2] Moved from 1717 (e).

prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~
~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~
~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

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

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

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

AGENDA ITEM D

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee

Date: December 6, 2004

From: Patricia F. Harris
Executive Officer

Subject: Request for Waiver of 1717(e)

Advanced Pharmacy Solutions is requesting a waiver of California Code of Regulations section 1717(e) so that they may deliver Synagis to a licensed home health agency for administration at the patient's residence.

ADVANCED
Pharmacy Solutions
Critical Home Care Specialists

October 25, 2005
Patricia Harris
Executive Secretary
California State Board of Pharmacy

Dear Patti,

VIA FAX AND OVERNIGHT UPS
EMERGENCY WAIVER REQUEST

Attached please find the new DHS Policy Statement regarding the Synagis Injection program for Medi-Cal beneficiaries to begin on November 1, 2004.

I specifically call your attention the third paragraph, section "b" whereby prescriptions filled pursuant to B&P Code 4051 may be delivered, under arrangement with a licensed home health care, directly to the HHA (licensed Home Health Agency) for administration by the HHA at the patient's place of residence.

I have reviewed this new DHS policy with Dennis Ming and we have both come to the conclusion that a waiver from the Board of Pharmacy under the California Code of Regulations 1717e would be required.

Background: Synagis is a heat labile, life sustaining injection for the prevention of RSV (respiratory syncival virus) in certain compromised infants. It requires a professional nurse to reconstitute the medication within a few hours of the administration time and as such, we propose to deliver patient specific prescriptions directly to the licensed HHA as authorized in the DHS Policy Statement. We currently have 465+ fragile infants that we intend to begin filling their prescriptions as soon as DHS and EDS solve their TAR and claiming issues. We expect this to be accomplished within the next 48 hours.

It is not feasible to deliver refrigerated containers directly to patients because of cost constraints and reliability of the caregiver to be present when the package arrives. **Therefore we are urgently requesting this emergency waiver as I do not feel DHS Medical Policymakers took 1717e into consideration during their recent emergency enactment of this new policy statement.**

Time is of the essence. Please contact me as quickly as possible to discuss how we can begin providing these prescriptions within the legal limits of the law.

Yours truly,

James H. Roache, Pharm. D.

26611 Cabot Road Laguna Hills California 92653-7103
PHONE: 949•348•7900 TOLL FREE: 800•464•7736 RxFAX: 949•348•7922 Resp/HME FAX: 949•348•7920

State of California—Health and Human Services Agency
Department of Health Services

California Department of Health Services
SANDRA SHEWRY
DIRECTOR

ARNOLD SCHWARZENEGGER
Governor

POLICY STATEMENT
PRIOR AUTHORIZATION AND BILLING INSTRUCTIONS FOR SYNAGIS

To ensure continued timely access to palivizumab (Synagis®) during the upcoming flu season.

The Department will allow certain Medi-Cal fee-for-service providers to bill on form HCFA 1500 for Synagis® 50mg using code X7441, and Synagis® 100mg using code X7439, for dates of service beginning October 1, 2004. Physician, clinic, and home health agency (HHA) providers will not be allowed to bill using these X codes. Physician and clinic providers will continue to bill for Synagis® on form HCFA 1500 using 90378. HHA providers will continue to bill for Synagis® on form HCFA 1500 using Z6918.

Providers that meet the following criteria may bill for Synagis on form HCFA 1500 using codes X7441 and X7439:

a) The provider operates an ambulatory infusion suite whereby the pharmacist is administering Synagis pursuant to the provisions of Business and Professions Code Section 4052(a)(5)(A) or,

b) The provider, under an arrangement with a licensed HHA, dispenses a Synagis prescription in accordance to the provisions of Business and Professions (B&P) Code Section 4051 either directly to the caregiver or the HHA for administration by the HHA at the patient's place of residence, provided that the HHA is not separately billing Medi-Cal for a skilled nursing visit under Z6900.

Providers that dispense Synagis in accordance to the provisions of B&P Code Section 4051directly to a HHA, physician's office or clinic for administration, whereby the HHA, physician's office or clinic separately bills Medi-Cal for the administration of Synagis will bill Medi-Cal through CAL-POS on-line system, CMC or paper using the drug's NDC.

All claims will require an approved TAR, which must be submitted to the Los Angeles Medi-Cal Field Office on fax line 1-866-816-4377.

All claims for Synagis using X7441 or X7439 will be paid at the rate of AWP minus 5% plus a one-time administration fee of $4.49.

All claims for Synagis using the product NDC will be paid at AWP minus 17% plus the dispensing fee of $7.25.

AGENDA ITEM E

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee December 3, 2004

From: Joan Coyne, Supervising Inspector
Board of Pharmacy

Subject: Amendment of Section 4104 of the
Business and Professions Code

Presently the Business and Profession Code, section 4104 reads:

(a) Pharmacies shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license.
(b) Pharmacies shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy.
(c) The board may, by regulation, establish requirements for reporting to the board conduct or incidents described in subdivision (a) or (b).

Currently there is no regulation in place that requires a pharmacy to report impaired licensees to the Board.

In my capacity as the Supervising Inspector of the PRP/Probation team, which oversees investigations of licensee's self-use of drugs and alcohol and monitors the probation and recovery program participation of our licensees, I recently made a review of a representative sample of complaints and cases investigated.

Review of those case investigation reports indicated a substantial number of incidents of theft and self-use of drugs, improper use of alcohol and obvious mental impairment by practicing pharmacists, were never reported to the Board. In many instances this included incidents where the discovery was made while the pharmacist was at work in the pharmacy filling and dispensing prescriptions and drug orders to patients.

It was only after additional incidents with subsequent employers or an arrest was the impaired pharmacist or technician was brought to the attention of the Board.

My research into these cases revealed that too many times, the pharmacy ownership merely requested the resignation of the individual or terminated him/her from employment. Or, in the case of large dollar value theft, often the ownership seeks restitution from the pharmacist or

technician in cash or a signed promissory note, then terminates him/her employment allowing the impaired individual to go out and seek employment from another pharmacy.

Because pharmacists are in short supply, many pharmacy owners only verify valid licensure and hire without asking for, or checking, employment references. Thus, by a pharmacy not being required to report the impaired employee, he/she is able to continue to compromise the health and safety of the public we serve.

In some cases, the Board didn't become aware of the impaired licensee until a serious prescription error was made or, the individual was reported by a patient, co-worker or conscientious employer at a new work location.

It was also discovered, many incidents came to the attention of the Board only through those subsequent investigations when prior employers were questioned and the Board learned an individual lost their prior employment because of chemical, mental or physical impairment affected their practice.

My limited review showed 22 cases where subsequent investigations would probably not have materialized had a prior employing pharmacy been required to report an employee whose practice was affected.

An impaired pharmacist or technician is a threat to the health and safety of the public and himself/herself. Early discovery of the impaired individual will not only protect the public we serve but will also allow intervention and hopefully rehabilitation of that individual.

It is recommended Section 4101 be amended to read:

4104. (a) Pharmacies shall report to the board the identity of ~~have in place procedures for taking action to protect the public when~~ a licensed individual employed by or with the pharmacy if the licensed individual is known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license.
(b) Pharmacies shall report to the board the identity of ~~have in place procedures for taking action to protect the public when~~ a licensed individual employed by or with the pharmacy if the licensed individual is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy.
~~(c) The board may, by regulation, establish requirements for reporting to the board conduct or incidents described in subdivision (a) or (b).~~

AGENDA ITEM F

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: December 6, 2004

From: Patricia F. Harris
Executive Officer

Subject: **Implementation of SB 151 (Chapter 406, Statutes of 2003) Requirements for Prescribing and Dispensing Controlled Substances**

Over the last year, the Board of Pharmacy has been implementing the changes to the prescribing and dispensing requirements for Schedule II controlled substances. The board has been working very hard educating pharmacists and prescribers on the new requirements and has been coordinating efforts with the Bureau of Narcotics Enforcement (BNE), the Medical Board of California, other prescribing boards and the professional associations. Since January 2004 (and before), the board has provided over 30 presentations on SB 151 that have included telephone conference calls that have involved large number of individuals.

Starting January 1, 2005, written prescriptions for all controlled substances must be on tamper-resistant security prescription forms that have been printed by a board-approved printer and must contain specific elements. There is no specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required elements.

If a pharmacist has questions concerning the validity of the prescription, the board is advising that the prescription should be treated like any other questionable prescription – call the prescriber to verify the prescription. If the form does not contain the proper features, it may indicate that a board-approved printer did not print it. Such prescriptions should be reported to the BNE at (916) 319-9062.

In summary the changes that take effect January 1, 2005 are:

- Triplicate prescription forms are no longer valid.
- All written controlled substance prescriptions must be on the new controlled substance prescription forms printed by an "approved" printer (oral and fax orders for Schedules III-V are still permitted).
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.

- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.
- The exemption for Schedule II prescriptions for the terminally ill remains in effect (H&S Code 11159.2). (This exemption doesn't apply to Schedule III prescriptions.)

To further aid in the implementation of the new controlled substance laws, the board has prepared a series of articles that will appear in the January newsletter and on the board's Web site. **(Attachment 1)**

Meanwhile, the Department of Justice (DOJ) is proposing some amendments and additional provisions to make technical changes to effectuate the administration of the CURES program **(Attachment 2).**

The proposed amendments are as follows:

- DOJ would be the originating agency for fingerprint processing (instead of the Board of Pharmacy).
- DOJ would collect a fee for processing criminal background checks.
- The applicant class that that must submit criminal background checks would be clarified.
- The Board of Pharmacy and DOJ would be authorized to make any examination of the books and records of any applicant or visit and inspect the business.
- The Superior Court would be authorized to order a prescriber not to order or obtain or use any additional prescription forms during a pending criminal action based on the request of the law enforcement agency bringing the criminal action.
- The approved security printers would be required to print security prescriptions forms with a vendor identification code issued by DOJ.
- The security prescription form would be required to have a check box by the name of each prescriber to be checked to identify the prescriber issuing the prescription when there are multiple prescribers on one security prescription form.

DOJ is requesting that the Board of Pharmacy support these proposed changes. Staff is recommending that the board support them and in addition is proposing additional amendments. It is staff's recommendation that the Board of Pharmacy no longer approve security printers. The board absorbed this workload initially to assist with the transition from the triplicate prescription form to the new tamper-resistant forms printed by "approved" printers. It is no longer necessary that both the Board of Pharmacy and DOJ approve the printer. It should be the sole responsibility of DOJ.

ATTACHMENT 1

SB 151 Requirements for Prescribing and Dispensing Controlled Substances

Senate Bill 151 has brought changes in the controlled substance prescribing and dispensing requirements. A major change is the elimination of the triplicate forms used for prescribing Schedule II controlled substances and use of easier to order tamper-resistant prescription forms that are purchased from designated security printing companies.

The Board has a number of educational materials on its Web site to aid pharmacists, prescribers and patients in understanding the new requirements, which will be in effect January 1, 2005.

To help you in finding answers to prescribing questions regarding these changes, an annotated index for the contents of the key prescribing laws (Health & Safety Code) is offered below. This index provides a quick overview of where in law particular provisions can be found. The exact text of SB 151 can be found at the Board's Web site, *www.pharmacy.ca.gov*, and a question and answer segment is also at that site.

Tamper-resistant prescription forms

Health & Safety Code Sections

11029.5 Defines "security printer"

A person approved to produce controlled substance prescription forms pursuant to Section 11161.5.

11161.5 Applying to become an approved security printer

Contains the requirements for: applying for approval by the Department of Justice and the Board of Pharmacy to print tamper-resistant prescription forms, delivery of forms to the prescriber, and record-keeping requirements for printers.

11162.1 Requirements for tamper-resistant prescription forms

Describes all the features required for tamper-resistant forms and information to be entered on the forms by the prescriber. Included is a requirement that the form contains either (A) a statement printed on the bottom of the prescription blank that the "Prescription is void if more than one controlled substance prescription is written per blank" or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

Details tamper-resistant prescription form requirements for the designated prescriber of a *licensed health care facility*.

Prescribing Schedules II – V controlled substances

11159.2 Exception to triplicate prescription requirements; terminally ill patient

Includes retention of requirements for a Schedule II prescription written on a regular plain prescription form for a "terminally ill" patient—must still include notation "11159.2 exemption."

11164 Requirements for writing and dispensing Schedule II-V prescriptions

Includes all entries required on a controlled substance prescription. Directions for handling a Schedule II prescription that contains errors or uncertainties are found in Title 16 of the California Code of Regulations section 1761(a).

11164.1 Controlled substance prescriptions written by out-of-state prescribers

Allows filling such prescriptions when delivered to out-of-state patients and requires the reporting of Schedules II and III prescriptions to the Department of Justice

Business & Professions Code Sections

4170 Dispensing by the prescriber: requirements and restrictions

Includes definition of "prescriber" and details labeling and packaging requirements

Oral and faxed prescriptions

Health & Safety Code Sections

11164 Faxing of prescriptions for Schedule III-V controlled substances

Permits Schedule III-V control substances to be dispensed upon an oral or electronically transmitted prescription. Note: Faxing a prescription written on the tamper-resistant forms will produce the word "*VOID*" across the face of the prescription, so prescribers are encouraged to use a regular form when faxing.

11167 Faxing of Schedule II controlled substance prescriptions allowed in an emergency

Describes the emergency circumstances that allow the faxing of a Schedule II controlled substance prescription. This section lists all the requirements for a

pharmacist who receives an oral, electronic data transmission, or a written order not made on a tamper-resistant prescription form.

11167.5 Faxing of Schedule II controlled substance prescriptions for specified inpatients, residents, and home hospice patients

Contains pharmacists' procedures upon receipt of an oral or faxed Schedule II prescription for a patient of a licensed skill nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice

See Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health & Safety Code for definitions of "*licensed health care facility.*"

Controlled Substance Utilization, Review, and Evaluation System (CURES)

Health & Safety Code Sections

11164.1 Schedule III added to CURES data collection

Beginning January 1, 2005, all Schedule II and III prescriptions must be reported to the CURES data collection vendor, Atlantic Associates (see below).

11165 CURES

Fully describes the purpose of and procedures for pharmacies to report Schedules II and III prescriptions to the CURES data collection vendor. Questions regarding the reporting procedures should be directed to Atlantic Associates at 1-888-492-7341.

Dispensing physicians with questions regarding CURES should contact the Bureau of Narcotic Enforcement (BNE) at (916) 227-4051.

11165.1 Obtaining patient's medical history from CURES data

Allows prescribers to request patient's history from the Department of Justice

To request a patient history of controlled substance prescriptions from the CURES, pharmacists or physicians can download a Patient Activity Report (PAR) request form by visiting the Board of Pharmacy Web site, *www.pharmacy.ca.gov/pharmacy/secure/pharmacy_forms_request.htm.* Complete the appropriate PAR form and fax it to the BNE at (916) 227-5079.

What to Look for on the New Tamper-Resistant Prescription Forms

Beginning January 1, 2005, written prescriptions for controlled substances must be on tamper-resistant security prescription forms that have been printed by a Board-approved printing company. To prevent fraud or diversion, these forms must contain specific security features (Health & Safety Code Section 11162.1 et seq.). There is no one specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required features.

Security Features

The law requires that the list or description of the required security features must be printed on the security prescription form. The list/description may be printed **anywhere on the form** (e.g., in warning bands along the edges of the form's face or listed on the back of the form). The description should tell what and where the features are on the form and how to test them.

Examples of what a new security form might look like are on the following pages. These are examples only—actual form designs and security feature application will vary significantly from form to form and from printer to printer. However, all forms are required to have specific security features and preprinted prescriber information.

More specific information about the security features required on these forms, as well as other new requirements for prescribing and dispensing controlled substances can be found on the Board's Web site at *www.pharmacy.ca.gov*.

Important Note: If you have questions concerning the validity of the prescription, treat it like any other questionable prescription—call the prescriber to verify the prescription. If the form does not contain the proper features, it may indicate that it was not printed by a Board-approved printer. Such prescriptions should be reported to the Bureau of Narcotic Enforcement at (916) 319-9062.

WHAT TO LOOK FOR ON THE NEW TAMPER-RESISTANT PRESCRIPTION FORMS

Beginning January 1, 2005, written prescriptions for controlled substances must be on tamper-resistant security prescription forms that have been printed by a Board-approved printer and must contain specific elements (Health & Safety Code Section 11162.1 et seq.). There is no one specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required elements. Security features are used to prevent fraud or diversion.

Description of Security Features

The law requires a description of the security features be printed on the security form. Some forms describe each feature in a list on the back of the prescription; however, some forms describe features in "warning bands" across the face or along the edge of the prescription. The description should tell what and where the features are on the form and how to test them.

The specific security feature components are:

1. **Latent Repetitive Void Pattern**— the word "void" appears all over the front of a security prescription form if it is scanned, photocopied or faxed. Consequently, if a prescription is to be faxed, prescribers are encouraged to use plain paper prescription forms (not security prescription forms) for this purpose. A pharmacist receiving a "void" faxed prescription should always use his or her professional judgment when filling the prescription and contact the prescriber anytime there are questions concerning a prescription's validity (just as a pharmacist would do with any prescription).
2. **Watermark**— a printed watermark of the words, "California Security Prescription," must be seen on the back of the security form. The watermark is often very light but can be seen by holding the form at an angle.
3. **Chemical Void**—any area exposed to ink solvents (e.g., acetone) will cause a "void" pattern to appear or will appear heavily stained. This feature is important to prevent unauthorized changes to a security form after the prescriber has written the prescription.
4. **Thermochromic Ink**—a feature (e.g., a symbol or text) printed in this ink will change color or disappear temporarily when exposed to heat, such as rubbing briskly with your fingers or with hot breath. An important aspect of this ink is that the feature returns to its original color when it cools.
5. **Opaque Writing or Microprinting**—the opaque writing disappears if the prescription is lightened or microprinted text so small that it cannot be detected without a magnifier, and which becomes a solid line when copied.
6. **Quantity Check-off Boxes**—six boxes with specific drug quantity amounts listed with each box. The prescriber checks off the box that matches the number of tablets or capsules prescribed. This feature is important to prevent alteration of the quantity ordered after the prescription is written. The law requires specific quantity boxes to be listed:

   1-24
   25-49
   50-74
   75-100

151 and over

7. **Unit Designation** —there must be a space for designating the unit if the prescribed drug is not in tablet or capsule form (e.g., "ml" for milliliter, "sol" for solution, etc).
8. **Single or Multiple Drug Statements** – security forms must have one of two statements at the bottom on the face of the prescription that delineates a single drug prescription versus a multiple drug prescription:
   - "Prescription is void if more than one controlled substance prescription is written per blank; or
   - "Prescription is void if the number of drugs prescribed is not noted" and a line provided for the prescriber to write in or circle the number of drugs prescribed.

Other required components on the security forms include:

- **Preprinted Prescriber Information** —the security prescription forms must include the name, category of licensure, license number, and federal controlled substance registration number of the prescriber, already preprinted on the form. There is an exception:
  - **Forms for Institutional Use**—there are special provisions that may be used only by a health care facility licensed by the Department of Health Services (DHS) pursuant to Health & Safety Code 1250. The facility must **designate a prescriber** to order forms, receive delivery, distribute the forms to authorized prescribers within the facility, and record the names, federal controlled substance registration numbers, license numbers, and quantity of forms issued. The facility must maintain the records for three years. The designated prescriber's name, category of licensure, license number, and federal controlled substance registration number is preprinted on the form. The form must also include the facility's name, address, category of licensure, and DHS license number. A blank area is provided for the actual prescriber to print or stamp his or her name, category of licensure, license number, and federal controlled substance registration number when the prescription is written. It is important to note that a prescription written on an institutional style form is not valid without the actual prescriber information filled in on the form.
- **"Do Not Substitute" Check-off Box** - this statement must appear on the form, and if checked off, indicates the prescriber's order not to substitute another drug for the prescribed one. The prescriber must also personally initial the check box.
- **Form Batch Numbers**—requires that every batch of forms have a unique lot number printed on the forms and that each form within that batch is numbered sequentially, beginning with numeral one.

If you have questions concerning the validity of the prescription, treat the prescription like any other questionable prescription—call the prescriber to verify the prescription. If the form does not contain the proper features, it may indicate that it was not printed by a Board–approved printer. Such prescriptions should be reported to BNE at (916) 319-9062.

INSTITUTION OR FACILITY SECURITY PRESCRIPTION FORM SAMPLE

Institution forms can only be used by health care facilities licensed under Health & Safety Code section 1250. Generally, these are 24-hour acute care hospitals, skilled nursing facilities, etc. The forms are preprinted with the facility and the facility's "designated prescriber" information as indicated below. The actual prescriber information will be printed, handwritten, or stamped on the form when the prescription is written.

▪ VOID APPEARS WHEN COPIED ▪ REVERSE RX ▪ MICROPRINT SIGNATURE LINE ▪ CA WATERMARK

Institution's State License Number 9999999-0001
Institution Name
Address
City, State Zip
Designated Prescriber: Designated Prescriber Name, Category of Licensure, DEA Number, State License Number

Prescriber Name & Category of Licensure | **DEA Number** | **State License Number** | **Telephone Number**

Name _____ DOB _____
Address _____ Sex: ❒ M ❒ F

1) Quantity: ❒ 1–24 ❒ 25–49 ❒ 50–74 ❒ 75–100 ❒ 101–150 ❒ 151 – over
Unit _____ Refills: 0 – 1- -2 – 3- -4- -5
❒0 Do Not Substitute Initials _____

2) Quantity: ❒ 1–24 ❒ 25–49 ❒ 50–74 ❒ 75–100 ❒ 101–150 ❒ 151 – over
Unit _____ Refills: 0 – 1- -2 – 3- -4- -5
❒ Do Not Substitute Initials _____

3) Quantity: ❒ 1–24 ❒ 25–49 ❒ 50–74 ❒ 75–100 ❒ 101–150 ❒ 151 – over
Unit _____ Refills: 0 – 1- -2 – 3- -4- -5
❒ Do Not Substitute Initials _____

SAMPLE ONLY – ACTUAL FORMS WILL VARY SIGNIFICANTLY

X _____ Date _____

Prescription is void if the number of drugs is not noted: _____

▪ THERMOCHROMIC INK SYMBOL ▪ QUANTITY CHECK BOXES ▪ CHEMICAL VOID PROTECTION

- **Batch/Lot Numbers** – Unique batch and sequential lot numbers assigned by approved security printers. Numbers are not tracked by the State.
- **Actual Prescriber** – the prescription is not valid without the actual prescriber information filled in.
- **Opaque Writing** fades or disappears when photocopied repeatedly to lighten.
- **Six quantity check boxes** allow quick confirmation that the quantity prescribed has not been altered.
- **Do Not Substitute** –prescriber must check box and initial
- **Refills** – CII drugs cannot be refilled, only CIII – V can be refilled.
- **Description of security features** in warning bands on face or listed on back of prescription. (see sample of backside)
- **Thermochromic ink** feature changes color or disappears temporarily with hot breath or when rubbed briskly. It slowly returns to normal as it cools.
- **Microprint signature line –** seen only with a magnifier, which becomes a solid line when copied.
- **Statement** allows multiple prescriptions on one form. Prescribers must note the number of drugs prescribed.

Alternatively, prescribers may order a form designed to write only single drug prescriptions. See the previous form sample using a single drug prescription format.

SAMPLE BACKSIDE OF SECURITY PRESCRIPTION FORMS

Security Features:

- RX logo disappears or changes color temporarily with hot breath or when rubbed briskly with finger.
- Opaque Rx fades or disappears with repeated attempts to lighten prescription on copier.
- Microprinted text signature line becomes solid line when copied.
- California Security Prescription watermark on back.
- Repetitive VOID pattern appears across face when copied.
- VOID pattern or stain appears where attempts are made to chemically alter the prescription.
- Quantity range checked confirms quantity prescribed.
- Unique batch number and each form sequentially numbered.
- Order not to substitute.
- Single drug prescription format.
- Preprinted prescriber information.

SAMPLE ONLY – ACTUAL FORM DESIGNS WILL VARY

- **California Security Prescription Watermark** printed in opaque ink– hold at an angle to view.
- **Description of Security Features** (may be on the face of prescription in warning bands instead, see blue bands on sample forms)

SINGLE PRESCRIBER OR GROUP PRACTICE SECURITY PRESCRIPTION FORM SAMPLE

▪ VOID APPEARS WHEN COPIED ▪ REVERSE RX ▪ MICROPRINT SIGNATURE LINE ▪ CA WATERMARK

Z999999-0001

Group Practice Name ☐ Prescriber Name, Category of Licensure, DEA Number, State License Number
Address ☐ Prescriber Name, Category of Licensure, DEA Number, State License Number
City, State Zip ☐ Prescriber Name, Category of Licensure, DEA Number, State License Number
Telephone Number ☐ Prescriber Name, Category of Licensure, DEA Number, State License Number

Name _____ DOB _____
Address _____ Sex: ☐ M ☐ F

Rx

SAMPLE ONLY – ACTUAL FORM
DESIGNS MAY VARY SIGNIFICANTLY

Quantity:
☐ 1–24
☐ 25–49
☐ 50–74
☐ 75–100
☐ 101–150
☐ 151 – over

Unit _____
Refills: 0 – 1- -2 – 3- -4- -5
☐ Do Not Substitute
Initials____

X _____ Date _____

Prescription is void if more than one controlled substance is written per blank

▪ THERMOCHROMIC INK SYMBOL ▪ QUANTITY CHECK BOXES ▪ CHEMICAL VOID PROTECTION

Batch/Lot Numbers – Unique batch and sequential lot numbers assigned by approved security printers. Not tracked by the State,

Opaque Writing fades or disappears when photocopied repeatedly

Six quantity check boxes allow quick confirmation that the quantity prescribed has not been altered.

Refills – CII drugs cannot be refilled, only CIII – V can be refilled.

Do Not Substitute – prescriber must check box and initial

Statement that Identifies form as a **single drug** prescription form

Thermochromic ink feature changes color or disappears temporarily with hot breath or when rubbed briskly. It slowly returns to normal as it cools.

Microprint signature line – seen only with a magnifier and becomes a solid line when copied, faxes or scanned.

Description of security features in warning bands on face or listed on back of prescription.

Alternatively, prescribers may order a form designed to write multiple prescriptions on one form. See the next form sample using a multiple drug prescription format. 12/04

ATTACHMENT 2

DEPARTMENT OF JUSTICE - LEGISLATIVE PROPOSAL
2005

LEG UNIT DRAFT NUMBER: 22

I. DIVISION AND BUREAU/SECTION SUBMITTING THE PROPOSAL

Bureau of Narcotic Enforcement, Controlled Substance Utilization, Review and Evaluation System (CURES)

II. TITLE

Proposed technical changes to Pain Treatment and Diversion Act of 2003, Health and Safety Code §, 11159.2 et seq.)

III. SUMMARY

The proposed amendments and additional provisions make technical changes to effectuate the administration of the CURES Program.

IV. BACKGROUND

A. Existing Law

Pursuant to SB 151 (Chapter 406, Statutes of 2003) implementing the "Pain Treatment and Diversion Act of 2003," the Controlled Substances Utilization Review and Utilization Review and Evaluation System (CURES) became permanent. (See Health and Safety Code §, 11159.2 et seq.) CURES is administered by the DOJ, Bureau of Narcotic Enforcement (BNE). SB 151 made several notable changes, among those the official "triplicate" prescription form issued by BNE was discontinued for Schedule II controlled substances and a new secure forgery resistant prescription form was adopted for Schedule II through IV drugs. CURES was also authorized to initiate the collection of Schedule III drug information, necessitating changes in the CURES technology and data collection procedures. Among other things, BNE, in conjunction with the Board of Pharmacy, was mandated new duties in the approval of vendors of the new security prescription forms. Among the new duties, CURES must obtain criminal background checks on applicants seeking to become vendors of the secure prescription form. This has included vendors from out of state and Canada. New requirements were also imposed on prescribers in the information provided to CURES. The proposals below address needed clean up and technical changes to facilitate the effective operation of CURES and the program duties of BNE.

SB 151 was not submitted by DOJ but directly impacted a DOJ program. Since these are operational changes that favor DOJ, DOJ should assume responsibility for addressing these changes.

B. Problem

1. Health and Safety Code, § 11161.5 (Approval of security printers)

Number One:

The Act would be amended to specify that DOJ, and not the Board of Pharmacy (BOP), will control the manner in which fingerprints are provided. Under SB 151, the BOP was designated as the agency that first receives applications from vendors seeking approval to print the new security prescription forms. In doing so, the Board was identified as the agency to control obtaining fingerprints. Hence, the BOP is required to obtain fingerprints for DOJ to clear. This has led to delaying the approval process when the application is finally received by DOJ. Additionally, operational needs are presently not being met, specifically with approving out-of-country vendors with the BOP as the lead agency in the fingerprinting process. Full records are also not made available to DOJ under the present statutory scheme.

Currently, the BOP processes the vendor applications. The application includes a live scan form to be taken with the applicant to the place they have their fingerprints live scanned at DOJ or sent to DOJ. At this time, the live scan form contains the originating agency number (ORI) and mail code for the Board of Pharmacy. This means that when the fingerprints are processed by DOJ, DOJ must treat this as an application for the BOP and provide the clearance or rapp sheet information directly back to them as the submitting agency under the guidelines of applicant processing. The BOP then forwards this information to CURES at DOJ, as part of the completed application package. This manner of dissemination is not the norm. Additionally, as the requesting agency, it is the BOP that currently receives all subsequent arrest information for current approved vendors and it is up to the BOP to pass this information on to CURES. This leaves a critical information gap when the DOJ, as CURES, assumes its role in the applicant approval process.

Another problem with this process is that the information the BOP receives from DOJ is limited to arrests with dispositions. If there is an entry on the rapp sheet that does not have a disposition, the arrest information must be removed before dissemination to the BOP. If DOJ were the processing agency DOJ would receive the arrest information as the submitting agency with the authority to receive and review such information.

Accordingly, with the amendment, the live scan form can be changed to reflect DOJ as the submitting agency with DOJ's ORI and mail code, thereby allowing the response to go directly to DOJ as well as all subsequent arrest information. The above proposed processes are consistent with existing criminal background policy and practice.

Number Two:

The Act would be amended to allow DOJ to collect a fee for processing criminal background

checks when a vendor applies to become an approved security printer of prescription forms. Each applicant shall pay at the time of filing an application for a permit a fee determined by the department which shall not exceed the application processing costs of the department. This is consistent with DOJ policy of a fee for services and similar legislation governing, for example controlled substance transactions under the "precursor" statutes. See Health and Safety Code §, 11106 (h). The impact will be on those vendors that apply after the enactment of this legislation. The far majority of vendors will already have been approved before this amendment. The fee, however, is an important cost recovery item.

Number Three:

The Act would be amended to specify and define the applicant class that must submit criminal background checks. The statute presently refers only to the "applicant" but does not specify who the applicant class is. BNE has already discovered that it must have the authority to require backgrounds of individuals that will directly handle the secure prescription forms. Specifying the applicant class also will comply with DOJ policy and to allow for consistency as found in related precursor statutes where the applicant class is specified. See Health and Safety Code §, 11106 (d)(2). The impact will fall more on BNE and DOJ since BNE will request more criminal background checks. Nonetheless, BNE must have the specified authority for a more expansive class to facilitate background checks and avoid legal challenge.

Number Four:

The Act would be amended to authorize the BOP and the DOJ (BNE) to make any examination of the books and records of any applicant or visit and inspect the business. This authority is necessary given the approval authority already provided and is needed to comply with DOJ policy for auditing and enforcement as found in related precursor statutes. See Health and Safety Code §, 11106 (c). The impact will fall more on BNE since it will be authorized to conduct examinations as resources permit.

2. Health and Safety Code, § Section 11161 (Judicial Enforcement)

The Act would be amended to authorize the Superior Court to order a prescriber not to order or obtain or use any additional prescription forms during a pending criminal action. The law enforcement agency bringing the action will be directed to notify the DOJ of such orders. This amendment addresses an important omission in the enforcement scheme. The amendments also bring the statute current since triplicate prescription blanks will no longer be in use. This will impact prescribers in a criminal proceeding but is a technical change to authorize the court to prevent a prescriber from getting new prescription forms, thus evading a more limited order to turn existing forms in to the court.

3. Health and Safety Code, § Section 11162.1 (Prescription From Features)

Number one:

The Act would be amended to require approved security printers to print security prescription forms with a vendor identification code issued by the DOJ. The Act omitted any identifier on the new security prescription forms that would identify the security printer who issued the form. Hence, there is no manner to confirm that a form was issued by an approved security printer and no way to trace back a form to a specific printer. This will address important fraud concerns. The impact will be on vendors but the costs to add an identifier should be negligible.

Number two:

The Act would be amended to require a check box by the name of each prescriber on a security prescription form to be checked to identify the prescriber issuing the prescription when there are multiple prescribers on one security prescription form. Pharmacists have identified problems in identifying the prescriber based solely on the signature of the prescriber. The check box will serve the purpose of identifying the prescriber. The impact will be on prescribers but it will be negligible.

4. Health and Safety Code sec. 11190 (Direct Dispensing)

The Act would be amended to require a prescriber who directly dispenses controlled substances to submit the information to the DOJ in a format set by the department. The amendment would leave the format open to adjust for changing technology. The format will be specified by regulation. Presently, prescribers are authorized to submit the information in either hard copy or electronic form. This change is necessary to meet the submission needs of the CURES program. The impact will be solely on prescribers who directly dispense controlled substances as opposed to prescribers that write a prescription and the prescription is filled by a pharmacist.

V. PROPOSALS

None of these proposals have ever been introduced in the Legislature. There is no need for urgency legislation. These proposals are projected to address the present problems affecting the administration of the CURES program under BNE.

A. Suggested Legislation

1. Health and Safety Code, § 11161.5 (Approval of security printers)

Proposed Amended Statute:

Section 11161.5

(b) . . . . . .

(5)(A) . . . . .

(B) The ~~applicant~~ *Board of Pharmacy* shall ~~also~~ provide *the applicant with the means and*

direction to provide fingerprints *and related information*, in a manner specified by the ~~Board of Pharmacy~~ *Department of Justice*, for the purpose of completing state, ~~and~~ federal *or foreign* criminal background checks.

(C) The Department of Justice shall require an applicant to have their fingerprint images and related information captured for submission to the Department of Justice, for the purpose of obtaining information as to the existence and nature of a record of state, federal or foreign level convictions and state, federal or foreign level arrests for which the Department of Justice establishes that the applicant was released on bail or on his or her own recognizance pending trial. Requests for federal level criminal offender record information, received by the Department of Justice, pursuant to this section, shall be forwarded to the Federal Bureau of Investigation, by the Department of Justice.

(D) The Department of Justice shall respond to the Office of the Attorney General with information pursuant to section 11105 (l) of the Penal Code.

(E) The Office of the Attorney General shall request subsequent arrest notification, from the Department of Justice, as provided under Section 11105.2 of the Penal Code, for all applicants described in subdivision (b).

(F) Each applicant shall pay at the time of submitting fingerprints and related information to the Department of Justice a fee determined by the Department of Justice to be sufficient to cover all processing or investigative costs generated from or associated with completing state, federal or foreign criminal background checks.

. . . . .

(d) The Board of Pharmacy or the Department of Justice may deny a security private application on any of the following grounds:
(1) The applicant, *any individual owner, partner, corporate officers, manager, agent, representative, employee or subcontractor for the applicant, who has direct access, management or control of controlled substance prescription forms,* has been convicted of a crime. [Remainder as is.]

. . . . . .

(5) The Board of Pharmacy or Department of Justice determines that the applicant failed to demonstrate adequate security procedures relating to the production and adequate security procedures relating to the production and distribution of controlled substance prescription forms. *Applicants shall authorize the Board of Pharmacy and the Department of Justice, as a condition of approval, to make any examination of the books and records of any applicant or visit and inspect the business hours, as deemed necessary to enforce this section.*

2. Health and Safety Code, § Section 11161 (Judicial Enforcement)

Proposed Amended Statute:

Health and Safety Code, § Section 11161

(a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation . . . , the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, . . . issue an order which requires the practitioner to surrender to the clerk of the court all ~~triplicate prescription blanks or~~ controlled substance prescription forms in the practitioner's possession at a time set in the order *and which prohibits the practitioner from obtaining, ordering or using any additional prescription forms. The law enforcement agency obtaining the order shall notify the Department of Justice of this order.*

(b) The order provided by . . . . . Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender *and prohibit obtaining, ordering or using* all ~~triplicate prescription blanks or~~ controlled substance prescription forms with supporting . . . . [remainder as is]

3. Health and Safety Code, § Section 11162.1 (Prescription Form Features)

Proposed Amended Statute:

Health and Safety Code, § Section 11162.1

(a) The prescription forms for controlled substances shall be printed with the following features:

. . . . .
(11) An identifying number assigned to the approved security printer as issued to the approved security printer by the Department of Justice.

. . . . .

(3) Forms ordered pursuant to this subdivision that list multiple prescribers on one prescription form shall have a check box by the name of each designated prescriber and each designated prescriber who signs the prescription form shall identify themselves as the prescriber by checking the box by their name.

~~(3)~~ *(4)* . . . .
~~(4)~~ *(5)* . . . .

4. Health and Safety Code sec. 11190 (Direct Dispensing)

Proposed Amended Statute:

Health and Safety Code, § Section 11190

(G) (2): Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in ~~either hard copy or electronic form~~ *a format set by the Department of Justice.*

B. Alternative Solutions

Regulations will be promulgated that will address program administration issues as a supplement to the present statutory scheme.

Regulations, however, will not resolve the statutory shortcomings that the amendments address.

C. Public Policy

These amendments address program administration issues. The CURES program is now permanent. It is in the interest of all parties that work with the CURES program to have the program effectively administered.

AGENDA ITEM G

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: December 7, 2004

From: Patricia F. Harris
Executive Officer

Subject: SB 1307 (Figueroa)
Chapter 857, Statutes of 2004

Last year, the Board of Pharmacy sponsored SB 1307 (Figueroa). Governor Schwarzenegger signed the bill, which becomes effective January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. The following is a summary of those changes.

Electronic Pedigree for Dangerous Drugs (New)
B&PC 4034—requires an electronic "pedigree" by January 1, 2007. Said pedigree will contain 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 a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the drug.
The pedigree must contain all of the following information: (1) the source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source (2) the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers (3) the business name, address, and if appropriate, the state license number, including a California license number if available, 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.
The application of the pedigree requirement in pharmacies will be subject to review during the Board's sunset review in 2008.

Embargoed Dangerous Drugs or Devices (New)
B&PC 4084 and 4085—allows Board inspectors to embargo dangerous drugs or devices that are suspected of being adulterated or counterfeit by affixing a tag or other marking to the drug. If a Board inspector determines that an embargoed dangerous drug or device is not adulterated or counterfeit, the inspector may remove the tag or marking. It is unlawful for any person to remove, sell, or dispose of an embargoed dangerous drug or device without the Board's permission.

Furnishing Dangerous Drugs to Specified Entities and Violation Penalty (New)
B&PC 4126.5—permits pharmacies to furnish dangerous drugs only to:

- A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired;
- The pharmaceutical manufacturer from whom the dangerous drug was acquired;

- A licensed wholesaler acting as a reverse distributor;
- Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
- A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law;
- A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs; and
- Another pharmacy under common control.

Violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with such a pharmacy may result in a fine of $5,000 per violation.

Surety Bond for Wholesalers (New)
B&PC 4162—requires applicants for the issuance or renewal of a wholesaler license to submit a surety bond of $100,000 or other equivalent means of security to the Board. The purpose of the bond is to secure payment of any administrative fine imposed by the Board and any cost recovery ordered. If the applicant's annual gross income for the previous tax year is less than $10,000,000, a surety bond for $25,000 will be accepted. Additionally, a surety bond of $100,000 may be required for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to the Pharmacy Law. A single surety bond or equivalent means of security acceptable to the board will satisfy this requirement for all licensed sites under common control. This section becomes effective January 1, 2006.

Pedigree Required (New)
B&PC 4163— presently allow manufacturers and wholesalers to acquire or furnish dangerous drugs or devices only from or to those authorized by law to possess or furnish those dangerous drugs or devices. This section is in effect until January 1, 2007, when it will be repealed unless a later enacted statute is enacted before that date. If this section is repealed, the new section will prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug at wholesale without a pedigree. Additionally, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree. This section becomes operative on January 1, 2007.

Extension May be Allowed for Implementing Pedigree Requirement for Wholesalers (New)
B&PC 4163.5—authorizes the Board to extend the time allowed for implementing electronic technologies to track the distribution of dangerous drugs within the state if the Board determines that manufacturers or wholesalers cannot meet the requirement by January 1, 2007. The pedigree requirement compliance date may then be extended until January 1, 2008.

Extension May be Allowed for Implementing Pedigree Requirement for Pharmacies (New)
B&PC 4163.6—authorizes the Legislature to extend the time allowed for pharmacies to implement electronic tracking the distribution of dangerous drugs within the state if the Legislature determines that it is not economically and technically feasible for pharmacies to comply with the requirement by January 1, 2007. The date for compliance with the requirement may be extended to January 1, 2009.

Wholesaler Tracking System of Individual Sales of Dangerous Drugs (Amended)
B&PC 4164—effective January 1, 2006, will require licensed wholesalers to 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.

No Business License for any Wholesaler Not Licensed by the Board (New)
B&PC 4168—prohibits a county or municipality from issuing a business license to a wholesaler who does not have a current wholesaler license issued by the Board.

Wholesaler Sales Requirements (New)
B&PC 4169—prohibits the following:

- The purchase, trade, sale, or transfer of dangerous drugs or devices at wholesale to a person or entity that is not licensed with the Board as a wholesaler or pharmacy;

- The purchase, trade, sale, or transfer of dangerous drugs that the person knew or should have known were adulterated or misbranded;
- The purchase, trade, sale, or transfer of dangerous drugs or devices after the beyond use date on the label; and
- The failure to maintain records of the acquisition or disposition of dangerous drugs or devices for at least three years.

Violation of this section may result in a fine for each violation.

Excessive Furnishing of Dangerous Drugs by a Wholesaler to a Pharmacy (Amended)
B&PC 4301—defines acts of unprofessional conduct and authorizes the Board to take action against a wholesaler who clearly excessively furnishes dangerous drugs to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term facilities.

The Enforcement Committee will be monitoring the implementation of this legislation. One area of close oversight will be pedigree requirement. The bill requires an electronic pedigree by January 1, 2006 and gives the board the authority to extend the compliance date for wholesalers to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States.

It is anticipated that Radio Frequency Identification technology (RFID) will the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

Attached is recent background material regarding the RFID process. Additionally T3Ci, which is an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market, will demonstrate their technology solution for informational purposes only. As stated in their letter, they are involved in pilot testing their system with various manufacturers.

It is not the intent of the Board of Pharmacy to support or endorse any specific technological solution for the electronic pedigree requirement.

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News Release

FOR IMMEDIATE RELEASE
November 18, 2004

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NABP's NDAC Assembles for Inaugural Meeting and Soon After Develops Formal Recommendations

The National Association of Boards of Pharmacy®'s (NABP®) National Drug Advisory Coalition (NDAC) convened its inaugural meeting in early September and then concluded with formal recommendations in early October 2004. The NDAC was commissioned by NABP to develop criteria for determining which prescription drugs should be included on NABP's "National Specified List of Susceptible Products" because of counterfeiting or susceptibility to counterfeiting as well as to evaluate and revise NABP's "National Specified List of Susceptible Products" as needed. In this capacity, the Coalition will serve as an advisory resource to the NABP Executive Committee, which will review the Coalition's final recommendations.

On February 20, 2004, NABP released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy,* were provided to assist state boards of pharmacy in maintaining the integrity of the United States medication distribution system through the regulation of wholesale distributors. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the

(— more —)

updated Model Rules, are designated as the "National Specified List of Susceptible Products." NABP hopes that states will adopt NABP's "National Specified List of Susceptible Products" as wholesale distributor regulations are revised.

The NDAC, appointed by the NABP Executive Committee, consists of representation from the state boards of pharmacy, American Medical Association, American Society of Health-System Pharmacists, Healthcare Distribution Management Association, National Association of Chain Drug Stores, Pharmaceutical Distributors Association, Pharmaceutical Research and Manufacturers of America, and United States Pharmacopeia. Ex-officio members, who serve as resources for the Coalition, include Food and Drug Administration, an independent counterfeit expert, and representation from the wholesale distribution and pharmaceutical manufacturing industries.

Following presentations on the NABP Model Rules for the Licensure of Wholesale Distributors (Charisse Johnson, NABP), Florida Prescription Drug Protection Act (Jerry Hill, bureau chief of Pharmaceutical Services, Florida Department of Health), and an Overview of Counterfeiting (Lewis Kontnik, Lew Kontnik Associates), the Coalition discussed the development of criteria for determining prescription drug products to be included on the NABP "National Specified List of Susceptible Products." Pfizer US Pharmaceuticals representative Peggy Staver discussed Pfizer's efforts to address counterfeit drugs via enhanced business practices, regulatory and legislative action, industry initiatives, and various technologic solutions.

After evaluating a number of resources and recommendations including Florida's Specified Drug List criteria the Coalition developed criteria to serve as a guideline for determining which prescription drugs should be listed. Suggestions recommended by the Coalition include:

- The addition of Viagra® to the NABP "National Specified List of Susceptible Products";
- The exclusion of veterinary prescription drugs and devices from the scope of the Coalition and NABP's "National Specified List of Susceptible Products"; and

(— more —)

- The inclusion of prescription drug products that are noted to be in limited supply due to a national shortage for significant periods of time.

The recommendations of the Coalition have been forwarded to the NABP Executive Committee for review and final approval. The Executive Committee will release its final decisions regarding the criteria and the "National Specified List of Susceptible Products" in the upcoming weeks.

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

-30-

FOR IMMEDIATE RELEASE
P04-103
November 15, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA ANNOUNCES NEW INITIATIVE TO PROTECT THE U.S. DRUG SUPPLY THROUGH THE USE OF RADIOFREQUENCY IDENTIFICATION TECHNOLOGY

The Food and Drug Administration (FDA) today stepped up its efforts to improve the safety and security of the nation's drug supply through the use of radio frequency identification (RFID) technology. FDA launched this effort by publishing a Compliance Policy Guide (CPG) for implementing RFID feasibility studies and pilot programs that are designed to enhance the safety and security of the drug supply. This action continues FDA's commitment to promote the use of RFID by the U.S. drug supply chain by 2007.

In a related action, the FDA announced that it is creating an internal "RFID Workgroup" whose charge is to monitor adoption of RFID in the pharmaceutical supply chain, pro-actively identify regulatory issues raised by the use of this new technology, and develop straightforward processes for handling those issues. FDA believes that the workgroup will improve communication with members of the supply chain on RFID related issues and should facilitate both the performance of pilot studies and the collection of data needed to formulate policy.

RFID is a state-of-the-art technology that uses electronic tags on product packaging to allow manufacturers and distributors to more precisely keep track of drug products as they move through the supply chain. It is similar to the technology used for tollbooth and fuel purchasing passes.

The FDA also applauded the initiatives announced by the pharmaceutical companies Pfizer, GlaxoSmithKline, and Purdue Pharma. Pfizer announced its plans to place RFID tags on all bottles of Viagra intended for sale in the United States as expeditiously as possible in 2005. GlaxoSmithKline announced that it intends to begin using RFID tags in the next 12 to 18 months on at least one product deemed susceptible to counterfeiting.

Purdue Pharma announced that it is placing RFID tags on bottles of OxyContin to make it easier to authenticate as well as track and trace this pain medication. Based on the availability of sufficient RFID tags, Purdue also plans to tag bottles of Palladone, a newly approved product to treat persistent, moderate to severe pain. OxyContin, which is a controlled substance has been subject to abuse as well as theft and diversion. FDA also acknowledged the leadership of Johnson & Johnson in establishing standards for RFID technology and participating in RFID pilot studies. Johnson & Johnson will continue to collaborate with industry partners to develop standards for ePedigree.

"Radio Frequency Identification technology is an innovative response to the challenge of counterfeit drugs," said Health and Human Secretary Tommy G. Thompson. "It is our goal to insure that the drugs available in the United States are among the safest in the world. However, we still must continue to be on guard against those who would exploit patients by selling counterfeit drugs."

"Today's actions were designed with one goal in mind: to increase the safety of medications consumers receive by creating the capacity to track a drug from the manufacturer all the way to the pharmacy," said Dr. Lester M. Crawford, Acting FDA Commissioner. "This use of innovative technologies to protect the public health is exactly the type of bold leadership we expect to see more of in this arena. We hope that other manufacturers, wholesalers, and retailers will follow this example by also becoming early adopters of RFID."

RFID technology makes it easier to ensure that drugs are authentic, and it also creates an electronic pedigree, or record of the chain of custody, from the point of manufacture to the point of dispensing.

Electronic pedigrees will improve patient safety and protect the public health by allowing wholesalers and retailers to rapidly identify, quarantine, and report suspected counterfeit drugs and conduct efficient, targeted recalls.

FDA considers electronic pedigrees to be a type of "electronic safety net" which utilizes technology that allows illicit drug transactions to be rapidly identified and, potentially, transmitted to the FDA thereby improving FDA's ability to conduct investigations of suspected counterfeiting or diversion of prescription drugs.

"We intend to work with industry and standard setting organizations to explore the feasibility of allowing FDA to access relevant electronic pedigree information, as that information would greatly improve our ability to minimize exposure of consumers to counterfeit drugs by facilitating rapid criminal investigations of illicit transactions," Dr. Crawford added.

Today's actions are key steps in implementing a major recommendation of FDA's report, issued February 18, 2004, titled "Combating Counterfeit Drugs." The report recommended that RFID technology be in widespread use throughout the pharmaceutical industry by 2007.

Although the pharmaceutical industry has taken several other important steps to test RFID technology, FDA believes that the actions announced today will provide a stimulus for even further activity in the next year. For example, FDA expects that RFID standard-setting activities and applied research in such areas as tag numbering, optimal frequency use, and database management will be accelerated.

FDA believes the CPG will clear the way for more pilot programs that involve RFID tagging of all packages of certain products, especially those that are highly likely to be counterfeited. FDA hopes that more firms will take this opportunity to use RFID technology to gain experience with transferring, storing, and securing the data that RFID provides.

The scope of the CPG is based on information FDA obtained concerning ongoing and planned RFID feasibility studies examining use of this technology for various business purposes including inventory control, and tracking and tracing of drugs.

To encourage these studies, the CPG announces FDA's intention to exercise enforcement discretion if studies falling within the parameters of the CPG trigger certain regulatory requirements.

Because of the importance of beginning RFID feasibility studies as quickly as possible, this CPG will go into effect immediately upon publication in the Federal Register. FDA will consider all public comments in any revision of the CPG.

Those interested in commenting on the CPG may submit their comments to: www.fda.gov/dockets/ecomments

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2004 NOV 18 PM 12: 38

News Release

FOR IMMEDIATE RELEASE
November 15, 2004

For more information contact:
Reneeta C. "Rene" Renganathan, Editorial Manager
847/318-7998; custserv@nabp.net

Electronic Safety Net – NABP Exploring the Creation of a Clearinghouse for Pedigree Data

The National Association of Boards of Pharmacy® (NABP®) is pleased to announce that it is taking further steps to protect the public health and maintain the integrity of the United States drug supply. Earlier this year, NABP released its Model Rules for the Licensure of Wholesale Distributors. These Model Rules contain provisions requiring the documentation, recording, and maintenance of a pedigree (Chain of Custody Record) for each package of drugs. The Model Rules anticipate that these records will be created and stored electronically. We note that the states of Florida and California have passed laws that either require or allow electronic pedigree records.

NABP supports the Food and Drug Administration's (FDA) policy that the use of radio frequency identification (RFID) technology is the best means to improve the security of the nation's drug supply. Electronic pedigrees will track and trace a drug product through the distribution system, from the time it leaves a drug manufacturer until it is dispensed to a patient by a pharmacist. We also support the need for access to relevant pedigree information in order for regulators to conduct investigations.

To facilitate the collection and maintenance of electronic pedigree information, NABP is announcing that it will establish a Task Force of state regulators, manufacturers, wholesalers,

(— more —)

retailers, government regulators, and information technology experts to explore the feasibility of creating and maintaining a clearinghouse for relevant information to establish an electronic pedigree. The Task Force will establish ways to facilitate the exchange of information in an effort to maintain the integrity and safety of the US drug distribution system. Additionally, the Task Force will work with EPC Global to create the necessary standards for the development of e-pedigree software. The NABP Task Force may also explore ways to establish an accreditation program for e-pedigree software platforms to assure connectivity of systems throughout the US that need to communicate to each other.

We would like to emphasize that NABP will act as an honest broker to facilitate the creation of policies and business rules for the exchange of information among trading partners. We envision that trading partners will make their own arrangements for exchange of information and use the advantages of the NABP Clearinghouse to improve these exchanges.

In February of this year, NABP released its revised Model Rules for the Licensure of Wholesale Distributors, which is part of the Association's *Model State Pharmacy Act and Model Rules*. The Model Rules were developed through a broad consensus process involving state and federal regulators, wholesale drug industry experts, national pharmacy organizations, and consumer groups. The Model Rules focus on critical areas of the licensure and regulation of wholesale distributors, identified by FDA and the states, that are essential to combating counterfeit drugs. Included in the Model Rules are specific provisions concerning the documentation, recording, and maintenance of a pedigree for drugs distributed through the wholesale distribution system.

Therefore, today we are announcing a major initiative intended to realize these goals as e-pedigree information becomes more widely available over the next few years.

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

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2004 NOV 15 PM 12: 18

News Release

FOR IMMEDIATE RELEASE
November 10, 2004

For more information contact:
Reneeta C. "Rene" Renganathan, Editorial Manager
847/318-7998; custserv@nabp.net

NABP Educates Pharmaceutical Industry on New VAWD Program

The National Association of Boards of Pharmacy® (NABP®), in partnership with BuzzeoPDMA, introduced the Association's Verified-Accredited Wholesale Distributors™ (VAWD™) program to pharmaceutical manufacturers during a seminar held November 4, 2004, in Iselin, NJ. Representatives from security, compliance, quality assurance, customer service, trade relations, government affairs, and legal counsel departments of pharmaceutical manufacturers were present as was Food and Drug Administration (FDA) and the manufacturers' trade association, Pharmaceutical Research and Manufacturers of America.

After the seminar, many of the participants indicated that they would recommend that their company require VAWD accreditation for its wholesale distributors. The representatives in attendance learned about the NABP Model Rules for the Licensure of Wholesale Distributors; the VAWD accreditation program including a review of the facility inspection process; state regulations pertaining to wholesale distributors; and a review of US v Rx Bazaar, a recent federal case involving wholesale distributors that were convicted of violations of the Prescription Drug Marketing Act. An interactive question-and-answer session provided for a welcome exchange of information between participants.

(— more —)

NABP began developing VAWD after FDA requested that NABP update its Model Rules for the Licensure of Wholesale Distributors, which are part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. Members of NABP's resulting Task Force on Counterfeit Drugs and Wholesale Distributors, which met in October 2003, revised the Model Rules and proposed the creation of an accreditation program and clearinghouse for wholesale distributors – a plan that was immediately supported by FDA – to further combat counterfeit drugs.

To help protect the public from the threat of counterfeit drugs infiltrating the United States' drug supply, the VAWD program will accredit wholesale distributors whose policies and operations meet the VAWD criteria and comply with state and federal laws. VAWD inspections will be conducted by trained BuzzeoPDMA inspectors. NABP is finalizing the VAWD criteria and will conduct several pilot inspections in November 2004. The target launch date for the VAWD program is December 2004. After its launch, NABP plans to hold additional educational programs for other interested stakeholders.

Founded more than a decade ago, BuzzeoPDMA, Inc, is a recognized industry leader in assisting companies to comply with the policies and regulations of the Food and Drug Administration (FDA), Prescription Drug Marketing Act (PDMA), Drug Enforcement Administration (DEA), Controlled Substance Act (CSA), as well as state health care regulations and licensing.

The National Association of Boards of Pharmacy (NABP) was founded in 1904 and represents all of the pharmacy regulatory and licensing jurisdictions in the United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, eight provinces of Canada, two Australian States, New Zealand, and South Africa. Its purpose is to serve as the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

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2004 JUL 28 AM 10: 53

July 27, 2004

California Board of Pharmacy
Attn. Ms. Patricia Harris
Executive Officer
400 R Street, Suite 4070
Sacramento, CA 95814

Dear Ms. Harris:

T3Ci is an applications software company located in Mountain View, California. Our enterprise software provides drug counterfeit and diversion detection as well as electronic drug pedigree for the pharmaceutical market. T3Ci's areas of expertise are RFID and enterprise applications.

During a recent pharmaceutical conference in Washington DC, we learned that California was considering a "pedigree law" modeled on the Florida pedigree law. Given our coming commercial solution and our leadership position in this area, we are requesting a meeting with the California Board of Pharmacy to present our technology solution to the counterfeit, diversion and electronic pedigree issues.

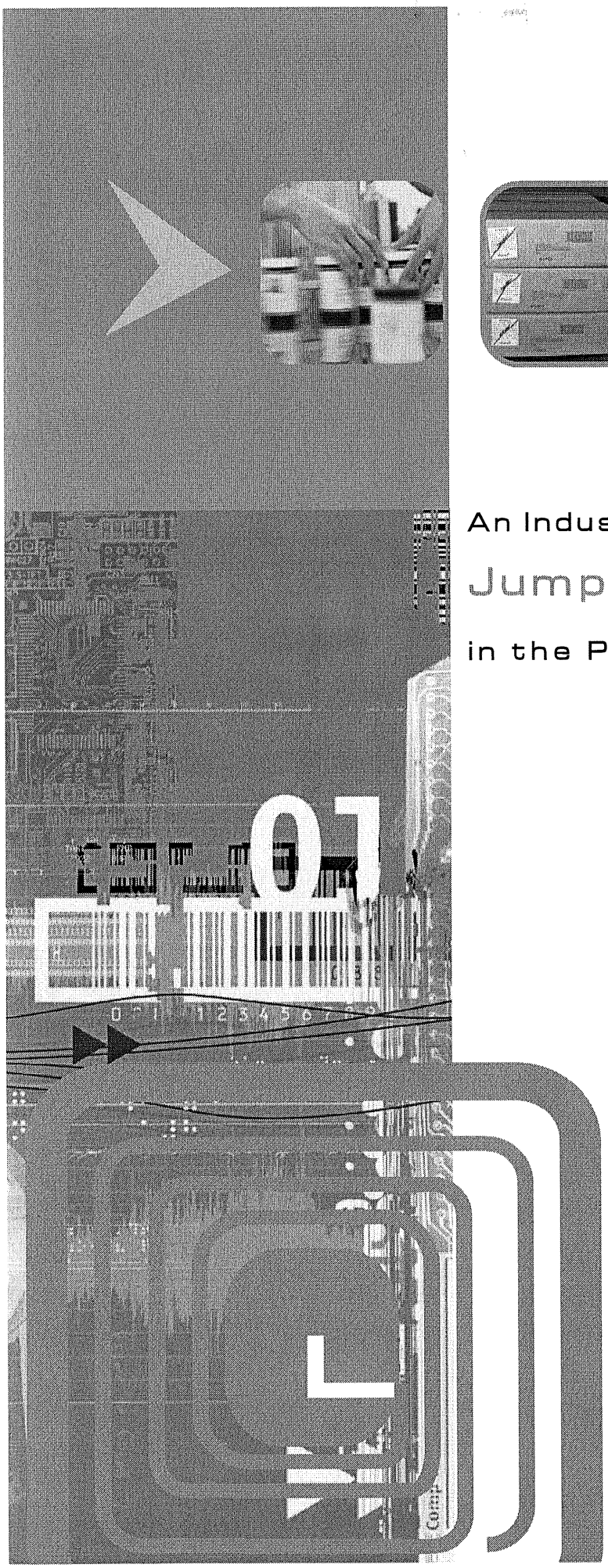
T3Ci was founded in October 2003. We currently have 12 employees in California and we hope to grow to become a $100-250 Million company with 500+ California employees over the coming 5-7 years. Our first customer is Procter & Gamble seeking a solution to the so called Wal-Mart RFID mandate. We are currently in discussions with 14 of the 20 largest pharmaceutical manufacturers and the largest pharmaceutical distributors. Three of these major drug companies have agreed to pilot our system for detecting counterfeit drugs and diversion starting in September this year. We believe these will be the "first ever" pharmaceutical pilots of a counterfeit, diversion and electronic pedigree system.

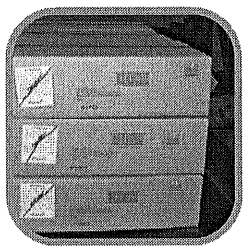
Our goal with the meeting would be to inform the California Board of Pharmacy of the technology that will become available for counterfeit, diversion and electronic pedigree this fall. We have spoken to some 25 large pharmaceutical suppliers, distributors and pharmacies. They have all indicated a strong interest in RFID technology and associated systems. It is their view that the current "paper pedigree law" in Florida is expensive and cumbersome. We wish to demonstrate to you that our type of technology solution has significant advantages over a paper-based system.

We will make ourselves available at a time and date of your convenience between August 12 and September 10. Our presentation and a Q&A session would take between 60 and 90 minutes. We look forward to meeting you.

Sincerely,

Peter Rieman
Executive Vice President
Direct: 1-650-969-5203, email: prieman@T3Ci.com





An Industry Working Group Report on

Jump-Starting RFID/EPC

in the Pharmaceutical Supply Chain

September 2004
Executive Summary

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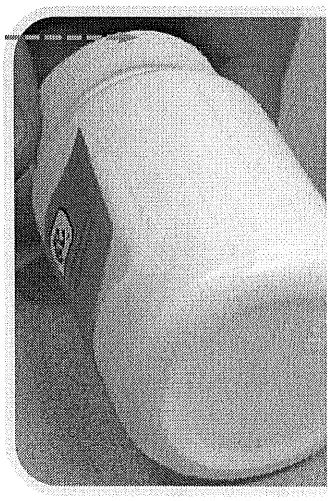
RFID could be used to create a safe and secure supply chain, streamline reverse logistics, and increase the accuracy and efficiency of distribution and pharmacy operations.



1. Management Overview

A group of companies across the pharmaceutical supply chain came together in 2003 to explore the use of radio frequency identification (RFID) and Electronic Product Code (EPC) technology[1]—a pioneering effort in terms of its practical scope and industry breadth. This working group included the pharmaceutical manufacturers Abbott Laboratories, Barr Laboratories, Johnson & Johnson, Pfizer, and Procter & Gamble; pharmaceutical wholesalers Cardinal Health and McKesson Corp.; retail pharmacies CVS Pharmacy and Rite Aid; and industry trade associations including the Healthcare Distribution Management Association (HDMA) and National Association of Chain Drug Stores (NACDS).[2] Accenture served as program manager for the group.

Together, the participants wanted to assess the business value of emerging RFID/EPC technologies, standards, and processes, and to work toward establishing an industry operating model that addressed pharmaceutical industry business issues. The technology's use had gathered momentum and uptake in other industries. The project team sought practical experience with RFID/EPC to explore its potential within the pharmaceutical space.

From October 2003 through September 2004, the project team designed, tested, implemented, and verified a complete supply chain solution. The principal objectives were to assess whether RFID/EPC could be used to help create a safe and secure supply chain, streamline reverse logistics, and increase the accuracy and efficiency of distribution and pharmacy operations. A scenario-based approach was used to validate the solution, new processes, and benefits against the related business issues.

In an eight-week test, preceded by an eight-month design period, the 9 participant companies selected 10 products for the project, working through 16 business scenarios in 15 project locations. Nearly 13,500 units of real product were tagged, shipped, received, handled, tracked, and traced through the project's system, providing the project with first-hand experience in working with tags and EPC reader technologies.

This initiative was a "proof of concept" of RFID/EPC technology in the pharmaceutical distribution channel, and seen as potentially the first step towards broader adoption of RFID/EPC across the value chain. This report summarizes the findings of the organizations involved in the project, collectively known as "Release 1, Group 1." Five additional companies known as "Release 1, Group 2" later joined the initiative, and will complete their work in late 2004. The findings from the Release 1, Group 2 activities will be published as an addendum to this report.

[1]See Section 11 for Glossary.

[2]FDA and EPCglobal representatives also attended key meetings at the Steering Committee level.

Industry Context — The Growth of RFID/EPC

For some time, the consumer products, retail, and transportation industries had taken the lead in researching and applying RFID technologies for widespread use. A comprehensive study of RFID's potential to enhance pharmaceutical product manufacturing, distribution, and retail operations was a logical extension of those efforts. Some specific regulatory mandates unveiled in 2003 created a sense of urgency for exploring RFID in order for companies to comply. Two notable mandates were:

- The Florida Pharmaceutical "Pedigree Papers" requirements mandate that histories be maintained that identify previous sales and product information dating back to the drug manufacturer.
- Under Georgia's "Credit for Returned Expired Drugs" regulations, all wholesale drug distributors must make adequate provisions for the return of expired prescription drugs for up to six months after the labeled expiration date for prompt credit or replacement (to be received within 60 days). These regulations place the financial burden of expired product entirely on the wholesale drug distributors.

Industry and military initiatives have also propelled the reality of widespread RFID usage. Wal-Mart's RFID mandate has been widely credited with a general acceleration of the technology throughout the United States. By 2005, the retailer's top 100 suppliers must have RFID identification tags on shipping crates and pallets. In addition, Wal-Mart has also mandated that its Class 2 controlled pharmaceutical products suppliers use RFID tags bearing EPCs at the unit level by June 2004. The U.S. Department of Defense for its part will require all of its suppliers to put RFID tags on their shipping pallets and cases being delivered to the department's depots by January 2005.

Building Safe and Secure Supply Chains

As noted in a recent NACDS report, the World Health Organization estimates that 5-8 percent of drugs worldwide are counterfeit—meaning such drugs could represent from $7 billion to $26 billion of the $327 billion global market. The FDA's current anti-counterfeiting taskforce is investigating methods to secure the pharmaceutical supply chain by examining new technologies that utilize RFID. It has stated that it should be feasible to use RFID to track all drugs at the unit level in 2007. Other healthcare organizations are either advocating RFID or are predicting its inevitability.

> "RFID tagging of products by manufacturers, wholesalers, and retailers appears to be the most promising approach to reliable product tracking and tracing."
>
> "Combating Counterfeit Drugs" Report, FDA, February 18, 2004

Key Findings

At a fundamental level, the project achieved its objectives of demonstrating RFID/EPC's potential to address industry needs as described below. In assessing the outcomes, however, it is critical to once again note that this project was a proof of concept. It was conducted in a very controlled environment with a limited scope. As would be expected with a project of this nature, it included many manual processes that ultimately will require automation to achieve the desired benefits from this technology. There are many issues yet to be addressed and much more work remains before this technology and the resulting business applications are scaleable and ready for industry-wide adoption.

- Satisfying Increased Regulatory Requirements — The system effectively tracked selected pharmaceutical products from the manufacturer's distribution facilities through the supply chain to the point of dispensing, thereby helping to show their location on the distribution channel and electronically capturing all necessary "pedigree" information. However, the technology employed must improve significantly and the intra-industry information systems must be built before this requirement can be satisfied.

- Satisfying Increased Trade Channel Requirements – The project demonstrated the ability to manually tag pharmaceutical units and cases for selected products to enable track-and-trace capabilities in a manner similar to those required in emerging retailer mandates.

- Increasing Product Security and Consumer Safety – The system provided individual unit serialization that has the ability to enable track-and-trace functionality that could help prevent counterfeit product from entering the supply chain.

- Increasing Efficiency of Returns and Recalls – Since detailed information such as lot number, expiration date, and transaction date/time/location is available for each individual EPC, the project showed that the effort to identify product location when processing recalls and returns could potentially become less complicated and labor intensive.

- Increasing Labor Productivity – When conducting activities that currently require bar-code scanning of each individual item (such as shipping, receiving, or cycle counting), the project demonstrated the potential of RFID/EPC to increase labor productivity by allowing multiple items to be scanned at one time. Furthermore, since shipping and receiving would be more accurate, the administrative effort to follow up on shipment/receipt discrepancies may be reduced. It should be noted, however, that tag readability and reliability must improve significantly before this process is scaleable. There may be an incremental increase in the labor effort required as a result of changing systems and processes during the initial adoption of RFID/EPC.

- Increasing Order Accuracy – RFID/EPC technologies can provide validation of shipment and arrival at different points in the supply chain, thereby reducing over- or short-shipments of product, and increasing customer satisfaction.

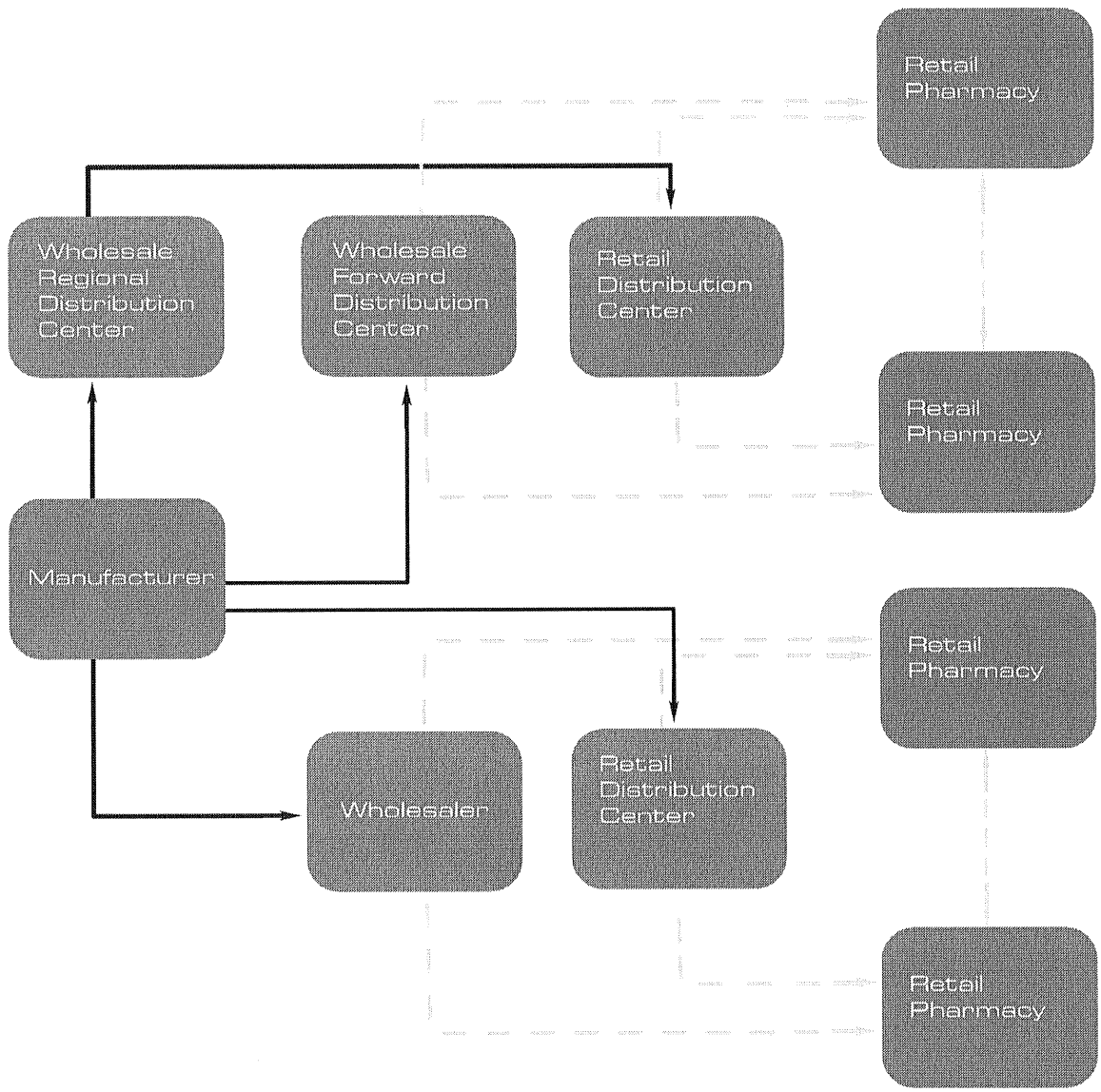
The final sections of this executive summary further discuss this project's findings. They also outline the considerable challenges ahead that will require a concerted effort by the industry and regulatory bodies alike to work through.

2. Project Approach

The project focused on assessing the ability of RFID and EPC applications to improve specific work processes—what the project team called business scenarios. These scenarios addressed four key categories: EPC Management, Safe and Secure Supply Chain, Streamlined Reverse Logistics, and Accurate Operational Efficiencies. (The sidebar at right shows a complete list of the16 scenarios.) Ten products and 15 distribution, wholesale, and retail locations were selected for the project.

In order to quickly and cost-effectively plan and execute this project and avoid any business interruption, a separate, standalone parallel process and system were created with no modifications to packaging or production processes and no integration with existing information technology (IT) systems. There was no attempt to validate the system according to FDA electronic records regulations.

Figure 1. Defined Product Flow Path



Project Business Scenarios

EPC Management

- Commission – (1) Manual update with product description, lot number, and expiration date (i.e., pedigree product information); (2) manual initialization of link between unit EPC and case EPC
- Decommission 1 – Automatic decommission of a unit EPC or case EPC after a designated time period of inactivity in "suspense" status
- Decommission 2 – Manual decommission of case or unit EPC tags

Safe and Secure Supply Chain

- Regulatory Compliance – Tracking product through the supply chain to create a pedigree
- Counterfeit Compliance 1 – Identification of counterfeit product based on Product Authenticity Reporting
- Counterfeit Compliance 2 – Automatic alert of counterfeit product based on invalid case or unit EPC tags
- Counterfeit Compliance 3 – Automatic alert of counterfeit product following the reuse of EPC tags after a period of inactivity or no reads
- Logistical Error – Identification of a supply chain logistical error based on valid case or unit EPC tags
- Product Theft 1 – Identification of missing or stolen product based on Shipping and Receiving Summary Reporting
- Product Theft 2 – Automatic alert of missing case or unit EPC resulting from theft occurrence on inbound shipment

Streamlined Reverse Logistics

- Product Expiration Management 1 – Identification of short-dated, recalled, or expired product via Inventory Management Reporting
- Product Expiration Management 2 – Identification of short-dated/expired/recalled product on receipt
- Expired/Recalled Product Return – Short-dated, expired, or recalled product return managed through return of EPC tags
- Product Recall Management – Manufacturers' ability to alert supply chain partners who have received product being recalled, and summarize the distribution history of the recalled product via Product History Reporting

Accurate Operational Efficiencies

- Shipping Operations – Outbound order shipping accuracy verification
- Receiving Operations – Inbound order receiving accuracy verification

3. Tag Design

The original design called for a plain tag—chip, antenna, and plain inlay with an EPC number printed on the front label—which would support business processes in lieu of bar codes and enable unit-level serialization. The tag needed to be small enough to be placed on pharmaceutical packaging without covering any existing labeling, it needed to be a UHF tag which is conducive to processes focused on shipping and receiving, and it needed to comply with EPCglobal Class 0 standards. The 1.2" x 1.4" tags selected from Matrics met these requirements. They came with factory-programmed EPC numbers with a known set of test numbers provided by Matrics to serve as a control (manufacturer-specific "real" EPC numbers were not obtained from EPCglobal).

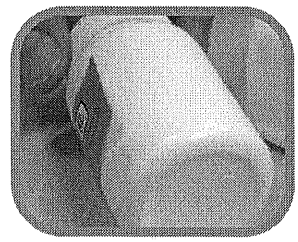
As the project team worked through the design with the participants' packaging, regulatory, and quality assurance experts—along with EPCglobal and the FDA—a number of issues arose that provoked the need for changes and additional features:

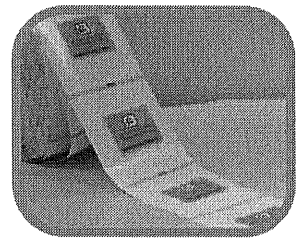
- Removable Tags and Adhesives –
  The project involved tagging trade packages containing real product. Pharmacists typically remove the product from these packages and dispense the medication to patients in vials.[3] Even though it was not expected such products would ever be dispensed in the original trade package, to avoid consumer concerns the group worked toward making tags removable to reduce the chances that tagged product would end up in a consumer's hands. At the same

[3]There was one exception: one product was in a blister pack and designed to be consumer dispensable.

time, the team needed to find an adhesive that would allow the tags to stay on during handling through the supply chain and avoid potential negative interactions with packaging or drug composition.

A group of specialists in labeling and quality assurance designed an innovative two-ply "coupon-style" tag. A clear base layer remains on the product for its lifetime, but the actual RFID tag, while adhering during the course of normal handling, can still be peeled off. With the two-ply "peel label" solution, manufacturers were able to use an adhesive that had been pre-approved for the clear base. Matrics (who made the tags) and CCL (who converted the tags into the two-ply labels) were able to use an adhesive that was appropriate for the RFID tag and that would have sufficient tack to attach to the base film.





- Design and Placement –
  Though tags needed to be small, they also had to be highly visible. Manufacturers wanted to ensure the tags were removed from their products prior to dispensing to consumers. Retailers were similarly keen to avoid consumer concerns. The tag label was designed using a bright orange color to ensure visibility for pharmacists.
- Tag Label Design –
  The project team went through several iterations on the information printed on the tag label. This was as a result of the group's desire to align with the public policy guidelines established by EPCglobal and the fact that the specific approach for implementing the guidelines was still evolving. (Many of the guidelines had originally been developed within the context of consumer packaged goods, which were not appropriate for pharmaceutical products.) Dialogue between the project team, EPCglobal, and the FDA resulted in the final tag label design that included wording ("Inventory control tag. Tag may be removed"), a human-readable EPC number, and the EPCglobal logo.

After the project was completed, the tags were removed from the products, and the products were put back into inventory for normal distribution.

Figure 2. Physical Architecture Overview

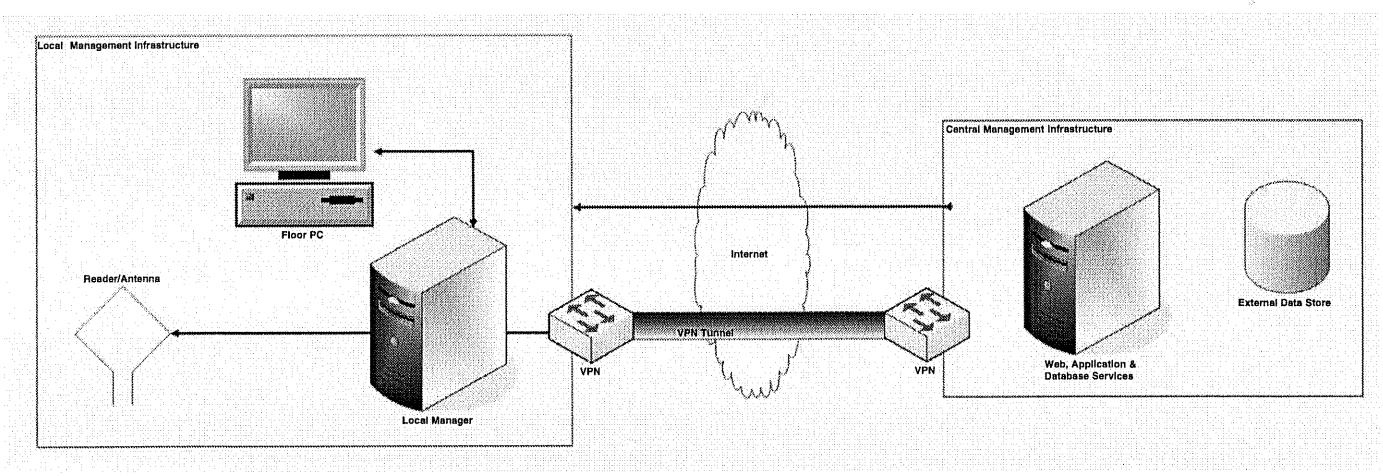
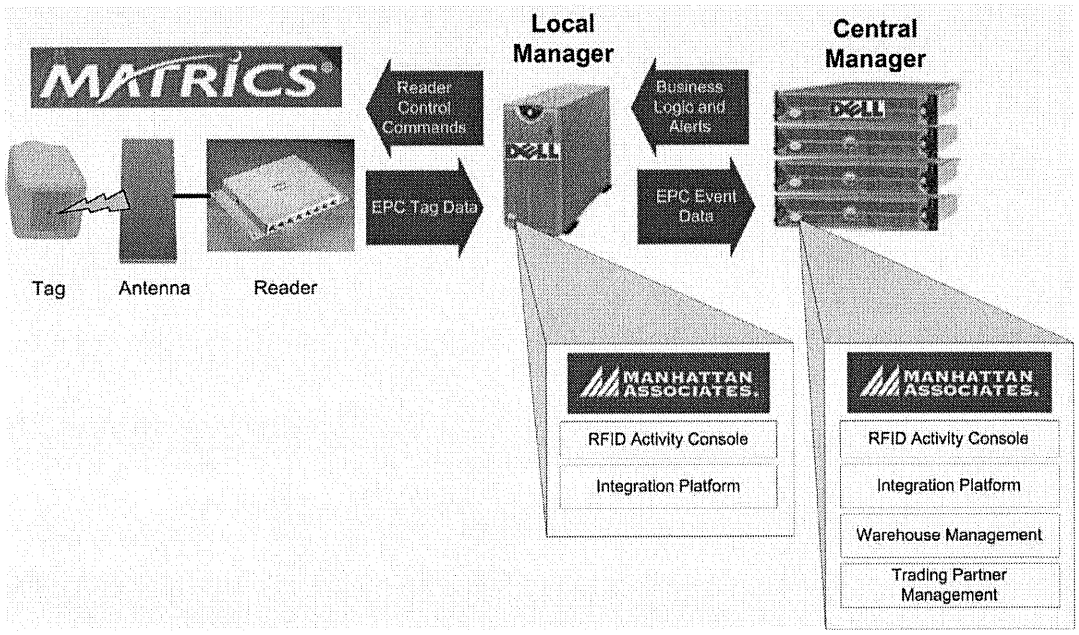


Figure 3. Conceptual Vendor/Product Fit



4. Technical Design

The goal of the project was to determine if RFID/EPC technology could enable and improve areas where key business issues exist. It did not set out to prove that the project's technical solution was an exact right fit for each company's specific situation. The technical infrastructure spanned 10 organizations that collected, analyzed, and acted on data generated by EPC movements. The architecture utilized a distributed network of readers and servers composed of four primary components:

- The RFID reader and antenna provided the input for the entire system. This component collected tag data from products and cases. Readers and antennas were located at each node in the supply chain.
- The local manager temporarily stored reader tag data, acted as the reader controller, and formatted EPC data so that it could be sent to the central manager. Each company had a local manager that could control many readers.
- The central manager was where the bulk of the functional logic resided and where tag data was permanently stored. The central manager was hosted in an Accenture data center, which included the capability to centrally monitor the local managers.
- A PC with a Web browser was used to access the application on the local and central managers, and control the readers.

The team advocated a buy (versus build) approach, and sought components aligned with emerging EPCglobal standards and which would allow flexibility for expansion during future releases. The architecture also needed to provide a secure channel for data collection, distribution, and storage.

Manhattan Associates' solution was selected since it provided the required functional capabilities along with a bundled RFID middleware capability. As discussed earlier, Matrics tags were selected. Consequently, this factor drove the reader selection decision. It should be noted that vendors selected for this implementation were selected based on the specific functional requirements outlined by the project team. No particular preference or vendor qualification beyond the scope of this project is indicated or implied.

The figure above shows the primary components in the project environment and where they fit into the infrastructure.

5. Working with Key Governing Bodies

Given that RFID/EPC is very new to the pharmaceutical space, it was important to understand the direction and policies of key public policymakers such as the FDA and EPCglobal to make the project's activities effective.

FDA

From the project's outset, participants sought guidance by the FDA on certain regulatory issues such as labeling, electronic records, and the effect of the electromagnetic energy associated with RFID on product quality. Regarding labeling and electronic records, the FDA decided to exercise "enforcement discretion" as applied to this specific project.

However, the FDA did request that manufacturers share the results of any product quality testing they conducted that investigated whether there were any effects of electromagnetic energy on drug efficacy, potency, and strength.[4] The pharmaceutical manufacturers developed and executed a testing protocol for the products and technology involved in this initiative, which was shared with the pharmaceutical industry. Once the analysis was complete, the results were shared with the FDA. As initially expected, based on the measurements taken, no adverse effects were found on the products that were tested, and the team moved forward using live product during this project. Testing proved a valuable exercise, since it provided factual data on the effects of electromagnetic energy on product quality.

EPCglobal

In addition to setting industry-driven standards for EPC, EPCglobal is also providing guidelines on the visual appearance of tags and communications for consumer awareness. EPC standards have evolved based on requirements driven by industries such as consumer products and retail. To complete this project, the team coordinated with EPCglobal to adjust the tag's visual and verbal characteristics, so that they were appropriate for pharmaceutical products. As the industry moves forward with RFID, EPCglobal's focus and standards will expand and mature to help make RFID projects in the pharmaceutical space more effective.

6. Special Project Decisions

Inferences Regarding Case Integrity

Due to the inherent physics limitations of UHF radio waves and their inability to penetrate certain materials (e.g., liquids and metals), initial tests indicated that not all units within a case could be consistently read by a reader. An important component in the project was the decision to make inferences about case integrity and authenticity. That is, even if only a portion of the individual units within a case were read, all the units could be inferred to be within the case by their association with the case tag. Depending on future business requirements and processes, inference logic may be unacceptable. Alternate approaches involving customized packaging/reader antennas, the use of high-frequency tags, and adjustments to processes—as well as matured technical solutions—may need to be leveraged to make unit-level tags trackable nearly 100% of the time.

Limitations to Data Visibility

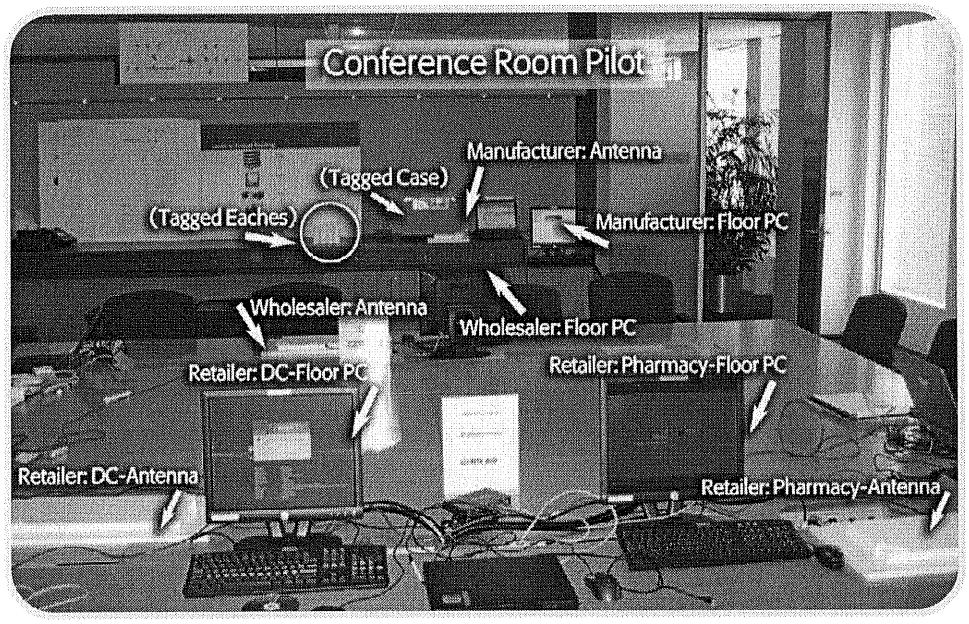
All participants in the project have major concerns with the potential to allow competitors to gain visibility into confidential company data such as inventory levels, shipping/receiving schedules, and prices. The project reinforced the need to establish sound, principle-based data-sharing work processes. For purposes of this proof of concept, the intent was to work with each organization to create a simple solution that demonstrated the project's ability to restrict confidential data. The final data visibility scheme was developed using three guiding principles:

1. Visibility was favored over restricted access. It was understood that in potential future releases, data access and visibility would likely become more restrictive.

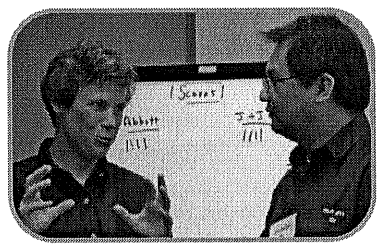
2. Authorization rules were kept simple. The processing logic behind data access and visibility was such that there was no confusion among users as to why an organization's visibility was enabled or restricted.

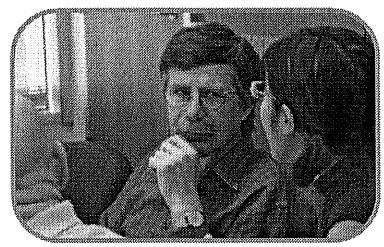
3. The solution demonstrated the ability to keep sensitive data confidential. The project exhibited the ability to restrict access to certain data based on the users' identity and their possession of the appropriate tag information.

[4] Only solid dosage form products were subjected to this testing and were used in the project.



The team conducted a conference room pilot to simulate a real-life supply chain—from manufacturer to wholesaler to retailer.





7. Verifying the Solution

Working through the various business scenarios the team had established, and going live with the selected RFID technology to execute them, comprised a stage of work called Verification. Prior to Verification, the team conducted a conference room pilot from April through May 2004, to simulate a real-life supply chain from manufacturer to wholesaler to retailer. This involved testing the system, training users, and creating a demo of the new environment to show interested parties outside the project.

Additional final preparations included:

- Supply Chain Analysis – Documenting how and when product would move through the supply chain. To the extent possible, the team wanted to test each scenario for each product at each location. Doing so required the team to conduct a supply chain analysis that laid out step-by-step volume flows describing what, how, and when the nine participant companies' locations would be shipping to each other.
- Exception Processing – In order to make the scenarios as realistic as possible (and to demonstrate how RFID might enable the handling of them), the team planned into Verification a number of exception simulations and forced these exceptions to occur. The five "exception groups" were theft, counterfeit/diverted, logistical error, expired, and recall.

To the extent possible, the team wanted to test each scenario for each product at each location.

8. Verification Results

The project was intended to assess the feasibility of leveraging RFID/EPC technology in an end-to-end supply chain context. The Verification stage of the project showed positive movement in that direction in two ways.

First, the Verification stage demonstrated that the RFID/EPC tags and readers were largely successful in and of themselves as mechanisms for tracking and tracing product.

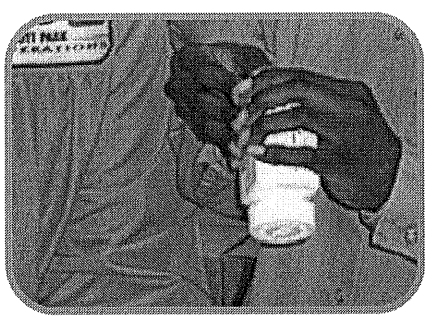
The project team set out to track 10 "real" products (not just empty bottles) through 15 locations. The manufacturers were required to verify the readability of the tags before applying them to the products. Then they were able to commission individual EPC numbers for specific product units and cases. The common hardware components selected for the project were quite reliable. Solid-dose packaging (bottles) as well as blister packaging could be read and tracked. In this limited proof of concept, the system was able to dramatically increase the visibility of the project's selected products as they moved through the supply chain.

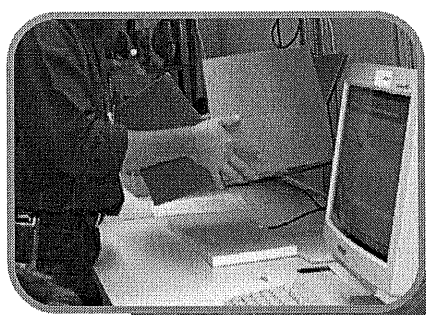
The application tracked tag readability statistics during Verification. The project team was able to read 98.6% of the case tags. In addition, when units were inside a case, the team was able to read 96.8% of the unit tags. Once Verification was complete, 99.9% of returned tags were functioning.

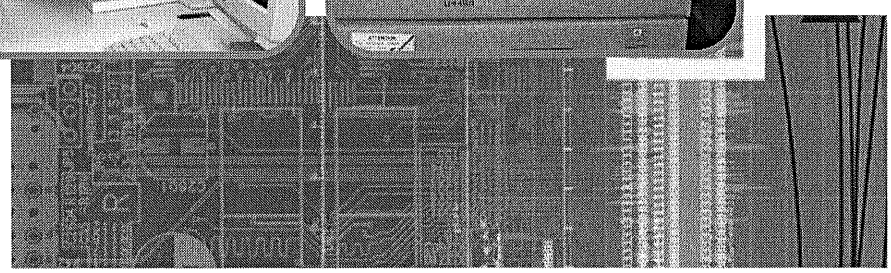
As the project progressed, and as personnel at various locations became more comfortable with the technology and how it worked, read rates improved. In addition, personnel found that success in read rates was often related to 1) time and diligence spent trying to read (e.g., holding the units/cases to reorient the tag in relation to the antenna), and 2) the number of antennas implemented.

Second, the Verification stage demonstrated the ability of this project to use RFID/EPC technology to execute 16 pharmaceutical industry scenarios at all 15 locations for all 10 products—a major undertaking.

The project's system and processes were able to simulate in a live environment a range of conditions in the supply chain. Nearly 30 participant personnel gained experience in working with the 16 scenarios, which allowed them to see how RFID/EPC can surface information about "suspicious" or irregular shipments such as potentially counterfeit or stolen products. By having continual real-time access to pedigree information on specific units, they were provided with much-improved visibility into where product was at all times and could query the system to track down missing product.







9. Key Conclusions

The project helped establish key facets of an industry operating model.

By creating a proof of concept that engaged major sectors of the supply chain, participants gained insight into what processes and supporting systems need to be in place to construct an industry operating model. The safety and security of the supply chain was a critical focus of the project. The new operating model will ultimately require unit-level serialization of products which could enable systematic detection of counterfeit product if it enters the supply chain, a previously unavailable capability. In addition, the project:

- Assessed the potential for RFID/EPC to electronically address important regulatory mandates such as the Florida Pedigree Requirements. This technology offers the potential to eliminate the need for a paper-based pedigree system, which is labor intensive and unreliable.[4]
- Helped to establish business rules and processes to facilitate returns, and designed a recall process that may provide a more efficient manner to execute this process using RFID/EPC technology.
- Developed and executed testing protocols that provided data indicating that electromagnetic energy did not affect the efficacy, potency, and strength of this project's solid-dosage products.
- Contributed research and developed workable solutions on tag frequency, label color, size, wording, and location on packages that could represent going-in positions for the industry.

The project allowed participants to rapidly learn and create innovative responses to significant project issues.

The project team addressed and resolved several critical practical matters in this first broad application of RFID/EPC. For example:

- Numerous obstacles on EPC tags were overcome to prove that pharmaceutical products can be tagged at the unit level. The project team showed that human readable numbers can go on tags and be used as a method of redundancy in case the tag is not functioning. It established an innovative two-ply tag system that worked well and satisfied the needs of manufacturers for adhering to the bottle during normal handling, but that could also be removed to reduce the chances of tags getting into the hands of consumers.
- The project arrived at some tentative solutions to address data visibility and security—a practical start in surfacing and exploring an issue that will likely be a key adoption hurdle for RFID/EPC in the industry.

The selected technology suite was completely appropriate and workable for the parameters of this project.

The primary objective was to focus on assessing business value, not on perfecting the technology. Furthermore, the project team needed to choose components that fell within the agreed-upon time and budgetary limits of this project. The team selected commercially available solutions and implemented them so that business scenarios could be run and experiences gained with reasonable effectiveness. It was understood that the solution would not be optimized for each location. For example, the single antenna used in the project was chosen for its simplicity and ease of use. Naturally, in a scaled-up version of the project, there would be multiple antennas throughout the facilities and dramatically enhanced capabilities (e.g., multidirectional reading).

[4] Discussions with regulatory bodies would be required to finalize such a capability.

It should be noted that the level of complexity to do a "simple proof of concept" was greater than anticipated given all the different participant companies involved. Such complexity is likely to grow much above what was present in this simple test environment as integration requirements grow.

The project underscored the importance of meeting infrastructure prerequisites to prepare for industry-wide adoption of RFID/EPC.

There are immediate measures that manufacturers, wholesalers, and retailers can take as preconditions for being effective with RFID/EPC technologies. For example, the broader lessons and issues on this project can be addressed through smaller scale initiatives within the four walls of organizations looking to implement RFID/EPC.

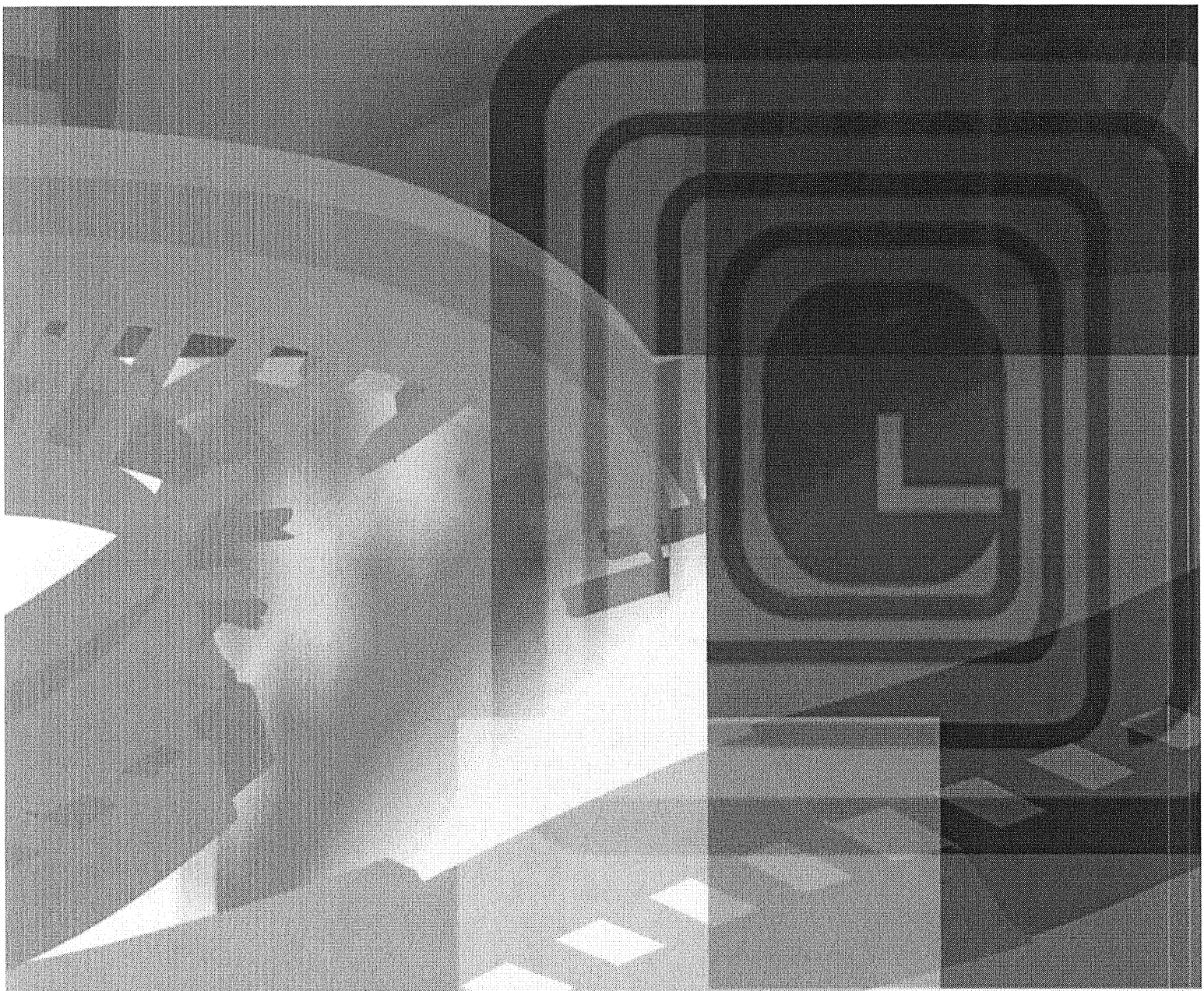
Implementing RFID/EPC technology affects many disciplines within an organization, and companies must work on integrating their efforts internally.

Implementing RFID/EPC technologies in any company requires close coordination and involvement across the organization—representatives from information technology, quality assurance, regulatory affairs, public relations, packaging, and operations for manufacturing, distribution, and stores. One specific example was the need to address public perceptions about the industry's goals in exploring RFID/EPC. Reassuring consumers will be a major task that many functional groups will need to address.

A collaborative, cross-supply-chain approach proved effective in pooling resources and sharing development assets in order to gain benefits.

It is unlikely that any single member of the group could have gone as far as it did, or at the level of cost, without the collective knowledge, experience, assets, and learning of the others. No single firm could test the RFID/EPC technology and duplicate the interaction of the entire supply chain. Manufacturers, wholesalers, and retailers worked well together to address industry issues. The collective voice and collaboration of the supply chain participants were among the advantages to this group approach. For example, the project team identified and brought to the attention of EPCglobal and the FDA the need for standards and business practices relating to the use of RFID/EPC technologies that address the unique needs of the pharmaceutical industry.

The presence of an independent, trusted third party was also essential to keeping the group on a single path—facilitating collaboration, completing the project in accordance with the agreed-upon timeline, and coordinating external communications about the project. The coordination from a technical perspective was also important. Many different organizations and individuals (data center administrators, VPN engineers, facility engineers, network specialists, security specialists, etc.) needed to be orchestrated and move in concert to complete the design, deployment, and support activities.



It is unlikely that any single member of the group could have gone as far as it did, or at the level of cost, without the collective knowledge, experience, assets, and learning of the others.

10. The Future of Leveraging RFID/EPC across the Pharmaceutical Industry

Full-scale implementation on an industry-wide basis will be more complex than many believe, requiring more time than anticipated to refine issues unique to the pharmaceutical industry. Requirements for systems and packaging—especially in addressing data sharing and consumer concerns—in this highly regulated environment will present greater costs and efforts than those of other industries.

Other key conclusions about RFID/EPC's future include the following:

The technology must continue to evolve for an effective full-scale industry implementation.

RFID technology is improving every day. Vendors, hearing recent feedback about practical applications of the technology, are responding appropriately and quickly. An example of an issue being addressed by vendors is tag quality. At each step of the process of converting the tag into the label, a sizeable percentage was not useable due to problems with the tags, labels, or printing. The rate of defective finished tag labels (approximately 20%) would not be acceptable outside this project's limited scope.

Tag manufacturing and converting processes will need to improve significantly to provide tags with defect rates at least as low as other packaging components that pharmaceutical manufacturers currently use. The technology will also need to advance such that tags will function effectively with liquids, biologics, and cold chain products, among others, as well as in mixed-tote shipments. Finally, tag costs need to decrease significantly.

Additional technology issues that must be addressed include:

- Greater consideration will have to be given to how RFID hardware interacts with other devices.
- In order to support the type of distributed network that an RFID implementation requires, updates will need to be made at all locations to support communications to new RFID data exchange partners.
- The testing of hardware after deployment is critical to ensuring that both networks and hardware are configured properly. This can be a time-consuming activity that needs to be taken into account when multiple organizations are all trying to coordinate and move to the same schedule.

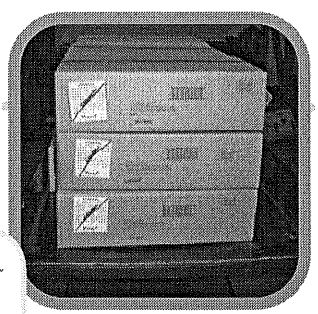
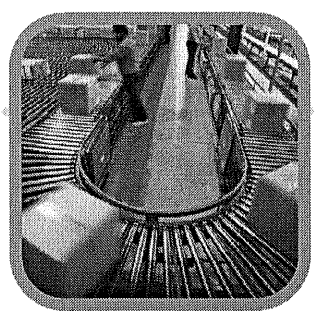
The participants' understanding and experience in working with RFID/EPC in the pharmaceutical industry has grown tremendously; but they need to keep learning.

The project was highly valuable in how it surfaced issues that the team either did not contemplate going in or did not believe would present difficulties. The highly regulated nature of the industry and privacy concerns drove many of these. For example, time-consuming issues were encountered around tag size, wording, acceptable adhesives, and location, to name a few. Working through these issues has provided valuable insight.

Other issues, however, will require additional study. For example, it will be critical to determine how to devise scaleable solutions that address data security and visibility. So will solidifying the steps to obtain validation for systems and processes, as well as approaching the significant effort to integrate RFID/EPC technology with core transaction systems. The table at right shows the range of potential issues to widespread adoption of RFID/EPC.

The industry needs to continue to actively engage with Federal/state regulatory agencies, standards-setting organizations, and industry trade associations to gain involvement in forthcoming releases of this project.

Creating reasonable consistency of standards globally should be a key goal. It will also be critical to mutually establish timetables that reflect the state and effectiveness of RFID/EPC technology and associated processes, and the pharmaceutical industry's experience in leveraging them.

Key Project Characteristics	Potential Issues for Widespread Adoption
The solution operated with a centralized system and a single instance for all companies.	What would be the development time and investment implications of creating a decentralized, heterogeneous environment?
Tags were placed on packages manually, on the exterior, at the manufacturers' distribution sites.	How could tags either become integral to packaging or at least be applied automatically?
There was no integration of systems; this system was a stand-alone, parallel system that required duplicate data entry.	What would be the development time and investment implications of integrating RFID technology and applications with core transaction and other legacy systems?
There was "full" visibility of information (or more visibility than would probably be permitted outside the project).	What would be the process for sorting through and managing restrictions on visibility—and how would those outcomes impact the value of RFID/EPC?
The team made inferences regarding case integrity.	What steps would be needed to achieve close to 100% readability at the unit level?
The project focused on a subset of processes that when improved by the use of RFID/EPC would provide varying amounts of benefits to each segment of the supply chain.	How could separate components of the supply chain be addressed that do not provide benefits to all supply chain segments—e.g., pharmaceutical retail operations and warehouse management—without undercutting the learning and value of having an end-to-end supply chain involved?
The system was not validated.	What would be the process for obtaining validation?
Only cases and units were tagged at the manufacturer.	What about pallets, interpacks, and totes? What about co-packers or repackaging occurring at locations other than manufacturers?
Solid dosage products with easy handling requirements were selected.	What about liquids and biologics with "difficult" handling characteristics (e.g., refrigeration requirements)?
EPC test numbers were used.	What happens when "real" EPC numbers are used?
A single antenna was used in a secluded area of the distribution center.	How would multiple antennas placed in ideal locations (some of which may already have little space, or environments with physically challenging conditions such as susceptibility to extreme temperatures, shock, dirt, and damage) be effectively installed?
The project operated in a virtual team environment, with a central coordinating group working with local contacts at each company.	How would a centralized management structure work, when a larger team and more complex activities would need to occur locally at each company?
Reasonably easy control of consumer privacy issues could be achieved by manually removing tags from packages.	What issues would be involved in mass tagging?
Given its narrow scope, the project played a very limited role in educating consumers about RFID/EPC.	What effort would be involved in educating consumers about RFID/EPC's benefits and dispelling misconceptions?
The project included large companies from three segments of the pharmaceutical supply chain—manufacturers, wholesalers, and chain drug retailers.	How can other segments of the pharmaceutical value chain (biotechs, hospitals, clinics, independent pharmacies, mass merchants, secondary wholesalers, etc.) be included to broaden industry adoption to achieve greater benefits? How can small businesses be involved?

Moving Forward...

This project achieved its stated objectives—assessing the potential for RFID/EPC technology to provide business value in an end-to-end supply chain context, and helping to establish an industry operating model. Perhaps most important, it established a forum for the industry to start asking the tough questions and providing companies with the knowledge and confidence to move forward with RFID/EPC. Fortunately, the enthusiasm for this group's efforts has only grown since its inception. The group has already begun discussing how to take the next steps towards making the use of RFID/EPC in the pharmaceutical industry a reality, and hopes that others in the industry will join in discussing how to move forward.

11. Glossary

RFID

Radio Frequency Identification technology (RFID) is an advanced method to collect product, event, and/or transaction data quickly and easily. Items to be tracked are tagged with a small chip and antenna. When the tag is in close proximity of a reader, it receives a low-powered radio signal and interacts with a reader exchanging identification data and other information. Once data is received by the reader, it can be sent to a computer for processing.

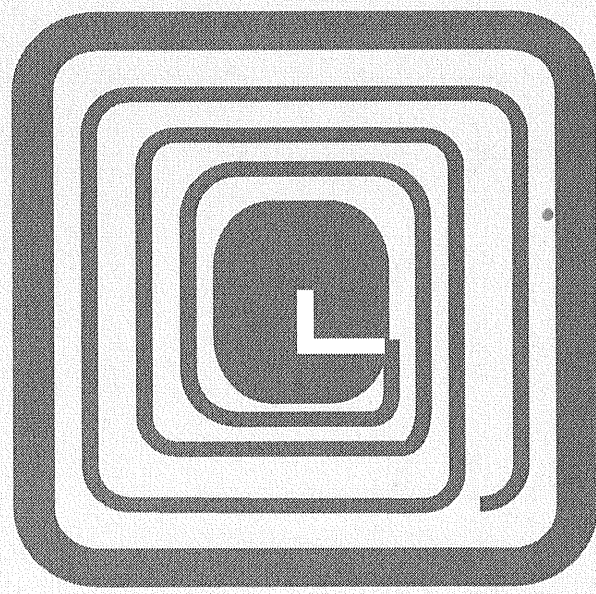
EPC

The Electronic Product Code™ (EPC) is an identification scheme for universally identifying physical objects via RFID tags and other means.[5] EPC technology allows everyday objects to be uniquely identified and connected in a dynamic, automated supply chain that joins businesses and consumers together in a mutually beneficial relationship.

Bar Coding and RFID/EPC

Bar coding is a line-of-sight technology, meaning that each individual item has to be handled to scan the bar code with a reader. In addition to being labor intensive and time consuming, this method has potential for error in reading the same unit twice or missing a unit because it is done at the item level, not the serial number level. RFID tags enable automatic, non-line-of-sight identification, reducing the possibility of errors and the labor necessary to achieve the same results. Although the EPC numbering standard uniquely identifies products, its implementation will evolve over time with applications driven by market and consumer demand. Therefore, bar codes and RFID tags will coexist for some time to come.

[5] EPC Tag Data Standards, Version 1.1 Rev. 1.24



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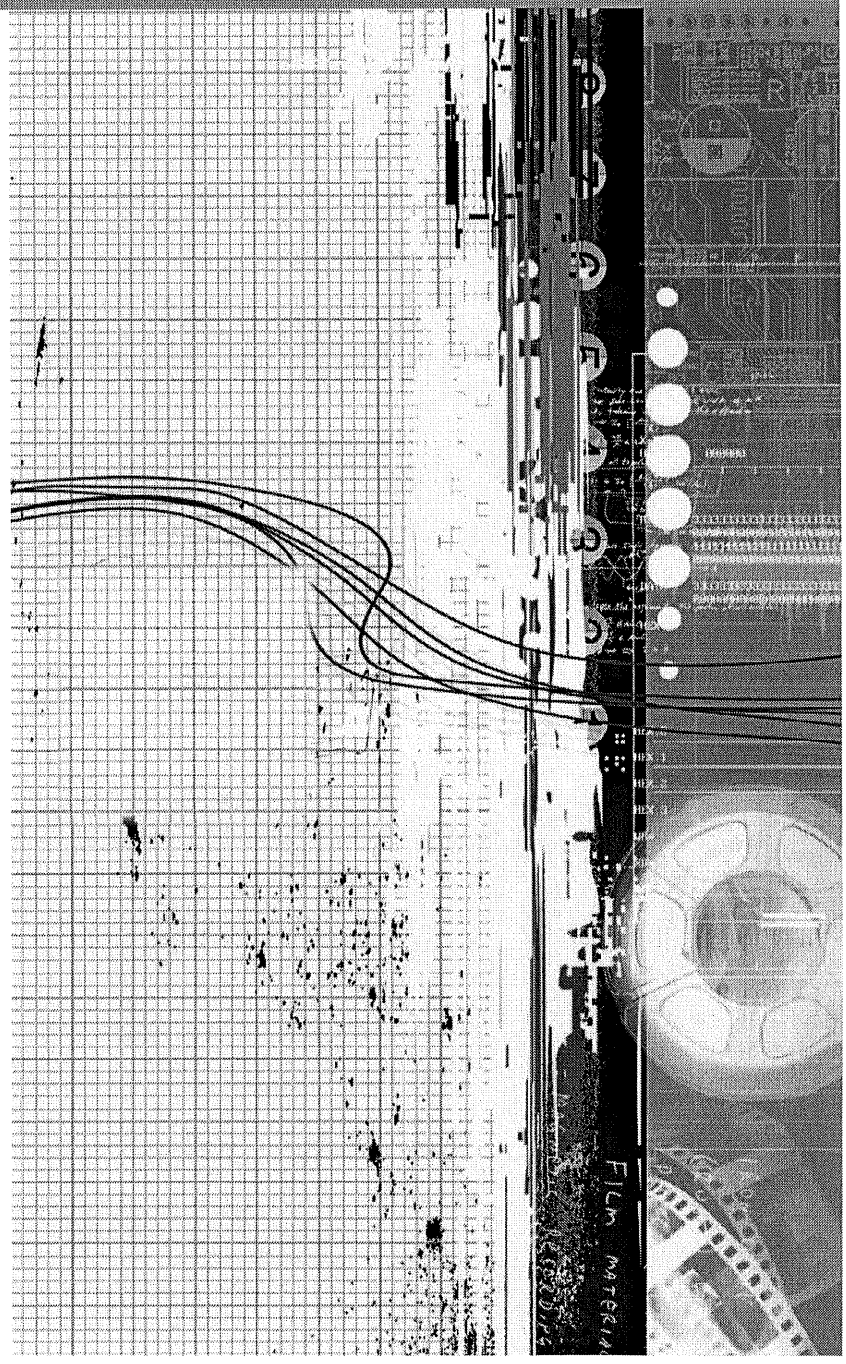

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AGENDA ITEM H

College of Pharmacy

Western University
OF HEALTH SCIENCES

The discipline of learning. The art of caring.

Presented by: Jesse F. Martinez, PharmD, FASCP
Executive Director of External Affairs and Development
Sam Shimomura, PharmD, FASHP, CGP
Associate Dean Professional and Student Affairs

An information item to the Board of Pharmacy, Enforcement Committee, on a Pharmacist-in-Charge C.E. program.

December 15, 2004

Background

We are responding to a call from our WesternU Dean's Advisory Council and our Dean, Dr. Max Ray that WesternU provide leadership in offering a course of study in the skills required to become a pharmacist-in-charge as established by the California Board of Pharmacy.

There have been key changes made in our 12-week Advanced Elective course in our curriculum this year. Both the community pharmacy practitioner track and the community pharmacy management track with an emphasis in independent pharmacy ownership will include training in the requirements to serve as a pharmacist-in-charge.

In addition, we plan to develop a 15-hour "certificate" course designed to prepare a licensed pharmacist in the knowledge, skills and requirements to serve in a pharmacist-in-charge position. We plan to offer this "certificate" program to all interested licensed pharmacists in convenient sites in southern and northern parts of the state starting in the second quarter of 2005.

Resources

The vision for the pharmacist-in-charge "certificate" C.E. program is a format which includes an experiential component with workshop discussions and lectures presented by experts with "real world" experience. Our faculty will include attorneys, pharmacy managers, industrial security representatives, medical waste disposal experts and faculty from the WesternU College of Pharmacy. We are also asking for participation from the Board of Pharmacy. A member of the State Board of Pharmacy and/or State Board Inspector with expertise in the Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment form would make a valuable addition to the training program. The final format that includes the BOP representative is open at this time.

Course of Content

The core for the pharmacist-in-charge certificate program will be in the areas of compliance in the BOP's self assessment form. An advisory group will be convened to review the content of the Advanced Elective course and select relevant portions to include in the PIC "certificate" program. We want the content to be meaningful to PICs presently in this position and candidates considering this position.

Funding

WesternU will take full responsibility for funding the pharmacist-in-charge "certificate" program. We have already generated interest within the private sector for funding. There is a considerable interest from pharmacy chains and others that lack specific training programs for pharmacist-in-charge and are prepared to support such a program.

AGENDA ITEM I

Changes in Pharmacy Law for 2005

The Assembly and Senate bills listed in this article were signed in 2004, and unless otherwise specified, take effect January 1, 2005. The new and amended statutes are paraphrased or summarized below, but you are urged to review the exact language of the statutes at the Board's Web site *www.pharmacy.ca.gov*.

SB 1307 (Figuroa)
Chapter 857, Statutes of 2004

Electronic Pedigree for Dangerous Drugs (New)
B&PC 4034—requires an electronic "pedigree" by January 1, 2007. Said pedigree will contain 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 a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the drug. The application of the pedigree requirement in pharmacies will be subject to review during the Board's sunset review in 2008.

Embargoed Dangerous Drugs or Devices (New)
B&PC 4084 and 4085—allows Board inspectors to embargo dangerous drugs or devices that are suspected of being adulterated or counterfeit by affixing a tag or other marking to the drug. If a Board inspector determines that an embargoed dangerous drug or device is not adulterated or counterfeit, the inspector may remove the tag or marking. It is unlawful for any person to remove, sell, or dispose of an embargoed dangerous drug or device without the Board's permission.

Furnishing Dangerous Drugs to Specified Entities and Violation Penalty (New)
B&PC 4126.5—permits pharmacies to furnish dangerous drugs only to:

- A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired;
- The pharmaceutical manufacturer from whom the dangerous drug was acquired;
- A licensed wholesaler acting as a reverse distributor;
- Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
- A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law;
- A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs; and
- Another pharmacy under common control.

Violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with such a pharmacy may result in a fine of $5,000 per violation.

Surety Bond for Wholesalers (New)
B&PC 4162—requires applicants for the issuance or renewal of a wholesaler license to submit a surety bond of $100,000 or other equivalent means of security to the Board. The purpose of the bond is to secure payment of any administrative fine imposed by the Board and any cost recovery ordered. If the applicant's annual gross income for the previous tax year is less than $10,000,000, a surety bond for $25,000 will be accepted. Additionally, a surety bond of $100,000 may be required for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to the Pharmacy Law. This section becomes effective January 1, 2006.

Pedigree Required (New)
B&PC 4163— presently allow manufacturers and wholesalers to acquire or furnish dangerous drugs or devices only from or to those authorized by law to possess or furnish those dangerous drugs or devices. This section is in effect until January 1, 2007, when it will be repealed unless a later enacted statute is enacted before that date. If this section is repealed, the new section will prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug at wholesale without a pedigree. Additionally, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree. This section becomes operative on January 1, 2007.

Extension May be Allowed for Implementing Pedigree Requirement for Wholesalers (New)
B&PC 4163.5—authorizes the Board to extend the time allowed for implementing electronic technologies to track the distribution of dangerous drugs within the state if the Board determines that manufacturers or wholesalers cannot meet the requirement by January 1, 2007. The pedigree requirement compliance date may then be extended until January 1, 2008.

Extension May be Allowed for Implementing Pedigree Requirement for Pharmacies (New)
B&PC 4163.6—authorizes the Legislature to extend the time allowed for pharmacies to implement electronic tracking the distribution of dangerous drugs within the state if the Legislature determines that it is not economically and technically feasible for pharmacies to comply with the requirement by January 1, 2007. The date for compliance with the requirement may be extended to January 1, 2009.

Wholesaler Tracking System of Individual Sales of Dangerous Drugs (Amended)
B&PC 4164—effective January 1, 2006, will require licensed wholesalers that distribute controlled substances, dangerous drugs or devices within or into California to report all sales of those products that are subject to abuse. Wholesalers will be required to 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.

No Business License for any Wholesaler Not Licensed by the Board (New)

B&PC 4168—prohibits a county or municipality from issuing a business license to a wholesaler who does not have a current wholesaler license issued by the Board.

Wholesaler Sales Requirements (New)
B&PC 4169—prohibits the following:

- The purchase, trade, sale, or transfer of dangerous drugs or devices at wholesale to a person or entity that is not licensed with the Board as a wholesaler or pharmacy;
- The purchase, trade, sale, or transfer of dangerous drugs that the person knew or should have known were adulterated or misbranded;
- The purchase, trade, sale, or transfer of dangerous drugs or devices after the beyond use date on the label; and
- The failure to maintain records of the acquisition or disposition of dangerous drugs or devices for at least three years.

Violation of this section may result in a fine for each violation.

Excessive Furnishing of Dangerous Drugs by a Wholesaler to a Pharmacy (Amended)
B&PC 4301—defines acts of unprofessional conduct and authorizes the Board to take action against a wholesaler who clearly excessively furnishes dangerous drugs to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term facilities.

Fee Bases Increased (Amended)
B&PC 4400—authorizes an increase in the fee bases for initial and renewal license applications and penalties.

AB 2184 (Plescia)
Chapter 342, Statutes of 2004

Automated Drug Systems in Skilled Nursing and/or Intermediate Care Facilities (New)
B&PC 4119.1—allows a pharmacy to provide pharmacy services to a skilled nursing facility or an intermediate care facility through the use of an automated drug delivery system that need not be located at the same location as the pharmacy. Operation of the drug delivery system must be under supervision of a pharmacist who need not be physically present and is allowed to supervise the system electronically.

AB 2660 (Leno)
Chapter 191, Statutes of 2004

Prescription Labeling Requirements (Amended)
B&PC 4040, 4052, 4060, 4076, 4111and H&SC 11150 —permits pharmacists to sign orders for dangerous drugs when initiating or adjusting drug regimens under protocol;

requires pharmacists to register with the DEA if they are authorized to initiate or adjust drug therapy under protocol; permits the possession of a controlled substance dispensed pursuant to a drug order signed by a pharmacist; requires a prescription label to include the name of the practitioner, including a pharmacist, who ordered the drug; permits pharmacists to order controlled substances pursuant to a protocol; no longer requires the name of the supervising physician (of certified nurse midwives, nurse practitioners, physician assistants) to be on prescription labels.

AB 2682 (Negrete McLeod)
Chapter 887, Statutes of 2004

Out-of-State Distributor to Become Nonresident Wholesaler and Exemptee-in-Charge to Become Designated Representative-in-Charge (New)
B&PC 4161—requires any person located outside California that ships, mails, or delivers dangerous drugs or devices into this state at wholesale to be considered an "**out-of-state distributor**" and be licensed by the Board. (However, those who ship, mail or deliver dangerous drugs or devices only to wholesalers in this state are exempt from the license requirement.) An out-of-state distributor's license may not be issued or renewed until the out-of-state distributor identifies and notifies the Board of the designation of an exemptee-in-charge. The exemptee-in-charge will be responsible for the company's compliance with all laws governing wholesalers. The nonresident wholesaler must identify and notify the Board of a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge. This section is in effect until January 1, 2006.

After that date, an out-of-state distributor will be known as a "**nonresident wholesaler**," requiring a license issued by the Board. A separate license will be required for each place of business owned or operated by a nonresident wholesaler. Such license will be renewed annually and non-transferable. At the time of initial application for licensure or renewal of a nonresident wholesaler license, the applicant must submit in writing to the Board the following information within 30 days of a change in that information:

- Its agent for service of process in this state;
- Its principal corporate officers, if any, as specified by the Board;
- Its general partners, if any, as specified by the Board; and
- Its owners if the applicant is not a corporation or partnership.

A report containing the above information must be made within 30 days of any change of ownership, office, corporate officer, or partner. A nonresident wholesaler must comply with all directions or requests for information from the Board, or regulatory or licensing agency of the state in which it is licensed. Nonresident wholesalers must maintain records, in a readily retrievable form, of dangerous drugs and devices sold, traded, or transferred to persons in this state and must at all times maintain a valid, unexpired license, permit or registration in the applicant's state of residence.

The Board will not issue or renew a nonresident wholesaler license until the applicant identifies a "**designated representative-in-charge**" (previously exemptee-in-charge) and notifies the Board in writing of that person's identity and license number. Additionally,

the Board must be notified within 30 days of a change in the designated representative-in-charge. The designated representative-in-charge will be responsible for the company's compliance with all laws governing wholesalers. The Board may issue a temporary license under certain conditions and for periods of time that the Board determines to be in the public interest.

Surety Bond for Nonresident Wholesaler License (New)
B&PC 4162.5—requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000 for each site to be licensed, 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 Board may accept a surety bond of $25,000 if the nonresident wholesaler's annual gross receipts of the previous tax year is ten million dollars or less, but the surety amount would revert to $100,000 if the nonresident wholesaler has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this section. The Board may make a claim against the bond if the licensee fails to pay a fine with 30 days of the issuance of the fine or when the costs become final. A single surety bond or other equivalent means of security acceptable to the Board will satisfy the bond requirement for all licensed sites under common control as defined in Section 4126.5. This section becomes effective January 1, 2006, and extends to January 1, 2011, unless an enacted statute repeals or extends those dates.

SB 1159 (Vasconcellos)
Chapter 608, Statutes of 2004

Furnishing Hypodermic Needles and Syringes Without Prescription (Amended)
B&PC 4145, 4147 and H&SC 11364—until December 31, 2110, authorizes a pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project, which would be created to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C.

SB 1913 (Business and Professions Committee)
Chapter 695, Statutes of 2004
Omnibus Measure

Delivery of Dangerous Drugs or Devices (New)
B&PC 4059.5—requires dangerous drugs or devices delivered to a pharmacy to be signed for by and delivered to a pharmacist but also authorizes a pharmacy to take delivery of dangerous drugs or devices when the pharmacy is closed and no pharmacist is on duty if:

- The drugs are placed in a secure storage facility in the same building as the pharmacy;

- Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or devices have been delivered;
- The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or devices have been delivered;
- The pharmacy maintains written policies and procedures for the delivery of dangerous drugs or devices to a secure storage facility;
- The agent delivering dangerous drugs or devices leaves documents indicating the name and amount of each dangerous drug or device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and devices delivered to the secure storage facility and for obtaining and maintaining records relating to the delivery.

Prescriber Dispensing Dangerous Drug to Emergency Room Patient (New)
B&PC 4068—permits a prescriber to dispense a dangerous drug, including a controlled substance, to an emergency room patient if **all** of the following apply:

- The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- The dangerous drug is acquired by the hospital pharmacy;
- The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- The hospital pharmacy retains the dispensing information and, if the drug is Schedule II or III controlled substance, reports the dispensing information to the Department of Justice pursuant to H&SC 11165;
- The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and
- The prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.

Records of Manufacture, Sale, Acquisition and Disposition of Dangerous Drugs or Devices (New)
B&PC 4081—requires all records of manufacture, sale, acquisition, or disposition of dangerous drugs or devices to be open to inspection during business hours and retained for at least three years from the making. A current inventory must be kept by every manufacturer, wholesaler, pharmacy, veterinarian, laboratory, clinic, hospital, or institution who maintains a stock of dangerous drugs or devices. The name "exemptee-in-charge" will be changed to "designated representative-in-charge" on January 1, 2006. After that date, the owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible with the pharmacist-in-charge or representative-in-charge for maintaining the records and inventory. The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

Site Licenses (New)

B&PC 4107—prohibits the Board from issuing more than one site license to a single premise except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license to compound sterile injectable drugs to a pharmacy.

Environment for Compounding Sterile Injectable Products (New)
B&PC 4127.7—As of July 1, 2005, requires a pharmacy to compound sterile injectable products in one of the following environments:

- An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom with a positive air pressure differential relative to adjacent areas;
- An ISO class 5 cleanroom;
- A barrier isolator that provides an ISO class 5 environment for compounding.

Veterinary Teaching Hospital (New)
B&PC 4170.5—permits veterinarians in a veterinary teaching hospital operated by an accredited veterinary medical school to dispense and administer dangerous drugs and devices and controlled substances from a common stock.

Foreign Graduates (Amended)
B&PC 4200—adds certification by the Foreign Pharmacy Graduate Examination Committee to requirements for pharmacist licensure.

Pharmacist/Intern Ratio and Intern Hours Requirement Changed (New)
B&PC 4208 and 4209— defines "intern," details requirements for registration and qualifying for pharmacist licensure examinations. Intern affidavits (hours and experience) must be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Interns must have at least 1,500 hours of intern experience before applying to take the pharmacist licensure examination. Section **4114** authorizes pharmacists to **supervise two intern pharmacists at one time**.

Compounding by Pharmacy Technicians (Amended)
H&SC 11207—clarifies language that permits a pharmacy technician to compound, prepare, fill or dispense a prescription for a controlled substance when assisting a pharmacist.

AGENDA ITEM J

Meeting dates for the Licensing Committee are: March 16th, June 15th, September 21st, and December 14th.