ATTACHMENT B

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814
(916) 445-5014 FAX (916) 327-6308

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

WHOLESALER
DANGEROUS DRUGS & DANGEROUS DEVICES
SELF- ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 18.

All references to "drugs" throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B & P) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Wholesaler Name _____

Address _____ Phone _____

Wholesaler E-mail address (optional) _____

Ownership: Please mark one

○ sole owner ○ partnership ○ corporation ○ LLC

○ non- licensed owner ○ Other (please specify) _____

CA Wholesaler Permit #_____ Expiration Date_____

Other Permit #_____ Expiration Date_____

DEA Registration #_____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Daily_____ Sat_____ Sun_____ 24 Hours ○

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC#/RPH#_____ Expiration Date_____

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

1. _____ DR#/RPH#_____Exp. Date _____

2. _____ DR#/RPH#_____Exp. Date _____

3. _____ DR#/RPH#_____Exp. Date _____

4. _____ DR#/RPH#_____Exp. Date _____

5. _____ DR#/RPH#_____Exp. Date _____

6. _____ DR#/RPH#_____Exp. Date _____

7. _____ DR#/RPH#_____Exp. Date _____

8. _____ DR#/RPH#_____Exp. Date _____

9. _____ DR#/RPH#_____Exp. Date _____

10_____ DR#/RPH#_____Exp. Date _____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes	No	N/A	
☐	☐	☐	Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B & P 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**
☐	☐	☐	Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note:: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B & P 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

Premises, fixtures and equipment:

Yes	No	N/A	
☐	☐	☐	Are clean and orderly
☐	☐	☐	Are well ventilated
☐	☐	☐	Are free from rodents and insects
☐	☐	☐	Are adequately lit
☐	☐	☐	Have plumbing in good repair
☐	☐	☐	Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])
☐	☐	☐	Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

☐ ☐ ☐ Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

☐ ☐ ☐ Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

_____

_____

_____

Yes No N/A

☐ ☐ ☐ Does this business operate only when a designated representative or pharmacist is on the premises? (CCR 1781)

The wholesale premises is equipped with the following specific security features:

☐ ☐ ☐ There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐ The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐ The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

Yes No N/A

☐ ☐ ☐ Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B & P 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge / Owner Responsibilities

Yes	No	N/A	
☐	☐	☐	The owner and the designated representative-in-charge both equally responsible for maintenance of the records and inventory. (B & P 4081[b])
☐	☐	☐	Is the designated representative-in-charge responsible for the wholesaler's compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B & P 4160[d])
☐	☐	☐	The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B & P 4305.5[a])
☐	☐	☐	The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B & P 4160[d], 4331[c]) The appropriate form for this notification is a "Change of Designated Representative-in-Charge," which is available on the board's website.
☐	☐	☐	The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (B & P 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

4. Designated Representative/Pharmacist

Yes	No	N/A	
☐	☐	☐	If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B & P 4100, 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes	No	N/A	
☐	☐	☐	Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B & P 4163[b], 4169)

Yes No N/A

☐ ☐ ☐ If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B & P 4081, 4332)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

6. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])

☐ ☐ ☐ When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

7. Drug Stock

Yes No N/A

☐ ☐ ☐ Is all drug stock open for inspection during regular business hours? (B & P 4081[a])

☐ ☐ ☐ Are all drugs you order maintained in a secure manner at your licensed wholesale premises?. You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B & P 4167)

☐ ☐ ☐ Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B & P 4342[a])

Yes No N/A

☐ ☐ ☐ Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

☐ ☐ ☐ Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR1307.21)

☐ ☐ ☐ When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

Describe how you verify a business or person is appropriately licensed. (B & P 4059.5[a] [b][d], B & P 4169)

_____

_____

List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

Yes No N/A

☐ ☐ ☐ Are drugs only furnished by your business to an authorized person? (B & P 4163[a]) Note: An authorized person can be a business or natural person.

Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ your business is a "reverse distributor"?

☐ ☐ ☐ the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B & P 4126.5[a])

Are all drugs that are purchased from another business or are sold, traded or transferred by your business:

☐ ☐ ☐ completed with a business licensed with this board as a wholesaler or pharmacy?

☐ ☐ ☐ free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ beyond their use date (expired drugs)? (B & P 4169)

List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

☐ ☐ ☐ comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ comply with all applicable federal regulations regarding the exportation of dangerous drugs?

Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B & P 4059.5[e])

_____

_____

Yes No N/A

☐ ☐ ☐ When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987). Effective January 1, 2007, an electronic pedigree must accompany all drugs (B & P 4163), even those for which your business is an authorized distributor.

☐ ☐ ☐ If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B & P 4380)

☐ ☐ ☐ Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B & P 4341, B & P 651, CCR 1766)

☐ ☐ ☐ Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B & P 650)

_____

_____

Yes No N/A

☐ ☐ ☐ Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B & P 4066, CFR 1301.25)

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

Yes No N/A

☐ ☐ ☐ Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B & P 4166[a])

List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B & P 4059.5[a])

☐ ☐ ☐ Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B & P 4059[d])

☐ ☐ ☐ All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B & P 4059.5[c])

☐ ☐ ☐ If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B & P 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

11. Controlled Substances

Yes No N/A

☐ ☐ ☐ Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

Yes	No	N/A	
☐	☐	☐	Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])
☐	☐	☐	Are DEA requirements for storage of Schedule III controlled substances being met? (specific requirements are listed in CFR 1301.72[b])
☐	☐	☐	Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])
☐	☐	☐	Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])
☐	☐	☐	Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, has created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.07)

List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

Yes	No	N/A	
☐	☐	☐	Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)
☐	☐	☐	If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)
☐	☐	☐	Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])
☐	☐	☐	If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])
☐	☐	☐	If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

Yes	No	N/A	
☐	☐	☐	If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances.(CFR 1301.74[f])
☐	☐	☐	If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[f])
☐	☐	☐	Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)
☐	☐	☐	When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.09 [b])
☐	☐	☐	If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.11)
☐	☐	☐	When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1309.05[b])
☐	☐	☐	For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.09[e])
☐	☐	☐	Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances?
☐	☐	☐	Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.12)
☐	☐	☐	Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the

making? (B & P 4081, CCR 1718, CFR 1305.09[d], 1305.13[a] [b], and H & S 11252, 11253, 1304.03)

Yes	No	N/A	
☐	☐	☐	Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])
☐	☐	☐	Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

Does your business always comply with the following requirements:

Yes	No	N/A	
☐	☐	☐	Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])
☐	☐	☐	Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.16)
☐	☐	☐	Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1304.74[c])
☐	☐	☐	Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CFR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

12. Policies and Procedures

Does this business maintain and adhere to policies and procedures for:

Yes	No	N/A	
☐	☐	☐	Receipt of drugs?
☐	☐	☐	Security of drugs?
☐	☐	☐	Storage of drugs? (including maintaining records to document proper storage)
☐	☐	☐	Inventory of drugs? (including correcting inaccuracies in inventories)
☐	☐	☐	Distributing drugs?
☐	☐	☐	Identifying, recording and reporting theft or losses?
☐	☐	☐	Correcting errors?
			Physically quarantining and separating:
☐	☐	☐	returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?
☐	☐	☐	drugs that have been partially used?
☐	☐	☐	drugs where the outer or secondary seals on the container have been broken?

Yes No N/A

☐ ☐ ☐ drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?

☐ ☐ ☐ drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity? (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

13. Training

Yes No N/A

☐ ☐ ☐ Is training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

14. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B & P 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.

☐ ☐ ☐ Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B & P 4059[d])

☐ ☐ ☐ Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])

☐ ☐ ☐ Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the

prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

Yes No N/A

☐ ☐ ☐ Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

15. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B & P 4059[b])

☐ ☐ ☐ Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B & P 4081[a], 4105[c], 4081, 4332, 4059.5[a])

☐ ☐ ☐ Are all purchase and sales records retained in a readily retrievable form? (B & P 4105[a])

☐ ☐ ☐ Is a current accurate inventory maintained for all dangerous drugs? (B & P 4081, 4332, 1718)

☐ ☐ ☐ If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B & P 4105[b])

☐ ☐ ☐ Are required records stored off-site only if a board issued written waiver has been granted?

If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

Yes No N/A

☐ ☐ ☐ Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

Yes No N/A

☐ ☐ ☐ Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])

☐ ☐ ☐ Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

☐ ☐ ☐ Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B & P 4162[a][4]):

_____

_____

Yes No N/A

☐ ☐ ☐ Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B & P 4083)

☐ ☐ ☐ Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B & P 4315[e])

☐ ☐ ☐ If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

16. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ A designated representative-in-charge who terminates employment at this business, must notify the board within 30 days of the termination (B & P 4101[b], 4305.5[c].

☐ ☐ ☐ The owner must report to the board within 30 days the termination of the designated representative-in-charge or pharmacist (B & P 4305.5[a])

Yes	No	N/A	
☐	☐	☐	The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)
☐	☐	☐	The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1304.74[c])
☐	☐	☐	Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)
☐	☐	☐	The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B & P 4201[i], CCR 1709[b])
☐	☐	☐	When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B & P 4164[a])
☐	☐	☐	Effective January 1, 2006 your business will develop and maintain a tracking system for 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. Your system must: 1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities 2. identify purchases of any dangerous drugs at preferential or contract prices 3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B & P 4164[b])
☐	☐	☐	I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B & P 4201[g])
☐	☐	☐	The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)
☐	☐	☐	If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

17. Additional Licenses/Permits Required

List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B & P 4107, CFR 1305.11[a], B & P 4059.5[e])

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____ hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

Legal References

All references to California Business & Professions Code (B & P) are Chapter 9, Division 2 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Code of Regulations (CCR) are to Title 16 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Health & Safety Code (H & S) are to Division 10, Uniform Controlled Substances Act (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) or Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws (http://www.dhs.ca.gov/ps/fdb/PDF/Sherman1-1-2004.pdf).

All references to United States Code of Federal Regulations (CFR) are Title 21, Chapter II Part 1300, Drug Enforcement Administration, Food and Drugs and codified Controlled Substances Act (CSA) (http://www.deadiversion.usdoj.gov/21cfr/index.html).

California Board of Pharmacy
400 R Street, Suite 4070
Sacramento CA 95814
(916) 445-5014
fax: (916) 327-6308
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 74
www.lawtech-pub.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Prescriber Boards:

Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
fax: (916) 263-2387
http://www.medbd.ca.gov

Dental Board of California
1432 Howe Ave. #85
Sacramento, CA 95825
(916) 263-2300
fax: (916) 263-2140
http://www.dbc.ca.gov/

Board of Registered Nursing
400 R Street, Suite 4030
Sacramento, CA 95814
(916) 322-3350
fax: (916) 327-4402
http://www.rn.ca.gov/

Board of Optometry
400 R Street, Suite 4090
Sacramento, CA 95825
(916) 323-8720
fax: (916) 445-8711
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
2720 Gateway Oaks Drive, #350
Sacramento, CA 95833
(916) 263-3100
fax: (916) 263-3117
http://www.ombc.ca.gov

Physician Assistant Committee
1424 Howe Avenue, #35
Sacramento, CA 95825
(916) 263-2670
fax: (916) 263-2671
http://www.physicianassistant.ca.gov

Board of Podiatric Medicine
1420 Howe Avenue, #8
Sacramento, CA 95825
(800) 633-2322
(916) 263-2647
fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
1420 Howe Avenue, #6
Sacramento, CA 95825
(916) 263-2610
fax: (916) 263-2621
http://www.vmb.ca.gov

Federal Agencies:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov
Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm
Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm
Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html
Online DEA 106 Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

DEA Registration Support (all of CA):
(800) 882-9539

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles CA 90012
(888) 415-9822 or (213) 621-6960
(Registration)
(213) 621-6942 or 6952
(Diversion or Investigation)

DEA – San Francisco
450 Golden Gate Avenue
San Francisco CA 94102
Registration: (888) 304-3251 or
(415) 436-7900
Theft Reports or Diversion: (415) 436-7854

DEA - Sacramento
4328 Watt Avenue
Sacramento CA 95821
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (916) 480-7100
or (916) 480-7250

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or
(213) 621-6960
Diversion or Investigation: (909) 328-6000
or (909) 328-6200

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (559) 487-5402

DEA – San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (510) 637-5600

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (408) 291-7620
or (408) 291-2631

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (530) 246-5043

ATTACHMENT C

washingtonpost.com Sign In | Register Now

PRINT EDITION | Subscribe to The Washington Post

NEWS OPINIONS SPORTS ARTS & LIVING Discussions | Photos & Video | Entertainment Guide CLASSIFIEDS JOBS CAR

SEARCH: News Web powered by YAHOO! SEARCH Top 20 E-mail

Advertisement

Print This Article
E-Mail This Article

MOST VIEWED ARTICLES
Print Edition On the Site

Advertisement

RSS NEWS FEEDS
Top News
Print Edition
What is RSS? | All RSS Feeds

EDITORIAL

Advert

Imported Drugs and the Law

Tuesday, October 4, 2005; Page A22

Advert

FOR MORE than a year, the Montgomery County Council has been trying to figure out a way to promote the importation of cheap prescription drugs from Canada for use by thousands of county employees and retirees. And for more than a year, the council has been given legal opinions saying that to do so would be prohibited by federal law. To date, those opinions have been issued by the Maryland attorney general's office, the County Council's own lawyer and two law firms retained by the school board, among others. The message is clear: It's time for the council to fold.

Instead, it is forging ahead. Council President Tom Perez plans to introduce legislation that would enable the importation of discount drugs from Canada not only for county employees but also for all county residents. Mr. Perez (D-Silver Spring) says he has already lined up at least six co-sponsors on Montgomery's nine-member council; the measure looks likely to pass easily, possibly with the support of County Executive Douglas M. Duncan (D), who has embraced the goal of securing cheap drugs for county residents.

WHO'S BLOGGING?
Read what bloggers are saying about this article.
Icarus Fallen :: Main Page
Full List of Blogs (1 links) »
POWERED BY Technorati

It's easy to sympathize with the council's purpose in pressing the issue as far as it has. A handful of states and cities, including Boston, have adopted legislation allowing the imports. Those states and cities have suffered no legal consequences -- not yet, anyway. Montgomery officials believe the county would save millions of dollars annually if employees had the right to fill long-term prescriptions online from Canadian mail-order pharmacies that the county has vetted for safety and reliability. Co-payments could also decline as a result of lower prices of imported drugs. From a national policy perspective, as we've said before, it's unwise to

maintain a system by which Americans pay sharply higher drug prices than the rest of the world.

But whether or not the law banning prescription drug importations is right or fair, it's clear. As the various attorneys who have examined the issue have said, the county would incur a risk, including the possibility of expensive lawsuits or criminal prosecution, by going ahead with a policy that runs afoul of U.S. law. The school system is also at risk: The school board says it will follow suit if the county enacts legislation, but doing so in defiance of federal law could imperil significant amounts of federal funding.

Mr. Perez is an energetic council president whose concern for his constituents is genuine. He argues that whatever legal risk the county runs is minimal, since the Food and Drug Administration, having turned a blind eye to drug imports elsewhere in the country, would be unlikely to single out Montgomery. In the worst-case scenario, he says, the FDA would seek to shut down the county's program. Maybe. But the fact remains that the council is flirting with lawlessness. The right way to challenge federal legislation is to seek to overturn it, not to defy it.

Print This Article E-Mail This Article

© 2005 The Washington Post Company

Advertising Links What's this?

Montgomery County, MO Real Estate
Coldwell Banker Gundaker helps you search for homes online in Montgomery County, MO. View thousands of listings. Multiple photos and virtual tours.
www.cbgundaker.com

Montgomery County, OH Real Estate
Coldwell Banker West Shell helps you search for homes online in Montgomery County, OH. View thousands of listings. Multiple photos and virtual tours.
www.cbws.com

Your Portal to Montgomery County, TX
Considering a change of pace? Come to Montgomery County, TX and see the incredible new real estate opportunities of Buffalo Springs. Reasonable prices, great location: Montgomery has it all.
www.montgomerytexas.com

SEARCH: News Web go powered by YAHOO! SEARCH

NEWS | OPINIONS | SPORTS | ARTS & LIVING Discussions | Photos & Video | Entertainment Guide CLASSIFIEDS

washingtonpost.com: Contact Us | About Us | Work at washingtonpost.com | Advertise | Media Center | Site Index | Site Map
Archives | E-mail Newsletters | RSS Feeds | Wireless Access | Make Us Your Homepage | mywashingtonpost.com
The Washington Post: Subscribe | Subscriber Services | Advertise | Electronic Edition | Online Photo Store | The Washington P
The Washington Post Company: Information and Other Post Co. Websites

© Copyright 1996- 2005 The Washington Post Company | User Agreement and Privacy Policy | Rights and Permissions

YAHOO! NEWS

Back to Story - Help

Canadian online pharmacies a better deal for meds

REUTERS

By Amy Norton
Tue Sep 20, 9:57 AM ET

Americans could save hundreds or even thousands of dollars a year on brand-name prescription drugs if they use a Canadian Internet pharmacy instead of their local drug store, researchers reported Monday.

On average, their study found, Americans could save 24 percent on their prescriptions if they shopped at an online Canadian pharmacy rather than a U.S. drug chain. Depending on the type of drug and how many prescriptions a person has, the savings could add up to hundreds or thousands of dollars a year.

The findings, published in the Annals of Internal Medicine, add to the contentious issue of U.S. consumers' "importation" of medications from Canada, where the government sets price controls on prescriptions.

Faced with high drug prices at home, some Americans -- an estimated 2 million last year -- have been mail-ordering their prescriptions from Canadian online pharmacies. And some cities, counties and states have programs in place to help them do it.

It is generally assumed that brand-name drugs are cheaper in Canada. However, no study had actually compared prices at Canadian online outlets with those of large U.S. chain drug stores, according to authors of the new study, led by Dr. Mark J. Eisenberg of McGill University in Quebec.

In their comparison, the researchers found that the biggest deals were for the psychiatric drug Zyprexa -- $1,159 in yearly savings -- the diabetes medication Actos and the heartburn drug Nexium.

Certain widely used brand-name drugs -- including other heartburn medications and some cholesterol-lowering statin drugs -- were among those with the largest cost savings, at $600 to $700-plus per year.

Drug importation is technically illegal in the U.S., but individuals are allowed make small cross-boarder purchases of prescriptions for their own use. The U.S. Food and Drug Administration has come down against the practice, however, saying it cannot ensure the safety or quality of medications from foreign sources.

For their part, Canadian health officials have said the country must not become a cheap drug store for U.S. consumers. Earlier this year, Canada's health minister announced proposals to curb the nation's Internet pharmacy business; under the plan, officials would have the right to ban bulk exports of drugs when they thought it necessary to prevent a drug shortage in Canada. They would also require foreign customers to have some "relationship" with a Canadian doctor, though it's unclear what that will ultimately mean.

The new study compared prices for 44 top-selling brand-name drugs at 12 Canadian Internet pharmacies with those available on the Web sites of three major U.S. drug chains: CVS, Rite Aid and Walgreens.

Of the Canadian pharmacies, most were connected to drug stores with actual physical locations, while two were solely "intermediary" businesses that filled their orders through one or more independent pharmacies.

Eisenberg and his colleagues used an online company, pharmacychecker.com, which evaluates Canadian Internet pharmacies, to find sites that met key safety standards-including proper licensing of the supplying pharmacy and requirements that consumers submit a doctor's prescription.

Of the 44 drugs the researchers evaluated, 41 were cheaper at the Canadian pharmacies; the only exceptions were three drugs for impotence.

The study looked only at brand-name drugs because research has shown that generic versions of prescription medications are actually cheaper in the U.S.

Given that, Americans could opt for generics, if they're available, Eisenberg told Reuters Health. However, he added, many people are reluctant to take generics, and if they want brand names, they will "almost assuredly" save money by turning north of the border.

Experts do urge consumers to make sure they are buying from a legitimate pharmacy that requires a prescription from their doctor. Many bogus Web sites claiming to be Canadian outlets have been set up to lure Americans in search of cheaper drugs.

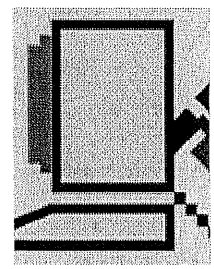
SOURCE: Annals of Internal Medicine, September 20, 2005.

Copyright © 2005 Reuters Limited. All rights reserved. Republication or redistribution of Reuters content is expressly prohibited without the prior written consent of Reuters. Reuters shall not be liable for any errors or delays in the content, or for any actions taken in reliance thereon.

Copyright © 2005 Yahoo! Inc. All rights reserved.
Questions or Comments
Privacy Policy -Terms of Service - Copyright/IP Policy - Ad Feedback

October 2005

Prescription drugs: The facts about Canada



Canada's d distribution anc systems are less foster counter

Illustration by Bob

Even though the practice is illegal, Americans in droves have been importing prescription drugs from Canada. Last year, an estimated 2 million U.S. citizens spent $800 million on medicines purchased from Canadian pharmacies by fax, phone, or Web site. That's 33 percent more than in 2003. A long list of states and cities, including Kansas, Illinois, Minnesota, Missouri, New Hampshire, Wisconsin, Boston, and Portland, Maine, have set up programs to help residents and employees import Canadian drugs priced on average 25 to 50 percent below those on the U.S. market.

What's happening is controversial. The U.S. Food and Drug Administration stands foursquare against imports, arguing that it cannot ensure they are safe. Many Americans, however, believe that buying from Canada, a familiar next-door neighbor, is no more dangerous than picking up a prescription at a local drugstore. Almost 70 percent of the 1,400 people surveyed by the Henry J. Kaiser Family Foundation and the Harvard School of Public Health in November 2004 sa allowing citizens to order drugs from Canada would make medicines more affordable wit sacrificing safety or quality.

Here's the reality of the government's arguments against buying from Canada:

Canadian drugs are not as safe as U.S. drugs. False. The FDA maintains that "many obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs, are, in fact, of unknown quality." Furthermore, FDA officials have exp the concern that news of product recalls issued in Canada may not reach U.S. consume

But Canada's manufacturing and regulatory system is comparable to that of the U.S., ac an October 2003 study by the state of Illinois' Office of Special Advocate for Prescription FDA critics counter, moreover, that the agency cannot entirely ensure the safety of drug manufactured in the U.S.

The Illinois study also concluded that Canada's pricing and distribution system is less lik foster the drug counterfeiting that concerns the FDA. Drugs in the U.S. typically move th multiple vendors (manufacturers, wholesalers, repackagers, retailers, second repackage before reaching the patient. In Canada, medications are dispensed mainly in typical dos shipped in sealed packages directly from manufacturer to pharmacy. In a June 2004 rep U.S. Government Accountability Office said that all of the prescription drugs it ordered fr Canadian Internet pharmacies contained the proper chemical compositions, were shippe accordance with special handling requirements, and arrived undamaged.

In addition, if a recall is issued for a drug sold in Canada, Canadian pharmacies are req alert all consumers who purchased the affected lot, regardless of where they live. "This i recall policy that has been in place in industrialized countries for decades," says Andy Tr president of the Canadian International Pharmacy Association (CIPA), an industry group certifies Canadian pharmacies.

Canadian drugs are not always cheaper. True. To see how much consumers can exp save by buying from Canadian pharmacies, we asked PharmacyChecker.com, a group t evaluates online pharmacies, to compare drug prices from its highest-rated Canadian an Web sites. (See Brand name vs. generic costs.) When we compared the lowest prices o known brand-name drugs from both Canadian and U.S. sources, the Canadian pharmac consumers between $72 and $226 per prescription (including shipping charges). Such medications are cheaper in Canada in large part because its federal Patented Medicine Review Board has the authority to limit prices that it deems to be excessive.

But in a similar comparison, a U.S. site had the best prices for the five most prescribed g drugs. Because generic drugs cost less, the savings are less: from $7 to $31 per prescri "The larger, more competitive generic market in the U.S. helps keep prices down," says McGinnis, the FDA's director of pharmacy affairs.

You could get arrested. True but unlikely. Ordering prescriptions from Canadian Web s violates the Federal Food, Drug, and Cosmetic Act, which generally makes it a crime for other than the original manufacturer to import a drug, even if it was first manufactured in

So far, however, the FDA has focused its enforcement efforts only on those who "comm drug importation. One example: RxDepot, an Oklahoma prescription drug service that w to shut down in 2003. But there are currently no plans to charge consumers. McGinnis s are allowed to exercise enforcement discretion, and it's not our policy to go after individu

Many Internet sites are not legitimate pharmacies. True but avoidable. CIPA warns t Web sites selling medications have been created to lure U.S. consumers seeking cheap Patients who order from such sites run the risk of receiving medications that are subpote improperly handled, or counterfeit. Furthermore, the FDA says some Web sites may not that a drug they sell you is obtained from an overseas supplier. "You may be sent a drug originated in Australia, Great Britain, or Pakistan," says McGinnis. "We don't know anyth the strength, quality, or purity of those medications."

Patients, however, can avoid such problems by ordering only from pharmacies that have thoroughly scrutinized by CIPA. To display a CIPA seal on its Web site an online pharm have a valid Canadian license, submit to a quarterly on-site inspection, and keep person information confidential in compliance with PIPEDA, the Canadian privacy act similar to Health Insurance Portability and Accountability Act, or HIPAA, in the U.S.

The online pharmacy must also require you to submit a valid prescription and medical hi to check for possible drug interactions. And CIPA members must let you know in advanc are supplying you with a medication from another country so you have the right to refuse find a list of the 37 Canadian pharmacies with CIPA seals at *www.ciparx.ca/cipa_pharmacies.html*.

Another source of information about online pharmacies is PharmacyChecker.com, whos process is similar to CIPA's. It also provides prices and customer feedback.

WHAT TO DO

The flow of prescription drugs from Canada may not last forever. Ujjal Dosanjh, the Can Health Minister, proposed on June 29 that a new supply network be established to keep the nation's drugs and that bulk shipments to the U.S. be stopped if the system detects shortage. In addition, he proposed a requirement that "an established patient-practitione relationship" should exist before a physician may prescribe any medications. Whether or means that U.S. citizens will have to meet face-to-face with a Canadian doctor before th purchase drugs will not be determined until sometime this fall, when the minister plans t introduce legislation.

But whatever happens, you should take the following steps before ordering:

• Check Consumer Reports Best Buy Drugs (*www.CRBestBuyDrugs.org*) to learn about options, including generics and over-the-counter drugs, that could save you money.

• Ask your doctor to prescribe generic drugs, which cost much less than brand-name dru
Remember to buy them in the U.S., where they are generally cheaper than in Canada.

• If you need a high-priced, brand-name drug, check with the Partnership for Prescriptior
Assistance (*www.pparx.com*; 888-477-2669), which lets you find out in one step whether
eligible for any of the 275 programs that offer cost savings to consumers.

• If ordering from Canada is the only way you can afford the medication you need, go to
PharmacyChecker.com for recommendations of approved outlets, and look for the CIPA
protect yourself.

**For complete Ratings and recommendations of appliances, c
trucks, electronic gear, and much more, subscribe today anc
access to all of ConsumerReports.org.**

Copyright © 2001-2005 Consumers Union of U.S., Inc. No reproduction, in whole or in part, without written permission.
This site best viewed with IE 5.0 and above, or Netscape 6.0.

Texas Places Prescription Drug Reimportation Law on Hold To Allow Time for Review of Federal Complaint
[Sep 01, 2005]

Texas has placed on hold a new state law that will allow residents to purchase less-expensive medications from Canada to allow state attorneys time to review a complaint from the federal government that the measure violates a federal law related to prescription drug imports, the *Houston Chronicle* reports. The Texas law, part of a broader measure scheduled to take effect on Thursday, will require the Texas State Board of Pharmacy to provide information on a Web site to help state residents purchase prescription drugs from as many as 10 Canadian pharmacies. In addition, the law will require the board to inspect the pharmacies to ensure that they meet Canadian and U.S. safety standards. Acting FDA Associate Commissioner Randall Lutter prompted the review of the legislation with a letter to Gov. Rick Perry (R) that raised concerns about potential safety risks. Lutter also wrote that the federal Food, Drug and Cosmetic Act supersedes the law (Robison, *Houston Chronicle,* 8/31). In response to the letter, the board asked state Attorney General Greg Abbott (R) to review the legality of the Texas law. Gay Dodson, executive director and secretary of the state pharmacy board, said that the board does not plan to take action on the law until Abbott issues an opinion. The inspection of the Canadian pharmacies required under the law "is not equivalent to licensure," but "the procedure ... would be equivalent to the board condoning, if not promoting, these Canadian pharmacies shipping prescription drugs into Texas," Dodson wrote in a letter to Abbott (*AP/Fort Worth Star-Telegram*, 8/31). State Rep. Scott Hochberg (D), who sponsored the Texas law, said that the measure does not violate federal law. He said, "States clearly have the right and responsibility to protect the health and safety of their residents, and Texas has a compelling interest to inspect Canadian pharmacies as long as they continue to solicit drug sales to Texans" (*Houston Chronicle*, 8/31).

Email this story to a friend

Link to this story.

Print this story.

Save this story in my saved links.

TOP

Health Care Marketplace

NPR's 'Talk of the Nation' Discusses Health Savings Accounts
[Sep 01, 2005]

NPR's "Talk of the Nation" on Tuesday included a discussion of health savings accounts, a "relatively new alternative" that some employers have begun to offer to encourage employees to "assume more responsibility" for health care costs (Conan, "Talk of the Nation," NPR, 8/30). Under the 2003 Medicare law, HSAs are

THE WALL STREET JOURNAL. ONLINE

FORMAT FOR PRINTING sponsored by TOSHIBA Don't copy. Lead.

August 30, 2005

PAGE ONE

Tangled Web

For Entrepreneur, Online Drug Sales Meant Fast Profits

Mr. Kolowich Smuggled Pills From Mexico, Then India; A Big Hit With Viagra

FBI Gets Clues From a Laptop

DOW JONES REPRINTS

This copy is for your personal, non-commercial use only. To order presentation-ready copies for distribution to your colleagues, clients or customers, use the Order Reprints tool at the bottom of any article or visit: www.djreprints.com.

• See a sample reprint in PDF format.
• Order a reprint of this article now.

By HEATHER WON TESORIERO
Staff Reporter of THE WALL STREET JOURNAL
August 30, 2005; Page A1

Browsing the Internet on Halloween night in 1998, Mark Kolowich read that Viagra was difficult to get in Great Britain while the government decided whether to pay for it. The owner of a struggling San Diego picture-frame business smelled a new commercial opportunity.

Mark Kolowich

In a couple of weeks, Mr. Kolowich says, he had procured the anti-impotence pills from Tijuana, Mexico, where they could easily be obtained without a prescription. He started selling the pills to United Kingdom buyers on a rudimentary Web site, which later became known as WorldExpressRx.com. Within five years, Mr. Kolowich was selling a wide array of prescription drugs to thousands of customers around the world. By one U.S. government estimate, he made as much as $7 million, but he says he made much more.

Eventually, Mr. Kolowich was arrested for importing and selling counterfeit drugs, mail fraud and money laundering. In April 2004, he pleaded guilty to all four counts and is now serving a 51-month prison term at the low-security Federal Correctional Institution in Lompoc, Calif., near Santa Barbara.

But for years, he was able to evade investigators from the Food and Drug Administration, border officials from U.S. Immigration and Customs Enforcement and the Federal Bureau of Investigation. The 45-year-old Mr. Kolowich agreed recently to discuss in detail his commercial operations, and how he was able to stay one step ahead of the law for so long. In a four-hour interview -- clad in prison khakis, 40 pounds lighter than when he was living the high life, sitting in plastic chairs in the prison's visitors lounge -- he offered a rare look into the rapidly expanding, often shady, sector of online pharmaceutical sales.

Though Viagra and other anti-impotence remedies are available with a prescription at legitimate pharmacies, there's a thriving online market for these drugs, where customers can obtain the pills anonymously and with ease. But online pharmacies are largely unregulated and unmonitored by health authorities. In many cases, site operators such as Mr. Kolowich are unlicensed to sell or prescribe prescription medications. Since October 1999, the FDA's Office of Criminal Investigations has made about 180 Internet drug arrests, most of which have resulted in convictions.

PILL SALES

• Fake-Drug Sites Keep a Step Ahead[1]
08/10/04

New sites are constantly sprouting up. Like Mr. Kolowich, criminals set up online drug sites because they're inexpensive to create and hard to shut down. Counterfeit supplies are widely available and easy to smuggle. Drug makers consider other versions of their patent-protected drugs to be counterfeit. **Pfizer** Inc.'s Viagra patent is valid in the U.S. until March 2012.

There are "tens of thousands of URLs, which lead back to thousands of online pharmacies," according to Michael Allison, chairman and chief executive officer of ICG Inc., a Princeton, N.J., firm that investigates fraudulent Internet activity for companies. ICG estimates that 80% of drugs sold online are considered counterfeit by drug manufacturers, although others in the industry caution that such figures are hard to prove.

Mr. Kolowich remembers a life as the youngest of eight children in a rich, roving family. He says he spent some of his childhood aboard an 82-foot yacht in the Caribbean and attended a British boarding school. One of his sisters confirms this account. Mr. Kolowich's father was an entrepreneur who made a fortune selling a trucking business. He says his father, now deceased, also served 30 days in prison for tax evasion.

Job to Job

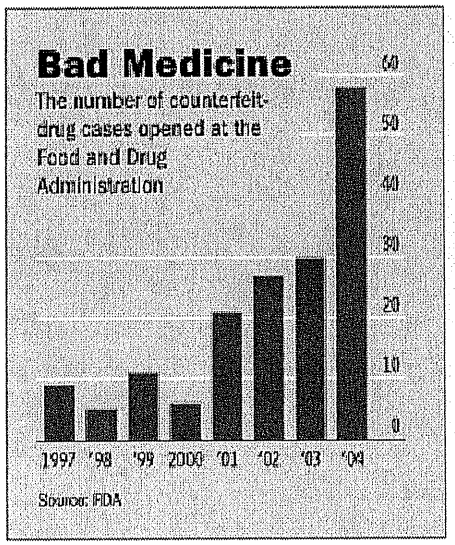
Mr. Kolowich never went to college. He never graduated from high school. He says he passed a high-school equivalency exam back in the U.S. and then hopscotched from job to job, including as an overnight federal-funds trader and as an airline ticketing agent. He never held a position for long.

Then came the Halloween inspiration. Mr. Kolowich taught himself how to build a Web site from a few books on e-commerce. Recalling his days at the British boarding school, he sprinkled the site with words such as "chemist" and "fortnight." He figured out how to use aboveboard businesses to his advantage.

He opened a bank account with the First Bank of Beverly Hills, listing his business as selling "health supplements." The bank sold its merchant-accounts unit in June 2001. First Bank of Beverly Hills Chief Executive and President Joseph W. Kiley, who wasn't with the bank when Mr. Kolowich said he did business with it, said he wasn't aware of this particular case.

Since he initially targeted British customers, Mr. Kolowich procured London-based telephone numbers from j2 Global Communications Inc., a company that sells phone numbers for more than 1,300 cities around the world. Customers would think they were calling England, while Mr. Kolowich and his employees would take the calls in California, according to the criminal complaint filed by the government.

Christine Brodeur, a spokeswoman for j2 Global, confirmed that Mr. Kolowich had an account, and said the company reserves the right to terminate service if it determines a customer is acting illegally. She says the company wasn't contacted by law enforcement regarding Mr. Kolowich.



In the first week his Web site was live, Mr. Kolowich says, he got 40 orders. He drove to Tijuana to buy what he says were Pfizer-made Viagra pills from a pharmacy, smuggling them back to San Diego in his Lexus. Mr. Kolowich says he was able to make bulk purchases without a prescription from a local Tijuana pharmacy. He had no license to prescribe or sell prescription drugs.

As business picked up in the first few months of 1999, Mr. Kolowich grew savvy about getting past border-patrol protocol. He says he stuffed the pills under the seat and floor mats -- every place but the trunk. A spokesman for U.S. Customs and Border Protection says that "every car, every person does undergo some level of inspection." But he adds that the high volume means "the officer has precious few seconds" sometimes for the inspection.

In his first year, Mr. Kolowich says, he had revenue of $985,000 from his Viagra sales. He then diversified, selling what he says were also real versions of weight-loss drug Xenical, painkiller Celebrex and hair-loss drug Propecia, bought in Mexico at pharmacies. Law-enforcement agents say that the drugs Mr. Kolowich sold were tested and though they contained some active ingredient, they weren't manufactured by pharmaceutical companies that had patented them.

Mr. Kolowich hired three employees for customer service and filling orders, and merged several sites he had built into one: WorldExpressRx.com. A growing number of U.S. customers, particularly those with college-campus mailing addresses, bought from the site. In his second year, he says, he brought in revenue of $3 million.

In early 2001, Mr. Kolowich got a big break when he read an article online about "generic Viagra" made by the Indian drug company Ranbaxy Laboratories Ltd., under the name Caverta. In the past, India hasn't recognized U.S. pharmaceutical patents, spawning a thriving industry in knockoff drugs.

Mr. Kolowich says he and a friend flew first class to Mumbai. Carrying $40,000 in cash, he says, he met with people at Ranbaxy who politely told him that the drug wasn't for export. But he says someone at the company gave him the name of a local wholesaler whom he met six hours later. He won't identify his tipster. A spokesman for Ranbaxy, informed of Mr. Kolowich's account, declined to comment on it and would only say, "Ranbaxy abides by all local laws, rules and regulations in all countries where it has operations."

Mr. Kolowich says he paid cash to the local wholesaler at 48 cents a pill -- well below the $7 a pill he was paying in Mexico. Online, he charged $13 a pill for his Mexican supply. Viagra sells for about $10 a pill when purchased through legitimate outlets. Back in the U.S., he planned to sell Ranbaxy's Caverta pills for $6.50 each, a 1,200% markup. He bought 80,000. The pills were red triangles, as opposed to Viagra's blue diamonds. He jammed them into two large suitcases.

Mr. Kolowich encountered some unexpected resistance on his India trip. It took him several weeks to negotiate the supply deal. The cash payment, he says, "was a red flag" to the wholesaler, who photocopied every U.S. bill he had brought and asked for a "one-page due diligence" document about his creditors. He passed himself off as a doctor, saying he had an online pharmacy on the side.

Then in Mexico City, on the way back to San Diego from India, customs officials opened his bag. When they discovered his Caverta pills, Mr. Kolowich says, he was swarmed by security. He showed them a business card from a Tijuana pharmacy. Because he couldn't communicate well in Spanish, Mr. Kolowich says, he engaged in charades to explain that the drugs were for impotence. He says some men took a small sample of the pills, disappeared for a while, and let him proceed after they returned. He then drove the drugs over the border to San Diego.

Gabriela Deffis Ramos, a spokeswoman for Mexican customs, said customs didn't have a record of the incident.

About that time, Mr. Kolowich says, he received six months' notice from the First Bank of Beverly Hills saying it would be terminating his account. According to the bank's Mr. Kiley, many banks were getting suspicious about online businesses after there were a number of high-profile scams. Banks had started requiring these businesses to carry high minimum balances, charging high fees for all transactions -- and sometimes cutting them off.

Mr. Kolowich quickly adjusted. He got Deutsche Bank in Munich and Bank of Montreal in Vancouver to take his accounts. Spokesmen for Deutsche Bank and Bank of Montreal declined to comment on the case. Realizing that other online pharmacies had similar banking difficulties, he set up a new business to help them out, according to law-enforcement agents. He would allow other online druggists to become "affiliates" of WorldExpressRx.com, and would then manage their accounts for them. He'd charge them a transaction fee as low as 5%, a big savings for the pharmacists paying up to 9% at mainstream banks. Mr. Kolowich says he invested $200,000 in software to handle the new financial side of his operation, and took in daily revenue on it of $50,000 to $60,000.

The drug side of the business was expanding sharply as well. He says the India supply line expanded and became the major source for his business, which advertised the Caverta pills as "generic Viagra." He made a second trip to India and sent a friend on a third, but eventually, he had his Indian drugs shipped to Mexico, and hired someone to smuggle them over the border. He says he paid about $1 million to people in Mexico for smuggling. A federal investigation later uncovered letters and wire transfers from an Indian-based company requesting Mr. Kolowich pick up his shipment in Mexico.

He had plenty of money left over to enjoy a lavish lifestyle. According to law-enforcement agents familiar with the case, he drove a leased Porsche with the license plate "BLU PIL." He says he drank $3,000 bottles of Bordeaux wine and fed a cocaine habit. "My whole life I always wanted to come up with an idea that would succeed, and here it was working," says Mr. Kolowich.

'Mark, It's Just Europe'

All the time his business expanded, Mr. Kolowich says, he wrestled with what he was doing. He was thrilled by a business success at last, but knew he was breaking the law. "I think I've unleashed a lion, the Internet's booming...I think I've got something pretty unique," he recalls feeling. "But I'm also doing something highly illegal." Mr. Kolowich had no license to sell or

import prescription drugs. Further, he didn't report income from his business. He told himself it was OK: "My inner voice said, 'Mark, it's just Europe.' "

When he expanded beyond Europe, and into the U.S., he still felt he was performing a service for his clients, an argument he stresses repeatedly in the prison interview. His customers, he says, frequently thanked him via email and phone calls. And he says that he never crossed the line to selling controlled substances, which he described as "dangerous drugs." Still, drugs sold without a prescription can pose serious health risks. For instance, patients taking nitrate-containing drugs such as heart medications shouldn't take Viagra, since the combination could cause a dangerous drop in blood pressure, according to a Pfizer spokesman.

In the fall of 2003, Mr. Kolowich told his girlfriend, Odette Pidermann, currently serving an 18-month sentence for crimes related to WorldExpressRx.com, he was getting out of the business by New Year's. In an interview last February before she began her prison sentence, Ms. Pidermann, who pleaded guilty to charges of conspiracy and mail fraud, said that she was drawn into the activities because of her relationship with Mr. Kolowich.

But "Jan. 1 came and went," he says, and instead of quitting, he only dove deeper into the illegal pharmaceutical world. Rather than just selling pills he purchased, he began negotiating a deal to manufacture his own knockoff pills in Mexico, according to the U.S. attorney's office in San Diego.

Mr. Kolowich's fate took a turn when a former employee of his firm happened to pawn a laptop. Law-enforcement agents familiar with the case say a person hired by the pawn shop to do the routine cleaning of the computer's hard drive notified authorities after discovering images of pills and other WorldExpressRx.com documents. That triggered an FBI investigation. According to the criminal complaint, law-enforcement agents also made several undercover purchases from Mr. Kolowich's site.

On March 22, 2004, Mr. Kolowich and his girlfriend landed at the San Diego International Airport, back from a ski vacation at a luxury resort in western Canada. Authorities trailed him as he got off the plane and walked through the airport. They arrested him and his girlfriend at the baggage carousel. They didn't resist.

"After the initial shock," says Mr. Kolowich, "it was a big relief."

Write to Heather Won Tesoriero at heather.tesoriero@wsj.com[2]

URL for this article:
http://online.wsj.com/article/0,,SB112536602276326345,00.html

Hyperlinks in this Article:
(1) http://online.wsj.com/article/0,,SB109209398946487014,00.html
(2) mailto:heather.tesoriero@wsj.com

Copyright 2005 Dow Jones & Company, Inc. All Rights Reserved

This copy is for your personal, non-commercial use only. Distribution and use of this material are governed by our **Subscriber Agreement** and by copyright law. For non-personal use or to order multiple copies, please contact Dow Jones Reprints at 1-800-843-0008 or visit **www.djreprints.com**.

Daily Health Policy Report

Email this story to a friend.
Print this story.
View entire Policy Report.

Prescription Drugs | 10 Canadian Pharmacies Apply to Nevada for Licenses To Sell Prescription Drugs to State Residents
[Aug 24, 2005]

Ten Canadian pharmacies have submitted applications to the Nevada State Board of Pharmacy seeking licenses to sell prescriptions drugs to state residents, officials said on Monday, the *AP/Nevada Appeal* reports (Bosshart, *AP/Nevada Appeal*, 8/23). Friday was the deadline to submit applications and a $500 filing fee. Louis Ling, general counsel for the pharmacy board, said he had expected no more than three applications (Ryan, *Las Vegas Sun*, 8/23). Under a state law that took effect July 1, Nevada residents will be able to purchase a 90-day supply of some medications from Canadian pharmacies through a state-run Web site (*Kaiser Daily Health Policy Report*, 6/22). The pharmacy board will review the applications at its Sept. 7 and Sept. 8 meetings. Ling and a pharmacy inspector will conduct on-site inspections of the approved pharmacies during the week of Sept. 19. Consumers should be able to order drugs from licensed pharmacies through the Web site by the end of September, Ling said (*AP/Nevada Appeal*, 8/23). The site will include links to the pharmacies' Web sites and provide information on how to order prescriptions from the pharmacies. State residents will be able to fax their prescription to the Canadian pharmacies to be filled. Keith Macdonald, executive director of the pharmacy board, said consumers could save up to 40% by buying reimported prescription drugs, but he also noted that generics usually cost the same in Canada as in the U.S. (*Las Vegas Sun*, 8/23).

HEALTH

A long-distance pharmacy

By Kelly Hartog August 21, 2005

Nathan Jacobson, founder of MagenDavidMeds.com, says that as long as medication prices in the U.S. remain unregulated, customers will seek pharmaceuticals abroad. Israel, he says, can provide them safely and efficiently.

As pharmaceutical prices within the United States continue to climb, many North Americans are turning to foreign countries to purchase their prescription medications at more affordable prices.

Some physically cross the border to buy them in Canada, while others are looking further afield to purchase their medications from online pharmacies.

Based at the Weizmann Science Park in Rehovot, MagenDavidMeds is providing Israeli medications at prices up to 70% lower than in the US, which does not regulate pharmaceutical pricing.

The company, which bears no relation to Israel's ambulance rescue service Magen David Adom, has been in operation for almost two years, and is the first Israeli-based online pharmacy network to provide prescription drugs to US residents.

It is the brainchild of 50-year-old entrepreneur Nathan Jacobson, who holds joint Israeli/Canadian citizenship. According to Jacobson, by the end of its first year in operation, MagenDavidMeds was receiving around 400 orders per day.

"I'd love to claim I was the person who came up with the idea of online pharmacies but that was started in Canada," Jacobson told ISRAEL21c. "But I'm close to some of the people who were involved with online meds in Canada. We took the Canadian model and replicated it."

In reality, it wasn't as easy as it sounds. To set up MagenDavidMeds, Jacobson retained an Israeli lawyer and a doctor and spent six months researching not only whether it was economically feasible, but whether it could also be done out of Israel legally. After the research was completed, the plan was presented to health minister Danny Naveh. "We got his support and then created an alliance with the Association of Independent Pharmacists of Israel and got them on board."

RELATED STORIES

Clinical trials? Do them in Israel!

'Breakthrough' drug proven effective against Parkinson's disease

RELATED SITES

Magen David Meds

SEAR

NEW

Registe
weekly
highligl
ISRAEL

Enter e

MOR

Stories

Israeli
asked
Founda
treatm

A long-

A priva
that at
worldw

All ISR
stories

Points

A big I

Overco
togethe

A legac

All ISR
of Viev

HEAL

Americ
Fellows

Americ
Soroka

Israel I
Biologi

BioIsra
Science

And MagenDavidMeds.com was born.

Customers can either order their prescriptions online or by fax by simply typing in the name and dosage of their drug, attaching the prescription from their physician, filling in a customer agreement form and customs declaration and paying either by electronic check or credit card. Orders are processed within 72 hours, and the medications arrive on the customers' doorstep within 2-3 weeks. It's that simple.

This leads to the question why other companies haven't jumped on the Israeli medication bandwagon.

"Money," responds Jacobson. "So far we don't have any other competition from Israel, because most people don't have the money to do this. It's a heavy investment. And it's all self-funded." But it's an investment, he says, that is well worth both his money and his effort.

"I love Israel and I can't say that in strong enough words," says Jacobson, who had a Jewish day school education in Canada. "I grew up living, eating, breathing, Israel."

So great was his love, that as soon as he turned 18, he moved to Israel just so that he could join the Israeli Army. His stay was cut short when he had to return to Canada after he completed his army service because his father was very ill, and he remained. Yet to this day, he still retains strong ties to the country, including owning a home in Tel Aviv.

"I sit on the board of the Tel Aviv Foundation and was recently approached to join the board of the Meir Medical Center in Kfar Saba," he says.

It's this personal connection to Israel that makes MagenDavidMeds' mission two-fold; not only to provide affordable prescription drugs, but also to support the country.

Two percent of all gross sales at MagenDavidMeds are donated to the Israel non-profit charity Aleh Negev, which provides medical and rehabilitative care for severely disabled children. And MagenDavidMeds also helps independent pharmacists in Israel by helping them do business.

"They're being beaten up by large chains, and the local neighborhood pharmacies are being wiped out," says Jacobson.

While MagenDavidMeds is marketed heavily towards the Jewish community, particularly those who want kosher medications, or simply wish to support Israel, the network also has non-Jewish purchasers.

SUP
ISR
with a
contri

Look through the Internet and you'll discover what appear to be "other" online companies providing medications from Israel, including CanadaMeds, CrossBorderMeds and TotalCarePharmacy. They are, in fact, MagenDavidMeds.

"These are also our sites," says Jacobson "which focus heavily on promoting the safety and security of Israeli medications as well as the prices of the Israeli medications.

"Israel has the safest drugs in the world," he states proudly. "It needs to, in the same way unfortunately that El Al has to be the safest airline in the world. So Israel's packaging is the safest packaging against counterfeiting and tampering." Safety, naturally, is a key concern of customers when it comes to buying medication online.

Jacobson says the network is growing every month. "We're very successful and I'm thrilled." He credits his success to what he terms "doing the job properly. We take care of our clients, we have professional customer support, and a very good Website."

Another huge feather in MagenDavidMeds' cap is that the network has worked closely with the Israeli Postal Authority. "We're their largest client," says Jacobson. "We've been able to convert their system to English for our patients to track their medications online during the shipping process."

Jacobson sees no reason why the purchase of online medications from Israel will slow down as long as the pharmaceutical companies still retain a powerful lobby in the US and can block regulation of pharmaceutical prices. In fact, he's already looking for ways to expand.

"I recently had a senior representative of the African-American community in the US come to me to talk about creating a specific African-American site for Israeli medications," he says.

In the meantime, MagenDavidMeds is continuing to thrive, and while Jacobson runs several other successful businesses, this one is very close to his heart. "I wanted to have a reason to spend more time in Israel," he says. "And this was an opportunity that allowed me to do so."

Kelly Hartog is a free-lance writer based in Los Angeles.

PRINTER FRIENDLY VERSION

EMAIL THIS TO A FRIEND

TALKBACK! RESPOND TO THIS ARTICLE

Daily Reports

Daily Health Policy Report

Daily HIV/AIDS Report

Daily Reproductive Health Report

First Edition

Email Alert Sign-Up

Search All Daily Reports Archives

e.g. Prescription Drugs
Quick Search

Site Search

Daily Health Policy Report

Email this story to a friend.
Print this story.
View entire Policy Report.

Prescription Drugs | Prescription Drug Names in U.S., Abroad Lead to U.S. Consumers' Confusion When Buying Medications in Other Countries
[Aug 16, 2005]

The *Wall Street Journal* on Tuesday examined a safety alert issued by the not-for-profit Institute for Safe Medication Practices identifying several drugs in the U.S. that have the same name as drugs with different ingredients sold by other manufacturers on the global market. Problems can arise when travelers refilling prescriptions abroad or U.S. residents importing less-expensive medications get the wrong drug, possibly causing unexpected drug interactions or delayed treatment. No regulatory body exists to track brand names globally, but the World Health Organization works to match generic drug names with standardized International Nonproprietary Names. FDA has the authority to approve drug names only in the U.S. but acknowledges that the conflicts can exist abroad. The international drug name problem came to light recently after a Michigan man was hospitalized following a trip to the former country of Yugoslavia during which his prescription for hypertension drug Dilacor XR was mistakenly refilled with the Serbian version of Dilacor, which is a heart-failure drug. Because of the large number of drugs worldwide, the problem of identical or similar brand names is likely to grow, according to the *Journal*. The U.S. market includes 10,800 brand-name and generic drugs, according to the Pharmaceutical Research and Manufacturers of America. Some experts believe hundreds of thousands of drugs exist worldwide. In order to address the drug name issue, companies, hospitals and doctors can use consulting references books such as "Martindale: The Complete Drug Reference" or electronic databases such as Micromedex, but those references might not be exhaustive or up to date, according to the *Journal* (Chase, *Wall Street Journal*, 8/16).

Daily Health Policy Report

Email this story to a friend.
Print this story.
View entire Policy Report.

Prescription Drugs | Generic Medications More Expensive in Canada Than in U.S., Research Suggests
[Aug 09, 2005]

The *Los Angeles Times* on Tuesday examined the prices of generic prescription drugs in Canada and the U.S. Various research shows that, while brand-name prescription drugs are usually cheaper in Canada than in the U.S., generics are usually more expensive in Canada than in the U.S., the *Times* reports. An HHS study of five popular generic medicines found that U.S. prices for generic drugs were about 32% lower than Canadian prices. In addition, a study released earlier this year by the Fraser Institute -- a Toronto-based public policy organization that opposes price controls on brand-name drugs -- found that Canadian prices were an average of 78% higher than U.S. prices for the 100 top-selling generic drugs and that Canadians could save $2 billion to $5 billion annually if the Canadian generic market was as competitive as the one in the U.S. Brett Skinner, director of pharmaceutical and health policy research for the Fraser Institute, said U.S. generics are generally cheaper than Canadian generics because there is more competition in the generics market in the U.S. According to Skinner, it is difficult for foreign generic competitors to enter the Canadian market because of government drug-approval regulations. He said, "We have very few companies competing for sales -- two companies take up nearly 70% of the market for the top 100 drugs." The reimbursement policies in Canada's provinces also inflate prices, Skinner said. Many U.S. consumers are unaware that generics are more expensive in Canada, and they might be spending more than $100 million annually on Canadian generic drugs, Skinner estimates. Tom McGinnis, director of pharmacy services for FDA, said, "We have a feeling that there is a lot of misconception that everything outside the United States is cheaper" (Alonso-Zaldivar, *Los Angeles Times*, 8/9).

Daily Reports
THE COMPREHENSIVE SOURCE

Daily Health Policy Report

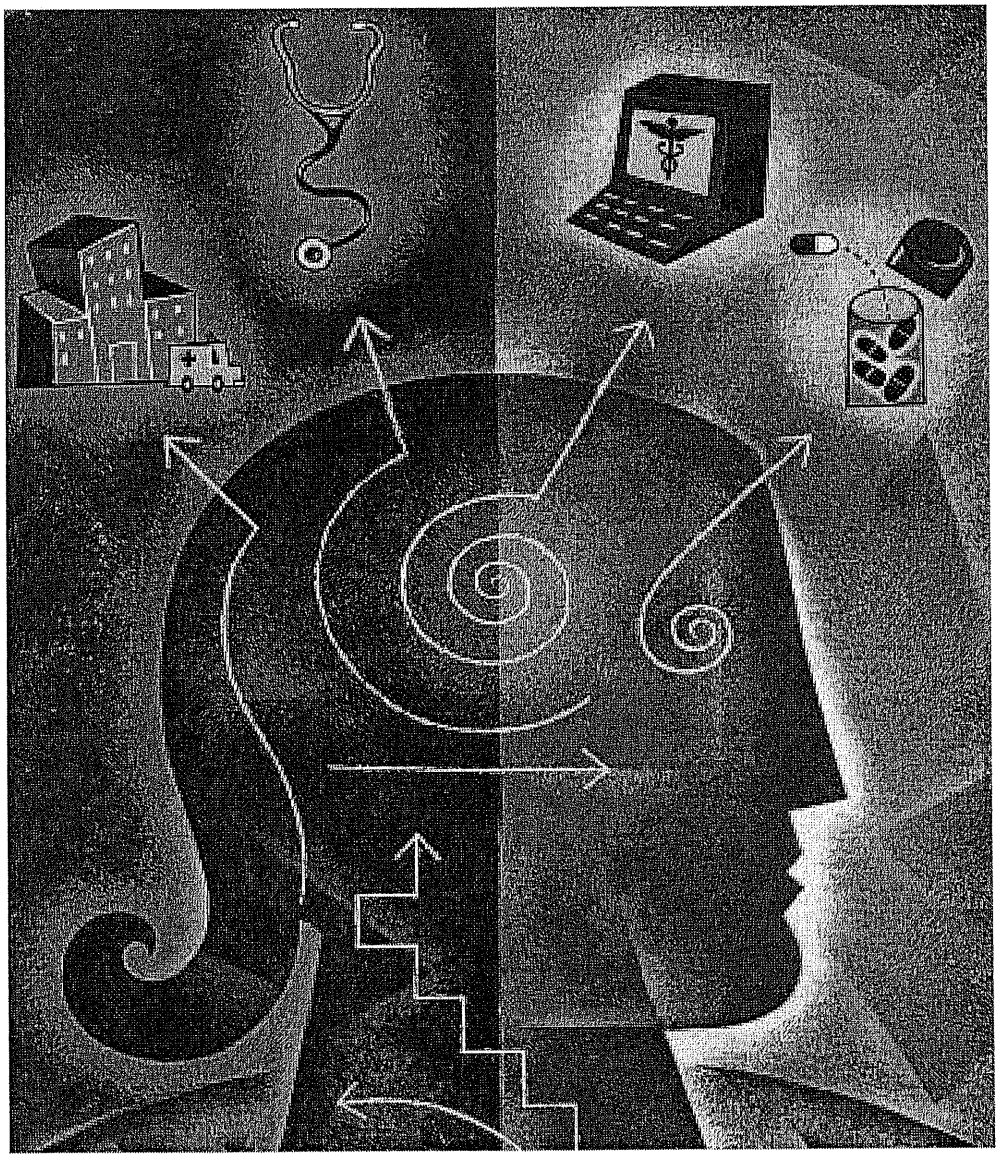
Email this story to a friend.
Print this story.
View entire Policy Report.

Prescription Drugs | Frist To Allow Senate Floor Vote on Vitter Prescription Drug Reimportation Bill
[Jul 28, 2005]

Senate Majority Leader Bill Frist (R-Tenn.) has agreed to hold at least one floor vote on a bill (S 109) sponsored by Sen. David Vitter (R-La.) that would allow the purchase of lower-cost prescription drugs from other nations, *The Hill* reports (Young, *The Hill*, 7/27). The legislation is identical to a companion bill (HR 328) introduced in the House by Rep. Gil Gutknecht (R-Minn.) in January and a revised version of legislation that Gutknecht sponsored in 2003. The original bill would have allowed U.S. pharmacists to import prescription drugs manufactured in 25 industrialized nations, provided that the medications are manufactured by companies that use counterfeit-resistant technologies and that the companies have registered their production operations with FDA (*Kaiser Daily Health Policy Report*, 3/30). According to *The Hill*, Vitter earlier this month agreed to lift a hold on the confirmation vote for FDA Commissioner Lester Crawford "only after he was satisfied that Frist would not block his efforts to move legislation on drug imports." Vitter said that the vote on the bill likely will occur this fall as a proposed amendment to the fiscal year 2006 agriculture appropriations bill, which funds FDA. According to Vitter, Frist said that he would "work in good faith" to hold a separate debate and vote on Vitter's bill in the event the amendment receives more than 60 votes in the Senate; lawmakers likely would remove the amendment from the larger bill in conference. Vitter said that the amendment likely would receive 60 votes, adding, "Reimportation, in general, has clear majority support." He added that Frist did not specify when the debate would occur. Amy Call, a spokesperson for Frist, said that he did not make an "absolute commitment" to hold debate on the Vitter bill but would "work in good faith to find floor time" (*The Hill*, 7/27).

ATTACHMENT D

CALIFORNIA
HEALTHCARE
FOUNDATION



E-Prescribing

ihealthreports

Prepared by First Consulting Group
November 2001

E-Prescribing

Prepared for:
CALIFORNIA HEALTHCARE FOUNDATION

Prepared by:
Peter Kilbridge, M.D.
with assistance from Katy Gladysheva
First Consulting Group

ihealthreports

November 2001

Acknowledgments

First Consulting Group is a leading provider of information-based consulting, integration, and management services to health care, pharmaceutical, and other life sciences organizations in North America and Europe. Advancing from an early focus on health care systems, FCG has expanded its service offerings to meet the complex needs of all the major sectors in an increasingly sophisticated health care marketplace.

The authors would like to acknowledge the assistance of the following individuals who agreed to be interviewed for the report: Rita Amalfitano of The Medical Group, Beverly, Massachusetts; Dr. Andrew Barbash of Mid-Atlantic Permanente Medical Group; Dr. Shahe Komshian of San Jose Medical Group, San Jose, California; and Cheryl Norris of Kokomo Family Care Clinic, Kokomo, Indiana. They would also like to thank the Institute for Safe Medication Practices for information on state regulations on e-prescribing and Erica Drazen and Jane Metzger of Emerging Practices for their review and suggestions.

The **California HealthCare Foundation**, a private philanthropy based in Oakland, California, focuses on critical issues confronting a changing health care marketplace by supporting innovative research, developing model programs, and initiating meaningful policy recommendations.

The iHealth Reports series focuses on emerging technology trends and developments and related policy and regulatory issues.

Additional copies of this report and other publications in the iHealth series can be obtained by calling the California HealthCare Foundation's publications line at 1-888-430-2423 or visiting us online at www.chcf.org.

ISBN 1-929008-77-5
Copyright © 2001 California HealthCare Foundation

Contents

5 **Overview**

7 **Purpose**

9 **I. What Is E-Prescribing?**
The Potential Benefits
Requirements for Physician Adoption of E-Prescribing
Perceived Value of the System
Affordability

16 **II. Business Models for E-Prescribing**
Eight Principles of Business Models
Sponsorship-Based and Transaction Fee-based Models

19 **III. Operational Considerations of E-Prescribing**
E-Prescribing and the Prescription Management Process
Operational Issues for the Large Practice
Security, Confidentiality, and HIPAA Rules

28 **IV. Technology: Applications**
Ambulatory Medical Record Systems
Mobile E-Prescribing
E-Prescribing Applications

33 **V. Technology: Hardware, Software, and Operating Systems**
Devices and Operating Systems
Connectivity: PC and Network Connections for the PDA

37 **VI. Future Challenges and Emerging Patterns**

39 **Appendices**
Appendix A: Representative Vendors Offering Mobile Electronic Prescribing
Appendix B: Glossary

43 **Endnotes**

Overview

ELECTRONIC PRESCRIBING (E-PRESCRIBING) IS the use of an automated data entry system to generate a prescription, rather than writing it on paper. Automation of the outpatient prescribing process has many potential benefits to different health care stakeholders. Patients and physicians benefit from:

- Improved patient safety, through generation of legible prescriptions that have been checked by the computer for possible harmful interactions;
- Better formulary adherence, through checking against health plan formularies at the point of prescribing;
- Streamlined communication of prescriptions to pharmacies, resulting in receipt of clean, legible, formulary-adherent prescriptions, thus reducing calls back to physician offices to clarify inconsistencies; and
- Improved patient satisfaction, through rapid prescription fulfillment and fewer errors.

Pharmaceutical companies, health plans, pharmacy benefit managers (PBMs), and employers can benefit as well. Pharmaceutical companies seek data on physician prescribing habits, as well as opportunities to market directly to physicians using new technologies. Health plans and PBMs are looking for new ways to control drug expenditures through improved adherence to formularies; they want to use physician prescribing data to improve their products and services. Pharmacies and PBMs benefit from process efficiencies associated with clean, accurate prescriptions.

Technologic advances, particularly new handheld devices with user-friendly interfaces, and wireless network technologies offer new approaches to encouraging physician adoption of computers. A number of vendors have developed e-prescribing software applications for these devices, which they are marketing to physician practices. Most such vendors base their revenues on sale of information to third parties, or on transaction-based charges to pharmacies, PBMs, and physicians. To date, physicians have been asked to pay modest fees for the use of these systems. Applications typically perform formulary and drug-drug interaction checking. Increasingly, applications are being bundled with other clinical applications such as charge capture, laboratory ordering and results viewing, and dictation.

Although experience to date is limited, many physicians who have tried e-prescribing are satisfied with the benefits they have enjoyed. Most commonly cited are improved efficiencies associated with decreased call-backs from pharmacies. The advantage of safer prescribing and patient satisfaction associated with increased convenience are also mentioned. Experienced users list the following as important success factors for implementation of e-prescribing: Cultivate and use an enthusiastic physician champion to promote adoption; implement functions incrementally and sequentially, rather than all at once; consider reducing physician workload during the initial implementation phase; and keep the system simple to use.

E-prescribing can also be performed using ambulatory electronic medical record systems (AMRs), which offer several advantages, including a more robust database of patient information available at the point of prescribing. The disadvantages are system cost, complexity, and far greater difficulty of implementation, compared with mobile prescribing systems.

In spite of the apparent benefits of e-prescribing, these systems have been slow to gain popularity with physicians. Possible reasons for this include the difficulty of marketing to the large percentage of practitioners in small and medium-size practices; physician skepticism about the actual value delivered by e-prescribing; technology market instability; and physicians' desire for a broader range of functions before changing their workflow to accommodate mobile computing.

Early experience indicates that the benefits of e-prescribing are real, and outweigh the costs of implementation. It seems likely that e-prescribing is here to stay; the rate of adoption is less certain and will depend upon a multitude of factors.

Purpose

PRESCRIBING MEDICATION IS THE PHYSICIAN'S most frequently used, efficacious, and potentially dangerous therapeutic tool, outside of surgical intervention. The proper or improper use of prescription drugs has a profound effect on patient outcomes, and, because prescription drugs are expensive, the physician's selection of drugs has a major impact on the cost for hospitals and health plans. These same costs generate the vast revenue streams that support pharmaceutical companies—the world's most profitable industry. Thus, management of prescription medications directly or indirectly affects every stakeholder in health care.

The prescribing process is an important component of workflow in every physician practice and hospital unit. But the traditional approach to medication management is inefficient and error-prone, entailing six basic processes: selecting a drug; checking for allergy, drug-drug, and other interactions; checking formulary; handwriting prescription; and mailing or giving the paper prescription to the patient for hand-carrying to the pharmacy.

Several industry trends are converging to create interest in utilizing new technologies to improve the prescribing process. The technologic advances include Web technologies and business models, handheld devices with user-friendly interfaces, and wireless network technologies, all of which offer new approaches to encouraging physician adoption of computers. At the same time, industry-wide concern about patient safety—in the wake of the 1999 Institute of Medicine report "To Err Is Human"—has spurred interest in employing technologies to simplify and enhance the safety of the prescribing process. Rapidly increasing costs of prescription drugs are prompting health plans to seek new approaches to improving formulary adherence among physicians. Pharmaceutical companies are seeking new avenues to reach physicians for advertising purposes, and drug companies and others seek access to data on physician prescribing patterns.

As a result of these trends, there is a high level of industry interest in the topic of electronic prescribing. Yet what exactly "electronic prescribing" (e-prescribing) means depends on whom you ask. In addition, different parties perceive different benefits from e-prescribing, making the construction of a coherent business model around the process challenging.

The purpose of this report is to clarify the concept of e-prescribing and examine its status in practice today—how it is used; business considerations of different parties; obstacles to adoption; and prospects for the future.

I. What Is E-Prescribing?

FOR THE PURPOSES OF THIS REPORT, E-PRESCRIBING is defined as "Entering a prescription for a medication into an automated data entry system (handheld, PC, or other), and thereby generating a prescription electronically, instead of handwriting the prescription on paper." A typical scenario for e-prescribing is shown in Figure 1 on the following page.

This definition does not specify the nature of the data entry device or software or the extent to which the prescription is communicated electronically beyond the walls of the physician's office.

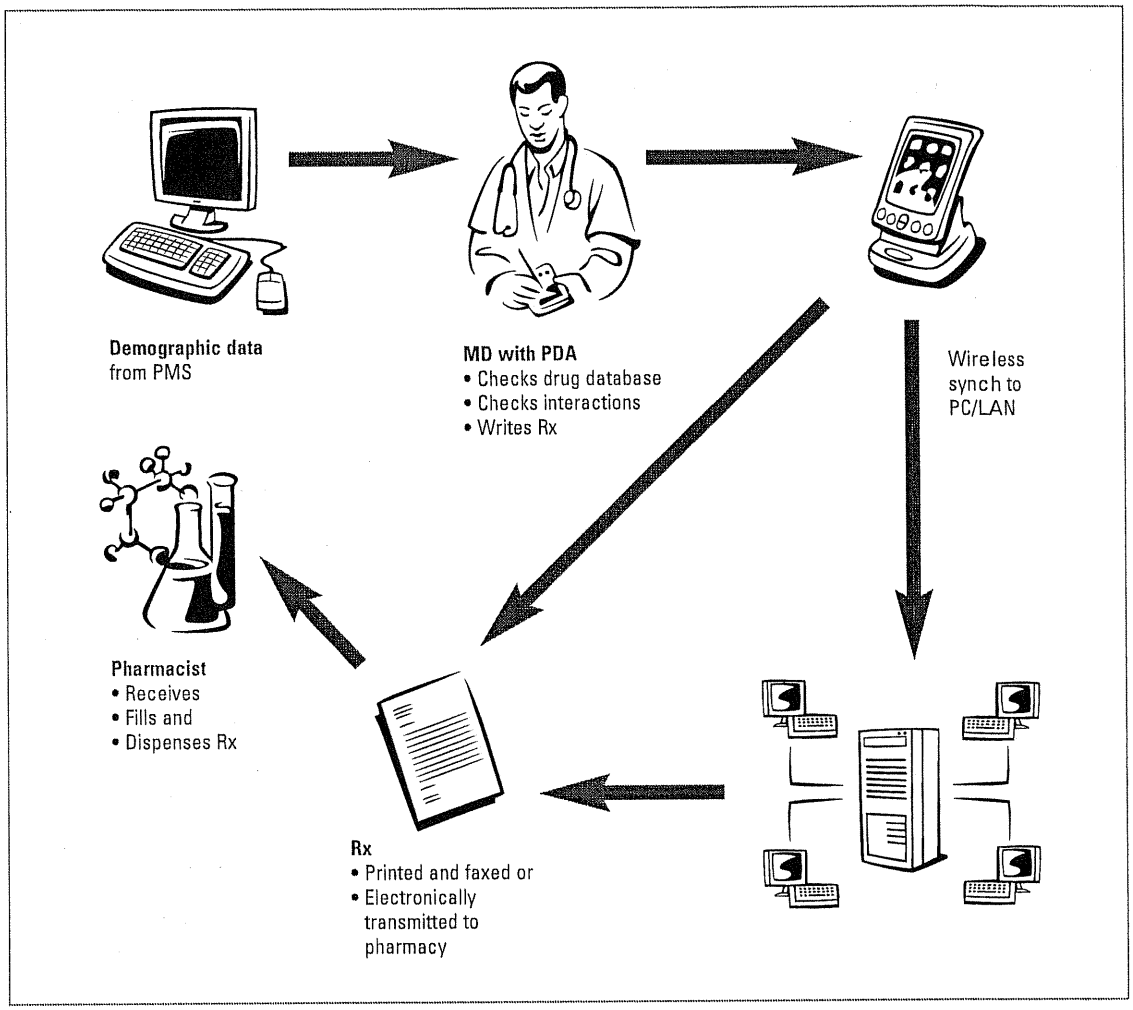
While the definition does not specifically exclude inpatient electronic prescribing (intentionally, as ideally the processes for prescribing in inpatient vs. outpatient settings would be identical), this report concentrates on electronic prescribing in the outpatient setting for three reasons. First, at present the two prescribing processes are entirely different in terms of physical setting, workflow, organizational entities (hospitals vs. retail pharmacies), and information requirements. Second, the important topic of electronic prescribing in the inpatient setting has been discussed at length in a previously published *Primer on Physician Order Entry*.[1] Finally, the ambulatory environment is the focus of industry interest in e-prescribing today.

At present, e-prescribing in the ambulatory setting occurs in two principle forms: using handheld devices loaded with e-prescribing software, or using ambulatory electronic medical record (AMR) systems, which can be done on a PC or, in some cases, on a handheld device. Both technologies are discussed, although the mobile prescribing model is emphasized, as this is where there is the greatest amount of activity at present.

The Potential Benefits

Given the complexities and inefficiencies inherent in the traditional approach to prescription management, it is not hard to imagine potential benefits from automation. In the best conceivable scenario, improvements in efficiency, accuracy, and appropriateness of medication prescribing would yield a variety of benefits to patients, physicians, and payers. In addition to potentially improving current processes, electronic prescribing introduces new potential sources of value to some parties, such as "e-detailing" to physicians by pharmaceutical companies.

Figure 1. Typical E-Prescribing Scenario



Benefits to Patients

First and foremost, patients stand to benefit from the enhanced safety of the medication management process afforded by e-prescribing (see Figure 2, page 14). In the inpatient setting, automated prescribing has been shown, when properly implemented, to reduce medical errors and adverse drug events.[2a, 2b] In the outpatient setting adverse drug events are a frequent cause of hospital admission and morbidity.[3] A movement championed by the Institute for Safe Medication Practices, calls for the universal adoption of e-prescribing and the abandonment of handwritten prescriptions by the year 2004,[4] for the improvement of prescribing safety.

In the ideal scenario, prescriptions would be checked against a patient's current medications, allergies, diagnoses, body weight, and age for possible interactions, appropriateness, and dosage. Prescriptions would be legible, and patient information about their medications, including indications, properties, side effects, and instructions for administration, would be dispensed with the medication. The e-prescribing system would build and maintain a permanent record of the patient's medication history over time. Patient adherence to medication regimens could potentially be improved through closed-loop communication of refill data to payers and physicians.

Patients would benefit from improved efficiencies as well. Prescriptions would be sent electronically to the patient's pharmacy of choice by secure electronic connection and would be available for pickup upon the patient's arrival. Alternatively, prescriptions for chronic care drugs would be communicated automatically to the mail order pharmacy. Automated formulary checking would ensure that patients received drugs on their health plan or PBM formulary whenever possible, reducing costs to patients.

Benefits to Physicians

Physicians would benefit from an effective e-prescribing system in several ways. The increased safety and accuracy of the prescribing process created by improved access to data and clinical decision support would serve to enhance physician satisfaction and peace of mind. Financial benefits could accrue as well, as malpractice insurers offered discounted premiums for use of such systems. Perhaps the greatest benefit to physicians would come in the form of enhanced efficiencies gained by reducing the number of call-backs from pharmacies—regarding illegible prescriptions, non-formulary medications, potential drug interactions, incorrect dosages, renewal requests, and the like. One industry estimate holds that pharmacists make 150 million calls a year to physicians to clarify prescriptions.[5] Greater patient satisfaction would also enhance physician satisfaction and improve patient retention.

Benefits to Health Plans and Pharmacy Benefit Managers (PBMs)

Health insurers and PBMs would benefit through financial savings associated with better formulary adherence, less therapeutic duplication, and reduction in incurred costs associated with adverse drug events. In addition, they could benefit through improved access to data on physician prescribing patterns and patient medication profiles, which would support better medical and formulary management programs. They would also benefit from higher patient satisfaction and retention and improved patient adherence to therapeutic regimens.

What's Good for GM Really Is Good for America!

Like health plans and pharmaceutical companies, large employers have begun taking an active interest in e-prescribing. Since the release of the 1999 IOM Report "To Err is Human," which set out the costs of medical errors in human and financial terms, these influential stakeholders have been championing patient safety.

The Leapfrog Group, a coalition of large employers, is establishing incentives for hospitals to implement computerized physician order entry as a means of reducing medication errors. General Motors, a prominent Leapfrog purchaser—and the largest private health insurance purchaser in the country—is going farther. GM will work with an Internet medical records company, Medscape, to share the costs of providing mobile e-prescribing systems to 5,000 Medscape physician users who care for GM employees, in the interests of improving safety and curbing prescription drug costs. The company, with 1.2 million workers and retirees, spends $1 billion annually on prescription medications.

The system, Medscape Mobile, will permit access to patients' electronic medical records at the point-of-care, as well as performing e-prescribing. The initial pilot project will provide data for Medscape and GM to analyze prescribing patterns and medication safety. GM and Medscape will share the cost savings accruing from the use of the system.[6]

Benefits to Pharmaceutical Companies

The chief opportunities for pharmaceutical companies to realize value from e-prescribing include an alternative route for access to physicians for detailing and access to physician prescribing data for use in marketing and sales planning. In addition, improved patient adherence to medication prescriptions would directly increase revenues from drug sales.

Other parties stand to gain as well: Employers could benefit from reduced health care costs and healthier, more satisfied workers; medical risk (malpractice) insurers could benefit from reduced claim losses; and Internet pharmacies could continue to thrive on e-prescriptions. Some of these benefits are summarized in Table 1.

Table 1. Potential Benefits of E-Prescribing

BENEFIT	Description	Mechanisms	Benefactors
Improved Safety of Prescribing Process	Reduced adverse drug events due to safer prescriptions; results in less harm to patients and lower costs of care	• Complete, legible prescriptions, properly formatted • Prescriptions checked for drug-drug, drug-allergy, drug-disease interactions • Prescriptions checked for proper dose for age, weight	• Patient • Physician • Health plan • Employer • Malpractice insurer
Reduced Costs Through Improved Efficiencies	Automated prescribing process results in greater accuracy, fewer inconsistencies, better adherence to intended course of therapy and formulary restrictions	• Fewer pharmacy call-backs to physicians to clarify prescriptions, formulary issues • Savings to plans, PBMs, and patients through better formulary adherence • Greater convenience to patients: prescriptions ready for pickup upon arrival at pharmacy	• Physician • Pharmacy • Health plan • PBM • Patient
Improved Sales, Marketing	E-detailing; access to prescribing data	• E-detailing enhances access to physicians for pharmaceutical companies; • Prescribing data facilitates better marketing planning	• Pharmaceutical company • Health plan • PBM
Improved Product Design	Access to physician prescribing data, patient medication data	• Data permit better medical management, formulary management	• Health plan • PBM

Requirements for Physician Adoption of E-Prescribing

For e-prescribing to provide value to anyone, physicians must use the systems, and the systems must, in turn, deliver the functions that enable realization of the benefits above.

Physician adoption of e-prescribing systems depends, in turn, on three principal requirements: fit with practice workflow, provision of perceived value to the physician, and affordability. In other words, the system must be useable without incurring significant inconvenience; it must be perceived by practitioners as better in some way than what they have now; and it must be inexpensive.

Workflow Considerations

The system's fit with physician workflow has implications for hardware and system software functionality. E-prescribing applications should have user-friendly interfaces (easily navigated screens, menus, etc.), and should offer as much patient-specific data as is practical to the prescribing physician. At a minimum this includes basic patient demographic data (name, date of birth, address, medical record number, insurance information). Such data should be automatically imported into the e-prescribing application from the office practice management system (PMS). This can be done on a daily batch basis, based on the physician's office schedule for the day.

The choice of device has implications for workflow as well. Small handheld devices are more convenient to carry and handle than the larger, tablet-type devices or PCs. The method for communication between mobile devices and other systems is also an important consideration. For example, devices that require synchronization by docking with networked cradles are less convenient than ones that synchronize continuously via wireless local area network (LAN) technology. These considerations are further discussed in the section on technology, page 28.

Perceived Value of the System

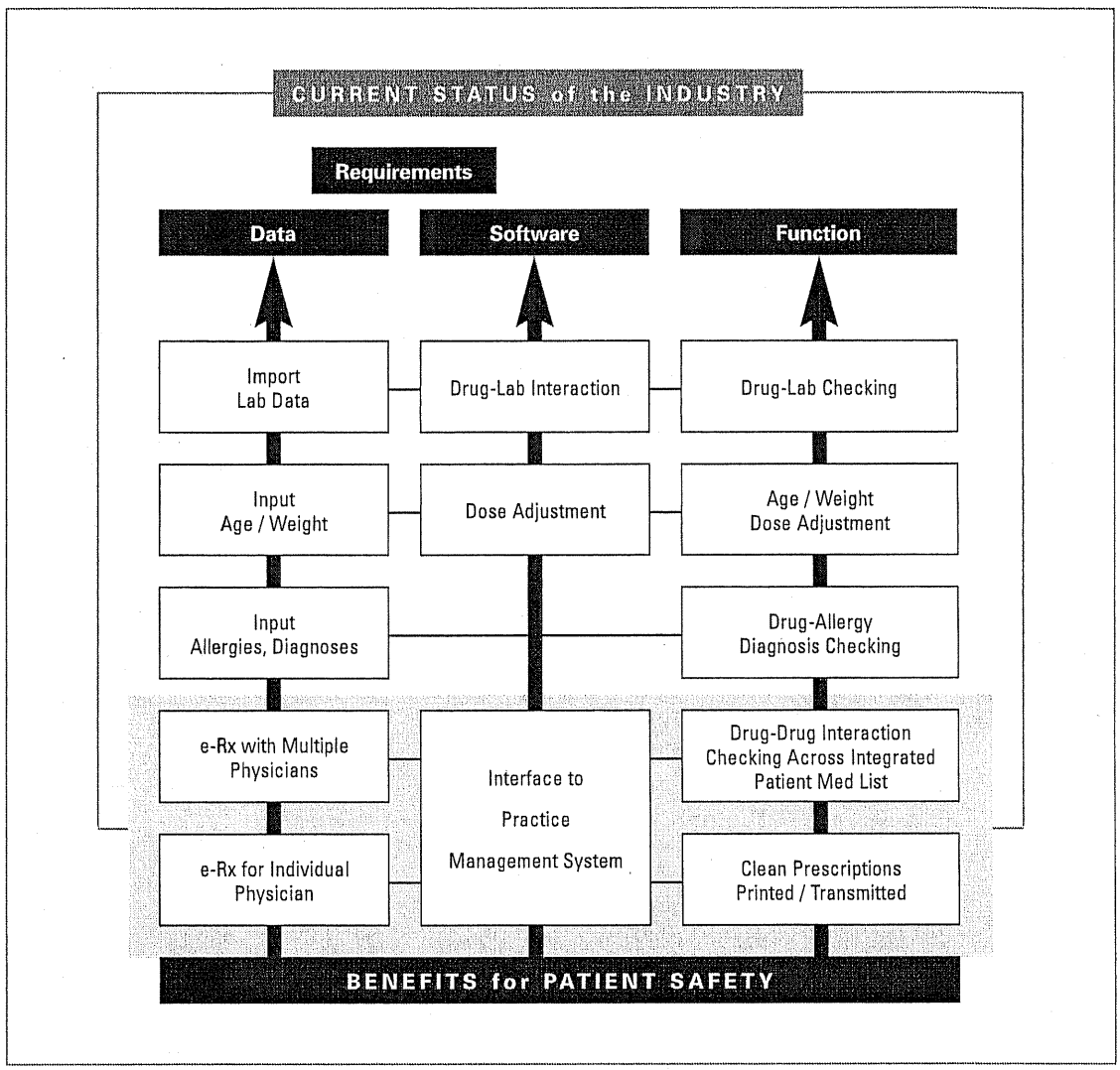
Better data availability and clinical decision support for prescribing depend on the functionality of the particular e-prescribing application in use. Databases accounting for the majority of managed care formularies in the United States are available and widely used by mobile prescribing vendors, making formulary checking generally straightforward.

Virtually all of today's e-prescribing applications offer extensive menu-driven drug databases and perform, at a minimum, drug-drug interaction checking. The ability to detect drug-drug interactions presupposes that a patient's previous and still-current medications were prescribed through the same application and are, therefore, recorded in the system database. Often this is not the case, as patients frequently receive prescriptions from different physicians, who may work in different practices and, therefore, do not use the e-prescribing system. In addition, different vendor systems vary in the length of time they retain prescribing data before purging them.

The ability to perform drug-allergy and drug-diagnosis checking is dependent on the ability to enter these data types into the system. Some vendors require entry of diagnosis or allergy information prior to prescribing; others do not have such functionality. Dose adjustments based on age and weight are not commonly possible with today's applications; such functions are particularly important in working with pediatric and elderly populations, and could contribute further to prescribing safety.

Most mobile e-prescribing systems in use today are implemented so as to print prescriptions locally at the physician office, to be handed to the patient, or to fax prescriptions to the patient's pharmacy. Few prescriptions are sent electronically, for a variety of reasons. First, some states prohibit transmitting prescriptions electronically, although it is generally believed that these barriers will be eliminated in the near future.

Figure 2. Improved Patient Safety with E-Prescribing



(see box on state regulations, on the following page). Second, many physician offices are not yet prepared to send electronic prescriptions to pharmacies, nor are some pharmacies able to receive them. Finally, concerns about security and confidentiality remain unresolved. Recent efforts to develop an electronic prescribing exchange may remove some of these barriers.[11] In the meantime, cleanly printed or faxed prescriptions should remove much of the inefficiency of the current manual prescribing process and, thus, yield many of the benefits of convenience to physicians.

Other kinds of functions may appeal to physicians as well. Applications increasingly being bundled with e-prescribing include charge capture (which enhances revenue capture), laboratory and diagnostic test ordering, and results lookup online. Preliminary evidence suggests that most mobile prescribing vendors are moving in the direction of offering multiple applications as a package; this could serve to accelerate physician adoption of e-prescribing systems.

State Regulations on Electronic Prescriptions

Currently, 11 states have laws prohibiting electronic transmission of prescriptions; two states plus the District of Columbia don't even allow electronic faxing of prescriptions. But that's just the tip of the complexity iceberg of state-by-state regulation of electronic prescribing.

Below is a snapshot of the current state of regulations, as of March 2001, and it's certain to change quickly. For example, New Jersey is currently working to change its laws to legalize e-prescriptions.

- Eleven states prohibit e-prescription transmission from both in-state and out-of-state prescribers: the District of Columbia, Georgia, Idaho, Maine, Maryland, Nebraska, New Jersey, New Mexico, South Carolina, South Dakota, and Vermont.
- Four states allow electronic transmission of prescriptions with the exception of certain drug types:
  - Kentucky, Texas, and Wisconsin: No Schedule II substances
  - New York: No controlled substances
- Three states allow electronic transmission from in-state prescribers only: Hawaii, Wisconsin, and Arizona (for AZ, electronic transmission of information is permitted, but a hard copy must be received by the pharmacy).
- Electronic transmission of prescriptions from both in-state and out-of-state prescribers is not addressed by state legislation in Alabama, Alaska, Guam, Montana, Oregon, Pennsylvania, Puerto Rico, Rhode Island, and Wyoming.
- Electronic transmission of prescriptions from out-of-state prescribers only is not addressed in state legislation in Arizona and Utah (in-state transmission is specifically permitted).
- Three states limit faxing of prescriptions. In Vermont and the District of Columbia, neither phone nor electronic faxing of prescriptions is allowed; Alabama permits only phone faxing of handwritten prescriptions.

Source: [8, 9, 10, 11]

Affordability

Physicians whose practices do not generate significant profits have been loath to invest substantial capital in new information systems that are not absolutely essential to their operations. While e-prescribing vendors differ in their approach to licensing fees for physicians, no mobile prescribing vendors in the market at the time of this writing (as distinct from ambulatory medical record products that include e-prescribing) charge in excess of $250 per month per physician, and some products are offered free of charge.

II. Business Models for E-Prescribing

THE PHYSICIAN USER BASE IN THE PRACTICE OF electronic prescribing is still small.[12] According to a recent study, four to seven percent of physicians are currently generating prescriptions electronically, with 25 percent interested in doing so in the future. Allscripts, an e-prescribing vendor with one of the largest user bases, reports having 15,000 physician users as of February, 2001.[13]

The current user market is divided across the products of a handful of e-prescribing vendors. Appendix A lists some of the more prominent companies at the time of this writing. New vendors continue to appear. The low level of market penetration implies significant opportunity for vendors—both established and emerging—to gain large numbers of new users. While the availability of venture financing has declined significantly in the past year, and while it is likely that a market shakeout will eventually result in the dominance of a small number of companies, at the time of this writing, the dominant feature of the market is that of opportunity.

Vendors of e-prescribing applications are attempting to leverage combinations of benefits to different parties in such a way as to provide value to all and generate revenues for themselves. To be successful, they must cobble together coalitions to provide the up-front capital infusion required to establish a user base, and providing the necessary functionality to those users to ensure payback to investors and revenues for the vendor. This is proving to be a tricky task.

Eight Principles of Business Models

Following are some of the principles, or assumptions, that underlie today's e-prescribing business models:

1. ***While the physician is the target user of e-prescribing systems, he or she is not the paying client.*** Most vendors believe that physicians will not pay the full cost of e-prescribing systems, and therefore cannot be counted on as a significant revenue source. Some vendors believe that physicians must make a token investment in the system—in the range of $50 to $200 per-month, per-physician—in order to increase their commitment to making the system work.

2. ***Ability to improve formulary adherence is valuable to health plans and PBMs.*** Managed care organizations that bear the risk for medication costs can realize substantial savings by improving physician use of preferred medications. In addition, many health systems and IPAs with at-risk medication contracts also benefit from better formulary adherence.

3. ***Access to physicians (face time or screen time) is valuable to pharmaceutical marketers.*** Pharmaceutical companies spent $4.3 billion on physician detailing in 1999.[7] Recent studies indicate that electronic detailing (e-detailing) over the Internet is far more cost effective than print advertising.

4. ***Aggregate data on prescribing patterns are valuable to multiple parties.*** Pharmaceutical companies pay large amounts of money for industry prescribing data for use in marketing and sales development efforts. In addition, health plans and PBMs could benefit from having such data on their members, as it would assist in product design, medical/disease management, and other business and care improvement activities.

5. ***E-prescribing can improve patient adherence to medication regimens, which translates to increased sales for pharmaceutical companies, healthier patients, and lower costs to insurers.*** This assumption is the least well verified. It is not clear that current implementation models for e-prescribing will yield the kind of closed-loop feedback on medication adherence (i.e., physicians being informed of patient adherence to a refill schedule for chronic medications; patients being reminded that they should be needing a refill) required to improve compliance.

6. ***E-prescribing yields improved patient satisfaction, which will translate to greater patient loyalty to physicians and health plans.*** While this assumption seems logical, experience is currently too limited to support it with data. Anecdotally, patients do appreciate immediate transmission of their prescription to the pharmacy.

7. ***Electronic transactions save receiving parties money compared with paper-based transactions.*** This argument has been the primary fuel behind the business models of many Internet health care connectivity models. It has been estimated that health plans and PBMs would pay $0.65 to $1.50 for each electronic, formulary-verified prescription and that pharmacies would pay $0.25 each to receive clean electronic prescriptions.[14]

8. ***Enhanced patient safety reduces costs for several parties.*** Malpractice insurers are willing to discount premiums for physicians who use e-prescribing systems. At least one national carrier offers discounts to physicians using a particular vendor's e-prescribing product. The Leapfrog Group, a coalition of large employers committed to obtaining "giant leaps forward" in the quality of patient care, has targeted automated prescribing in the inpatient setting as one of their three initial initiatives. Leapfrog member General Motors has committed to funding the provision of e-prescribing systems to physician practices, in the interest of reducing adverse drug events.[6]

Sponsorship-based and Transaction Fee-based Models

Several parties—pharmaceutical companies, health plans, and PBMs in particular—stand to realize substantial financial benefits from the adoption of e-prescribing by physicians. Most vendor business models are, therefore, structured around some version of sponsorship or subsidization of e-prescribing systems by one or more of these players. For example, a pharmaceutical company might pay the majority of the costs for system purchase and implementation for some number of user licenses, with users paying a nominal fee.

In return, physicians might be asked to view several "e-detail" productions per month, and the e-prescribing vendor would agree to make available aggregate prescribing data to the pharmaceutical company for a fee, when such data had been accumulated in the system. In the case of health plans and PBMs, the *quid pro quo* is the use of appropriate formulary checking software by the plan's physicians.

Increasingly, there is discussion in the industry of transitioning from sponsorship models to transaction fee-based models in which revenues are generated by per-transaction fees based on the estimated value to the receiving parties. Such a structure generates revenues in direct proportion to transaction volume, and therefore will likely be more widely used once larger numbers of physicians have implemented e-prescribing systems, and as other transactional applications (e.g., laboratory test ordering) are bundled with e-prescribing on the same devices.

III. Operational Considerations of E-Prescribing

E-Prescribing and the Prescription Management Process

In order to describe the specific processes involved in e-prescribing, it is useful to examine the six-stage prescription management process in the outpatient setting and see how e-prescribing alters the process. (See Figure 3 on the next page.)

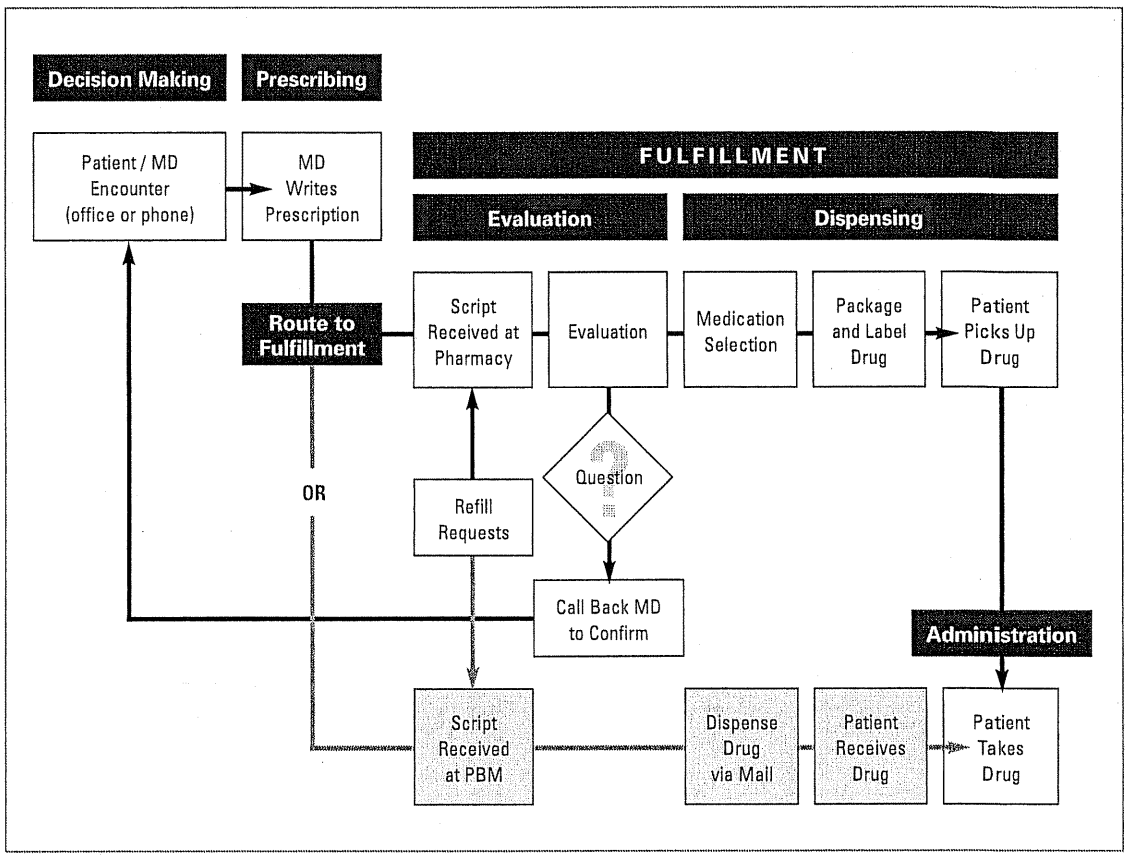
1. ***Decision making.*** The prescribing process begins with the clinician's assessment of a patient's condition and needs. The assessment is traditionally based on history taking (interviewing the patient; reviewing past records), physical examination, and review of any laboratory or other diagnostic studies. The clinician may at this point decide to order additional studies. He or she then arrives at a presumptive clinical diagnosis and selects a course of treatment that may include medications.

   The decision making stage is critical to understanding prescribing because information that should be gathered at that stage is essential to safe and effective prescribing. For example, failure to gather information about history of allergies, other diseases, and medications the patient is already taking may result in the prescribing of a medication to which the patient is allergic or to a dangerous drug-disease or drug-drug interaction.

   What are the implications for e-prescribing? In order to reduce adverse drug events through screening for drug-drug, drug-allergy, and drug-diagnosis interactions, data must somehow be entered into the system. Such data are not generally imported from practice management systems. Some systems allow the physician to manually enter diagnostic and allergy data at the time of history taking; others do not. Entering concurrent medications that have not been ordered through the system presents greater difficulties. With most of the mobile e-prescribing vendors there is no good way to enter this information. Ambulatory medical record vendors more commonly capture these data.

   Other applications that are increasingly being bundled with e-prescribing systems may improve the efficiency of the decision making process. The ability to view recent laboratory results is one example. Another is the ability to view previous diagnoses from charge capture data.

Figure 3. Outpatient Medication Management



2. *Prescription writing.* Having made a therapeutic decision and selected a class of drug, taking into consideration possible allergy, drug, and disease interactions, the physician writes the prescription. In the case of paper prescribing, this may involve selecting a medication, dose, duration, etc., from memory, or it may involve looking up information in a drug reference source.

   With e-prescribing, the clinician is generally able to access the patient's demographic data (which have been imported from the practice management system); the clinician selects the patient's record and, using the prescribing application, selects a specific medication preparation, dose, route, and duration. This is generally done using pick lists on a handheld device; one manufacturer, however, offers voice-activated prescribing on a mobile computer. The application checks for adherence to any applicable formulary and alerts the clinician to any potential allergic or other drug interactions. In most mobile e-prescribing applications, the logic to perform these functions is located in the handheld device; but in some cases synchronization of the device with a local or even remote server is required to complete the checking process. Separate drug reference applications may be packaged with the e-prescribing software, facilitating lookup of additional information.

3. ***Communication to pharmacy.*** If a prescription is handwritten, the clinician hands it to the patient who takes it to the pharmacy; or in some cases, a first-time prescription may be telephoned to the pharmacy. (With certain exceptions, renewals are commonly handled by telephone.) In the case of e-prescribing, when all requisite checks have been completed, the clinician submits the prescription for dispensing. This may involve synchronizing a mobile device using a docking cradle, beaming the prescription information to a printer or network infrared port, or synchronizing automatically over a wireless local area network. Depending on the vendor system, the prescription may then be printed in the physician's office and given to the patient to fill, faxed to the patient's pharmacy, or sent electronically to the patient's pharmacy. At the time of this writing, most system implementations use the print or fax option; electronic transmission of prescriptions is possible, but currently less common. Prescriptions may also be sent electronically to PBMs' online pharmacies or Internet pharmacies (see box to the right).

Case in Point: The Medical Group, Beverly, MA

Vendor	PenChart
Product	PenChart medical record
In use since	1998
Number of physicians using the product	22

The experience of this Massachusetts practice sheds some light on the advantages of prescribing from an integrated AMR system. The PenChart ambulatory medical record system provides mobile prescribing functionality in the context of an integrated medical record. A mobile touch pad device is used for most data entry and lookup functions.

As implemented at The Medical Group, the system performs drug-drug, drug-allergy, drug-diagnosis, and formulary checking; other rules can be written into the system as well. Prescriptions are faxed to pharmacies electronically, and are ready for patients as soon as they arrive to pick them up. The practice uses the system for prescription renewal as well as first-time prescriptions.

Rita Amalfitano, the group's executive director, sees the electronic processing of refills as one of the system's greatest benefits. Using the AMR's workflow functionality, requests can be routed electronically within the practice to a single designated nurse; the system has eliminated a multiple-day backlog they experienced with their previous manual process. The principle disadvantage of the system is the need to hand-input formulary exceptions; staff have not been able as of this writing to download current formularies for the product. Amalfitano would also like to see a notification protocol implemented with the electronic faxing function, to alert them to server problems before prescriptions are sent.

Where Do the Online Pharmacies Fit In?

Internet pharmacies were riding high on the dot-com boom of 1999. PlanetRx once boasted a share price of $150; Drugstore.com and others attracted top industry talent and vast quantities of venture capital. Forrester Research predicted that online prescribing would reach $15 billion a year by 2004. Two years later, PlanetRx has been delisted from the NASDAQ and the Internet pharmacies are falling as fast as they rose. What happened? Will Web pharmacies survive in any form?

The entire ehealth sector suffered badly following the NASDAQ crash of spring, 2000. But other fundamental problems with the Internet pharmacy business concept plagued these companies from the outset. Revenues depended on low margin, over-the-counter, and non-medication items plus prescription drugs; in the long run, companies hoped that prescription sales would increase and carry a larger portion of the revenue growth. Unfortunately, they failed to make adequate allowance for several realities of the retail prescription drug market.

First, most consumers have prescription drug plans that are operated by PBMs. Consumers purchasing prescriptions at retail pharmacies exercise this benefit by paying a modest co-pay; the pharmacy manages the PBM relationship. Consumers who don't buy through their PBM pay full price. It took the e-pharmacies a while to build the needed PBM partnerships; and during this time, many PBMs built their own Web pharmacies, some of which are now generating significant revenues: Merck-Medco processed 4.2 million prescriptions in 2000, generating $460 million in revenues—more than all of their online competitors combined.[15]

Second, e-pharmacies are excluded automatically from half of the prescription market, since about half of all prescriptions are written for same-day pickup. Patients needing antibiotics for an acute infection will not wait a week for their drugs to come in the mail.

Finally, e-pharmacies have fared badly in the brand recognition game. With PBMs and retail chains with established brands opening their own online sites, and online-only stores unable to fill a substantial subset of consumers' needs (for same-day prescriptions), e-pharmacies have spent large amounts of cash in unsuccessful bids to establish themselves with consumers. With venture capital shunning the sector, e-pharmacies must find new ways to build brand awareness.

Recently, online pharmacies have been redirecting their efforts toward new partnerships and marketing models.[16] Some are launching co-branding campaigns and discount plans with local health plans and providers or contracting to provide chronic medications to populations. In any case, the e-pharmacy of the future appears better adapted to addressing niche applications than to transforming the industry.

4. ***Fulfillment.*** Having received the prescription by paper, fax, or electronic submission, the pharmacist enters the order into the pharmacy's information system, checks for any known contraindications, and then dispenses the medication to the patient. A similar process occurs with mail-order prescriptions. If a prescription is faxed or electronically communicated, the prescription may be ready when the patient arrives at the pharmacy. In any case, a prescription written from an e-prescribing system will be machine printed, easily legible, and likely conform to an available dosage and preparation of the medication. Also, there is none of the uncertainty or opportunity for misinterpretation afforded by a telephoned prescription. This saves all parties considerable inconvenience associated with call-backs to the physician's office and reduces the likelihood of transcription errors.
5. ***Administration.*** In the outpatient setting patients (or whoever is caring for them at home) are responsible for self-administering their medications. While e-prescribing processes do not play a direct role here, byproducts of their use—such as patient medication information that can be generated by some systems—could assist patients in the proper use of their medications and alert them to potential side effects or food or drug interactions.
6. ***Prescription renewals.*** The volume of work generated by renewal requests in the average physician office practice can be nearly overwhelming. Office practice nurses have told us they spend up to 50 percent of their time answering telephone renewal requests. Many offices set up separate renewal lines, sometimes with automated systems to record the requests. Frequently, renewals are checked for appropriateness by nursing staff and filled without consulting the physician, according to practice-specific guidelines.

The impact of e-prescribing systems on the renewal process is not entirely clear. In principle, the technology could facilitate the renewal process from the physician's point of view; it is easier to see the prior prescription online and point-and-click to perform the renewal. Often renewals are not handled directly by the physicians but by other office staff. If non-prescribing clinicians in the office have access to the system, it speeds the renewal process by allowing rapid access to the patient's medication record; the process would be further accelerated if these non-prescribing personnel were permitted to use the system to dispense the renewal prescription.

However, because workflow surrounding renewals differs significantly from that for first-time prescriptions, mobile prescribing applications may not be as easily implemented for this process. A number of organizations that are adopting e-prescribing have specifically excluded the renewal process from their initial implementation for this reason. E-prescribing for renewals works better in the context of an AMR, where a physician or other clinician can easily view the patient's problem list and other relevant information, in addition to the medication list.

Security, Confidentiality, and HIPAA Rules

Any technology that generates physician- and patient-specific data also generates concerns about the use and security of the data. These concerns are heightened in the case of e-prescribing technologies because a stated intention of some vendors is the sharing of these data with third parties for commercial purposes. Thus, the use of e-prescribing technology raises a series of questions that must be addressed.

Most patient data available to physician practices is considered confidential as a matter of course. The advent of the pending HIPAA (Health Insurance Portability and Accountability Act) regulations on security and privacy carries important and specific implications for the use of e-prescribing technology.

Case in Point: San Jose Medical Group, San Jose, CA

Vendor	Allscripts
Product	TouchScript Personal Prescriber
In use since	November 1999
Number of physicians using the product	134

Dr. Shahe Komshian, CEO of the San Jose Medical Group, is enthusiastic about his organization's experience with electronic prescribing, calling it "the most intelligent decision we have made for our practice." The group implemented the Allscripts Personal Prescriber in late 1999 and has succeeded in bringing on board all but two of its physicians as users.

At the time of this writing the group uses the system exclusively for first-time prescriptions; further functionality will be implemented soon, including charge capture, laboratory test ordering and results lookup, and e-dictation. As implemented at their site, the system performs formulary checking plus drug-drug, drug-allergy, and drug-diagnosis interaction checking to promote safe prescribing. The drug-diagnosis feature is possible because the system requires inputting the patient's diagnosis before writing prescriptions.

As to the benefits of the system, Dr. Komshian points to time-savings, both for physicians and patients. Immediate savings are realized due to reduced call-backs from pharmacists and patients. After physicians became facile in the system's use—about two months—they perceived up-front time-savings as well. Komshian's top two recommendations for a successful e-prescribing implementation:

- Do not start without some solid internal champions.
- Implement new functions incrementally.

There are two ways in which HIPAA regulations could potentially apply to e-prescribing technology and practices. First, the HIPAA standards for electronic data interchange (EDI) dictate the content and format for certain categories of electronically transmitted patient data. At present, e-prescribing is excluded from these regulations, which apply only to payer-related transactions, though this could change in the future. However, security/privacy regulations will apply to all organizations that are electronically transmitting any of the covered payer-related transactions. As most practices perform such transactions, these regulations will affect most practices that would use e-prescribing systems.

Operational Issues for the Large Practice

One of the great advantages of mobile e-prescribing systems is their relative ease of implementation, in comparison with the effort required to implement an AMR. But some of the potential benefits of e-prescribing are directly proportional to the number of physicians in a practice who use the system. Uniform usage promotes the building of a more complete patient medication record on the system, which in turn facilitates better interaction checking, easier cross-coverage of patients by others in the practice, and more uniform workflow around prescription management throughout the office. It appears that implementing e-prescribing systems at large practices, while easier than putting in place a full-blown AMR, holds a number of challenges.

Several important implementation factors change when an e-prescribing system is made operational across a large practice, compared with a single practitioner or small number of physicians. First, workflow changes affect a larger number of non-prescribing staff, who must be trained to use the system or follow new procedures for certain aspects of care provision. Second, there is likely to be a greater variance in the level of enthusiasm for the system among the larger number of physicians. This holds important implications for successful implementation because, if only a portion of the physicians in the practice use a new e-prescribing system, dual and potentially conflicting workflows are created, which creates havoc in practice administration.

Users at large practices that have implemented e-prescribing systems point to success factors much like those for successful AMR implementation:

- Have several physician champions who tirelessly promote the adoption of the system and work to resolve problems as they appear.
- Implement new functionalities incrementally. For example, start with e-prescribing, then add results lookup or charge capture (when practical). This allows physicians and staff time to get used to the technology and to changes in workflow.
- Consider reducing physician workload slightly at the beginning of implementation to allow time to work out problems.
- If doing a phased implementation involving a subset of practitioners at the outset, recruit the most enthusiastic users for the pilot and celebrate their successes publicly.
- Recognize the trade-off between level of functionality and simplicity of implementation. Some organizations establish basic functionality of e-prescribing as quickly and as broadly as possible and elect to delay addition of valuable functions—such as doing renewals electronically or adding results lookup—in order to address other priorities first.

Operational Issues for the Large Practice

One of the great advantages of mobile e-prescribing systems is their relative ease of implementation, in comparison with the effort required to implement an AMR. But some of the potential benefits of e-prescribing are directly proportional to the number of physicians in a practice who use the system. Uniform usage promotes the building of a more complete patient medication record on the system, which in turn facilitates better interaction checking, easier cross-coverage of patients by others in the practice, and more uniform workflow around prescription management throughout the office. It appears that implementing e-prescribing systems at large practices, while easier than putting in place a full-blown AMR, holds a number of challenges.

Several important implementation factors change when an e-prescribing system is made operational across a large practice, compared with a single practitioner or small number of physicians. First, workflow changes affect a larger number of non-prescribing staff, who must be trained to use the system or follow new procedures for certain aspects of care provision. Second, there is likely to be a greater variance in the level of enthusiasm for the system among the larger number of physicians. This holds important implications for successful implementation because, if only a portion of the physicians in the practice use a new e-prescribing system, dual and potentially conflicting workflows are created, which creates havoc in practice administration.

Users at large practices that have implemented e-prescribing systems point to success factors much like those for successful AMR implementation:

- Have several physician champions who tirelessly promote the adoption of the system and work to resolve problems as they appear.
- Implement new functionalities incrementally. For example, start with e-prescribing, then add results lookup or charge capture (when practical). This allows physicians and staff time to get used to the technology and to changes in workflow.
- Consider reducing physician workload slightly at the beginning of implementation to allow time to work out problems.
- If doing a phased implementation involving a subset of practitioners at the outset, recruit the most enthusiastic users for the pilot and celebrate their successes publicly.
- Recognize the trade-off between level of functionality and simplicity of implementation. Some organizations establish basic functionality of e-prescribing as quickly and as broadly as possible and elect to delay addition of valuable functions—such as doing renewals electronically or adding results lookup—in order to address other priorities first.

Security, Confidentiality, and HIPAA Rules

Any technology that generates physician- and patient-specific data also generates concerns about the use and security of the data. These concerns are heightened in the case of e-prescribing technologies because a stated intention of some vendors is the sharing of these data with third parties for commercial purposes. Thus, the use of e-prescribing technology raises a series of questions that must be addressed.

Most patient data available to physician practices is considered confidential as a matter of course. The advent of the pending HIPAA (Health Insurance Portability and Accountability Act) regulations on security and privacy carries important and specific implications for the use of e-prescribing technology.

Case in Point: San Jose Medical Group, San Jose, CA

Vendor	Allscripts
Product	TouchScript Personal Prescriber
In use since	November 1999
Number of physicians using the product	134

Dr. Shahe Komshian, CEO of the San Jose Medical Group, is enthusiastic about his organization's experience with electronic prescribing, calling it "the most intelligent decision we have made for our practice." The group implemented the Allscripts Personal Prescriber in late 1999 and has succeeded in bringing on board all but two of its physicians as users.

At the time of this writing the group uses the system exclusively for first-time prescriptions; further functionality will be implemented soon, including charge capture, laboratory test ordering and results lookup, and e-dictation. As implemented at their site, the system performs formulary checking plus drug-drug, drug-allergy, and drug-diagnosis interaction checking to promote safe prescribing. The drug-diagnosis feature is possible because the system requires inputting the patient's diagnosis before writing prescriptions.

As to the benefits of the system, Dr. Komshian points to time-savings, both for physicians and patients. Immediate savings are realized due to reduced call-backs from pharmacists and patients. After physicians became facile in the system's use—about two months—they perceived up-front time-savings as well. Komshian's top two recommendations for a successful e-prescribing implementation:

- Do not start without some solid internal champions.
- Implement new functions incrementally.

There are two ways in which HIPAA regulations could potentially apply to e-prescribing technology and practices. First, the HIPAA standards for electronic data interchange (EDI) dictate the content and format for certain categories of electronically transmitted patient data. At present, e-prescribing is excluded from these regulations, which apply only to payer-related transactions, though this could change in the future. However, security/privacy regulations will apply to all organizations that are electronically transmitting any of the covered payer-related transactions. As most practices perform such transactions, these regulations will affect most practices that would use e-prescribing systems.

Security Regulations

The pending security regulations will require that affected organizations have in place certain measures for securing the electronic transmissions of patient data. These are principally vendor requirements. While the rules may be modified, at the time of this writing they include the following elements:

- ***Secure point-to-point electronic transmission of the prescription.*** If transmission occurs over a public network, as is likely, then encryption is the required industry standard.
- ***User access controls:*** an approach for determining who should have access to which pieces of prescribing and related viewing functionality and the technical capabilities to execute those access classifications.
- ***Entity (user) authentication:*** the technical methods for verifying authorized users (generally username/password, biometrics, or some combination).
- ***Audit trails:*** the ability to track who enters data and perhaps (yet to be clarified) who accesses data.
- ***Data authentication and integrity controls:*** technical measures to ensure data have not been changed or altered within the system or during transmission.

Privacy Regulations

The privacy component of the regulations will require that affected organizations adhere to certain standard practices surrounding confidentiality. While they are subject to modification, as of this writing they include:

- Providers must hold "business associates"—partners such as pharmacies, health plans, PBMs, e-prescribing vendors, and pharmaceutical companies—accountable for the use of patient-identifiable information they receive. In addition, patient data must be scrubbed of identifying information before they can be used for other than operational, treatment, and billing purposes. This clearly includes use for marketing and sales.
- Policies and procedures must be established that outline the organization's standards for using and disclosing patient-identifiable information, including employee discipline, and termination procedures.
- Staff must be trained in the organization's policies and procedures governing use and disclosure of patient-identifiable information.
- Patient consent must be obtained upfront at the time of registration, granting the organization permission to use or disclose the patient's health information for payment, treatment, or other health care operations.
- A patient privacy notice must be posted and available to patients, explaining all of the organization's routine uses and disclosures of protected health information, as well as the methods the organization uses to protect that information and the patients' rights with regard to that information.
- Use of patient-identifiable protected health information for marketing purposes is restricted to uses by and for the provider itself; this implies that patient authorization is required if the organization seeks to sell or share prescription information with another entity for marketing purposes.

Selling Clinical Data: The Privacy Problem

Recent business deals have pushed to the forefront of public debate questions of appropriateness and legality of sharing or selling clinical data. The AMA, concerned with the apparent ease of access that pharmaceutical marketers have to physician-specific prescribing data, is looking for ways to prevent DEA numbers from being used for purposes other than verification; and patients are concerned about receiving marketing materials for classes of drugs they are taking.[17] A deal between the American Medical Group Association and Aventis Pharmaceuticals to create a national database of claims, laboratory, and prescribing information from AMGA's members (representing 67,000 physicians) is raising eyebrows among privacy advocates and legislators. AMGA states they will not provide patient- or physician-identifiable information to Aventis, but observers are skeptical.[18] WebMD and Quintiles recently settled a feud over provision of claims data to Quintiles, which sells such data to pharmaceutical companies. WebMD expressed concerns about whether the data-sharing violated state privacy laws; under the resolution reached, WebMD will remove data that could be used to identify patients, such as zip codes and exact dates of birth.[19] Even the RxHub announcement by PBMs to promote electronic prescribing is being viewed warily by some who fear that patient-identifiable data will make its way upstream from the PBMs to their pharmaceutical parents and partners.[5]

The debate will likely continue for some time. While all of the parties under siege hasten to assure us that these concerns are unfounded, one thing seems clear: If patient-identifiable data—released without the patient's specific authorization for such use—reach pharmaceutical companies and other parties as a byproduct of the e-prescribing process, it will constitute a violation of the HIPAA privacy rules. While the care provider will likely be held primarily responsible, e-prescribing vendors may be culpable as "business associates." Such concerns cannot be taken lightly in an industry where some players' business plans depend upon such data sharing arrangements.

Some of the technical security requirements are being addressed today by most e-prescribing vendors (such as encrypted transmissions and user authentication controls). More problematic will be construction of user access controls and audit trail functions. These requirements will pose major challenges for all vendors of clinical information systems.

The privacy rules will likewise challenge provider organizations wishing to use e-prescribing. They must establish and adhere to contracts that describe accountability of vendor organizations, health plans, pharmacies, and others for their use of patient-identifiable data; they must obtain consent from patients for the use of such data and establish appropriate policies, procedures, and the like. While there are not at present specific rules about how some of these requirements must be met, most physician practices do not adhere to these standards today, but must do so if they are affected by the HIPAA rules.

Sharing Data with Third Parties

Privacy concerns surrounding the sale and use of customer data have brought a number of Internet companies into the crosshairs of public debate. In health care the debate is no less rancorous, as patient privacy advocates and physician professional organizations lobby for protection of patient- and physician-identifiable data, and companies scramble to understand the implications of being "business associates" of providers. At present, there is little oversight of the use of these data, aside from the implications of HIPAA legislation. Individual vendors must decide for themselves how to handle data sharing with third parties, recognizing that they will likely be subject to both the scrutiny of consumer advocates and HIPAA regulations.

IV. Technology: Applications

SEVERAL TYPES OF CLINICAL SOFTWARE applications contain e-prescribing functionality for the outpatient environment. These include ambulatory medical record systems and mobile e-prescribing systems.

Ambulatory Medical Record Systems

AMRs are complex, multifunctional software packages that support administrative and clinical operations of physician practices. Packages typically include scheduling, registration, billing, managed care, and patient care modules. Patient care functionality usually includes clinical documentation, clinical results lookup, workflow functions such as in-office messaging and ordering of tests and prescriptions. More complex systems offer decision support functions such as alerts and reminders. Increasingly, AMR development is moving toward greater use of Web technology, in terms of both user interface and for connectivity with outside parties (insurers, patients, etc.). Client-server architectures dominate, but there is increasing movement toward application service provider (ASP) models. Applications are accessed by PC, although at least one AMR vendor is currently launching a mobile prescribing module. Other vendors allow use of mobile devices for all functions as an adjunct to PCs or even as the primary user interface.

E-prescribing from an AMR platform offers the advantages of working in an integrated system and having access to far more sophisticated clinical decision support. As an integrated system the AMR offers simpler workflow around the prescribing function. Basic patient demographic data are already in the system for existing patients and do not need to be imported in daily batches from a separate system. Information from the prescribing application feeds into the patient's electronic medical record and can be sent to billing or other systems as needed. In particular, the prescribing application serves to build the patient's longitudinal medication record—a critical part of the patient's history.

AMR prescribing functions include, at a minimum, a drug database for medication ordering, using pick lists and drop-down menus; a formulary module to check for adherence to the patient's health plan formulary; and in-office printing of prescriptions. Many AMRs offer additional clinical decision support functionality, starting with drug-drug, drug-allergy,

Case in Point: Kokomo Family Care Clinic, Kokomo, IN

Vendor	McKesson
Product	PracticePoint Rx
In use since	September 1999
Number of physicians using the product	14

The Kokomo Family Clinic wanted to implement an AMR, but to do it incrementally. They chose McKesson's ASP PracticePoint product, and decided to start with e-prescribing. The product is currently used for new and renewal prescriptions; a separate module for laboratory management is being implemented. The practice sends prescriptions by fax server to pharmacies, or electronically to one mail-order pharmacy.

Cheryl Norris, system administrator, views the incremental implementation approach as key to Kokomo's success in building physician commitment. They reduced each physician's patient load by 10 percent for the first two weeks following implementation, to allow time to get used to the system. Norris also believes the ASP model saves time, and Kokomo physicians believe they are providing better quality patient care.

and drug-disease interaction checking. AMRs with rules engines can be programmed to offer condition-specific prescribing advice, recommend checking drug levels, and other alerts and reminders.

There are several disadvantages of AMRs in comparison with mobile e-prescribing systems. First, traditional client-server AMRs are very expensive. License and implementation costs range in the tens of thousands of dollars per physician, and ongoing support costs are also great. Web-based ASP model products are often less expensive and spread out the costs of implementation; some offer less depth of functionality, which facilitates implementation. Second, AMR systems must be used in environments where all practitioners and office staff at the practice are using the same system; and these systems drastically alter the way physicians and staff do their daily work. As a result, implementing an AMR system requires enormous time and expense in redesign of physician and office workflow to accommodate the new system. These factors of cost and extraordinary effort of implementation are important reasons why AMR systems have failed to achieve greater market penetration.

Table 2. Advantages of AMR vs. Mobile Systems for E-Prescribing

AMR E-Prescribing	Mobile E-Prescribing
Decision support based on access to more complete patient record at point of prescribing • Allergies • Diagnoses • Laboratories • Clinical documentation	Inexpensive to purchase and support
E-prescribing contributes to integrated AMR	Ease of implementation (depending on interface requirements)
Multiple users' data integrated in one patient record (possible with mobile e-prescribing, but less common)	Convenience of mobile platform
More sophisticated decision support can be programmed into prescribing module: appropriateness rules, adherence to care guidelines; etc.	Easy to update formulary, drug databases by download from Internet
Data more easily suited to aggregate, practice-level analysis (physician prescribing profiles, etc.)	Simplicity of use

Mobile E-Prescribing

Over the past several years a host of vendors have developed e-prescribing software for use on handheld mobile computers. This sector of the industry attracted large amounts of venture financing in the late 1990s as industry observers predicted that the convenience, user-friendliness, and ease of implementation of focused applications on personal digital assistant (PDA) platforms would lead to rapid adoption of e-prescribing, charge capture, and other applications by physicians. At the time of this writing, there are a handful of vendors established, to some degree, in this space and many more entrants.

While most vendors debuted with single-application systems, there is a trend toward bundling of applications, with vendors developing a suite of functions including prescribing, charge capture, e-dictation, and results lookup, plus access to assorted reference volumes.

E-Prescribing Applications

While there are variations in style of presentation and sequence of ordering, all e-prescribing applications have certain basic functions in common. First, all use a drug database for ordering, which contains a very extensive, though not exhaustive, list of prescription compounds, including generic and brand name preparations, and available forms (table, capsule, liquid, etc.) and doses. There are variations on the schema for looking up medications (by brand name vs. by generic, for example). Drug databases must be updated regularly by downloading a current version over the Internet.

To support formulary checking, e-prescribing applications must also include a health plan/PBM formulary database, against which to check prescriptions for formulary compliance. Databases are available that contain formularies from thousands of plans across the country; these are updated frequently, and revisions must be downloaded online on a regular basis.

A "favorites" list of medications most frequently ordered by each device's physician user is also fairly standard. The list speeds the selection of common medications. These vendors have the ability to perform, at a minimum, drug-drug interaction checking between medications currently or previously ordered through the system. Most mobile e-prescribing systems do not offer an easy method to populate the patient's medication record with medications prescribed off of the system; this makes drug-drug interaction checking incomplete in those instances (more common than not) where patients take medications prescribed by different physicians, not all of whom use an e-prescribing system.

The ability to input additional patient information, such as allergies and diagnoses, is more variable among vendors, although charge capture applications can address the latter.

Table 3. E-Prescribing Applications: Basic and Additional Functions

Basic	Additional
Drug database for prescribing	Associate diagnosis with prescription
Formulary checking	Drug-allergy interaction checking
Drug-drug interaction checking (for medications ordered on same system)	Drug-disease interaction checking
Favorites list of frequently-ordered drugs	Drug reference database

Interfaces

E-prescribing applications must have a mechanism for inputting or importing basic patient demographic data, by manual entry, and also, preferably, from a practice management system. The critical variations here surround the ease of implementing or, in some cases, developing these interfaces. Some vendors have ready-made interfaces constructed for one or more practice management systems; others will construct the interface for a charge, which can be substantial.

Availability or ease of development of interfaces to practice management systems depends in part on the e-prescribing vendor's relationship with different practice management system vendors. Some mobile prescribing vendors have ownership or tight business relationships with practice management system vendors, and may demonstrate a clear preference in interface development as a result. On the flip side, practice management vendors can make interface construction very difficult if they choose not to cooperate with an e-prescribing vendor whom they consider a competitor of theirs, or of a business partner. In selecting a vendor, ease of interfacing should be a prime consideration.

Case in Point: Mid-Atlantic Permanente Medical Group, Bethesda, MD

Vendor	EPhysician
Product	EPad
In use since	February 2001
Number of physicians using the product	12

Dr. Andrew Barbash and his colleagues at the Mid-Atlantic Permanente Medical Group implemented the ePad system in February 2001, and are already enjoying the benefits. The system as implemented currently employs formulary checking and drug-drug interaction checking, and the Facts and Comparisons drug reference. Prescriptions are faxed to pharmacies.

In addition to the satisfaction of providing better patient care, the practice's major benefit is in time savings from reduced pharmacy callbacks. The online medication reference tool has also proven quite useful. The one potential drawback they see to the system is the current requirement to synchronize the mobile device in a sync cradle with every prescription written, which is problematic for some physicians.

Dr. Barbash is particularly happy with the relationship Mid-Atlantic Permanente has been able to build with ePhysician. He praises their commitment to perfecting the product in use, before adding additional functionality, as well as their customer responsiveness in this, their largest facility implementation to date.

Charge Capture

Charge capture has become a popular application in its own right as it can assist practices in maximizing their revenue capture by greatly increasing the accuracy and efficiency of coding, the first step in the billing process. The application contains a database of ICD-9 and CPT codes that the provider uses to code each patient encounter or procedure. While several companies make stand-alone charge capture applications, some combine e-prescribing and charge capture. There are several benefits to this combination, beyond the convenience of housing two useful applications on one mobile device.

- First, assigning a diagnostic code to each patient allows the diagnosis to be included on the prescription, which serves to improve patient safety by providing the pharmacist with indication information.
- Second, capturing a diagnostic code permits at least partial construction of a patient problem list, which theoretically enables some level of checking for drug-disease interactions.

It should be noted that ICD-9 data, when coupled with prescriptions, are coveted highly by pharmaceutical companies as the combined data permit them to track off-label prescribing and other use patterns.

Results Lookup and Test Ordering

Several mobile computing vendors offer, or are close to rolling out, laboratory test ordering and results viewing, usually via interfaces with practice management systems or AMRs, or via connectivity arrangements with reference laboratories. It is not clear how extensive a longitudinal record of laboratory results will be maintained on these systems. The ability to view recent laboratory results while considering medications for a patient can be very valuable, for example, with medications that require titration to appropriate serum concentrations or with drugs that should not be given in the presence of certain laboratory anomalies (e.g., digoxin and low potassium). While not available from mobile prescribing vendors today, automated drug-laboratory interaction checking is an important component of clinical decision support for inpatient physician order entry. Such functionality could be developed for mobile e-prescribing applications in the future.

E-Dictation

Vendors are taking advantage of the digital dictation capabilities of mobile devices to offer online dictation and transcription services. Transcribed reports are generally accessed by PC and can be printed or otherwise included in the patient's medical record.

Drug References and Other Reference Sources

In addition to access to the prescribing database, it can be very useful to have easy access to prescribing information at the point of care; and accessing data quickly through a mobile application may be more convenient than looking through reference books. A recent study showed that 22 percent of the questions physicians have as they are seeing patients relate to medications.[20] Another study examining the utility of a drug reference database on a mobile platform showed that physicians and medical students saved time, gained prescribing knowledge, and felt that they provided better care using the system.[21] Several e-prescribing vendors bundle a drug reference application with their prescribing software.

V. Technology: Hardware, Software, and Operating Systems

THE PAST SEVERAL YEARS HAVE WITNESSED THE explosion in popular use of the mobile computing platform generally called the personal digital assistant (PDA). Devices such as the Palm Pilot offer the convenience of a pocket-size device on which to store and record contacts lists, addresses, and schedules; by connection with a PC or wireless network, devices can send and receive email and users can surf the Web.

This level of convenience, and the track record of broad user acceptance, underlie much of the current industry optimism surrounding the future of e-prescribing using these devices. If physicians are using PDAs to keep addresses and receive stock quotes, surely widespread adoption of electronic prescription writing should be right around the corner.

The specific characteristics of mobile computing devices should hold important implications for adoption of e-prescribing. This section discusses the common hardware, operating systems, and network connectivity technologies used by electronic prescribing systems. A more detailed description of the technology of wireless computing, including the standards utilized and specific hardware requirement for wireless communication, is contained in the CHCF publication, *Wireless and Mobile Computing.*[22] This report does not discuss the technology platform of the AMR, as it typically uses standard client-server architecture and platforms and is, therefore, generally well understood.

Devices and Operating Systems

PDAs can be categorized as either palm-size or handheld. Most of the smaller palm-size devices, manufactured by Palm or others, utilize some version of the Palm operating system. Handheld computers primarily use Microsoft's Windows CE operating system. The relative benefits of the two operating systems are outlined in Table 4. Briefly, the Palm system operates a small touch screen that is manipulated with a stylus; data can be entered using menus or a simple character recognition language. The Windows CE system presents an interface that more closely resembles the standard PC desktop and is manipulated by a small keyboard and/or touch screen. The Palm system drives smaller devices and is somewhat simpler to use; the Windows system offers greater functionality.

Table 4. Comparison: Palm vs. Windows CE[14, 23]

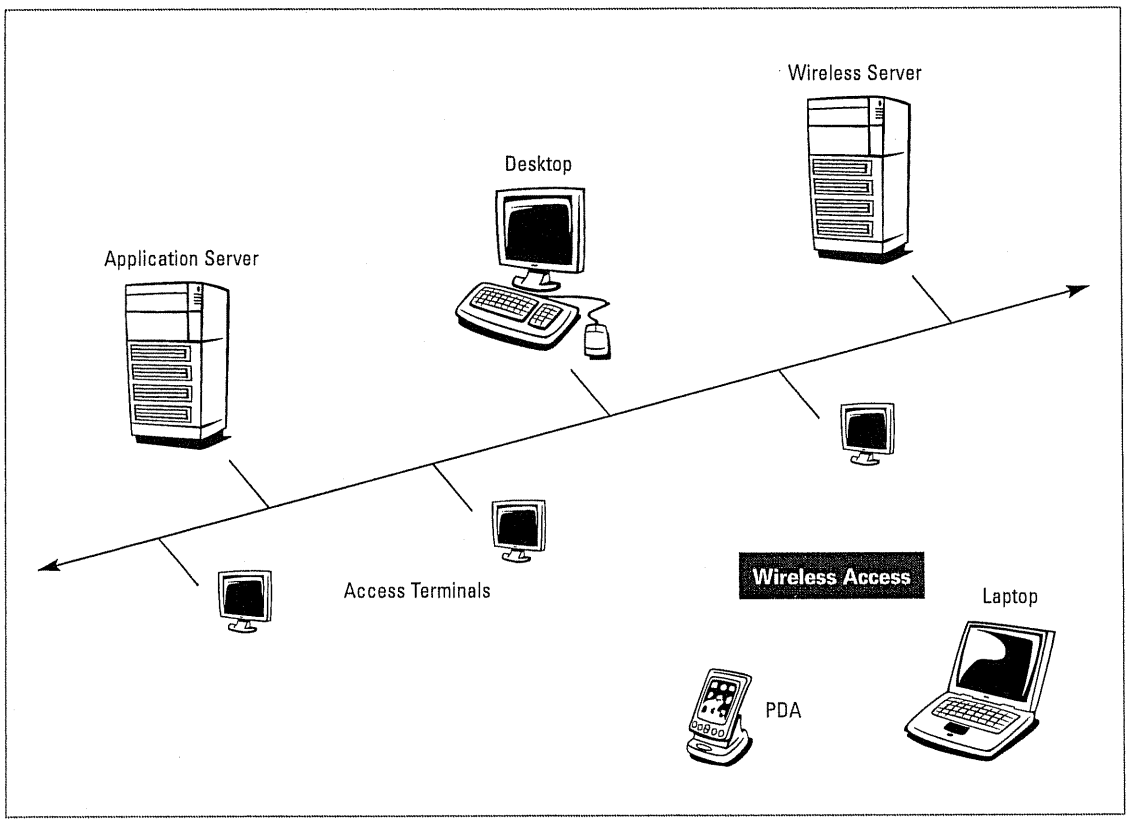
Palm OS Advantages	Windows CE Advantages
• Simple interface	• More versatile than Palm OS
• Low memory requirement	• More advanced graphics
• Long battery life	• More features available, including multimedia applications
• High system stability/reliability compared with Windows devices	• Broader audio and video support
• Wireless Web access available for select models	• Ability to read documents created in compatible software, such as MS Word and Excel
• PDAs with Palm OS tend to be smaller in size and weight (most fit into a lab coat pocket)	• Color display

Connectivity: PC and Network Connections for the PDA

PDAs can connect with desktop PCs via a synchronization cable and cradle or using radio frequency technology. They can also connect and exchange data over a physician practice's local area network (LAN). Entire LANs can also be constructed to be wireless, with transmitter/receiver devices—called access points—serving as the link to a traditional LAN (see Figure 4). While different hardware vendors have used a variety of communication protocols, a single standard appears to be emerging (IEEE 802.[22] The various models of PDA are capable of different kinds of connectivity; some have wireless LAN adapters integrated into the device while others can use PC cards to provide this connectivity.

Approaches to connectivity hold important implications for workflow around e-prescribing. For example, a requirement to physically synchronize the PDA following the input of each patient's prescriptions, in order to send the prescriptions to the printer, fax server, or electronically to the pharmacy, causes some degree of inconvenience in the course of practice. If a wireless LAN is to be used, positioning of the access points must be carefully planned to ensure coverage of all practice areas where physicians may wish to access the network.

Figure 4: Wireless LAN



Wireless LAN technology has other limitations that may affect the convenience of e-prescribing. These include:

- Slow data transfer speed compared with wired LAN (7 Mbps vs. 10-100 Mbps).
- Potential for frequency interference with biomedical equipment (more of an issue in a hospital setting).
- Lack of data interface standards with legacy information systems (requires that the mobile computing vendor construct point-to-point interfaces).

In the typical physician practice setting, only the last of these represents a major inconvenience for e-prescribing. Interface issues are discussed on page 31.

PDAs can also communicate with some devices, such as printers and other PDAs, using infrared technology. Some mobile e-prescribing systems require the physician to "beam" new prescriptions to the infrared port of a local printer after seeing each patient.

Other Connectivity Modes

Wireless WAN (wide area network) represents another connectivity technology, in which satellite networks provide radio frequency coverage of large geographic areas. There is limited experience in the use of WAN technology for e-prescribing. Wireless Internet, a technology based on mobile phone communications standards, may find favor for e-prescribing systems in the future.

Connectivity from the Practice to the PBM or Pharmacy

Most e-prescribing systems currently implemented do not send prescriptions electronically but rather transmit them via electronic fax or simply print the prescription in the physician's office and hand it to the patient. When prescriptions are sent electronically, an industry EDI (electronic data interchange) standard is typically used. This format provides a degree of security beyond that of standard email.

The development of better standards for transmission of e-prescriptions may be accelerated by the PBM industry's RxHub initiative. This effort, sponsored by PBMs, could facilitate the establishment of connectivity from physician offices to PBMs and pharmacies. The RxHub founders state that the new standards will meet all HIPAA security requirements.

PBMs Create a New E-prescribing Exchange: RxHub

Three pharmaceutical benefits management companies are striving to create an electronic exchange system that will facilitate the sending of prescriptions electronically. Advance PCS, Express Scripts, and Merck-Medco will collaborate—and invest $20 million a piece—to create RxHub, a system that will establish electronic communications standards for e-prescriptions and adhere to HIPAA and other privacy standards. The standards will also incorporate encryption technology to ensure security of transmissions.

The new system will facilitate connectivity between physicians and PBMs. The goal is to route prescriptions directly to the PBMs for formulary checking before being sent to pharmacies. An added benefit: Development of the system should increase incentives for all pharmacies to wire themselves to receive e-prescriptions.[11]

VI. Future Challenges and Emerging Patterns

DESPITE COMPELLING POTENTIAL BENEFITS, AND even a gathering literature of success stories, adoption of e-prescribing by physicians has been slow as of this writing. Mobile prescribing vendors have revised downward their projections of users for the coming year as implementations have fallen behind earlier predictions.

There are a number of possible reasons for the sluggish progress of use of e-prescribing. Several aspects of the structure of the health care industry are likely contributing.

1. ***The difficulty of marketing new technologies to physicians in small and medium-size practices.*** These doctors constitute the majority of practicing physicians, and their geographic dispersal and independence make them difficult to approach in an organized way. Such practices often use only basic practice management systems; even the adoption of this technology occurred only after the complexity of practice administration reached a point where their value was unquestionable. While prescription management may reach a similar level of complexity in the future, it is doubtful that most practitioners experience a clearly felt need for such systems today. Thus adoption will continue to be driven by marketing—by vendors, other physicians, patients, or the media; e-prescribing technology will not sell itself.
2. ***Marketplace instability.*** Physicians may hesitate to invest the time and effort in adopting e-prescribing technologies in an uncertain marketplace. More companies are destined to fail than to succeed in this niche. With investor dollars becoming scarcer and companies failing to demonstrate positive cash flow, physicians may be waiting for the smoke to clear before selecting a system.
3. ***Skepticism about value.*** Physicians may also be skeptical about the value delivered by e-prescribing systems. Indeed, a realistic appraisal of the average system's functionality for reducing medication errors supports some skepticism. In terms of preventing drug interactions, many systems are currently checking for possible interactions with other medications, and perhaps, allergies; medication checking is limited to the drugs prescribed using the same office system. Given that many patients take medications from multiple prescribers, the list is likely to be incomplete.

Thus, in most cases, safety benefits are limited to production of legible prescriptions, checked against a partial list of current medications and, perhaps, allergies. These contributions are significant, but may not live up to the hopes or expectations of physicians considering the switch to e-prescribing.

4. ***Evolution of multifunction systems.*** While implementation lessons suggest practices are better off implementing only one or a few functions at a time, physicians considering e-prescribing or the adoption of mobile computing may be waiting for more multifunction systems to mature before selecting a product. The current movement in the field toward multifunction systems suggests that the vendors feel this is the direction of the market. However, as additional functional demands are put upon these systems, their current advantages relative to AMRs—simplicity, speed of implementation, cost—will likely be diminished. It could be argued that if simple, single-function e-prescribing applications were going to sweep the market, they would have done so by now.

It seems unlikely that concerns about privacy and security are inhibiting physicians from adopting e-prescribing. First, most offices are not transmitting prescriptions electronically—they are printing them locally or faxing them to pharmacies or PBMs. Second, many practices are already performing some electronic claims submissions, which raise many of the same concerns about security as e-prescribing. HIPAA privacy issues could pose challenges for some vendor business models, and require physician practices to examine carefully their contracts with vendors in the future; but these factors probably have not played a significant role in most physicians' consideration of e-prescribing up to the present time.

Several issues currently in play are likely to have profound influence on the future of e-prescribing. First among these are the HIPAA privacy rules, which if implemented in anything close to current form will significantly alter the nature of contracts between providers and their business partners. The rules will hold implications for vendor business models that depend on sharing patient data with third parties. All parties will have to guarantee and verify that patient information is adequately de-identified before it leaves the confines of operations/treatment/payment transactions.

Another evolving dynamic is the relationship between e-prescribing vendors and vendors of other health care IT systems. A great deal will be determined by the degree to which mobile computing vendors are able to integrate their platforms and applications to interact with health care legacy systems, including practice management systems. If past experience were the guide, there would be ample reason for pessimism, as lack of interoperability is the norm rather than the exception in health care.

Several patterns could emerge. One scenario—extrapolated from past experience and recent behavior of some mobile prescribing vendors—has mobile and enterprise vendors pairing up and offering well-integrated systems within the confines of their relationship. This typically restricts the ease of integration of a given mobile platform with those of other vendors. Another scenario involves increasing use of open standards for application building and communications; this could ameliorate the interface challenges and offer practices more vendor options to choose among.

In any case, it seems likely that outpatient e-prescribing, with its clear benefits and relatively few drawbacks, will eventually find its way into broader use in the physician community. The question is how quickly, and how widely will this occur? While enthusiastic analyst reports of two years ago were clearly too optimistic, there remains reason to expect that e-prescribing will play an increasing role in patient care in the future.

Appendices

Appendix A: Representative Vendors Offering Mobile Electronic Prescribing

Appendix B: Glossary

Appendix A: Representative Vendors Offering Mobile Electronic Prescribing

Vendor	url
Allscripts	www.allscripts.com
ePhysician	www.ephysician.com
iScribe	www.iscribe.com
PenChart	www.penchart.com

Appendix B: Glossary

Access Point—Radio based two-port network bridge that interconnects a typical wired Ethernet network to a wireless LAN segment.

Adverse Drug Event—An injury resulting from medical intervention related to a drug.[24]

Adverse Event—An injury caused by medical management rather than the underlying condition of the patient.

AMR (Ambulatory Medical Record)—Multifunctional software packages that support administrative and clinical operations of physician practices and typically include scheduling, registration, billing , managed care, and patient care modules. Sometimes referred to, especially in the inpatient setting, as EMR (electronic medical record).

Application Service Provider (ASP)—A vendor that deploys, hosts, and manages access to a packaged application for multiple parties from a central facility, charging a subscription use fee.

Beaming—Transfer of data or software programs from one PDA to another, or from a PDA to a desktop computer or a printer, using either infrared or radio-wave transmission.

EDI (Electronic Data Interchange)—A direct exchange of data files between two computers. Generally, EDI transmission is faster than electronic faxing and offers more security than email transmission of prescriptions.

Electronic Prescribing (E-Prescribing)—Entering a prescription for a medication into an automated data entry system (handheld, PC, or other), and thereby generating a prescription electronically, instead of handwriting the prescription on paper.

Ethernet—The IEEE standard 802.3. It is a network standard of communication using either coaxial or twisted pair cable. The most widely used for LAN communication, Ethernet typically runs at 10 megabytes per second, though newer systems use 100 Mbps or even a gigabit of transfer.

Formulary—A list of medications (both generic and brand names) that are covered by a specific health insurance plan or PBM.

Hand-held PC or Pocket PC—A more powerful handheld than a PDA, the pocket PC has many of the functions and capabilities of desktop and laptop computers.

IEEE 802.11b—Standard ratified by IEEE in late 1999 and supported by the largest WLAN vendors including Proxim, Lucent, Nortel, and Cisco.

LAN (Local Area Network)—A network that consists of computers that are located in physical proximity of one another and are all connected by wire cables.

Medical Error—The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim in the health care delivery process.

Medication Error—A mistake made at any stage in the provision of a pharmaceutical product to a patient.

Network—A set of computers interconnected with cables (LAN) or wireless (WLAN).

Palm Operating System (Palm OS)—Hand-held computer operating system developed by 3Com and characterized by operating simplicity and extensive information storage capacity.

PBM (Pharmacy Benefit Manager)—An organization contracted by health insurance plans to manage prescription medication benefits.

PDA (Personal Digital Assistant)—A handheld portable organizer; some with Internet access and email functions.

Subscription-based Model—One of two types of business models presently observed with the electronic prescribing vendors. The subscription-based model is based on a monthly fee charged for the use of the hardware and the electronic prescribing software; the fee may be charged directly to physicians or subsidized by a third-party payer. See also transaction-based model.

Sync Cradle—A device that holds the PDA and is connected (via a cable) to a desktop computer, allowing for transfer (syncing) of data in both directions between a PDA and a desktop PC or a network.

Transaction-based Model—The second of two types of business models behind electronic prescribing vendors currently on the market. Under this model, service fees are charged on a per-transaction basis, rather than on a flat monthly charge. Presently, the model works with subsidization by a third-party payer. See also subscription-based model.

Windows CE—Handheld computer operating system developed by Microsoft that includes scaled down version of Word, Excel, Access, and Internet Explorer.

WLAN (Wireless Local Area Network)—A system of three primary types, including two that are based on radio frequency (RF) with spread spectrum modulation schemes: direct sequence spread spectrum (DSSS) and frequency hopped spread spectrum (FHSS). The third type, infrared (IR), is based on light waves and, due to line-of-sight limitations, does not provide the mobility of the RF options.

Endnotes

1. *A Primer on Physician Order Entry.* California HealthCare Foundation, September 2000.

2a. Bates, D. W. et al., "Effect of computerized physician order entry and a team intervention on prevention of serious medication errors." *Journal of the American Medical Association,* 280(15):1311–6, October 21, 1998.

2b. Evans, R. S., et al., "A computer-assisted management program for antibiotics and other anti-infective agents." *The New England Journal of Medicine,* 338(4):232–8, January 1998.

3. Gandhi, T., et al., "Drug complications in outpatients." *Journal of General Internal Medicine,* 15:149–54, March 2000.

4. "A Call to Action: Eliminate Handwritten Prescriptions Within 3 Years!" *Institute for Safe Medication Practices,* http://www.ismp.org/MSAarticles/Whitepaper1.html.

5. Versel, N. "Script central: PMBs create electronic hub to link pharmacies, physicians." *Modern Physician,* 5(6):6, March 12, 2001.

6. "General Motors and Medscape Form E-Business Health Care Alliance." Medscape press release, January 25, 2001.

7. Conn, J. "Attention to detail: drug firms enlist PDAs to get prescription marketing data." *Modern Physician,* 5(2):8–9, January 15, 2001.

8. *Survey of Pharmacy Law,* National Association of Boards of Pharmacy, 60–61, 2000.

9. Chesanow, N. "Electronic prescribing: what does your state allow?" *Medical Economics Online,* January 30, 2001.

10. "N. J. May Let Doctors E-Mail Prescriptions," *The Associated Press,* February 19, 2001.

11. Freudenheim, M. "A Plan to Send Prescriptions Electronically." *The New York Times Online,* February 23, 2001.

12. Hoppszallern, S. "Physicians and the internet: taking the pulse." *Hospitals and Health Networks,* 75(2):50a, February 2001.

13. Japsen, B. "Allscripts Healthcare Stock Drops 40% on Revenue Shortfall." *Chicago Tribune Online,* March 1, 2001.

14. Fisher, J., and R. Wang. "The Cure Is In Hand: Bringing Information Technology to Patient Care." *WR Hamrecht & Co.,* October 2000.

15. "merkmedco.com Announces Record Internet Prescription Volume for the Year 2000; World's Largest Online Pharmacy Fills Over Four Million Internet-Based Prescriptions For Plan Members." *Business Wire,* January 31, 2001.

16. Bazzoli, F. "Prognosis unclear for internet pharmacies." *Internet Health Care,* 26–33, March 2001.

17. Albert, T. "Doctors Ask AMA to Assure Some Privacy For Their Prescription Pads." *AMNews,* December 25, 2000.

18. Conn, J. "Questions abound: AMGA-Aventis data venture draws support, skepticism." *Modern Physician,* 5(6):10–11, March 12, 2001.

19. "Judge Continues Order That WebMD Send Claims Information to Quintiles." *The Wall Street Journal Interactive Edition,* March 19, 2001.

20. Ely, J. W. et al., "A taxonomy of generic clinical questions: classification study." *The British Medical Journal,* 321:429–432, August 12, 2000.

21. Rothschild, J., et al., "Survey of Physicians' Experience Using a Handheld Drug Reference Guide." *Informatics Review,* January 2001, reprinted from "Converging Information, Technology, and Health Care" Proceedings of the 2000 AMIA Annual Symposium. J. M. Overhage, editor.

22. Turisco, F., et al. *Wireless and Mobile Computing,* California HealthCare Foundation, April 2001.

23. Chesanow, N. "Put a computer in your pocket." *Medical Economics,* 77(20):76–124, October 23, 2000.

24. *To Err is Human: Building a Safer Health System.* Institute of Medicine, Washington, DC: National Academy Press, 1999.

25. Wilson, D. G. et al., "Medication errors in paediatric practice." *European Journal of Pediatrics,* 157(9):769–74, 1998 .

CALIFORNIA
HEALTHCARE
FOUNDATION

476 Ninth Street
Oakland, California 94607
Tel: 510.238.1040
Fax: 510.238.1388
www.chcf.org

ATTACHMENT E

AMENDED IN ASSEMBLY AUGUST 30, 2005

AMENDED IN SENATE JUNE 30, 2005

AMENDED IN SENATE JUNE 15, 2005

Senate Concurrent Resolution No. 49

Introduced by Senator Speier

May 17, 2005

Senate Concurrent Resolution No. 49—Relative to medication errors.

LEGISLATIVE COUNSEL'S DIGEST

SCR 49, as amended, Speier. Medication errors panel.

This measure would create a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The measure would require the panel to convene by October 1, 2005, and to submit to the *Assembly Committee on Health and the* Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006.

Fiscal committee: no.

1 WHEREAS, Numerous studies establish that medication errors
2 cause injury and death to patients and consumers; and
3 WHEREAS, The Institute of Medicine estimates the cost for
4 treatment of drug-related morbidity and mortality may run nearly
5 $77 billion a year nationally; and
6 WHEREAS, Research demonstrates that most injuries
7 resulting from medication errors are not the fault of any

individual health care professional, but rather represent the failure of a complex health care system; and

WHEREAS, The Federal Food and Drug Administration has approved 122 chemical compounds since 2002, and over 17,000 existing trade and generic names of products exist, many of which sound alike or are spelled alike; and

WHEREAS, These products are also packaged and distributed in similar shapes and forms; and

WHEREAS, The demand for prescription drugs is expected to substantially increase; and

WHEREAS, Medication errors occur in all settings in which prescription drug products are prescribed, dispensed, furnished, ordered, or otherwise provided; and

WHEREAS, Many factors contribute to a poor understanding by many consumers and patients about their prescriptions, including frequent switching of generic brands that are each different colors and shapes so that the same drug looks different and confuses the patient making it hard to easily spot mistakes; overworked pharmacists; reduced time with physicians for patients to be given important drug information; patients seeing multiple physicians that may be unaware of each other's care plans; patients often using vitamins, herbs, and over-the-counter drugs that can react with the medications they take and that both the physician and pharmacist do not know about; and

WHEREAS, Research has demonstrated that improved communication between patients and their health professionals is the most effective means of reducing errors and drug misadventures and improving health care outcomes; now, therefore, be it

Resolved by the Senate of the State of California, the Assembly thereof concurring, That a special panel be formed to study causes of medication errors; and be it further

Resolved, That the Legislature shall convene the panel no later than October 1, 2005; and be it further

Resolved, That the panel shall recommend improvements, additions, or changes to be constructed and implemented for the significant improvement of the health care system by reducing errors associated with the delivery of prescription and over-the-counter medications to consumers; and be it further

~~*Resolved,* That the panel membership shall consist of appointees of the Senate Committee on Health and the Assembly Committee on Health; and be it further~~

Resolved, That the Speaker of the Assembly shall appoint to the panel a member of the faculty of a school of pharmacy, a representative of the California Pharmacists Association, a representative of the California Association of Health Plans, a representative of the Pharmaceutical Research and Manufacturers of America, a member of the California Medical Association, a *member or representative of the Assembly Democratic Caucus, a* member or representative of the Assembly Republican Caucus, and a consumer representative; and be it further

Resolved, That the Senate Committee on Rules shall designate the chair and appoint to the panel a representative of the California Retailers Association Chain Drug Committee, a member of the California Society of Hospital Pharmacists, a representative of the Generic Pharmaceutical Association, a representative of a public health organization, a member of the California Nurses Association, a representative of ~~the American Association of Retired People~~ *AARP*, a representative of the Consumer Health Care Products Association, *a member or representative of the Senate Democratic Caucus,* and a member or representative of the Senate Republican Caucus; and be it further

Resolved, That the members of the panel shall not receive compensation, but shall be reimbursed from private sources for necessary travel expenses for the purpose of attending meetings of the panel, including any public meetings that the panel schedules, *and the panel shall be funded by private sources*; and be it further

Resolved, That the panel shall submit to the Senate Committee on Health *and the Assembly Committee on Health* a preliminary report of its conclusions and recommendations by March 1, 2006, and a final report of its conclusions and recommendations no later than June 1, 2006; and be it further

Resolved, That the Secretary of the Senate transmit copies of this resolution to the author for appropriate distribution.

O

ATTACHMENT F

in-Pharma Technologist.com

Breaking News on Pharmaceutical Technology

Free Newsletter Your ema

Search OK

since All

News Headlines Industry Drivers

News Headlines
Materials & Formulation
Processing & QC
Packaging
Industry Drivers

All news articles
September 2005
August 2005
Previous months

Products & Markets
Product & Supplier News
CPhI 2005 Preview
Market Reports
Events

Business Tools
Free Newsletters
All Newsletters
All Sites
Corporate News Service
News Syndication

Free Newsletter
Your email OK
All newsletters

Rhodia
Pharma Solutions

PALL Life Sciences
Filtration. Separation. Solution.

Fake drug sales 'could nearly double by 2010'

Phil Taylor

14/09/2005 - **A US think tank, The Centre for Medicines in the Public Interest, has released a new report projecting counterfeit drug sales to reach $75 billion in 2010, a 92 per cent increase from 2005.**

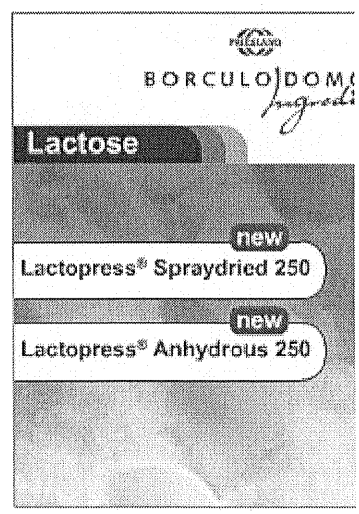
The report comes on the heels of major arrests for drug counterfeiting in China, Canada, and the US. In the most recent example at the end of August, the US Food and Drug Administration (FDA) and the US Attorney for the Western District of Missouri, indicted 11 individuals, a drug repacker, and two wholesale distributors in cases related to the sale of allegedly counterfeit versions of Pfizer's cholesterol-reducing drug Lipitor (atorvastatin) originating in Latin America. A case involving Lipitor – the world's top-selling medication – has also recently been uncovered in the UK.

"The business of selling fake prescription drugs to unsuspecting consumers is burgeoning, and is a global industry," said Peter Pitts, senior fellow for health care studies at the Pacific Research Institute and director of the CMPI.

Pitts' report estimates counterfeit drug sales will grow 13 per cent a year through to 2010, compared to just 7.5 per cent estimated annual growth for global pharmaceutical commerce. Many of the products sold via drug traffickers contain ingredients that could be harmful, and these products are coming from illegal operations with very poor controls. Many of these operations use phony, fly-by-night websites, he said.

The American debate about health care affordability and access is directly linked to international prescription drug counterfeiting. Not only are counterfeit drugs extremely dangerous and many times lethal, but also they are a potential source of funding in the murky world of crime and terror.

"Nearly $39 billion, or 11 per cent of global pharmaceutical commerce will be counterfeit this year," added Mr. Pitts. *"By 2010, that number will nearly double. We must enact controls to strengthen the security of our health care system from outside threats."*



Get the latest Market Report

counterfeit

Related News

FDA claims progress in battle against f
FDA finds new evidence for cross bord
Giuliani report claims imports hike cour

The findings of the report will no doubt be used by the US pharmaceutical industry in its efforts to negotiate a block on cross-border trade. The industry is particularly against the practice by US consumers of ordering cheaper prescription drugs from Canada and other foreign countries – which eats into profits and allegedly creates a door for the entry of counterfeit drugs into the US marketplace.

"The increasing flow of counterfeit drugs represents a significant public health threat," said Dr. Scott Gottlieb, Deputy Commissioner for Medical and Scientific Affairs at the U.S. Food and Drug Administration. We must step up our efforts to safeguard the drug supply -- we certainly should not weaken those controls."

In July 2003 the then Commissioner of Food and Drugs Mark McClellan, formed a Counterfeit Drug Task Force specifically to tackle the issue of increasing drug counterfeiting. One of the findings of the task force was that companies should make use of track-and-trace technologies – such as bar coding and radiofrequency identification (RFID) tagging – to make it harder to get fake drugs into legitimate distribution channels.

The release of the report comes just ahead of a conference, to be held on 20 September in Washington DC, that will bring together international experts on illegal pharmaceutical regulation, security, and trade to discuss the threat of illegal, cross border drug trafficking.

RFID pilot a success, says Aegate
One in seven drugs fake worldwide, cla
No security issue from parallel trade, sa
Vietnam takes action against drug fake

News Archives

All news for September 2005
All news for August 2005

Copyright - Unless otherwise stated all contents of this web site are © 2000/2005 – Decision News Media – All Rights I
For permission to reproduce any contents of this web site, please email our Syndication department: Administration &
Full details for the use of materials on this site can be found in the Terms & Conditions.

Subscribe to Other Decision News Media E-newsletters - Pharmaceutical & Science

- Pharmaceutical Technology
- Drug Discovery
- Pharmaceutical Contract Services
- Biopharmaceutical Science and Business
- Laboratory Equipment
- Cosmetics Formulation & Packaging - North America
- Cosmetics Formulation & Packagir

Your email address Confirm registration Access Decision News Media e-newsletters for food & bevera

All Decision News Media sites

Food & Beverage Development - Europe - Supplements & Nutrition - Europe - Food Processing & Packaging - Food Marketing and RetailingSupple

Contemporary OB/GYN NEWSLIN

DRUG TOPICS THE ONLINE NEWSMAGAZINE FOR PHARMACISTS

Thursday, Sep 1, 2005

How to cut your counterfeit risk

CONTINU
More th
on-line
the late
JOIN C
Sign up fc
Drug Topi
Email Adc
Confirm E
First Nam
Last Nam

Aug 22, 2005
By: Laurel I. Wala, Esq.
Drug Topics

Over the past five years, the number of counterfeit drug cases in the United States has skyrocketed. Between 2000 and 2004, the number of counterfeit drug cases initiated by the Food & Drug Administration's Office of Criminal Investigations rose by more than 900%, from just six cases in 2000, to 58 cases in 2004.

The FDA and other players in the drug distribution industry are taking steps to combat the infiltration of counterfeit drugs into legitimate commerce. However, implementing new technology, such as radio frequency identification, will take time. Meanwhile, the victims of counterfeit drugs are understandably enraged. Many are seeking recourse through lawsuits against the only targets they can identify: drugmakers, wholesalers, and pharmacies. Although final decisions have yet to be rendered, so far the courts are permitting the cases to go forward against the dispensing pharmacies (even while dismissing many of the claims against the manufacturers and wholesalers).

In the cases currently pending, the plaintiffs are presenting a wide variety of claims, including negligence, breach of implied warranties of merchantability and fitness for a particular purpose, breach of express warranty, fraudulent concealment, and consumer fraud. Significantly, these cases do not claim that the pharmacy knew the dispensed drug was counterfeit, but rather that the pharmacy should be liable even without such knowledge. Based on the fact that the drug in the bottle did not match the prescription or the label, plaintiffs claim that the pharmacy: did not correctly fill the prescription; misbranded the drug under the Food, Drug & Cosmetic Act; or breached an affirmative representation that what it was selling was the authentic drug.

The plaintiffs also maintain that pharmacies should be liable for failing to take reasonable steps to verify that the prescription drugs they sell are genuine.

So the question becomes, how can pharmacies minimize their liability risks in such lawsuits? The following steps may help reduce instances of counterfeiting and also serve as evidence that a pharmacy acted reasonably and without negligence in the event that it is named in a counterfeiting lawsuit.

1. Pay particular attention to products considered to be at "high risk" for counterfeiting. Establish procedures to regularly check labels, drug appearance, condition of packaging, and so on. The National Association of Boards of Pharmacy has established a list of "Susceptible Products," which can be found at www.nabp.net/.

2. Subscribe to the FDA's MedWatch E-List (www.fda.gov/medwatch/), which delivers counterfeit drug safety alerts via e-mail.

3. Establish the integrity of drug suppliers—
a. Ask wholesalers to provide a written description of anticounterfeiting measures (e.g.,

compliance with the Healthcare Distribution Management Association's Voluntary Guidelines for Pharmaceutical System Integrity posted at www.healthcaredistribution.org/) and product sources. (If possible, incorporate this description into your purchase agreement.)
b. Regularly check with your state board of pharmacy, department of health, or other appropriate state agency for information regarding problematic wholesalers in your state. Request that they post such information on state Web sites.
c. Use secondary distributors only if they can provide written verification that they are authorized distributors purchasing directly from authorized manufacturers and are in good standing with the applicable state licensing agency.
d. If purchasing from a distributor that does not buy directly from the manufacturer, require and closely scrutinize pedigrees (complete sales histories) of the products being purchased.

4. Alert staff pharmacists to consider whether an unusual adverse drug reaction or unusual medication response could be the result of a counterfeit product. Take comments and complaints about products (such as a change in effectiveness or change in taste) seriously and investigate them promptly.

5. Negotiate strong contractual warranties and indemnifications from wholesalers and distributors. Require an express warranty that the product delivered is what the label says it is and that it has met all storage standards.

6. If you encounter a questionable product, contact the manufacturer and wholesaler in writing to determine follow-up steps to verify authenticity. If the product is confirmed as unauthentic, contact the FDA through the MedWatch program.

In today's litigious climate, pharmacies cannot ignore the possibility of being sued for dispensing counterfeit drugs, even if they did so unknowingly. However, by implementing some commonsense policies and procedures, pharmacies can greatly reduce their risk of a bad outcome if they become embroiled in such a lawsuit.

Laurel I. Wala, Esq. is a partner at the Phoenix Law Group of Feldman, Brown, Wala, Hall & Agena (www.phoenixlawgroup.com/).

About the Author

Laurel I. Wala, Esq.

About Laurel I. Wala, Esq.
See more articles by Laurel I. Wala, Esq.

Order Reuse Permissions
RIGHTSLINK

S
B
WWW
Economics
WWW
PAT
Cli
po
Select
Allerg
Busin
Cardi
Clinic
Cosm
Derm
Emer
SEARC
View A

U.S. Food and Drug Administration

FDA News

FOR IMMEDIATE RELEASE
P05-57
August 31, 2005

Media Inquiries:
Catherine McDermott, 301-827-6
Consumer Inquiries:
888-INFO-FDA

Federal Authorities Cease Sale and Distribution of Counterfeit Lipitor

The U.S. Food and Drug Administration (FDA) and the United States Attorney for the Western District of Missouri, Kansas City, Missouri, today announced the indictments of 11 individuals, a drug repacker, and two wholesale distributors in cases related to the sale of Lipitor, a popular cholesterol reducing drug.

The indictment alleges numerous charges including conspiracy to sell counterfeit, illegally imported and misbranded drugs as well as conspiracy to sell stolen drugs. The conspiracy involved the manufacture of counterfeit Lipitor at a clandestine facility in Central America, the purchase of genuine Lipitor intended for distribution in South America, and the illegal importation into the United States of both products.

"This case demonstrates that the FDA will take the necessary steps to protect the drug supply in America," said FDA Commissioner Dr. Lester Crawford. "I am pleased that the U.S. Attorney's Office and FDA have been able to put together this case and stop these fraudulent schemes to sell pharmaceuticals of unknown safety and efficacy to the public."

In 2003, Albers Medical Distributors, Kansas City, MO, (a drug wholesaler) distributed over $20 million in illegally imported and counterfeit Lipitor that was sold to H.D. Smith Wholesale Drug Company (Wood Dale, IL). H.D. Smith distributed these Lipitor tablets throughout the U.S. The counterfeit Lipitor was repackaged by Med-Pro, Lexington, NE., a drug repacker. All three participants in this scheme were named in the indictment today. It is believed that these counterfeit Lipitor products are out of circulation.

In addition, it is alleged in the indictment that members of the conspiracy distributed pharmaceuticals stolen from GlaxoSmithKline and Roche Pharmaceuticals and counterfeited drugs The FDA's Office of Criminal Investigation (OCI) was able to put together the case by tracing back the various steps in this scheme. OCI was able to document where the chemicals and products came from, where the counterfeit was being manufactured, and how it was distributed.

Working together with the U.S. Attorney's Office in the Western District of Missouri, these findings led to today's indictment of all parties involved.

####

RSS Feed for FDA News Releases [what's this?]

Get free weekly updates about FDA press releases, recalls, speeches, testimony and more.

ATTACHMENT G

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

ENFORCEMENT COMMITTEE MEETING

September 13, 2005
Hilton Burbank Airport & Convention Center
2500 Hollywood Way, Director A & B
Burbank, CA 91505

Present: William Powers, Chair, Board Member
Marian Balay, Board Member
Stan Goldenberg, R.Ph., Board President and Member

Staff: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Joshua Room, Liaison Counsel, Deputy Attorney General

Call to Order

Chair William Powers called the meeting to order at 9:45 a.m. He apologized for the late start due to a flight delay. It was announced that committee member David Fong would not be attending the meeting due to other commitments related to Hurricane Katrina.

Importation of Prescription Drugs

Chair Powers reported that the importation of prescription drugs is an ongoing issue that continues to be on the agendas of the Enforcement Committee and Board of Pharmacy meetings.

Articles were provided. It was noted in one article that an organization called Partnership for Prescription Assistance (**www.pparx.com** at 888-477-2669) lets consumers find out in one-step, eligibility information for any of the 275 programs that offer cost savings to consumers.

Proposed Revisions to the Disciplinary Guidelines

Executive Officer Patricia Harris explained that the Board of Pharmacy has adopted via regulation its disciplinary guidelines. The board follows these guidelines in its disciplinary actions. They are used by Administrative Law Judges (ALJs) when issuing proposed decisions and the executive officer in negotiating stipulations. The last major revisions to these guidelines were in 2001. She explained that

draft revisions were provided for the committee's review. The sections of the guidelines that were provided included the Introduction, Factors to be Considered in Determining Penalties, Mitigating Evidence and Standard and Optional Terms and Conditions of Probation. Staff will also revise the remaining sections of the Disciplinary Guidelines – Categories of Violations and Recommended Penalties and Model Disciplinary Orders – that are primarily an update of code sections and consistency with the model orders.

Ms. Harris stated that the revisions are to clarify language, ensure that the terms and conditions are consistent (where appropriate) for all license types, to modify language to ensure consistency with statutory changes and to add new terms of probation. She discussed the significant changes to the standard terms and conditions:

- Reporting to Board: Adds language clarifying that failure to comply with this term constitutes a violation of probation and results in an extension of probation.
- Notice to Employers: Requires that the direct supervisor, owner **and** pharmacist-in-charge (PIC) are required to be provided with notice of respondent's probation; requires that each new PIC be notified of respondent's probation; and clarifies that failure to comply constitutes a violation of probation.
- No Preceptorships, Supervision of Interns: Deletes the term "preceptorship" to reflect the new law change, adds cannot serve as a consultant and that assumption of any unauthorized supervision responsibilities constitutes a violation of probation.
- Reimbursement of Board Costs: Adds option of revocation of license without further notice or opportunity to be heard for failure to pays costs as directed, and clarifies that failure to pay costs will be considered a violation of probation.
- Tolling of Probation: Adds language that further defines the circumstances and when probation is considered tolled, clarified definition of "cessation of practice" and that failure to comply with notification requirements in this provision constitute a violation of probation.
- Violation of Probation: Adds language that clarifies clarify that automatic termination of any stay ordered by the board will take place as directed in specified conditions.
- Reexamination Prior to Resuming Work: Deletes this provision for an exemptee since examination of an exemptee is no longer required.

The significant changes to the optional conditions of probation for pharmacists and interns were discussed. They were:

- Actual Suspension: Moves the language to Model Orders.
- Restricted Practice: Adds the option of not working in a compounding pharmacy during probation. The committee recommended that this restriction be limited to a pharmacy licensed to compound injectable sterile drug products only and the compounding of these drug products.
- Pharmacist Examination: Updates this condition to reflect new statutory examination requirements (Multi-State Jurisprudence Examination), and adds the requirement for additional semester units for failing to pass the exam after four attempts.
- Mental Health Examination: Adds clarifying requirements for submission of name and qualifications of a licensed mental health practitioner for board prior approval, submission of commencement of psychotherapy, changes in treatment and practitioner, frequency of therapy and requirement of evaluation.

- Psychotherapy and Medical Evaluation: Adds provision of ongoing treatment until therapist recommends and board approves that no further treatment is needed, and that respondent must cease practicing at any time the treating therapist finds that the respondent cannot practice safely.
- Pharmacists Recovery Program (PRP): Clarifies automatic suspension for participants not in compliance with program, added requirement of respondent to pay administrative fees as invoiced by the PRP and added the option of requiring the respondent to work in a pharmacy setting with access to controlled substances for a period of six months prior to successful completion of probation.
- Random Drug Screening: Clarifies automatic suspension for confirmed positive tests.
- Abstain from Drugs and Alcohol Use: Adds provision that respondent shall not be in the same physical location as individuals who are using illicit drugs even if respondent is not personally ingesting the drugs.
- Supervised Practice: Adds requirement that respondent cannot practice pharmacy and that respondent's license is automatically suspended until the board approves the supervisor.

Ms. Harris also presented the proposed new terms and conditions of probation to be added to the disciplinary guidelines:

- Coordination and Monitoring of Prescription Use (for chemically dependent pharmacists and interns): This optional term requires the coordination and monitoring of respondent's prescription use for controlled substances and/or dangerous drugs by a physician, nurse practitioner or psychiatrist.
- Pharmacy Self-Assessment Mechanism (PSAM) (for pharmacists and interns): Requires respondent to complete the Pharmacy Self-Assessment Mechanism administered by the National Association of Boards of Pharmacy.
- No Being Designated Representative in Charge (DRIC): As a standard condition of probation, designated representatives (formerly called exemptees) cannot be designated representatives in charge.
- Posted Notice of Probation (premises): Requires all licensed premises on probation to post a notice of probation during the probation.

The committee discussed the proposed revisions. Supervising Inspector Joan Coyne whose team monitors the probationers and PRP participants explained that an increasing challenge to her team is the monitoring of probationers outside a licensed pharmacy. She explained that language was added to the tolling provision to clarify when a pharmacist ceases to practice pharmacy and probation is then tolled; however, it is difficult to determine when a pharmacist ceases to practice if the pharmacist is not practicing in a pharmacy. Probationers may be working in a position that requires licensure as a pharmacist but the position is not in a pharmacy or entity licensed by the board. Examples of these practice sites include insurance companies, Pharmaceutical Benefits Managers (PBMs) and Department Health Services (DHS) MediCal. The board often times has no ability to monitor the respondent in these types of "practice" settings. She stated that a provision is being added to the probation condition for pharmacists who must participate in the PRP to require the pharmacist to practice in a pharmacy and have access to controlled substances for six consecutive months in order to successfully complete the PRP. This provision is important to assure public safety prior to the pharmacist completing probation.

She suggested a similar approach for all licensees on probation. The committee discussed possible options and directed staff to provide these options to the board.

The committee recommended that the board consider the revisions to the disciplinary guidelines and to provide options regarding the monitoring of pharmacists as to whether the pharmacist must practice in a licensed pharmacy during part or all of probation.

Self-Assessment Form for Wholesalers

Executive Officer Patricia Harris reported that Supervising Inspector Judi Nurse prepared a self-assessment form for wholesalers. This form is modeled after the self-assessment form for pharmacies and its primary purpose is to promote compliance through self-examination and education. Supervisor Nurse explained that the Fraud/Drug Diversion Team also has the responsibility for routine compliance inspections of wholesalers and the self-assessment form would be a valuable tool for wholesalers to assure their compliance with pharmacy law. In addition, the form would assist with the routine compliance inspections. It has been her team's experience that when inspections are performed, usually the exemptee-in-charge is not available and the exemptee that is present is not familiar with the operations. This is frustrating in that the inspector has traveled a considerable distance for the inspection. She explained that if the self-assessment form was completed and available, the inspector would still be able to perform a comprehensive review of the operations.

It was suggested that the draft form be shared with the board's stakeholders for review and comment. The committee recommended that the board adopt a regulation to require the self-assessment form for wholesalers. The proposal would require wholesalers complete the form by July 1 of every odd-numbered year, whenever a new wholesaler permit has been issued, or there is a change in the exemptee-in-charge. It was noted that until such time that a regulation was adopted, the form would be available to wholesalers for self-guidance and completion on a voluntary basis.

Review of Citation and Fine Program

Chair William Powers stated that at the June Enforcement Committee meeting, the California Retailers Association (CRA) requested that the review of the board's Citation and Fine Program be placed on the agenda for discussion the next Enforcement Committee meeting.

As requested, the matter was placed on this agenda. Subsequently, CRA requested that the agenda item be deferred until the December 7th meeting. Mr. Powers stated that it would be on the agenda again for the December meeting; however, since the topic was already noticed, opportunity to discuss the program was also be provided. He stated that the committee was provided with an overview of the investigation process, historical data that gave a three-year overview of the citation and fine program since its inception, which included, the number of citations issued, the type of citations issued and the violations, the number of appeals and the result of those appeals.

Legibility of Prescriptions

Ms. Harris reported that at the July Board meeting, Pharmacist Jim Colucci requested that the board consider a future agenda item to require all prescriptions be printed, typed, or computer generated to improve legibility and prevent prescription errors. During the discussion, the board was reminded of previous legislation related that required the Medical Board of California to perform a study on e-prescribing.

The legislation was AB1589 (Chapter 464, Statutes of 2001), which required the Medical Board to consult with the Board of Pharmacy and commission a study to evaluate the electronic transmission of prescriptions by physicians and surgeons and report its results to the Legislature on or before January 1, 2003. The bill specified that the Medical Board's report include recommendations on whether the electronic transmission of prescriptions should be encouraged, methods to encourage physicians and surgeons and other specified persons to use this method to transmit prescriptions, and to identify systems to protect the privacy of patients, including the issuance of a digital certification. AB 1589 did not appropriate funds for the Medical Board to conduct the study.

In 2001, Medical Board staff consulted with Paul Riches, Legislation Coordinator for the Board of Pharmacy, who suggested that the Medical Board review a November 2001, California Health Care Foundation Report titled, E-Prescribing. The Medical Board reviewed the report, adopted it as meeting the requirements of AB 1589, and submitted the report to the Legislature. A copy of the report was provided.

It was also reported to the committee that current legislation, Senate Concurrent Resolution (SCR) 49 (Speier 2005) relating to medication errors, would create a panel to study the causes of medication errors and recommend changes in the health care system that reduces errors associated with the delivery of prescription and over the counter medication to consumers. The resolution would require the panel to convene by October 1, 2005, and to submit to the Assembly Committee on Health and the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006. It is anticipated that SCR 49 will be passed by the Legislature this session. A copy of the resolution was also provided.

The committee agreed that Pharmacist Colucci's request transcends many health professional boards and the issue of prescription legibility and its impact on patient safety and prevention of prescription errors and the e-prescribing as a solution should be considered by the SCR 49 panel.

Clarification of DEA Requirements

It was reported that on January 18, 2005, the Drug Enforcement Administration (DEA) published in the Federal Register a Solicitation of Comments on the subject of dispensing controlled substances for the treatment of pain. Most of the comments that the agency received sought clarification on the legal requirements governing the prescribing of schedule II controlled substances by physicians. Given the comments on August 26, 2005, the DEA reiterated its principles under the Controlled Substances Act and DEA regulations. A summary of the notice was provided:

- DEA stands firm that the act of a physician writing multiple prescriptions for a schedule II drug on the same day with instructions to fill on a future date is the same thing as writing a refill which conflicts with the provision of CSA that provides "No prescription for a controlled substance in schedule II may be refilled."

- DEA clarified that the Interim Policy did not mean that patients who have been receiving prescriptions for schedule II medications for several years for the treatment of severe pain or attention deficit hyperactivity disorder were required to see the physician each month in order to get another prescription. Physicians that properly determine there is a legitimate medical purpose and acting in their usual course of professional practice can determine whether a patient for whom they are prescribing a schedule II must be seen in person each time a prescription is issued or whether seeing the patient less frequently is consistent with sound medical practice and appropriately safeguards against diversion and misuse.

- If a physician decides to issue the schedule II prescription without seeing the patient, the physician can mail the prescription to the patient or to the pharmacy to be filled. Alternatively, the physician can fax a schedule II prescription to the pharmacy but the pharmacy must have the original signed prescription prior to dispensing the drug to the patient.

- The DEA and CSA regulations contain no specific limit on the number of days worth of schedule II controlled substance that a physician may authorize per prescription. However, any state limitations in place would apply.

DEA plans to complete its review of comments submitted last January and plans to issue a new Federal Register document. Ms. Harris explained that the board has taken the lead from Medical Board of California on this issue. In its April 2005*Action Report* publication, Medical Board of California (MBC) caution physicians regarding DEA's interim policy statement on prescribing Schedule II controlled substances. The interim policy statement prohibits physicians from issuing multiple prescriptions for Schedule II controlled substances on the same day to the same patient with instructions for the pharmacy to fill some of the prescription on a specific date in the future.

In its April 2005 newsletter, MBC stated that unless DEA changes its position, physicians must see their patients each time a prescription for a Schedule II drug is written. However, MBC provided clarification in its July newsletter that stated the term "see" has implied to some that patients must be seen "face to face" each time and this was not the board's intent. It is MBC's position that the amount prescribed and period for follow-up is not dictated by the DEA, and is subject to the standard of care. MBC provided the following statement as guidance and clarity to physicians who prescribe Schedule II controlled substances to their patients:

> *When prescribing Schedule II controlled substances to patients, the length of time and quantity of each Schedule II prescription should be based on the needs of each patient and must be within the standards of responsible prescribing.*

New Labeling Requirements – Physical Description of the Dispensed Medications

On January 1, 2006, new information must be added to labels on prescription containers dispensed from outpatient pharmacies. This requirement is the physical description of the dispensed medication, including its color, shape and any identification code that appears on the tablets or capsules. The exceptions to this labeling requirement are:

- Prescriptions dispensed by a veterinarian;
- Dispensed medications for which no physical description exists in any commercially available database;
- New drugs for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file; and
- When a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to section 1250 of the Health and Safety Code (e.g., acute care hospital, skilled nursing facility, and correctional treatment center) and the prescription drug is administered to a patient by a licensed certified nurse-midwife, nurse practitioner, physician assistant or pharmacist who is acting within his or her scope of practice.

This requirement appears in the Business and Professions Code section 4076(a)(11)(A).

Implementation of SB 1307 (Chapter 857, Statutes of 2004) Relating to Wholesalers

Last year, the Board of Pharmacy sponsored SB 1307 (Figueroa). Governor Schwarzenegger signed the bill, which became effective January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

The Enforcement Committee is monitoring the implementation of this legislation. One area of close oversight is the pedigree requirement. The bill requires an electronic pedigree by January 1, 2007 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.

The industry anticipates that Radio Frequency Identification technology (RFID) will be 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.

During the last year, the board and enforcement committee has had presentations from various companies displaying their electronic pedigree solutions. The first presentation was by T3Ci, an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market. They demonstrated their technology solution for the electronic pedigree. The next presentations were by SupplyScape and Acerity Corporation. SupplyScape

presented its electronic pedigree software program that enables a safe and secure pharmaceutical supply chain that complies with federal and state regulations to prevent counterfeit drugs. Acerity Corporation presented its security software program, which is an electronic authentication process. This system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications.

Ms. Harris reported that board has been participating in the Uniform Drug Pedigree meetings. This is a group of participants that represents manufacturers, wholesalers, and regulators. The purpose of these meetings is to provide a cooperative effort to develop uniform standards and regulations regarding electronic pedigrees. She also stated that through the board's participation with this group and others, a list of questions and answers are being developed that will be shared at the next enforcement committee meeting in December.

Lew Kontnik, Director of Brand Protection/Business Continuity for Amgen presented to the committee the challenges that Amgen has encountered in developing an electronic pedigree for its manufactured products. He stated that Amgen, a billion dollar company that is headquartered in California, is the leading human therapeutics company in the biotechnology industry. He demonstrated the challenges that their company is facing in the implementation of RFID technology to track the electronic pedigree of its liquid products. Primarily he showed how the placement of the radio frequency tag on the products have resulted with inconsistent and inaccurate readings by the scanner unless the scanner is in close proximity of the tagged item, which is not conducive to tracking large quantities of distributed product. He also stated that whatever mechanism is used to generate the electronic pedigree, it must be incompliance with good manufacturing practices (GMPs), which is regulated by the federal Food and Drug Administration (FDA).

Upon conclusion of his presentation, Mr. Kontnik presented his company's position that it will be extremely difficult to meet the January 1, 2007 deadline to implement an electronic pedigree for its manufactured drug products.

Adjournment

Chair Powers adjourned the meeting at 12:15 p.m.

ATTACHMENT H

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, Governor

Enforcement Team Meeting
September 13, 2005

1:30 p.m. – 2:30 p.m.

Present: Committee Chair William Powers
President and Member Stan Goldenberg
Executive Staff
Supervising Inspectors
Inspectors

Announcements/Introductions
The meeting began at 1:30 p.m.

Quality Improvement Efforts
Supervising Inspector Robert Ratcliff announced that there will be an inspector meeting November 15 – 17, 2005.

Enforcement Committee Discussions
The Enforcement Team discussed the agenda items from the Enforcement Committee gathering. Inspectors discussed the importance of monitoring probationers in a licensed pharmacy to assure public protection and compliance with pharmacy law.

Adjournment
The meeting was adjourned the meeting at 2:30 p.m.

ATTACHMENT I

Board of Pharmacy Enforcement Statistics
Fiscal Year 2004/2005

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Complaints/Investigations					
Initiated	407				407
Closed	548				548
Pending (at the end of quarter)	637				637
Cases Assigned & Pending (by Team)					
Compliance Team	68				68
Drug Diversion/Fraud	85				85
Mediation Team	99				99
Probation/PRP	28				28
Enforcement	15				15
Application Investigations					
Initiated	37				37
Closed					
Approved	21				21
Denied	5				5
Total*	34				34
Pending (at the end of quarter)	46				46
Citation & Fine					
Issued	189				189
Citations Closed	153				153
Total Fines Collected	$46,236.00				$46,236.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2004/2005

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	49				49
Pleadings Filed	38				38
Pending					
Pre-accusation	64				64
Post Accusation	75				75
Total	160				160
Closed**					
Revocation					
Pharmacist	4				4
Pharmacy	1				1
Other	11				11
Revocation,stayed; suspension/probation					
Pharmacist	9				9
Pharmacy	1				1
Other					
Revocation,stayed; probation					
Pharmacist	5				5
Pharmacy	2				2
Other	1				1
Suspension, stayed; probation					
Pharmacist					
Pharmacy					
Other					
Surrender/Voluntary Surrender					
Pharmacist	1				1
Pharmacy					
Other	3				3
Public Reproval/Reprimand					
Pharmacist					
Pharmacy	1				1
Other					
Cost Recovery Requested	$120,408.25				$120,408.25
Cost Recovery Collected	$46,386.35				$46,386.35

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2004/2005

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Probation Statistics					
Licenses on Probation					
Pharmacist	108				108
Pharmacy	16				16
Other	19				19
Probation Office Conferences	20				20
Probation Site Inspections	54				54
Probationers Referred to AG for non-compliance	3				3

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 09/30/05)

Program Statistics					
In lieu of discipline	1				1
In addition to probation	5				5
Closed, successful	0				0
Closed, non-compliant	4				4
Closed, other	0				0
Total Board mandated Participants	47				47
Total Self-Referred Participants*	16				16
Treatment Contracts Reviewed	40				40

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

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

As of September 30, 2005.

ATTACHMENT J

Enforcement Committee

2005-2006

First Quarter Report

July 1, 2005 thru September 30, 2005

Goal 1: **Exercise oversight on all pharmacy activities**

Outcome: **Improve consumer protection**

Objective 1.1: **To achieve 100 percent closure on all cases within 6 months by June 30, 2006.**

Measure: Percentage of cases closed or referred within 6 months.

Task:

1. **Mediate all consumer complaints within 90 days.**

Quarter 1: Based on **211** mediations/investigations sent to Supervising Inspectors for review.
Quarter 2:
Quarter 3:
Quarter 4:

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 90	24	11%						
91 to 180	11	5%						
181 to 365	1	0%						
366 and over	1	0%						

Task:

2. **Investigate all other cases within 120 days.**

Review total stats same as above

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 120	106	50%						
121 to 365	63	30%						
366 and over	5	2%						

Task:

3. **Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.**

Quarter 1: Based on **550** closed mediations/investigations.

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 180	405	74%						
181 to 365	123	22%						
366 to 730	18	3%						
731 and over	4	1%						

Task:	**4. Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any board-licensed facility when the operations of the facility poses an immediate threat to the public.** First Quarter: Nothing to report.
Task:	**5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports).** **CURES** **Number of pharmacies reporting to CURES and number of prescription records reported.** Pharmacies Records ▪ Quarter 1: **5,044** **2,799,811** **CURES reports provided to supervising inspectors and/or inspectors to aid in an investigation or inspection:** ▪ Quarter 1: **15** **CURES data used in complaint investigations:** ▪ Quarter 1: **20** **CURES compliance issues found in inspections:** ▪ Quarter 1: **10** **1782 Wholesaler Data Base:** No changes. Board has not been using 1782 reports for the last 3 to 4 years. **DEA 106 Theft/Loss :** ▪ Quarter 1: Approximately **42** investigations opened from DEA 106 loss reports.
Task:	**6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations.** The CURES Users Group is scheduled to meet the 2nd Wednesday of every month to work on pharmacy noncompliance and data issues as well as to improve database functionality. Additionally, the boards and DOJ have used these meetings to discuss issues and share information related to the implementation of SB 151. Meetings were held July 13 and September 14. BNE canceled the August and October meetings due to database issues. First Quarter: During a recent driver upgrade to the new CURES web-based database, the BNE encountered a corruption to the front end portion of the database. The front end is the part of the database that allows users the ability to run standard and ad hoc queries and reports. None of the data was lost, only lost query and report functionality. While BNE is fixing the web-based system, they have temporarily reinstated the previous Impromptu CURES database to allow users access to the data and the ability to run queries and reports. Each Quarter: An inspector and a supervising inspector continue to participate on the monthly diversion task force meetings regarding the importation of dangerous drugs, repackaging and distribution in the U.S.; monthly Oxycontin task force meetings in Ventura; FBI task force meetings; and diversion task force meetings in San Diego.

Task:	**7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public.** First Quarter: Nothing to report.
Task:	**8. Improve public service of the Consumer Inquiry and Complaint Unit.** First Quarter: ▪ Three new informational flyers were developed through UCSF addressing the issues of recalled medication, generic medication, and cutting drug costs. ▪ "What You Should Know Before Buying Drugs from Foreign Countries or the Internet" and "Tips to Save You Money When Buying Prescription Drugs", are now available in Chinese, Vietnamese, Spanish, and English languages. ▪ The board now has 24 consumer brochures and publications, including Health Notes. ▪ Board staff provided consumer information at the City of Sacramento Public Safety Center's Community Celebration on September 24, 2005. ▪ Board staff provided consumer information at the UCD Healthy Aging Summit on October 15, 2005.
Task:	**9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.** **Investigative Activities:** First Quarter: ▪ With the addition of Schedule III prescriptions added to the CURES database, the volume of data has grown too large to transmit to the inspectors via email. Staff developed a program to put on CD for each inspector that will automatically install an updated CURES data file to their laptops with the click of a button. CD's with updated CURES data files are mailed monthly to each inspector. ▪ To improve case management efforts, a monthly report is prepared and submitted to management. This report reflects the age of the case, who the case is assigned to, which cases are under review with the Supervising Inspector, cases that are referred to citation and fine and/or the Attorney General. The report identifies those cases not currently assigned. The report is also used as a tool to identify and locate those cases that have not had any recent activity. ▪ A request to allow the board the ability to download it's entire enforcement data base into Access has been submitted. This modification would enhance the board's reporting capabilities. If approved, January 1, 2005 is our target date for implementation. First Quarter: The request has been received and is awaiting assignment to a staff member in OIS. ▪ The department is currently evaluating tools to implement ad hoc reporting. Through the Enforcement Users Group meetings the latest information is that they are in the selection process and hope to be able to test the product soon. First Quarter: All vendor demonstrations are complete. The selection has not been announced. OIS has met with the Chief Information Officer and Project Executive Sponsor to discuss findings. The CIO and PES will determine what further action will be taken. ▪ Staff performed various updates to improve functionality of the various enforcement databases.

Inspection Activities – Automated inspection assignment status reports are sent to supervising inspectors weekly. Revisions and additions made to the automated inspection database include:

First Quarter:

- Color coding queries showing licensees that have already been scheduled for inspection, need to be scheduled for inspection, and those inspections completed had to be updated with new criteria now that the new 4 year inspection cycle has started.
- Revised wholesale and LSC automated reports to include assignment information.
- 75 security printers are currently approved to produce controlled substance prescription forms. 10 of the approved printers utilize the services of several hundred distributors that market their prescription products to prescribers.

Objective 1.2 — **To achieve 100 percent closure on all administrative cases within one year by June 30, 2006.**

Measure: — **Percentage closure on administrative cases within one year.**

Task:

1. **Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases.**

   - 7/05 DAG costs increase to $139 per hour. Board receives supplemental funding of $216 thousand to purchase the same level of AG services at a higher hourly rate.

Task:

2. **Aggressively manage cases, draft accusations and stipulations, and monitor AG billings and case costs.**

   - Case management and review of pending cases is a continuous process.

	Q1	Q2	Q3	Q4
Status memos sent to AG	**35**			
0-365 days	**21**			
366 + days	**21**			
Accusations reviewed	**39**			
Accusations needing revision	**7**			
Accusations filed	**38**			
Stips/proposed decisions reviewed	**15**			
Cases reviewed for costs	**10**			

Task:

3. **Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances.**

   First Quarter: Nothing to report.

Task:

4. **Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.**

   Administrative Case Management Database Program:

   First Quarter: No changes this quarter.

Objective 1.3:	**Inspect 100 percent of all licensed facilities once every 3 years by September 30, 2005.**
Measure:	**Percentage of licensed facilities inspected once every 3 years**

Task:

1. **Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.**
   - For all quarters, see response to Objective 1.1, Task #9

Task:

2. **Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.**

Inspection Statistics Background:

First Quarter:
On July 1, 2005, the board began its second 3 to 4-year cycle of inspections towards the goal of inspecting all sites once every 3 to 4 years (by June 30, 2009):

- Total number of locations identified to inspect from those licensed as of July 1, 2005 (does not include sites licensed after 7/1/05) to meet the board's goal of inspecting all sites once every 3 to 4 years was approximately **7,735**;
  - Total number of inspections completed **611**,
  - Total number of inspections to be completed by June 30, 2009 are **7,119 or 7.9%**.

- Total number of locations identified to inspect (including sites licensed before and after 7/1/2005) was approximately **7,915**;
  - total number of inspections completed **618**;
  - total number of inspections to be completed by June 30, 2009 are **7,292 or 7.8%**.

(Percent of all site inspections completed **7.85%)**

*inspection data as of 10/1/05

Total Number	**Q1**	**Q2**	**Q3**	**Q4**
Inspections Completed	**789**			
Total by Type				
Routines/Wholesaler-Vet-Retailer/Probation/PRP	**584**			
Sterile Compounding	**79**			
Investigation Inspections	**126**			
Status 3 (included in routines)	4			
Routine resulting in complaint investigation. (included above)	34			

Wholesaler/Vet Retailer Inspection Program – The board implemented the Wholesaler Inspection Program beginning March 1, 2005. Data are included in the previous table and shown separately here for reference only.

First Quarter: A total of **503** sites identified for inspection. As of 9/30/05, the Diversion Team has completed a total of **249** inspections since program inception.

	Q1	Q2	Q3	Q4
Wholesaler/Vet Retailer Inspections Completed	**79**			

Task:

3. **Seek legislation to mandate that periodic inspections be done on all board-licensed facilities**
   First Quarter: Nothing to report.

Objective 1.4 **Develop 4 communications in addition to the inspections program to educate board licensees by June 30, 2006.**

Measure: **Number of communication venues (excluding inspection program)**

Task:

1. **Develop the board's website as the primary board-to-licensee source of information.**

   - Public disclosure of disciplinary history on licensees is online.

   First Quarter Web Additions/Revisions

   - Posted board meeting dates for 2006
   - Posted board and committee information - agenda, materials & minutes
   - Regulation updates
   - Updated several application packets
   - Added new version of self-assessment forms
   - Created a page on Hurricane Katrina Information and Resources
   - Added newly approved Security Printers (total 77)
   - Updated the Script Newsletter Index
   - Sent out subscriber alert notifications to the board's e-mail notification list

Task:

2. **Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations.**
   - January 2005 Script Newsletter published.
   - October 2005 Script Newsletter published.

Task:

3. **Update pharmacy self-assessment annually.**

   First Quarter: Revised form so that fields can be filled in online. New version posted of the web
   - Regulation requiring 2005 version took effect 10/7/05.

Task:

4. **Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California.**

First Quarter C/E Presentations

- Supervising Inspector Nurse presented information about the board and how it investigates cases to a group of United States Attorneys on July 20.
- Supervising Inspector Nurse participated in a training module for federal investigators who will be monitoring fraud in the Medicare Prescription Drug Plan programs in San Diego on September 20.
- The board staffed a public information booth the City of Sacramento Public Safety Public Fair on September 24.
- The board will staff a public information booth on October 15 at the UCD Healthy Aging Fair.
- Supervising Inspector Ratcliff will present information on pharmacy law changes at a UFCW-Orange County Pharmacist Association continuing education conference on October 16.
- The board will staff an information booth at CSHP Seminar on October 21 and 22.
- Several board members will present information at this association meeting.
- Supervising Inspector Ming will present information about pharmacy law to a group of UCSD pharmacy students in mid-November
- Assistant Executive Officer Herold will present information about the board to a group of UCSD pharmacy students on November 28.
- Supervising Inspector Ming will present information about sterile compounding to a group of pharmacy technician students at Santa Ana College on November 30.
- Board Member Jones will present information about pharmacy technology at the NABP Fall Conference in December.

Task:

5. Hold quarterly Enforcement Committee Meetings

First Quarter:

- Meeting held 6/05. Discussed importation, use of automated devices in clinics. Interpretation of pharmacy law related to Interns, waiver requests for self-use automated delivery systems, and petitions for consideration.
- Meeting held 9/05. Discussed importation, disciplinary guidelines, self assessment for wholesalers, legibility of prescriptions, DEA requirements for prescribing Schedule II drugs, new labeling requirements, and electronic pedigree requirements.

Objective 1.5 **To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2006.**

Measure: **Percentage compliance with program requirements**

Task:

1. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program).

Pharmacists Recovery Program	Q1	Q2	Q3	Q4
Total # of PRP Participants	63			
Number Referred to PRP	6			
Number Closed from PRP	4			

	Probation Monitoring Program - Number on Probation	Q1	Q2	Q3	Q4
	Pharmacists	108			
	Pharmacies	16			
	Other	19			
	Citation and Fine	**Q1**	**Q2**	**Q3**	**Q4**
	Citations Issued	189			
	Fines Collected	$46,236			

Task:

2. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.

First Quarter: Currently in the process of establishing a database for the Citation and Fine unit. The database will automate the processes of creating letters, memos and statistics, which are currently completed by staff manually.

-working with staff in linking databases
-working with OIS to automatically receive monthly licensure information
-working with Citation and Fine unit to verify needs for letters and memos
-testing for integrity of statistical data

Objective 1.6 **Respond to 95 percent of all public information requests within 10 days by June 30, 2006.**

Measure: **Percentage response to public information requests within 10 days.**

Task:

1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions.

- Web Enforcement Look-Up – In production May 2004. Completed disciplinary actions are entered into the database on an on-going basis.
- Staff has begu scanning public disciplinary documents for availability as a PDF document on the Web Enforcement Look Up.

Task:

2. Establish on-line address of record information on all board licensees-

- Licensee address of record information became available on-line to public in December 2003.
  - Regulation to ban posting on Website the address of record of intern pharmacists goes to the board for adoption. If approved, the rulemaking files will be submitted to the Administration for approval in November 2005.

Task:

3. Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests.

	Total by Type of Requests Received	Q1	Q2	Q3	Q4
	Public	30			
	Licensees	24			
	Other agencies	29			
	License Verifications	223			

	Time Frame Records Requests Responded To	Q1		Q2		Q3		Q4	
		Number and Percentage Per Quarter							
	Within 10 days	**67**	**81%**						
	Over 10 days	**16**	**19%**						
	Time Frame License Verifications Responded To	**Q1**		**Q2**		**Q3**		**Q4**	
		Number and Percentage Per Quarter							
	Within 10 days	**210**	**94%**						
	Over 10 days	**13**	**6%**						

Objective 1.7 **Measure:**	**Initiate policy review of 25 emerging enforcement issues by June 30, 2006.** **The number of issues.**
Tasks (Issues)	1. Reimportation of drugs from Canada. ▪ Importation of Drugs - 2004: discussed at every Enforcement Committee meeting and board meeting. ▪ 1/05: discussed at Board Meeting. ▪ 3/05: discussed at Enforcement Committee Meeting. ▪ 4/05: discussed at Board Meeting. ▪ 6/05: discussed at Enforcement Committee Meeting. ▪ 7/05: discussed at Board Meeting. ▪ 9/05: discussed at Enforcement Committee Meeting. 2. Modification to the Quality Assurance Regulation regarding patient notification. (completed) 3. Proposals regarding wholesale transactions. ▪ Sponsored legislation (SB 1307). ▪ 1/05 – SB 1307 became effective. ▪ 1/05 – participated in NABP Task Force to develop e-pedigree elements. ▪ 1/05 – participated in NABP Wholesaler's Distributors Regulatory meeting and participated in NABP Task Force to develop e-pedigree elements. ▪ 2/05 – implementation of SB 1307. ▪ 4/05 – presentation to board on pedigree software ▪ 6/05 – two presentations to Enforcement Committee on pedigree software. ▪ 9/05 – discussed at the Enforcement Committee Meeting regarding the difficulty of implementation. 4. Clarification regarding prescription records by authorized officers of the law. ▪ 10/05: updated article in the board's newsletter. 5. Review of Pharmacy Law regarding the delivery of medications after the pharmacy is closed and a pharmacist is not present. ▪ Sponsored legislation SB 1913 ▪ 1/05 – bill passed, SB 1913 effective 6. Off-site order entry of hospital medication orders (Bus. & Prof. Code Section 4071.1). ▪ DOJ and board approved for controlled substances. 7. Prescriber dispensing. ▪ 5/03 Workgroup with Medical Board on proposal on prescriber dispensing by physician groups. 8. Implementation of federal HIPAA requirements. 9. Prohibition of pharmacy-related signage. 10. Implementation of enforcement provisions from SB 361. 11. Implementation of SB 151 (elimination of the Triplicate). ▪ 1/05 – new changes to controlled substance law took effect. Continued CE presentations.

- 2/05 – continued CE presentations
- 3/05 – discussed Q & A at Enforcement Committee meeting.
- 4/05 – discussed at board meeting.
- 6/05 – discussed at Enforcement Committee meeting.

12. Dispensing non-dangerous drugs/devices pursuant to a prescriber's order for Medi-Cal reimbursement
13. Authorized activities in a pharmacy.
14. Review of Quality Assurance Program.
15. Limited distribution and shortage of medications.
16. Conversion of paper invoices to electronic billing.
17. Automated dispensing by pharmacies.
18. Public disclosure and record retention of substantiated complaints.
19. Evaluation of QA regulation
20. Biometric technology
    - Statutory change (SB 1913), regulation proposal to implement.
    - 10/05 Regulation became effective.
21. Update of pharmacy laws related to PRP.
    - 10/04 –board approved statutory changes.
    - 2/05 – Legislation introduced – SB 1111.
22. Update of pharmacy law related to pharmacy technicians.
    - 10/04 –board approved statutory changes.
    - 2/05 – Legislation introduced – SB 1111.
23. Clean-up of "Letter of Admonishment" provision.
    - 10/04 –board approved statutory changes.
    - 2/05 – Legislation introduced – SB 1111.
24. Use of "kiosks: for drop-off of prescriptions.
    - 10/05 – board approved waiver for kiosks and regulation change
25. Use of self-services dispensing units for pick-up of refill prescriptions.
    - 10/04 – board approved statutory changes
    - 1/05 – board approved second waiver
    - 4/05 – board approved third waiver in conjunction with a study.
    - 6/05 – request to require "Pharmacy Service Plans" for approved waiver.
    - 7/05 Board approved two more waivers.
    - Overview of study by UCSD presented.
    - 9/05 Regulation change noticed.
26. Mandatory reporting of impaired licensees.
    - 1/05 –board approved statutory change
    - 3/05 – SB 1111 introduced
27. Electronic Prescribing Standards for the implementation of the Medicare Drug Improvement and Modernization Act (MMA) of 2003.
    - 3/05 – Discussed at Enforcement Committee meeting – no action necessary.
28. Prescribing Authority for Naturopathic Doctors
    - 2/05 – Met with Bureau of Naturopathic Doctors and other interested parties regarding proposed legislative changes to address inconsistencies in pharmacy law.
    - 2/05 – Requested legal opinion from DCA.
    - 4/05 Opinion provided to Board.
    - 6/05 Clean-up statutory provisions introduced in bill.
29. 6/05 - Pharmacy law clarification regarding pharmacist interns, orally and electronically transmitted prescriptions, and filling on non-security Rx form for controlled substances.
30. 6/05 – Use of automated drug delivery systems in clinics.
31. 6/05 – Request to repeal CCR 1717.2. (Board approved)
32. 6/05 - Legal requirements and process for Petitions for Reconsideration.
33. 9/05 – Proposed self-assessment for wholesalers.
34. 9/05 – Legibility of prescription – Refer to SCR49 Medication Error Panel for review.

	35. Revised self-assessment for pharmacies. ▪ 10/05 Regulation became effective. 36. Update regulation 1745 regarding the partial fill of Schedule II prescriptions. ▪ 10/05 Regulation change became effective.