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

Contact Person: Patricia Harris
(916) 445-5014

ENFORCEMENT COMMITTEE MEETING

June 22, 2005
9:30 a.m. – 12:30 p.m.

Holiday Inn Capitol Plaza
300 J Street
Sacramento, CA 95814
(916) 446-0100

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

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

AGENDA

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

A. Discussion Regarding the Importation of Prescription Drugs

B. Use of Automated Drug Delivery Systems as Authorized by B & P Code section 4186 in Clinics Licensed by the Board Pursuant to B & P Code section 4180 – Clarification of Pharmacy Law

C. Clarification of Pharmacy Law Related to Intern Pharmacists, Orally and Electronically Transmitted Prescriptions and Filling of Non-Security Prescription Forms

D. Recommendation to Repeal 16 CCR § 1717.2 – Notice of Electronic Prescription Files

E. Recommendation from the California Pharmacists Association (CPhA) to Require the Pharmacy to Submit a "Pharmacy Services Plan" When a Waiver is Granted pursuant to 16 CCR § 1717(e) to Use a Self-Service Dispensing Unit for Refill Prescriptions

F. Legal Requirements and Process for a Petition for Reconsideration

G. Implementation of SB 151 (Chapter 406, Statutes of 2003) – Requirements for Prescribing and Dispensing Controlled Substance Prescriptions as of January 1, 2005 and CURES Update

H. Implementation of SB 1307 (Senator Figueroa) Relating to Wholesalers
- Presentation by SupplyScape on its Electronic Pedigree Software
- Presentation by the Acerity Corporation on Its Technological Solution to Detect Counterfeits

I. Adjournment **12:30 p.m.**

Committee materials will be available on the board's website by June 17, 2005

AGENDA ITEM A

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee

Date: June 13, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Importation of Prescription Drugs**

This is a standing agenda item for the meetings of the Board and the Enforcement Committee. Attached are various articles that have appeared since the last board meeting.

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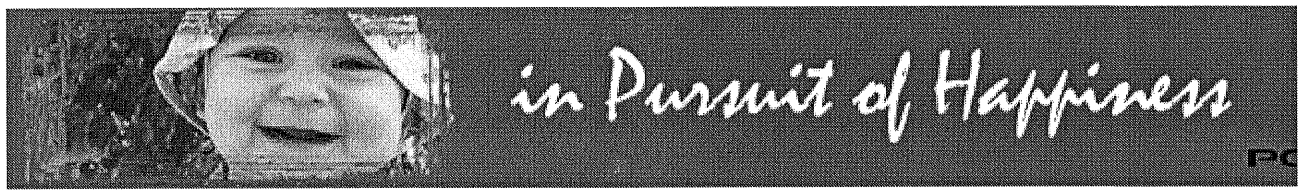

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Sun. Jun. 12 2005 2:28 PM ET

Internet pharmacies see consolidation as solution

Canadian Press

WINNIPEG — The political uncertainty surrounding Canada's Internet pharmacy industry has spawned some practical business realities in the last six months - fewer players, zero growth and, in some cases, no actual drug dispensing.

But even as the industry watches overseas pharmacies and suppliers carve out a bigger piece of a growing global market for cheaper prescription drugs for U.S. patients, it remains determined to survive in some form.

Just as determined, however, are opponents who see a federal crackdown as the only protection against potential drug shortages and price increases in Canada.

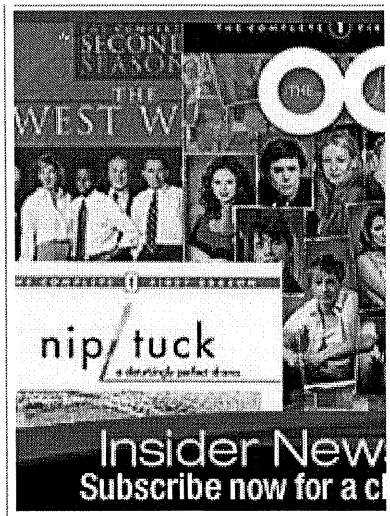
They're pinning their hopes on Health Minister Ujjal Dosanjh, who has been studying options ranging from banning bulk exports to the U.S. to tougher measures that would effectively drive the online industry out of Canada.

He's also keeping a close eye on the U.S. Congress, which is considering legislation that would allow unlimited drug imports from Canada.

One consultant who is helping online pharmacies "strategically consolidate" says the industry has evolved to the point where sweeping government intervention is no longer needed.

"There's going to be an ever-diminishing burden on the Canadian drug supply," said David MacKay of Resultz Strategic Planning and Relations in Winnipeg.

"It's getting to the point where most of the drugs imported by American patients will actually come from countries other than



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Canada."

MacKay, former executive director of the Canadian International Pharmacy Association, is helping smaller businesses partner with bigger Canadian pharmacies that have already spent the time and money to set up their own drug dispensing operations or partnerships overseas.

He estimates as many as three-quarters of all Internet pharmacies have incorporated some form of international supply to their business.

The amount of overseas business varies from pharmacy to pharmacy.

But MacKay acknowledges that in some cases, Internet pharmacies are no longer acting as pharmacies at all but are "merely call centres and a customer-service handling point for American orders."

Drug sales data compiled by IMS Health suggests the wholesale volume for Internet pharmacies has dropped about 10 per cent in the last year, to $551 million as of March 31 from $617 million at the end of the same quarter in 2004.

The figures sharply contrast with 2003 sales, which more than doubled 2002 sales, said Mark Maciw, senior director of supplier relations.

Maciw attributes the decline to fewer online pharmacies, supply restrictions imposed by several brand-name drug manufacturers, increased sales of some cheaper generic drugs and the higher Canadian dollar.

The retail value of the industry has been widely reported to be about $1 billion a year.

In Manitoba, the birthplace of the industry and home to many of the industry's jobs and sales, the number of Internet pharmacy licence holders has fallen sharply to about 45 from 61 over the last 18 months.

But that's little comfort to opponents such as the Canadian Pharmacists Association.

The group is part of a coalition of pharmacists, doctors and patients who have warned of disastrous drug shortages if U.S. legislators legalize bulk imports.

The association also wants online pharmacies banned from selling smaller quantities to individual U.S. patients.

Executive director Jeff Poston said his group wants Dosanjh to impose a residency requirement that would prevent pharmacists from filling prescriptions for people who don't normally live in Canada.

Ottawa also needs to make it easier for provincial pharmacy and medical regulatory bodies to share information with each other to discipline those who break the rules, he said.

Dosanjh could not be reached for comment but a spokesman said "his deliberations are well advanced."

The president of the Canadian International Pharmacy Association says turning to overseas drug dispensing has stabilized the industry.

But Andy Troszok said it won't be able to grow as long as brand-name drug manufacturers blacklist Internet pharmacies.

In the meantime, Canada risks losing its overall competitive edge if Americans eventually decide to skip Canadian online pharmacies as a middle man and go straight to the source.

"At the end of the day we have to be responsible," said Troszok, who operates an online pharmacy in Calgary.

"Canada should have an opportunity as a country in a global economy to be part of this industry. If Canada does not, other countries are lined up to do so."

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Ban Urged on Canadian Bulk Drug Exports

By Randall Palmer
Reuters
Friday, June 3, 2005; 11:41 AM

OTTAWA - Canada's parliamentary health committee, nervously eyeing U.S. legislative moves to buy cheap Canadian drugs, has called for a ban on the bulk exports of foreign-made pharmaceuticals.

A Conservative motion passed Thursday afternoon with the support of three of Parliament's four parties, including the governing Liberal Party. It would curb bulk drug exports only and would not ban sales to individuals by Internet pharmacies.

"Putting drugs in a trailer and shipping them across the border is just not on the cards," Conservative Member of Parliament Steven Fletcher said Friday.

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The proposal would be a pre-emptive strike against threats from U.S. pharmaceutical companies that they might halt shipments to Canada if the drugs are simply shipped back to the United States, and sold at levels that undercut U.S. prices.

It would also aim to avert some of the harsher crackdowns that Canadian Health Minister Ujjal Dosanjh has suggested might be necessary.

Dosanjh said in March that a ban on the bulk exports of drugs was only one of several options he was considering.

Other options included a total ban on export of price-controlled patented drugs, banning sales to people who are not resident or present in Canada, and making it illegal for Canadian doctors to countersign prescriptions from U.S. doctors -- three options that

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could effectively shut down Internet pharmacies.

"Ujjal Dosanjh has for months threatened to implement a heavy-handed shutdown of Canadian on-line pharmacies, yet has refused to ban bulk drug exports, a measure that would protect the on-line pharmacy industry and safeguard Canada's drug supply," a Conservative statement said.

Dosanjh's office had no immediate comment on whether he would follow the panel's proposals.

Several bills to allow importation of foreign drugs have been introduced in the U.S. Congress, and cities and states have also taken action. Washington state, for example, enacted a law last month which would enable retail pharmacies to import drugs from Canadian, British and Irish wholesalers.

But for the state law to take effect, the U.S. government would first have to lift its ban on pharmaceutical imports.

"We all know that the Americans could open their border to our drugs at any time," Fletcher said in a statement. "The solution that the Conservatives have proposed is simple and effective. Everyone wins. Just ban bulk exports."

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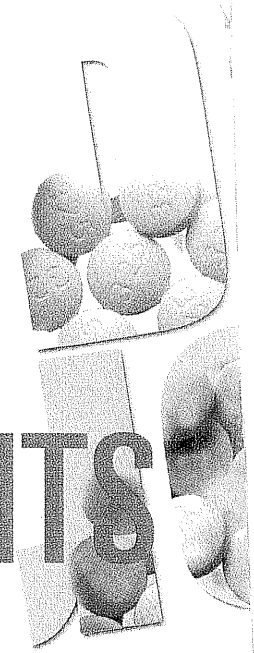
FOREIGN RXS: SAME NAME, DIFFERENT INGREDIENTS



Identical brand names and imported drugs—do we know what our patients are really taking?

By Michael R. Cohen, R.Ph.

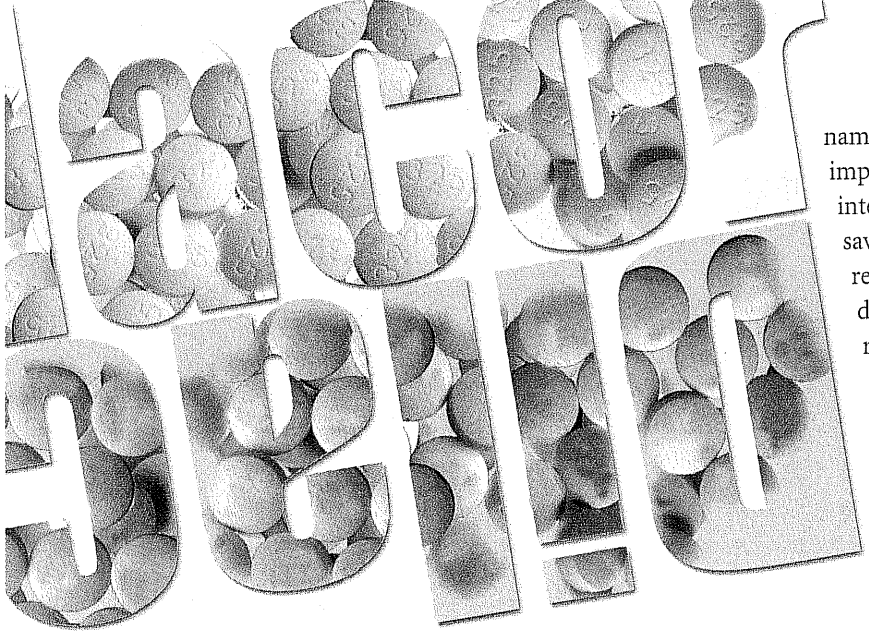
Most U.S. pharmacists are aware of some of the problems associated with importation of prescription drugs from other countries, such as counterfeiting and potentially lax regulatory drug approval processes. Many are not familiar, however, with the danger posed by multiple uses of the same brand name. Medications with familiar U.S. brand names may contain totally different active ingredients in another country, a situation that can cause serious harm to unsuspecting patients.

In one recent example, a patient who was traveling to Serbia ran out of Dilacor XR (diltiazem extended release), marketed here by Watson Labs. A Serbian pharmacist filled the prescription with digoxin 0.25 mg. In Serbia, Dilacor, marketed by a local company, is a brand name for digoxin. The patient continued to take digoxin without realizing it and was hospitalized after his return to the United States with life-threatening toxicity.

Global Naming Problems. There are a number of instances where brand names exist in different countries with completely different ingredients. Table 1 provides a few examples, but keep in mind that the problem is far more widespread. (Many other examples are listed in *Index Nominum* and *Martindale*, both available as subscriptions

Table 1: Examples of brand names that represent different active ingredients in foreign countries

U.S. Brand Name	Active ingredient(s), purpose, and manufacturer in US	Active ingredient(s), purpose, and manufacturer in foreign country
DILACOR	diltiazem angina, hypertension (Watson Labs)	digoxin (Serbia) congestive heart failure, arrhythmia (Zdravlje)
FLOMAX	tamsulosin benign prostatic hyperplasia (Boehringer Ingelheim)	morniflumate (Italy) inflammation, pain, fever (Chiesi)
NAQUA	trichlormethiazide diuretic (Schering)	furosemide (Portugal) diuretic (Bial)
NORPRAMIN	desipramine depression (Aventis)	omeprazole (Spain) peptic ulcer, GERD (CEPA)
SOMINEX	diphenhydramine insomnia (SmithKline Beecham Consumer)	promethazine (United Kingdom) insomnia (Thornton & Ross)
TREXAN	naltrexone opioid dependence (DuPont)	methotrexate (Finland, Hungary) malignant neoplasm, psoriasis, rheumatoid arthritis (Orion)
VIVELLE	estradiol estrogen deficiency, menopausal disorders, osteoporosis (Novartis)	ethinylestradiol, norgestimate (Austria) acne, tri-phasic oral contraceptive (Janssen-Cilag)



through Micromedex.) In addition, the brand name used for a foreign product may be available simultaneously in several countries, or it may represent additional unique medications in countries other than those listed. For example, while Dilacor is a brand name for diltiazem in the United States and digoxin in Serbia, it is also a brand name for barnidipine in Argentina and verapamil in Brazil.

Part of the problem is that companies planning to market a drug only in America might not perform a comprehensive search to assure that the proposed brand name is not used anywhere else in the world. If marketing the drug outside our borders, most large companies will perform searches in the major markets to be served because there is an interest in adopting a single global brand name. However, the proposed brand name might not be evaluated in every market because the necessary information may not be available.

On occasion, generic names of products in another country might be different than those used in the United States. However, there are international authorities, such as the World Health Organization's International Nonproprietary Name (INN) system, that control these situations and provide ongoing efforts to harmonize generic names worldwide. This is not so with brand names. Once a brand is marketed in certain countries, there is no universal system to monitor or prevent the same name from being used in other countries for different products.

When pharmacists are confronted with a foreign, unfamiliar generic name, they are likely to conduct further research. The much more potentially dangerous problem with brand names that represent different active ingredients is that the responsibility for preventing mistakes rests squarely in the hands of patients, who may have no idea that the wrong drug has been dispensed, and their health care providers, who may not know what their patients are really taking and do not investigate further because the drug name is familiar.

Error Risks With Reimportation. The issue of "same brand name, different drug" obviously has major safety implications, especially in light of the growing interest in drug reimportation to help consumers save money. Although it is against U.S. laws and regulations, several states are actively facilitating drug reimportation, even operating state-run websites that refer citizens to Canadian pharmacies. With Canada threatening regulatory change to make it difficult or impossible to fill prescriptions for U.S. patients, some states are exploring the option of importing medications from Europe. As with the patient who took the wrong Dilacor, the opportunity for medication errors is substantial unless we adopt good naming practices endorsed by global health authorities that minimize or prevent use of the same brand name for different products.

There are additional risks posed by reimportation of drugs—a wide range of name suffixes used in the United States for various dosage forms (CD, CR, ER, LA, SA, SR, TD, XL, etc.) may not correspond to those used for the same drug abroad. And while verbal orders are less likely when importing drugs from abroad, look-alike and sound-alike brand names can also play a role in errors. For example, Amyben is one branded product for amiodarone in the United Kingdom. Dispensing Amyben instead of Ambien (zolpidem tartrate) in the United States could have disastrous results.

Safety Recommendations. The Institute for Safe Medication Practices suggests reminding patients who are going abroad to carry an adequate supply of medications along with a list by both generic and brand name so they can confirm that the correct drug has been dispensed if supplies become depleted. When counseling patients who are using or considering using a source outside the United States for filling their prescriptions, mention the potential risks so that they can make a more informed decision.

Pharmacists should always match generic names and strengths with U.S.-prescribed medications when filling prescriptions from overseas providers. Refer to *Index Nominum* or *Martindale* to check whether a drug from a different country is the same as the U.S. drug with the same name. If you do not have access to either of these sources, check with your local Poision Control or Drug Information Center. ■

Michael R. Cohen, R.Ph., MS, ScD, is president of the Institute for Safe Medication Practices (ISMP), recognized worldwide as the premier education resource for understanding and preventing medication errors. ISMP efforts are built on a non-punitive approach and systems-based solutions. It focuses on improving the safety of medication distribution and use, naming, packaging, and labeling. For more information, visit ISMP online at www.ismp.org

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INTRODUCTION

Brand names are used for different drugs in different countries.

A patient traveling in Serbia ran out of *Dilacor XR* (diltiazem). He got a refill and landed in the hospital with DIGOXIN toxicity. It turns out that *Dilacor* is a brand name for digoxin in Serbia.

Dilacor is also a brand name for verapamil in Brazil...and the calcium channel blocker, barnidipine, in Argentina.

Norpramin is omeprazole...not desipramine...in Spain.

Flomax is an analgesic...not tamsulosin...in Italy.

Vivelle is an oral contraceptive...not an estradiol patch...in Austria.

Sominex is promethazine...not diphenhydramine...in the U.K.

Cartia XT is extended-release diltiazem in the U.S. But *Cartia* contains aspirin in Israel, Australia, New Zealand, and Hong Kong.

Some foreign names are very similar to ours. *Ambien* is zolpidem in the U.S...*Amyben* is amiodarone in the U.K.

The Institute for Safe Medication Practices supplies us with this important information. Mix-ups are now a real danger as people travel more...and drugs cross borders more often.

Tell patients who travel abroad to carry enough of their meds...and a list of their drugs by BOTH generic and brand name.

Warn patients who are getting drugs abroad to beware.

To find out the ingredients of a foreign drug, check with a drug info center. See our *Detail-Document* for a link to these centers. Or call 800-222-1222 to connect to your regional poison center. View Detail-Document #210401

PHARMACIST'S LETTER / PRESCRIBER'S LETTER

Detail-Document #210401

–This Detail-Document accompanies the related article published in–

PHARMACIST'S LETTER / PRESCRIBER'S LETTER

April 2005 ~ Volume 21 ~ Number 210401

A Different Drug, a Different Country, but the Same Brand Name?

Lead author: Joseph A. Woelfel, Ph.D., FASCP, R.Ph., Assistant Editor

Background

Can the same brand name drug contain a different active ingredient in a different country? The answer to this question is, unfortunately, yes. With the growing trend in drug reimportation from other countries, differences in actual drug content are being discovered for the same brand name. With increased travel to countries outside the US and Canada, greater and lengthened military service in foreign countries, and expanded use of the internet for less expensive prescription drugs, the possibility of acquiring a brand name drug with an unexpected active ingredient is increasing.

The Institute for Safe Medication Practices (ISMP) recently reported that a patient taking *Dilacor XR* (diltiazem extended release) 120 mg daily for hypertension received a different product with the same name while traveling in Serbia. This patient ran out of the US prescribed product and obtained *Dilacor* from a Serbian pharmacy. The pharmacist filled the prescription with the Serbian *Dilacor* brand which is digoxin. The patient did not notice the difference in product strength or appearance and continued to take the Serbian *Dilacor*. Because the patient felt that his hypertension was not being controlled, he elected to take extra daily doses. Three days later, he developed signs of digoxin toxicity, was admitted to an emergency facility, and treated with *Digibind* (digoxin immune FAB).[1]

Dilacor is also the brand name for the antihypertensive agents barnidipine in Argentina and verapamil in Brazil.[2]

Commentary

This is one example of the same brand name being used by different manufacturers for different drugs in other countries. There are several other examples. *Flomax* (tamsulosin) for benign prostatic hyperplasia manufactured by Boehringer Ingelheim for the US and Canadian markets shares the same brand name, *Flomax* (morniflumate), that is used for pain, fever, or inflammation as manufactured by Chiesi in Italy. The antidepressant, *Norpramin* (desipramine), produced by Aventis, is the anti-ulcer drug, omeprazole (*Norpramin*) in Spain where it is produced by CEPA. *Sominex* (diphenhydramine) is promethazine in the United Kingdom; *Vivelle* (estradiol) is ethinylestradiol, norgestimate by Janssen-Cilag in Austria; *Fiorinal* contains aspirin, butalbital, and caffeine but in Australia it is paracetamol, codeine, and doxylamine.[2]

Foreign over-the-counter (OTC) brand products may not be the same and may even have the same brand name as a prescription product. *Cartia* is an enteric coated aspirin product in Israel, Australia, New Zealand, and Hong Kong. In the US *Cartia XT* is extended release diltiazem. US and Canadian OTC brand name extensions create confusion due to the practice of reusing OTC brand names for products with different ingredients. *Unisom* in the US and Canada contains doxylamine whereas *Unisom SleepGels* contain diphenhydramine as marketed in both countries.[3]

Currently there is no international body that oversees brand name selection by pharmaceutical manufacturers. The World Health Organization has established general principles for devising international nonproprietary names for pharmaceuticals.[5] They also maintain international monographs for pharmaceutical substances.[6] Proprietary name regulation will be another major area for international observation, control, and safety.

As noted by the ISMP, brand name differences in foreign countries are one problem but so are differences in dosage forms for the same generic with their suffix listings. Drug dosage form release characteristics, as represented by the brand name suffix (*XR, LA, XL,* etc.) vary and can cause patients to receive too much or too little of an out-

More. . .

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of-country obtained medication. There is no international nomenclature standard for release characteristics.[2]

Look-alike and sound-alike brand name drug lists are readily available in the US and Canada. There is a great potential for patient safety problems with foreign look-alike and sound-alike brand names. *Unisomnia* in Great Britain is a benzodiazepine, nitrazepam, used for insomnia.[4] Nitrazepam's brand name is *Sonotrat* in Brazil. When written, it might be confused with *Sonata* (zaleplon) also used for insomnia in the US and Canada.[4] *Trexall* is methotrexate in the US but *Trexan* is naltrexone in Italy. *Amyben*, available in the United Kingdom, is amiodarone. If this were dispensed for the sedative, *Ambien* (zolpidem) a significant adverse event could occur.[2] *Trental* is pentoxifylline in the US and Canada. *Trentadil* is bamifylline, a bronchodilator, in France.[4] The antipsychotic, *Prolixin*, (fluphenazine) might look like and sound like *Prolixan* (azapropazone), a non-steroidal anti-inflammatory agent, used in some European countries.[4] International cautionary lists do not exist at this time for brand names.

Advice

Patients who are traveling abroad should have a complete list of their medications with both brand and generic names including the brand dosage form, dosage, use frequency, and purpose of use. They should bring a sufficient supply of their medications in labeled bottles or packages with allowances for unexpected travel delays. Should they need a refill, remind them to actively check the generic name, dosage form, and strength to confirm a match. If they are ordering medication from an internet pharmacy they should ask their prescriber to clearly write this same information on the prescription.

Healthcare professionals needing information on imported or foreign country medications may find references such as the Micromedex products, *Martindale: The Complete Drug Reference* and *Index Nominum International Drug Directory,* helpful. Lexi-Comp's *Lexi-Drugs International* is an additional source.

Drug information or poison control centers in the US can be contacted for help. In the US the national toll-free number is: 800-222-1222. The American Association of Poison Control Centers maintains a complete list of poison control centers. They include centers in Canada, New Zealand, Australia, and Puerto Rico. Their website can be found at: http://www.aapcc.org/findyour.htm. In Canada, a list of poison control centers can be found at: http://www.capcc.com or http://www.napra.org/practice/Toolkits/Toolkit6/poison_control.html. Be aware that every center may not be able to immediately answer a question, unless it is of an emergency basis.

Encourage reporting of potential product problems or actual occurrences. To report product problems in the US, call the FDA MEDWATCH program at 1-800-FDA-1088. The MEDWATCH program is also available on-line at www.fda.gov/medwatch. Or report to the USP Medication Errors Reporting Program in cooperation with the Institute for Safe Medication Practices at 1-800-23-ERROR or at www.usp.org/patientSafety/reporting/mer.html. In Canada, call the Canadian Adverse Drug Reaction Monitoring Program at 1-866-234-2345. The Canadian adverse reaction reporting form can be found at: http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adverse_e.pdf. It should be completed and faxed to 1-866-678-6789. You can also contact the Institute for Safe Medication Practices (ISMP) by calling 215-947-7797 or reporting on-line at www.ismp.org/Pages/communications.asp.

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References

1. Anon. Same name, different drug. *ISMP Medication Safety Alert*. January 13, 2005.
2. Anon. New dangers in the drug reimportation process: will we know what our patients are taking? *ISMP Medication Safety Alert*. January 27, 2005.
3. Woelfel JA. OTC brand name extensions. *Pharmacist's Letter/Prescriber's Letter* 2004;20(6):200613.

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4. Lexi-Drugs International Online 2005. Lexi-Comp Inc., Hudson, OH. http://.lexi.com. (Accessed March 23, 2005).
5. World Health Organization. General principles for guidance in devising international nonproprietary names for pharmaceutical substances. http://www.sho.int/medicines/organizatioin/qsm/activities/qualityassurance/inn/inngen.html. (Accessed March 15, 2005).
6. World Health Organization. Monographs for pharmaceutical substances. http://www.who.int/medicines/library/pharmacopoeia/037to146.pdf. (Accessed March 15, 2005).

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AGENDA ITEM B

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: March 4, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Clarification of Pharmacy Law – B & P Code 4186**

UCSF School of Pharmacy is working with the McKesson Corporation to set up a telepharmacy network for urban center indigent clinics.

It is assumed that these indigent clinics are licensed with the Board of Pharmacy pursuant to B & P Code section 4180. The proposal is to place an automated drug delivery system (ADDS) with a video-conferencing system in these clinics. The ADDS will be placed in the clinic with a video-consulting link to UCSF, School of Pharmacy where patients will receive consultative services from a pharmacist/pharmacist intern through the teleconference system.

The purpose of this presentation is to provide clarification as to the type of telepharmacy network that will be placed in these clinics. It appears that the physicians will dispense medications from the ADDS to the patients; however B & P Code section 4186(b) requires that the drugs be removed from the ADDS only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions, which can be done remotely by a pharmacist in California. Additionally, the law requires that a pharmacist must stock the ADDS and the ADDS must provide for patient consultation with a pharmacist via a telecommunication link that has two-way audio and video.

B & P Code section 4186(h) defines an ADDS as a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. This section also specifies the recordkeeping and accountability requirements for the ADDS.

While the UCSF School of Pharmacy's proposal will provide clinic patients access to pharmacists and pharmacist interns through a ADDS video-conferencing link, this is not the issue before the Enforcement Committee. The issue is whether the McKesson telepharmacy network meets the requirements of B & P Code section 4186 and can be placed in these clinics.

Telepharmacy Support for Urban Center Indigent Clinics
June 10, 2005

By: Clifton Louie, RPh, DPA, FACHE
Associate Dean, School of Pharmacy
Vice Chair, Department of Clinical Pharmacy
McKesson Chair for Pharmaceutical Information Technology

PURPOSE:

This concept paper is to promote the discussion and development of a telepharmacy network for urban center indigent clinics and a school of pharmacy. This network will be developed with the McKesson Corporation using their telepharmacy products and services.

BACKGROUND:

The share of the national population without health insurance rose for the second consecutive year in 2002, with an estimated 15 percent of the population, or 43.6 million people, lacking coverage. This represents an increase of 2.4 million uninsured individuals over 2001 levels. A 1.3 percent decline in employer-based insurance, coupled with overall population growth, prompted the decrease in coverage rates [US Census Bureau, 2003] California is no exception to the national trend, as the most recent California Health Interview Survey (CHIS) estimated an uninsured population of 6.3 million individuals (15 percent) in 2001. Despite the coverage of safety net programs like MediCal and Healthy Families, 86,000 uninsured children and adults (13% of the population) live in San Francisco. [The State of health insurance in California, 2002]

Individuals in poverty are the most likely to lack insurance. 30 percent of individuals under 100% FPL (10.5 million individuals nationwide) had no insurance in 2002, and 28% of the near poor (incomes between 100%-125% FPL) had no coverage. [US Census Bureau] Minorities are particularly likely to lack health insurance; 20 percent of African-Americans and 32 percent of Hispanics are uninsured.

As a result of this pervasive lack of coverage, indigent patients experience reduced access to indicated drugs and poor health outcomes. Pharmaceuticals are prohibitively expensive for this population; 37% of uninsured patients report they did not fill a prescription due to cost in the last 12 months, and 35% report skipping recommended treatments for the same reason (Kaiser 2003). Reduction in the use of essential drugs has been associated with higher rates of serious adverse events and emergency room visits (Tamblyn, 2001).

While lack of insurance is the greatest impediment to accessing treatments, other factors undermine the provision of care and compliance among indigent patients. First, many physicians, stretched thin in understaffed community clinics, must dispense prescriptions; this activity takes time from their traditional diagnosing and consulting roles. Second, few community clinics have pharmacies, thus patients do not receive prescribed drugs at the point-of-service. Third, pharmacists are rarely present in the indigent care environment, so patients do not receive proper pharmaceutical care. This problem is perpetuated because the shortage of pharmacists has driven qualified professionals to more lucrative roles outside of indigent care. Finally, existing assistance programs for needy patients do not provide immediate benefits. Patient Assistance Programs, for instance, provide therapies for eligible patients—but no drugs are made available for weeks or months it may take to process the paperwork.

An increasing population of uninsured patients depends on community clinics for pharmaceutical care. Yet these clinics cannot meet patient need due to a lack of in-house pharmacies and pharmacists. A crosscutting telepharmacy intervention could make pharmaceuticals available expediently and effectively.

Students within the schools of pharmacy require patient care experience in the ambulatory care setting as part of their professional training. At UCSF, these ambulatory experiences are more difficult to find. However, a more difficult find is an ambulatory clerkship or internship where a pharmacy student can gain community service experience and can be supervised efficiently. Gaining valuable experience within community indigent clinics would offer the students the value of community service. However, since there is a lack of pharmacists within these environments, the students cannot obtain the required supervision. Again, a crosscutting telepharmacy option could create community service learning possible for pharmacy students.

The urban center of San Francisco has 10 community indigent clinics throughout the city. For the most part, they are generally located in neighborhoods where there is a heavy concentration of the urban poor. These clinics are also organized according to ethnic or gender service orientations. For example, there is the Native American Free Clinic, the Asian Health Center and the Mission Neighborhood Health Center located in the heavily Latino-populated section of San Francisco. There is also the Lyon-Martin Women's Health Clinic.

Pharmaceutical Services offered in these indigent clinics are mixed. Few of the clinics have full functioning pharmacies. Some have dispensary licenses where the physician is responsible for dispensing medications. Many of the clinics belong to the San Francisco Community Clinics Consortium (SFCCC). The SFCCC provides a structure for group effort among the community clinics in order to effect efficiencies. The SFCCC have been discussing with members of the UCSF School of Pharmacy on efforts to expand pharmaceutical services for the indigent patients served by the community clinics. From these discussions, the concept of "focused therapeutics" was embraced as a possible strategy.

"Focused therapeutics" is a concept where the community clinics would like to marshal its resources to a few chronic conditions that consumed many of the clinics' resources. The key chronic conditions identified are:

- Diabetes
- Asthma and other pulmonary obstructive diseases
- Hypertension
- STD's

The list is not exhaustive and it only represents discussions with a few of the community clinic medical directors. The hope was to effectuate a strategy that may improve the situation for the patients and for the clinic operations.

THE PROPOSAL:

A pharmaceutical dispensing machine, coupled with a video-consulting system that connect pharmacists to patients, will address the unmet operational and health needs in a community clinic. The key features of the telepharmacy system are:

- Point-of-care pharmaceutical dispensing machines located within the community clinics
- The pharmaceutical dispensing machines only store medications dedicated to the community clinics' "focused therapeutics"
- A video-consulting link to connected to SFCCC's network and routed to the school of pharmacy
- Patients will receive pharmaceutical care from pharmacists/pharmacy students through teleconferencing system
- Physicians will dispensed medications from the dispensing machines to the patients
- A pharmaceutical vendor, such as McKesson, will replenish the dispensing machines.

OUTCOMES:

A. Patients
    - Indigent patients will have improved access to needed drug therapies
    - Patient compliance with drug regimen will improve
    - Patients' knowledge about their drug regimen will be enhanced. They will understand what their drugs do and how they should take them.
    - Patients' clinical outcomes will improve

B. Clinic

- Improved physician efficiency *(measured by # of patient visits before and after intervention, or # of prescriptions written)*
- Improved patient compliance with drug therapies→Less recurrence of disease, fewer patient visits *(Measure of fewer repeat patient visits for same disease)*
- Increased PAP enrollment, lower drug expenditures

C. Community

- Lower overall health expenditures for vulnerable population—early treatment may lead to fewer clinic or hospital visits
- Increased capacity in indigent patient care by involving pharmacy students

D. School of Pharmacy

- Increased student involvement in indigent care
- Enhanced ability to serve unmet health needs in the community

Question for the State Board of Pharmacy: It is my understanding that Section 4186 of the California State Board of Pharmacy Regulations requires a pharmacist to "authorize any removal of drugs from the automated cabinet". My question is that this requirement also true for an automated cabinet placed within an indigent clinic's dispensary?

PickPoint™ Corporation
Simplifying Pharmaceutical Automation

Simplifying Pharmaceutical Automation

PickPoint™ Corporation

FlexRx™ Tool Kit

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Simple

Affordable

Reliable

PickPoint's™

FlexRx™

Remote Solutions

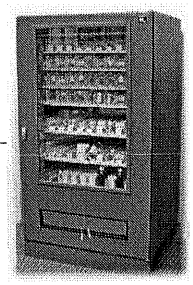
FlexRx™ Secure

After Hours & Remote Outpatient Dispensing

FlexWare™ Secure

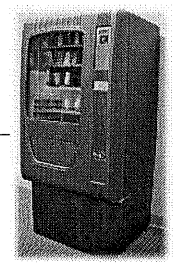
- Real-time monitoring of dispense history, replenishment needs, inventory, lot, and expiration dates from Central Pharmacy
- Dispenses items with bar code verification in less than 10 seconds
- Does not utilize patient data – alleviating HIPPA issues
- Satisfies JCAHO's "Same Standard of Care" Requirement
- Interacts with every pharmacy management system

LxS



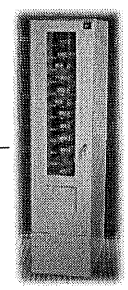
- Securely stores up to 121 rows of prepackaged line items at point of care locations (Avg. 12 items per row)
- Can accommodate nearly every package size available
- Reconfigurable by end users in seconds
- Optimal for ER's, Acute Care Clinics, and other locations that require larger formularies
- 40"W x 34"D x 72"H

NxS



- Securely stores up to 40 rows of prepackaged line items at point of care locations (Avg. 8 items per row)
- Optional refrigeration available
- Optimal for specialty clinics and physician practice groups
- 30"W x 27"D x 59"H

LxC



- Securely stores up to 24 rows of prepackaged line items at point of care locations (Avg. 8 items per row)
- Can be slaved to other units
- Optional refrigeration available
- Optimal for exam rooms or to store higher security items
- 16"W x 25"D x 67"H

PickPoint™ Corporation
Simplifying Pharmaceutical Automation

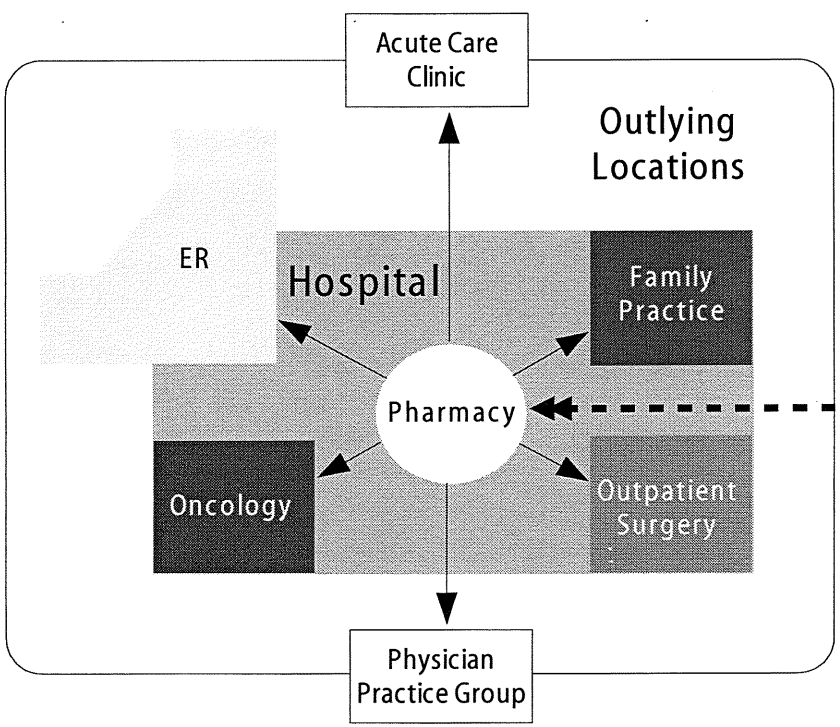
PickPoint™ FlexRx™

Decentralized (Remote) Outpatient Dispensing

Decentralized, aka "Remote," Dispensing has evolved out of necessity for most institutional health care providers. Due to compliance, labor and other cost control factors (e.g., pharmacy operating hours), most entities have moved a portion of their outpatient dispensing requirements to point of care locations (local and remote). Although an improvement, most Decentralized Dispensing environments still suffer from issues related to:

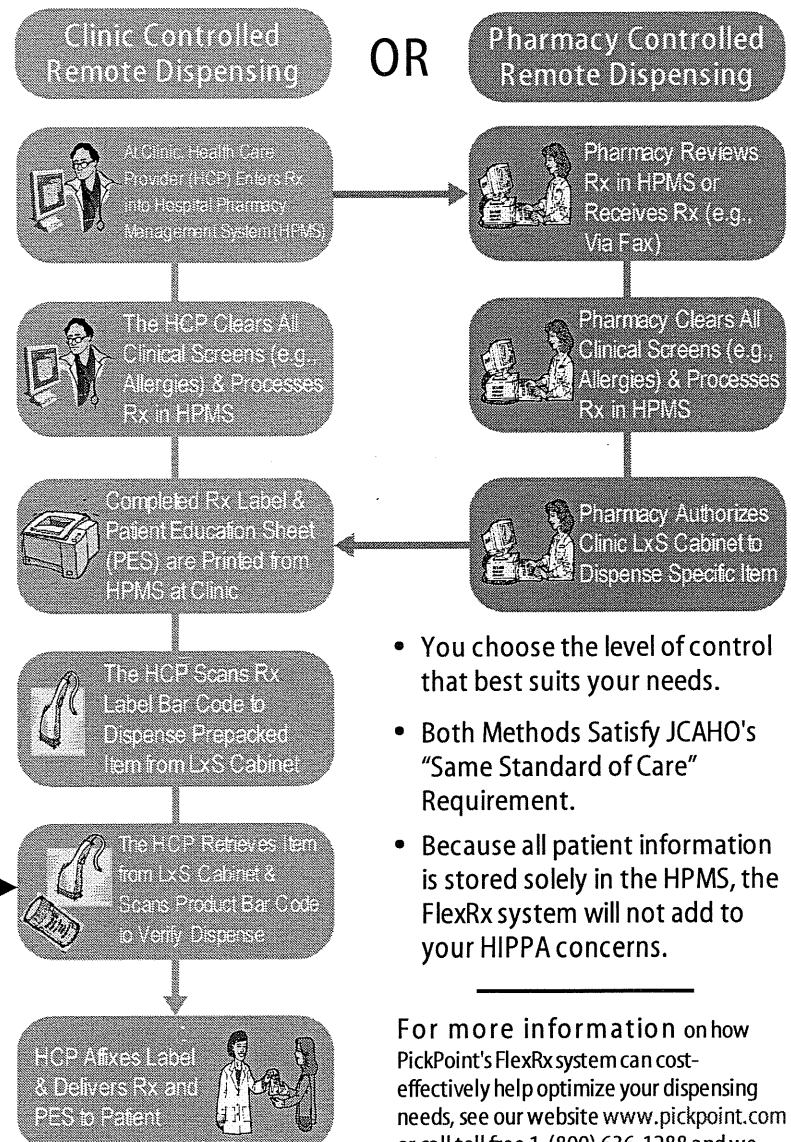
- Labor
- Logistics (Replenishment)
- Patient Safety
- Accountability
- Cost Control

PickPoint's FlexRx line of products help solve these issues by providing users with a cost-effective, easy to use system for securely storing and dispensing prepackaged items at point of care locations; complete with real-time audit trails of every transaction and bar code scanning to ensure patient safety.



Review & Replenishment

Workflow



- You choose the level of control that best suits your needs.
- Both Methods Satisfy JCAHO's "Same Standard of Care" Requirement.
- Because all patient information is stored solely in the HPMS, the FlexRx system will not add to your HIPPA concerns.

For more information on how PickPoint's FlexRx system can cost-effectively help optimize your dispensing needs, see our website www.pickpoint.com or call toll free 1-(800) 636-1288 and we will be happy to assist you.

Update on PickPoint FlexRx Automated Prescription Dispensing Machine

By: CPT(P) Andrew J. Vitt
Assistant Chief, Pharmacy Service
Fort Carson, CO

I'm writing to tell you all about an automated prescription dispensing machine called the FlexRx! Before I continue, let me say that this is a sincere message with the sole purpose of sharing our windfall with you, to hopefully help you achieve the same level of success we have experienced. Bottom line up front, the top three reasons why you should consider the use of the FlexRx are as follows:

1) Complete and simple compatibility with CHCS – Prescriptions entered in CHCS drop from the FlexRx, after scanning the bar code on the prescription label. Use of the automatic patient information sheets from the Lexmark printers makes the process complete, and almost as good as getting it from the pharmacy.

2) Improves patient safety and JCAHO compliance – Prescribers must enter prescriptions in CHCS to obtain the medication, which accomplishes the mandatory complete prospective review of the patient's profile. Built-in safety checks ensure the right drug is dispensed and labeled correctly.

3) Captures lost workload – All prescriptions dispensed are captured in CHCS. This increased our workload by approximately 2,000 prescriptions per month.

If you are looking for an automated dispensing system this one is worth a look, based on it's simplicity. Other systems require additional steps such as entering the prescription in CHCS and in the dispensing machine, or require entering the prescription in a separate database (using separate software and hardware), that will forward the prescription to CHCS.

We are the first DoD MTF to implement use of the FlexRx. We have a unit in two locations: one in our Emergency Room and one in our Primary Acute Care Clinic. PickPoint is working with us to make the equipment even more user friendly and even more comprehensive. However, until that happens, the following issues need to be addressed before putting the FlexRx into place at your facility:

1) Controlled substances - Current FlexRx machines were not intended to account for controlled substances. A narcotic cabinet is under development, but at the moment no automated process is available to record the dispensing process. At our MTF, pre-packed controlled substances are kept in a PYXIS Medstation, which must be accessed separately, but does keep accountability.

2) Prescription entry in CHCS – Pharmacy keys must be assigned to the prescribers utilizing the FlexRx. This is due to a CHCS glitch, which does not allow prescribers to clear clinical screenings from the Order Entry option. We give them access to Prescription Entry, Clear Clinical Screening and Label Reprint functions. We make it all user-friendly by creating a UDK for them to use. If CHCS goes down, for the safety of the patient and the provider, we encourage the patients to take written prescriptions to a 24-hour pharmacy honoring Tricare (for PDTS screen), or return the next day to have the prescription filled at the pharmacy.

Additional information about the PickPoint FlexRx can be found on their web site: http://www.pickpoint.com

For more information please see LTC Torkilson's initial article on the Flex Rx at http://www.armypharmacy.org/new_web/T_perle6.htm or contact us.
Preston Bryant (Retired Army Pharmacy Master Sergeant), Director, Government Sales, can be reached at preston@pickpoint.com or 1-800-636-1288.

After Hours Automated Prescription Dispensing Cabinet

LTC Edward A. Torkilson, Pharmacy Department
U.S. Army MEDDAC, Fort Carson, CO

Objectives

- Improve overall process of providing prescriptions from Patient Care Areas when the Main Outpatient Pharmacy is closed
- Capture unaccounted prescription data in CHCS
- Reduce medication errors
- Ensure Patient's medication profile contains all prescribed medications

Methods

- Identified significant problem with current after hours dispensing process in ER
- Researched options and discovered two different automated dispensing cabinet products
- Made decision to procure product with simplest concept and easiest to use

Conclusions

- Use of an automated dispensing cabinet, a full-sheet label printer and CHCS in the Emergency Room and Primary Acute Care Clinic has provided an excellent solution to an age old problem.
- Primary Care Provides now have a complete picture of Patient Medication Profile

Results

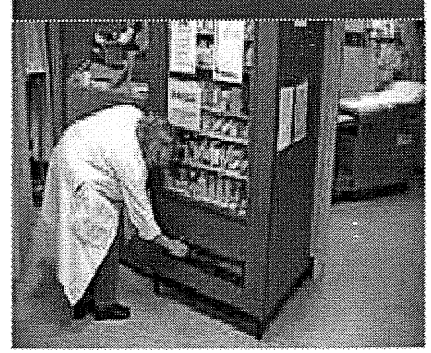
- Approximately 2,000 prescriptions are captured each monthly that were previously unaccounted for
- Patient receives high quality product including typed label and drug monograph
- Process is now at an acceptable safety level with numerous checks to reduce error risk
- Entire process can be safely completed in less than 3 minutes in 3 steps

Step 1: Enter Rx in CHCS

- Use of default procedures and mini-formulary for each cabinet, allows use of default directions & default quantity for quick drug selection and entry into CHCS
- CHCS will screen patient profile and will automatically print a label and handout

Step 2: Retrieve & Label Drug

- Scan bar code on prescription label to have drug drop from cabinet
- Scan bar code on drug to ensure correct drug is received
- Place label on drug



Step 3: Dispense to Patient

- Confidently dispense the correct medication, which is properly labeled and accompanied by detailed prescription information for the patient
- Use of a complete and exact process ensures that all safety measures were taken and that nothing was overlooked

ALASKA NATIVE MEDICAL CENTER

November 6, 2003

Peter Swidzinski
PickPoint Corporation
125 Railroad Ave
Danville, CA 94526

Dear Mr. Swidzinski:

Thank you very much for the opportunity to evaluate your equipment as part of the Telepharmacy Project within the Rural Anchorage Service Unit.

I am pleased to inform you that we plan on purchasing Telepharmacy equipment from your company. I am forwarding a copy of our scorecard that demonstrates the strengths and weaknesses of your product as it applies to our specific application.

It has been a pleasure working with you and your staff!

Sincerely,

ALASKA NATIVE MEDICAL CENTER
TELEPHARMACY PROGRAM

CAPT Douglas L. Herring
Assistant Chief Pharmacist
SCF Primary Care Center Pharmacy

Attachment

ANMC Criteria for Telepharmacy Equipment Selection

Scale 1 to 5
(1 = lowest, 5= highest)

Equipment Functionality	TSI Inc. (ADDS)	Pickpoint
A. Hardware		
# of items stored-	4	5
Able to configure for different sized product?	1	5
Touch Screen technology?	5	4
Double-locking mechanism?	yes	yes
Is cabinet equipped with alarm?	no	no
Does cabinet release more than 1 item per patient transaction?	yes	no
End user comments:	multiple qty drops do not work	must reenter for multiples
ANMC comments:	inconsistent on multiple qty to reenter and redo work not work le qty, increased wk load	does not show full profile since need to delete and reenter reenter for multiple qty
B. Software		
Integrated with ANMC network?	yes	no
Report features?	2	5
Perpetual inventory feature?	1	5
Password protected with operator fingerprint?	4	N/A
End user comments-	fingerprint not working either clinic	like anmc to control inventory
ANMC comments-	anmc dependent on reports from clinic	can view inventory from ANMC and respond right away
C. Video Link		
Integrated with ANMC network?	1	1
End user comments-	never worked	not been able to duplicate system working
ANMC comments-	reliant on AFHCAN and GCI	
D. Ease of Use		
Hardware		
End user-	4	5
ANMC-	4	4
Software		
End user-	3	5
ANMC-	5	4
E. Inventory Security		
Is cabinet double-lock mechanism?	yes	yes
Is cabinet fully alarmed?	no	no
Does software enable user to keep a perpetual inventory?	yes	yes
Does cabinet have ability to secure narcotics with a 3rd locking mechanism?	yes	yes
End user comments-	inventory has not been timely	can view inventory in real time
ANMC comments-	reports from clinic do not allow for timely ordering and distribution of meds from anmc	can get meds out within day or two
F. Patient Care and Safety		
End user-	5	5
ANMC-	5	5
G. Equipment Reliability		
A. Hardware		
End user-	4	4
ANMC-	3	4
B. Software		
End user-	3	5
ANMC-	5	4
H. Customer Service and Support		
A. Hardware		
End user-	1	5
ANMC-	1	5
B. Software		
End user-	2	5
ANMC-	1	5
I. Cost	3	4
J.Overall Value		
End user-	3	4
ANMC-	2	5
Total	**72**	**103**

ALASKA NATIVE MEDICAL CENTER

Development of a telepharmacy network to serve rural Alaska.

Herring DL, Keith MR. Alaska Native Medical Center, 4315 Diplomacy Drive, Anchorage, AK

Abstract:

Access to full service pharmacy operations is limited in rural Alaska. In an effort to increase access to pharmacy services including prospective pharmacist pharmacotherapy, safety review and counseling, a telepharmacy network was proposed. Previously, medications were restricted to limited pain; anti-infective and acute care medications administered as a short-term medication from clinic by non-pharmacist clinic staff. Approval was obtained through the Health Resource Services Administration (HRSA) to provide services to seven remote Community Health Center clinics in Southcentral Alaska and the Aleutian Island chain. A subsequent grant has been awarded to request start-up monies from HRSA to fund this project and will expand service to a total of eleven Community Health Center villages. Remote pharmacy dispensing machines were tested to determine the most reliable and effective system for the application. Pharmacists at the Alaska Native Medical Center in Anchorage remotely review medication orders for appropriateness and authorize dispensing at the remote site. Patients can be counseled via telephone or televideo. Written patient information materials can also be printed at the remote site. The initial project targeted 3000 patients. The program is intended to allow process assessment, analysis and improvement, with the intent of expanding services to additional remote sites. The telepharmacy program has allowed Alaskan's living in rural areas to receive prospective pharmacist pharmacotherapy and safety review as well as counseling.

Purpose:

To identify and select telepharmacy remote dispensing equipment allowing prospective pharmacist pharmacotherapy, safety review and counseling to patients living in remote communities with no pharmacy services.

Background:

Alaska has several hundred very small, relatively isolated, communities. Most of these villages are accessible only by plane or boat, with no access to immediate pharmacy care. In the past, the pharmacy at the Alaska Native Medical Center (ANMC) would pre-label unit of use medications, fly them to the village and have the midlevel provider or Community Health Aide Provider (CHA-P) give them to patients presenting to the clinic with acute problems. There was no pharmacist review of these prescriptions prior to the patients receipt. There was also a supply of acute narcotics in each village. Diversion, as well as appropriate record keeping, was a constant issue. On a positive note, all chronic medications were sent to ANMC where they were reviewed for appropriateness prior to being dispensed.

When the technology became available, in the form of automated drug dispensing units, it became clear that ANMC needed to improve the care it was giving its remote patients. It was decided that a pilot demonstration project using telepharmacy in remote bush sites in Alaska should be initiated.

ALASKA NATIVE MEDICAL CENTER

Development of a telepharmacy network to serve rural Alaska.

Herring DL, Keith MR. Alaska Native Medical Center, 4315 Diplomacy Drive, Anchorage, AK

Methods:

As many of the target communities (see figure 1.) were eligible for Community Health Center (CHC) status, due to their being medically under-served, we approached HRSA to gain ANMC pharmacy provider approval for a network of these CHCs. In April of 2003, we were granted status as an "alternative demonstration project" that allowed ANMC to provide pharmacy services to this network. In August of 2003 we received a grant from HRSA to provide startup monies for our telepharmacy project.

Commercially available telepharmacy equipment and services were investigated. Two products were identified that could potentially meet the pilot project need. The companies were contacted and informed that a comparison was desired to ascertain the optimal equipment for the services specified. Critical criteria for our needs included computer interface for pharmacist oversight and control, adaptability of hardware and software to meet our unique needs, and operational reliability due to the remote locations and lack of immediate technical support. Criteria for assessment were developed to allow objective performance comparison.

Our process for providing pharmacy services in real time via automated drug dispensing units, involves the following steps:

1. The prescription is faxed to the ANMC pharmacy

2. The electronic patient profile is reviewed to assure we are meeting all pharmaceutical care standards as well as assuring patient safety.

3. The prescription is entered into our computer system which communicates with the remote automatic drug dispensing unit via our telecommunications network.

4. A label prints in the remote village and the appropriate drug drops from the machine. Barcoding is used to verify that the drug on the label matches the drug dispensed from the machine.

5. The provider in the village affixes the label to the bottle and gives it to the patient

6. The pharmacist at ANMC then can counsel the patient via telephone or videoconferencing.

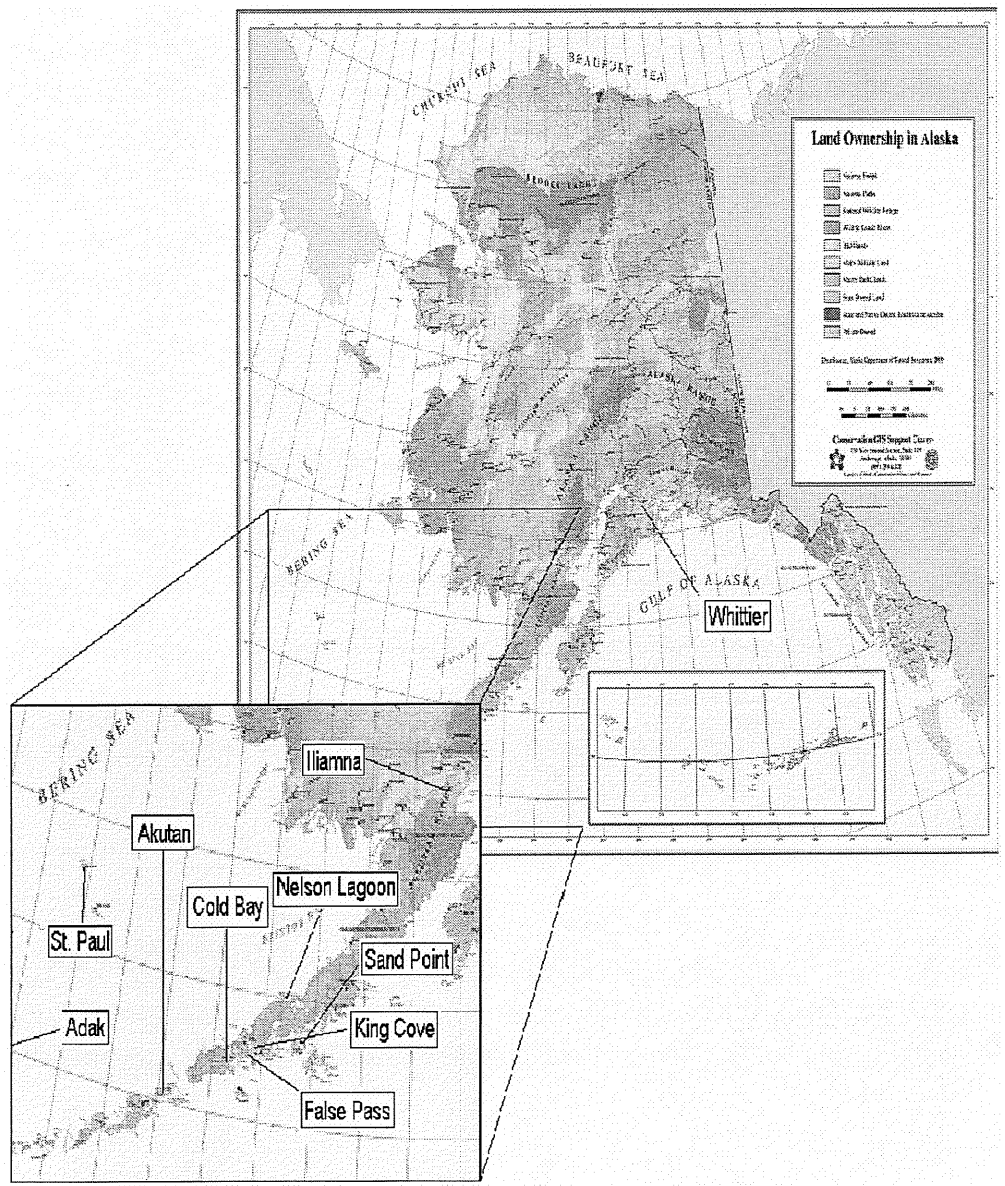
Five automated dispensing units were installed and services initiated in the spring and summer of 2003. An additional seven units have been ordered for installation. The pilot program operated in five sites using two different telepharmacy systems for six months. During the pilot phase, unmet needs were identified and modifications requested from the vendors. A final assessment was competed on 11/1/03.

ALASKA NATIVE MEDICAL CENTER

Development of a telepharmacy network to serve rural Alaska.

Herring DL, Keith MR. Alaska Native Medical Center, 4315 Diplomacy Drive, Anchorage, AK

Figure 1.



ALASKA NATIVE MEDICAL CENTER

Development of a telepharmacy network to serve rural Alaska.

Herring DL, Keith MR. Alaska Native Medical Center, 4315 Diplomacy Drive, Anchorage, AK

Results:

Table 1 is a summary of the features and functionality compared between the two automated dispensing machines. The products were rated on a 1-5 scale, with 1 being the least preferable. The vendor 1 product had the advantage of interface capability with our operating system and the ability to "drop" or dispense more than one item simultaneously. However, in practical application, both features were problematic and were not functional advantages.

The vendor 2 product had more configurable storage, preferable report and inventory functions, was rated as easier to use, more reliable and less expensive. The vendor 2 product and support was considered to be overall more adaptable and received a total score significantly above the vendor 1 product. The vendor 2 product was rated the preferable product and will be used exclusively for current and immediately planned expansion.

Table 1

Criteria for Telepharmacy Equipment Selection

Equipment Functionality		***Vendor 1***	***Vendor 2***	***Scale*** 1 to 5 (1 = lowest, 5= highest)
A. Hardware				
# of items stored-		4	5	
Able to configure for different sized product?		1	5	
Touch Screen technology?		5	4	
Double-locking mechanism?		yes	yes	
Is cabinet equipped with alarm?		no	no	
Does cabinet release more than 1 item per patient transaction?		yes	no	
	End user comments:	multiple qty drops do not work	must reenter for multiples	
	ANMC comments:	inconsistent on multiple qty, increased wk load to reenter and redo work	does not show full profile since need to delete and reenter for multiple qty	
B. Software				
Integrated with ANMC network?		yes	no	
Report features?		2	5	
Perpetual inventory feature?		1	5	
Password protected with operator fingerprint?		4	N/A	
	End user comments-	fingerprint not working either clinic	like anmc to control inventory	
	ANMC comments-	anmc dependent on reports from clinic	can view inventory from anmc and respond right away	
C. Video Link				
Integrated with ANMC network?		1	1	
	End user comments-	never worked	not been able to duplicate system working	
	ANMC comments-	reliant on AFHCAN and GCI		
D. Ease of Use				
Hardware				
	End user-	4	5	
	ANMC-	4	4	
Software				
	End user-	3	5	
	ANMC-	5	4	
E. Inventory Security				
Is cabinet double-lock mechanism?		yes	yes	
Is cabinet fully alarmed?		no	no	
Does software enable user to keep a perpetual inventory?		yes	yes	
Does cabinet have ability to secure narcotics with a 3rd locking mechanism?		yes	yes	
	End user comments-	inventory has not been timely		
	ANMC comments-	reports from clinic do not allow for timely ordering and distribution of meds from anmc	can view inventory in real time can get meds out within day or two	
F. Patient Care and Safety				
	End user-	5	5	
	ANMC-	5	5	
G. Equipment Reliability				
A. Hardware				
	End user-	4	4	
	ANMC-	3	4	
B. Software				
	End user-	3	5	
	ANMC-	5	4	
H. Customer Service and Support				
A. Hardware				

ALASKA NATIVE MEDICAL CENTER

Development of a telepharmacy network to serve rural Alaska.

Herring DL, Keith MR. Alaska Native Medical Center, 4315 Diplomacy Drive, Anchorage, AK

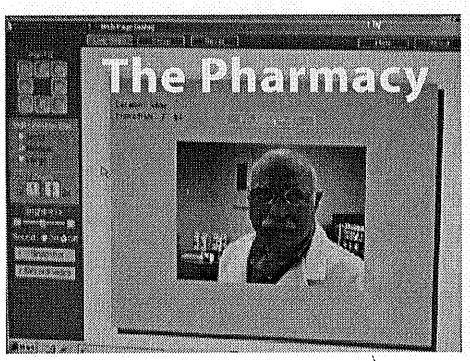
Discussion:

We were challenged with providing pharmaceutical care, in real time, to villages located hundreds of miles from the nearest pharmacy, most with no road system, accessible only via boat, snow machine, dog sled or airplane. Telepharmacy equipment provided us a method to provide this care. However the use of automated technology in remote areas with little or no infrastructure was without precedent

After a six month pilot comparing two telepharmacy dispensing solutions, we learned that our specific model for care delivery was so unique as to challenge the existing capabilities of each vendor. We soon discovered that the vendor willing to work with us and modify software and hardware quickly, was best able to help us achieve our goals. Customer service and product dependability were paramount for the same reasons. Our comparison resulted in the identification of a product that met the unique needs of providing pharmaceutical care to rural Alaska Natives. Planning is underway to expand the program to 40 sites.

PickPoint Corporation
Simplifying Pharmaceutical Automation

Video Conferencing

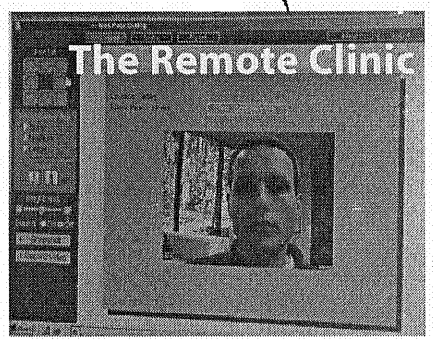


Video Conferencing

Video Conferencing provides "same standard of care" from miles away, allowing live monitoring of the FlexRx System and real time patient counseling from anywhere in the world.

This system features:

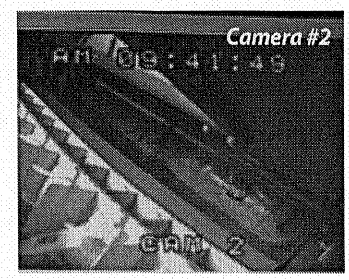
- ✔ Ethernet-enabled audo/video
- ✔ Built in pan and tilt - user can adjust camera for perfect viewing
- ✔ Remote monitoring by logging onto PickPoint's built-in webpage via Internet Explorer
- ✔ Motion sensing (optional) detects anyone using the machine and generates an automatic e-mail and attached "captured" image
- ✔ Multiple locations - View up to four locations simultaneously

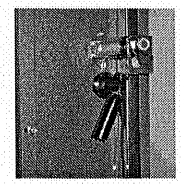


PickPoint Corporation
Simplifying Pharmaceutical Automation

FlexCam

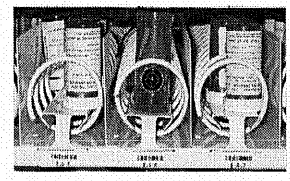
FlexCam, a network-enabled video system for monitoring remote pharmaceutical dispensing environments from any location; it's scalable and can record from up to 16 camera angles, while helping to protect your system integrity using motion-detected video recording.

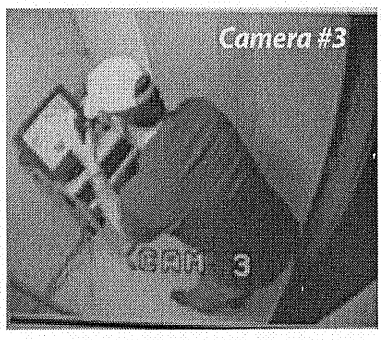




Network Enabled Video
Allows for real time monitoring of the FlexRx

Multiple Locations
View up to 16 locations simultaneously





Flexability

View all cameras at once or individually. Allows play back of a single image or multiple camera views.

Remote Monitoring

Oversee the FlexRx System "live" from any location via a network or by means of stored video with the play back feature

Motion Sensing

This unit also has motion detection for easy playback and minimal use of storage space

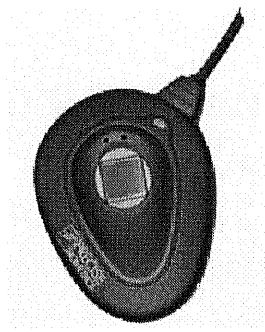
PickPoint™ Corporation
Simplifying Pharmaceutical Automation

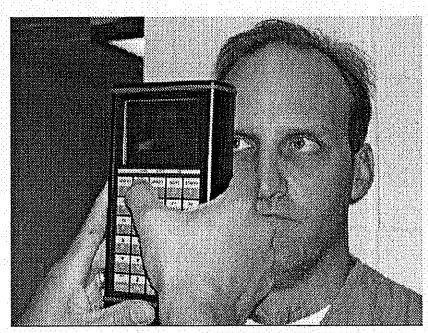
BioFlex

BioFlex will simplify the authentication/verification process with Fingerprint identification or Iris scanning of individuals receiving medications via a FlexRx System of pharmaceutical dispensing. This coupled with provider access authentication assures complete control of the dispensing process.

Biometric Fingerprint Recognition System

Quickly and accurately provides up to 27 points of identification.





Iris Scanning

The fastest, most accurate, and therefore the most scalable, of all biometric recognition technologies. Iris Scanning provides 273 points of identification; is non-invasive, completely safe, and is unparalleled in reliability and precision.

AGENDA ITEM C

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: June 8, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Clarification of Pharmacy Law - Intern Pharmacists, Orally and Electronically Transmitted Prescriptions and Filling of Non-Security Prescription Forms**

The Board of Pharmacy requested from its counsel clarification of certain statutes and regulations pertaining to two general areas of inquiry: (1) Whether licensed intern pharmacists may perform certain tasks, including "advanced" techniques such as emergency contraception protocols under Business and Professions Code section 4052, skin puncture under Business and Professions Code section 4052.1, or final checks on prescriptions; and (2) Whether and how California pharmacists may accept prescriptions not written on security prescription forms, and how these prescriptions fit with the treatment required of orally or electronically transmitted prescriptions.

In responding to this request, counsel advised the board that as always it should not issue any "regulation," guideline, criterion, or rule of general application, giving the agency's interpretation or application of its laws and/or procedures, or the like, except where the formal processes of the Administrative Procedure Act are followed. To avoid an underground regulation, counsel reminds the board that it should refrain from offering or suggesting a binding interpretation of law, or supplementing the existing law.

Performance of "Pharmacist" Tasks by Intern Pharmacists

The first inquiry is about the scope of practice authorized for intern pharmacists, and the propriety of their performance of certain specific tasks, including initiation of EC therapies, skin punctures, and/or final checks on prescriptions. On the one hand, there are concerns that certain "advanced" or "responsible" tasks are not appropriate for intern pharmacists who are not yet fully trained as pharmacists, and/or are not yet established as professionals in the pharmacy field. On the other hand, the board has heard from others that it is crucial that intern pharmacists get experience in all techniques and tasks they will later perform unsupervised, while they are still training, and that intern pharmacists should become accustomed to being responsible for pharmacy conduct.

The statute(s) pertaining to intern pharmacists, both presently and historically, appear to have adopted this second approach, placing no limits on the tasks to be performed by pharmacist

interns, and assuming they will act entirely as pharmacists while they are in supervised training. The present version of Business and Professions Code section 4114 reads as follows:

§ 4114. Intern pharmacists

(a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the supervision of a pharmacist whose license is in good standing with the board.
(b) A pharmacist may not supervise more than two intern pharmacists at any one time.

This language states, without limitation, that intern pharmacists "may perform all functions of a pharmacist." Accordingly, anything that a pharmacist may do, an intern pharmacist may do, so long as the pharmacist by whom the intern is supervised agrees/permits it (as these functions may only be performed by intern pharmacists "at the discretion of and under the supervision of" the supervising pharmacist), and so long as the supervising pharmacist is licensed in good standing.

This analysis will not change based on the language expected to be amended via SB 1111. SB 1111 will merely change "supervision of a pharmacist" to "direct supervision and control of a pharmacist," specifying that intern pharmacists may only perform functions of a pharmacist when their supervising pharmacist is on the premises and fully aware of the functions performed.

This analysis is also consistent with the history of section 4114. The current version of the statute was enacted in 2004. Before 2004, and since its initial enactment in 1965, Business and Professions Code section 4097, which became section 4114 in the 1996-97 reorganization of the Pharmacy Law, was even more explicit about the authorization of full intern practice:

§ 4097. Performance of duties by intern pharmacists; regulations; supervision[1]

An intern pharmacist may perform such activities pertaining to the practice of pharmacy as the board may determine by regulation. Whenever in this chapter the performance of an act is restricted to a registered pharmacist, such act may be performed by an intern pharmacist under the supervision of a registered pharmacist.

An intern pharmacist may perform such activities pertaining to the practice of pharmacy as the board may determine provided that at the time of performing such acts he was under the immediate, direct and personal supervision of a registered pharmacist, and provided further, that such registered pharmacist shall not supervise more than one intern pharmacist at any one time.

Thus, former section 4097, and section 4114 prior to its simplification in 2004, stated in no uncertain terms that any act "restricted to a registered pharmacist" could "be performed by an intern pharmacist under the supervision of a registered pharmacist."[2] This intention to authorize

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[1] Section 4097 was enacted in 1965, and remained unchanged from then until 1997, when it was moved, unchanged aside from cosmetic changes, to section 4114. This language persisted in section 4114 until amendments in 2004 modified section 4114 to its present appearance.

[2] Somewhat confusingly, former section 4097/4114, at the same time it gave this blanket authorization to intern pharmacists, also gave the Board the apparent authority to *limit* the scope of intern pharmacist practice by regulation. It does not appear this potential conflict ever came

pharmacy interns to perform the full scope of pharmacy practice (so long as they are supervised by a licensed pharmacist, the supervising pharmacist consents, and the supervising pharmacist is licensed in good standing with the Board) continues in the present version of section 4114, which states that an intern pharmacist "may perform all functions of a pharmacist . . ."

In sum, counsel has concluded that Business and Professions Code section 4114 places no limitation on the scope of intern pharmacist practice, other than that: (i) any task must be done under the supervision (soon to be "direct supervision and control") of a licensed pharmacist; (ii) the supervising pharmacist must consent/agree to the performance of any task by the intern pharmacist; and (iii) the supervising pharmacist must be licensed and in good standing with the Board. Section 4114 no longer allows the Board to limit intern pharmacists' scope of practice by Board regulation. Nor, in any event, are there any regulations attempting to do so. (See, e.g., Cal. Code Regs., tit. 16, §§ 1727, 1728).

Accordingly, properly supervised intern pharmacists may, with the consent/supervision of a supervising pharmacist, perform any function authorized for licensed pharmacists. Included in the authorized functions for both pharmacists and intern pharmacists, therefore, are EC therapies (Bus. & Prof. Code, § 4052(a)(8)), skin punctures (Bus. & Prof. Code, § 4052.1), and final check on prescriptions (Bus. & Prof. Code, §§ 4051, 4115; Cal. Code Regs., tit. 16, § 1793 et seq.).

Both the intern pharmacist and his/her supervising pharmacist must, however, meet any necessary prerequisites to performance of any particular function before that function is properly performed by the intern pharmacist. For instance, with regard to provision of EC drug therapy, pursuant to Business and Professions Code section 4052, subdivision (a)(8), prior to performing any procedure authorized under this paragraph, *both* the intern pharmacist (to ensure appropriate provision of services) *and* the supervising pharmacist (to ensure appropriate supervision thereof) must first (i) have participated in instituting and implementing standardized procedures/protocols meeting subdivision (a)(8)(A)(i) and/or (a)(8)(A)(ii), *and* (ii) have received the training required by subdivision (a)(8)(B). Obviously, intern pharmacists cannot receive CE credit for the training, but they must nonetheless have participated in an approved course of training on EC therapy.

Orally and Electronically Transmitted Prescriptions
Acceptance/Filling of Non-Security Prescription Form Prescriptions

The second area of inquiry pertains to what effect(s) ought to be given by pharmacists or pharmacies to written prescriptions not written on the security prescription forms required (as to controlled substances) by Health and Safety Code section 11150 et seq. (particularly 11162.1 and 11164). The board posed a number of specific questions/hypotheticals, including:

- (1) If the Board directs pharmacists to treat Schedule III-V prescriptions not written on the security prescription forms as "oral" prescriptions (under, *inter alia*, Cal. Code Regs.,

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to pass, however, as there do not appear to have been any regulations trying to limit intern practice.

tit. 16, § 1717(c)), is the pharmacist required to rewrite the prescription?

- (2) What if the pharmacist takes the oral order over the telephone and directly enters it into the computer, what is then required of the pharmacist?
- (3) What about prescriptions that are sent electronically from the prescriber's computer to the pharmacy's computer, what is required by Business and Professions Code section 4070, Health and Safety Code section 11164(b)(1) (and/or other statutes and regulations)?
- (4) With the advent of new technologies, does 16 C.C.R. § 1717(c) need to be rewritten?

Counsel explained that as a general matter, the law (at least pertaining to controlled substances) presently permits prescriptions to be transmitted by prescribers in only three ways (excepting chart orders, which are treated differently - Health & Safety Code, §§ 11159, 11159.1): (1) in written form, exclusively on security prescription forms; and, for Schedule III-V drugs plus Schedule II drugs for patients in licensed health care facilities, (2) orally or (3) by electronic transmission. (Health & Safety Code, §§ 11158, 11164, 11167.5). Present law does not permit prescriptions for controlled substances to be transmitted in any written form other than on a section 11162.1 security prescription form.

Present law further specifies that where a controlled substance prescription is transmitted orally or electronically, the pharmacist shall, *prior to filling the prescription*, produce a hard copy of the prescription, signed and dated by the pharmacist(s) (or other authorized person(s)) filling the prescription, containing the date and time of transmission, as well as specified information on the patient, prescriber, and pharmacist. (Health & Safety Code, §§ 11164(b)(1), 11167, 11167.5).

In addition, pharmacy statutes and regulations *further* specify or confirm that all oral and electronic prescription transmissions must be reduced to writing and properly identified before they are filled. (Bus. & Prof. Code, § 4070; Cal. Code Regs., tit. 16, § 1717(c)). Business and Professions Code section 4070 and 16 C.C.R. § 1717(c) each restate the general obligation of a pharmacy/pharmacist to reduce orally- and electronically-received prescriptions to writing prior to compounding, filling, dispensing, or furnishing. Section 4070 goes on to exempt pharmacies from the need to create hard copies of electronically transmitted prescriptions so long as all the information required by Business and Professions Code section 4040, plus the prescriber's name or identifier, can be produced in hard copy form for three years from the last date of furnishing. However, this exemption, by its terms, applies only to non-controlled substance (dangerous drug or device) prescriptions, unless a hospital or pharmacy has received specific permission/waiver under Health and Safety Code section 11164.5 to retain *electronic* records of such prescriptions. In other words, section 4070 (and 16 C.C.R. § 1717(c)) have no general application to treatment of orally- or electronically-transmitted prescriptions for Schedule II-V controlled substances.[3]

Thus, the general state of the law is as follows: (1) a controlled substance written prescription is validly filled only if it is written on a security prescription form; (2) an orally-transmitted prescription for any drug, whether a controlled substance or a dangerous drug, must be reduced to a writing meeting the requirements of Business and Professions Code section 4070 and/or 16 C.C.R. § 1717(c) [for dangerous drugs], and/or Health and Safety Code section 11164.1, 11167, and/or 11167.5 [for all Schedule II-V controlled substances] *prior to* being

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[3] Moreover, section 4070 does *not* exempt pharmacists from reducing *orally-transmitted* dangerous drug or device prescriptions to hard copy before filling, compounding, furnishing, etc.

compounded, filled, dispenses, or furnished; (3) an electronically-transmitted prescription for a Schedule II-V controlled substances, unless a hospital or pharmacy has been granted permission under Health and Safety Code section 11164.5 to retain only electronic records thereof, also must be reduced to a hard copy meeting all of these same requirements; and (4) an electronically-transmitted prescription for a non-Schedule II to V, non-controlled substance, can be filled without reducing the prescription to writing so long as the pharmacy is able to meet the requirements of Business and Professions Code section 4070.

Responding to the specific questions/hypotheticals posed, counsel provided the following applications of the above-stated general principles and understandings to those issues:

(1) For a pharmacist faced with a written prescription not made on a security prescription form, the board has advised that the best course for the pharmacist is to treat that prescription as if it had been orally transmitted. In doing so, however, a pharmacist must actually *transform* the writing into an oral prescription. In other words, the pharmacist *cannot rely* on the written document as assurance of the validity or accuracy of the prescription, and has to contact the authorized prescriber and orally verify and record all of the information that is required by Business and Professions Code section 4070 (dangerous drugs), Health and Safety Code section 11164(b)(1) (Schedule III-V drugs), or Health and Safety Code section 11167/11167.5 (Schedule II drugs in applicable circumstances).

In other words, a written prescription on an "old" triplicate form or any other non-secured prescription form is essentially irrelevant to the validity or accuracy of the prescription. The only purpose it serves is that there is no need for the pharmacist to entirely "recreate" a *new* hard copy of the prescription. Instead, the pharmacist may use the non-security form prescription to record the necessary information, and/or attach documents to that form containing that information. In the strictest sense, the pharmacist is not required to "rewrite" the prescription, but he or she must be sure that all of the pertinent information was received/verified orally, sign and date it, etc.

(2) As to the second question, pertaining to direct entry of orally-received prescriptions into a pharmacy computer, it does not appear that this procedure would exempt the pharmacist from the requirement(s) of hard copy production, personal signature and dating, and recording of all of the required information. Direct entry of orally-transmitted information is not "electronic transmission" exempting the pharmacy from keeping hard copies per Business and Professions Code section 4070 (dangerous drugs) or Health and Safety Code section 11164.5 (controlled substances). In other words, direct entry does not eliminate any of the hard copy requirements.

(3) The third question, pertaining to prescriptions sent electronically from a prescriber or hospital computer to a pharmacy computer, has been answered already by the foregoing general discussion. As a general rule, a hard copy of these prescriptions must be printed out, the required signatures affixed, the required information collected, and the hard copies retained. A hard copy of electronically-transmitted dangerous drug/device prescriptions need not be produced/retained when the conditions in Business and Professions section 4070 are all met, and a hard copy of an electronically-transmitted controlled substance prescription need not be produced/retained when permission is given and all of the conditions in Health and Safety Code section 11164.5 are met.

(4) Finally, counsel responded to the board's question as to whether it should consider revisions to California Code of Regulations, title 16, section 1717, subdivision (c), to account for technological updates. Because section 1717(c) only covers oral transmissions, it has not yet

really been affected by the increasing availability of electronic prescription transmission. However, if the board wanted to also specify treatment of electronically-transmitted prescriptions, either in affirmance of section 4070, or in addition thereto, it might want to include this treatment in section 1717. This might give the board some flexibility to respond to upcoming changes in these technologies.

AGENDA ITEM D

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: June 13, 2005

From: Jan E. Perez
Legislation Coordinator

Subject: **Repeal of CCR Section 1717.2**

On December 10, 2004 the Board received an email from Steve Gray, Kaiser Permanente, inquiring on the status of repealing California Code of Regulations (CCR) section 1717.2, Notice of Electronic Prescription Files. In his email Mr. Gray outlined the chronology of the board's efforts to repeal 1717.2; board discussion ran from January 2002 through September 2003 with the board taking no action to repeal the section. A review of the board's file on 1717.2 found that there is no written record as to why the board stopped its efforts to repeal 1717.2.

Paul Riches, former board Chief of Legislation and Regulation, recently recalled that the board did not pursue repealing 1717.2, because of concerns that repealing the section might conflict with provisions in the Confidentiality of Medical Information Act. Many laws governing the use of patient information require a patient to give their consent to having their medical records shared with additional parties. CCR 1717.2 is unique in that a patient's information is shared unless a patient specifically request otherwise. If, at some point, the board chooses to repeal 1717.2 it might be perceived as a move to limit patients' ability to control their medical record information. As such, its repeal might be met with significant opposition from privacy protection advocates.

system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

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

§1717.1. Common Electronic Files. [Effective October 22, 2004]

(a) For dangerous drugs other than controlled substances: Two or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file.
(b) For controlled substances: To the extent permitted by Federal law, two or more pharmacies may establish and use a common electronic file of prescriptions and dispensing information.
(c) All common electronic files must contain complete and accurate records of each prescription and refill dispensed.
(d) Common electronic files as authorized by this section shall not permit disclosure of confidential medical information except as authorized by the Confidentiality of Medical Information Act (Civil Code 56 et seq.).
(e) Pharmacies maintaining a common electronic file authorized by this section shall develop and implement written policies and procedures designed to prevent the unauthorized disclosure of confidential medical information.

NOTE:

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116 and 4117, Business and Professions Code and Sections 56.10 and 56.11 of the Civil Code.

§1717.2. Notice of Electronic Prescription Files.

(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:

NOTICE TO CONSUMERS:

This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies:

By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained in this way, please notify the pharmacist-in-charge.

(b) Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows:

I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file.

_____ (date)

_____ (signature of patient)

_____ (acknowledgment of pharmacist)

The pharmacist shall date and co-sign the form, and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.

AGENDA ITEM E

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: June 10, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Pharmacy Service Plans**

The California Pharmacists Association (CPhA) is recommending that the Board of Pharmacy require a pharmacy that is granted a waiver to use an automated drug delivery machine for refill medications to have a "pharmacy services plan" as a condition of granting the waiver.

CPhA is prosing that the pharmacy would be required to have a pharmacy services plan that would include a clear description of how the requested waiver would facilitate the provision of pharmacist care and improve patient care in the pharmacy. It would also include a description of how the pharmacy would monitor and measure the attainment of the plan's goal. The plan could also include a description of the anticipated impact on business operations, hours of operation and staff. It is recommended that compliance with the plan would be monitored by periodic visits by board inspectors. Failure to comply with the pharmacy services plan would be basis for withdrawal of the waiver, or other action by the board.

California Pharmacists Association

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BOARD OF PHARMACY
2005 APR 18 AM 11:32

April 12, 2005

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

Re: Requests to the Board for waivers to allow the use of drug delivery machines

Dear Ms. Harris:

As you are aware, the Board of Pharmacy has received several requests for waivers of the Pharmacy Law to allow the use of drug delivery machines, such at the Asteres ScriptCenter. In the past, such waivers have been granted to Longs Drugs and Safeway Stores and at the upcoming Board meeting in Sacramento, the Board will consider another such request, this time from the UCSD Medical Center.

On behalf of the California Pharmacists Association, I have raised concerns about the effect that granting these waivers will have on the interactions between pharmacists and consumers. The Board has been very generous in allowing CPhA to present these concerns and should be applauded for their willingness to discuss what I termed the "philosophical question" of moving toward the increased use of this type of technology in pharmacies. CPhA recognizes that use of technological advances of the type involved here is inevitable; yet, we also believe that the Board would be well advised to move cautiously and consider the full impact of these devices on consumers as well as on the role pharmacists play in monitoring ongoing drug therapies.

The arguments in favor of increased utilization of these devices are strong – the economic and competitive pressures on pharmacies today require that operational efficiencies be utilized where ever appropriate. At the same time, however, the Board needs to maintain the strides it has made over the last 10 years in improving the interaction and communication between pharmacists and consumers. I need go no further than the logo currently used by the California Board of Pharmacy – the dual image of a mortar and pestle combined with two people talking to each other. I note as well the Board's efforts in recent years to reach out and educate consumers about the realities of medication use and the value pharmacists can bring to improve their understanding of their medicines. This effort is reflected in the Board's "motto": "Be Aware, Take Care – Talk to your Pharmacist!" The excellence of the Board's efforts has been twice recognized by the National Associations of Boards of Pharmacy, an achievement for which the Board should rightly be proud.

Because of these consumer outreach efforts, it struck CPhA as out of character for the Board to so readily embrace a technology that, in our view, is likely to dramatically decrease the interaction between pharmacists and consumers. It is clear that the use of machines such as the Asteres ScriptCenter make the greatest economic sense only if used when the pharmacy itself is closed – that is, by extending the time during which consumers can access their refill medications with minimal cost in overhead and labor. We cannot deny the benefits that this brings to the retailer, nor can we question the fact that it will be somewhat more convenient for the consumer, or that consumers are exposed to the same minimal level

4030 Lennane Drive
Sacramento, California 95834
916.779.1400 • Fax 916.779.1401
www.cpha.com • cpha@cpha.com

of pharmacist interaction when their prescriptions are filled by mail service pharmacies. Regardless, we believe there must be a better way to promote the use of this technology while simultaneously providing a level of pharmacist care that is more in keeping with the consumer protection goals of the Board. We note as well that at least some of the Board members have expressed a desire for some means of measuring the impacts on consumers that occur as a result of using these machines. With this in mind, CPhA has a proposal for the Board to consider.

Some years ago, in new CPhA policy on pharmacy technicians, the Association incorporated the concept of a Board approved "pharmacy services plan" as a necessary component of any request to deviate from "standard" ratios or practices. A similar requirement currently exists in the pharmacy law in other states, including Washington[1]. CPhA believes requiring such a plan fits well as part of the consideration of waivers for automated delivery machines.

As envisioned here, a pharmacy services plan would be prepared by the pharmacy requesting the waiver and would include a clear description of how the requested waiver would facilitate the provision of pharmacist care and improve patient care in the pharmacy. It should also include a description of how the requesting pharmacy will monitor and measure attainment of the plan goals. The plan could also include a description of the anticipated impact on business operations, hours of operation and staffing. Compliance with the plan would be monitored by periodic visits by Board Inspectors. Failure to comply with the proposed pharmacy services plan would be a basis for withdrawal of the waivers, or other action by the Board.

Including a requirement for an approved pharmacy services plan provides the Board with clear objectives that can be evaluated over time. It also provides the Board members with a written record of how the pharmacy requesting the waiver proposes to maintain high levels of patient care when utilizing the automated drug delivery device. CPhA believes this type of review and ongoing evaluation is needed to ensure that waivers to use new technologies are not being sought purely for economic reasons at the cost of opportunities for pharmacist-patient interactions.

Incorporating a requirement for a pharmacy services plan at this point will provide the Board with valuable experience in dealing with such a system without significant administrative burden. The experience will be useful in developing the regulation language the Board has proposed to deal with the use of this and similar technologies in the future without having to go through the waiver process.

CPhA believes incorporating a pharmacy services plan into the requirements for a waiver request is a reasonable requirement for any entity seeking a waiver from the Board to use an automated drug delivery machine. We believe our proposal will result in the desired results of promoting the use of more efficient technology, responding to consumer and market needs and promoting the Board's ongoing efforts of improving pharmacist-patient communication. We are prepared to work with the Board and others involved in these waiver requests to make this idea work. We look forward to discussing this further with the Board at its next meeting.

Sincerely,

John Cronin

John A. Cronin, Pharm.D., J.D.
Senior Vice-President

[1] RCW 18.64A.040

AGENDA ITEM F

State of California
Department of Consumer Affairs

Memorandum

To: Enforcement Committee
Board of Pharmacy

Date: June 16, 2005

From: Patricia Harris
Executive Officer

Subject: Petitions for Reconsideration

AUTHORITY

When the board adopts a proposed decision of an administrative law judge (ALJ), the respondent (licensee) can appeal or protest all or part of the decision by filing a request (petition) for reconsideration. Oftentimes, the licensee is contesting part or all of the penalty and is requesting a reduction or modification of the disciplinary action. Petitions can be in the form of a letter and should clearly state the reasons or grounds for reconsideration.

The board itself may also order reconsideration of a decision on its own motion. This might be done on the request of staff or the Attorney General's Office for the purpose of correction or clarification of the decision.

The Administrative Procedures Act (APA) grants the board authority under Government Code section 11521 to order or grant the reconsideration of a decision. The power to order a reconsideration expires on or after the effective date of the decision. Petitions for reconsideration should be submitted well before the decision's effective date to allow the board sufficient time to consider the request. If not submitted timely, the effective date may be stayed in order for the board to decide whether to reconsider its decision. If the board takes no action within the time allowed for ordering reconsideration, the petition is deemed denied.

The APA does not specify the grounds on which an agency may grant or deny a stay of execution and the board's discretion in denying or granting a stay is broad. The board does not have to provide reasons for its action or inaction.

The respondent does not have the constitutional right to reconsideration and the board is not required to act on a petition. Seeking reconsideration is not a prerequisite to judicial review and not acting on a petition does not deny the respondent due process. The respondent still may file for judicial review under Code of Civil Procedure section 1904.5 within 30 days after the effective date of the decision.

DETERMINATION OF EFFECTIVE DATE

Section 11519 of the APA states that a decision shall become effective 30 days after it is delivered or mailed to the licensee unless; the agency specifically orders that the decision shall become effective sooner than 30 days after service of the decision, the agency itself orders the case to be reconsidered, or a stay of the effective date is ordered. Historically, the board has made the effective date of an adopted decision of the ALJ 30 days after its service.

CURRENT POLICY – Adopted April 2002 Board Meeting

The board's current policy for handling petitions for reconsideration of a board- adopted decision by an ALJ is as follows:

- Petitions received after the time allowed for reconsideration (on or after the decision's effective date): The petitioner is notified in writing that the board's authority to order reconsideration has elapsed and their option to file for judicial review.

- Petitions received not timely (within a few days of the effective date): The board president has the delegated authority to either stay the effective date of the disciplinary order to allow the board to decide whether they will agree to reconsider; or to not take action and consider the petition denied. The board president considers whether there are sufficient reasons provided by the petitioner to grant a request to issue a stay, or to deny the request. If the president decides to issue a stay of the effective date, a stay order of not more than 10 days is issued to allow the board time to decide whether to reconsider the decision. The petition will then be sent to the board for mail vote.

- Petitions received timely (within a sufficient time frame to have the board consider without issuing a stay order): Staff prepares the petition for board review by mail vote. Again, at this stage, the board is only making a decision on whether to reconsider its decision. If the board agrees to reconsideration, a stay order is issued allowing the board sufficient time to reconsider the decision.

Note: Although a licensee who agrees to a stipulated settlement also agrees to waive reconsideration rights, the board has applied its reconsideration policy to those disciplinary decisions adopted by stipulation.

RECONSIDERATION PROCESS

The boards' decision whether to consider a petition is done by mail vote. Because of the short time frame in which to make a decision, this is an expedited process and requires immediate mailing to the board and close monitoring of the mail votes, oftentimes requiring daily contact with board members.

During a mail vote, based on the information provided in the petition, the board is making a decision on whether to consider a petition. The board is not in the initial vote, deciding on the actual merits of the case or concluding the previously adopted decision should be set aside; it is merely, by its vote to grant reconsideration, concluding that there is adequate legal, factual, and/or policy basis for reviewing the factual findings, legal conclusions and/or disciplinary order.

If reconsideration is granted, the effective date of the penalty will be stayed to allow the board time to consider the issues raised in the petition. The board may reconsider by: (1) receiving written argument from the petitioner and the Attorney General's Office; (2) reviewing pertinent parts of the record or by taking additional evidence, or both, and at its option considering additional argument; or (3) assigning the matter back to the administrative law judge. The board considers the petition and additional written argument during closed session at the next regularly scheduled board meeting or, depending on the complexity of the request, by mail vote.

STATISTICS

In the last three years, the board has received 9 petitions for reconsideration. Five of those petitions were sent to the board for mail vote, three were denied by the board president, and one was received on the effective date of the decision, thus not timely and denied. All of the petitions were subsequently denied. Three of those have filed for judicial review and are still pending in the courts. One licensee did not request reconsideration, but requested a stay of the decision pending judicial review of the case. That stay request was denied and the writ review is still with the courts.

RECOMMENDATION

Due to the significant resources that are involved in processing petitions for reconsideration of those decisions and penalties already adopted by the board, and the immediate turn-around time required, it has been requested that the Enforcement Committee review the board's policy on considering petitions for reconsideration and granting stay orders and make a policy recommendation to the board.

The following are two recommendations for consideration:

1. Effective Date: Disciplinary decisions – either through stipulation or adopted proposed decisions – become effective 15 days after delivery and service to respondent, unless a different date, to be not more than 30 days after delivery, is specifically agreed upon.

2. Petitions for Reconsideration Submitted by Respondent: Do not take action on petitions submitted by respondents – whether timely or untimely, whether as a result of a stipulated settlement or an adopted proposed decision. The board members delegate to the board president the authority not to take action on these petitions and that notice be sent to the licensee that action will not be taken by the board on his/her right to judicial review.

3. Board Reconsideration: Where reconsideration is requested by board staff or the Attorney General's Office, the board members delegate to the board president the authority to grant reconsideration and stay the effective date of the order to allow the board sufficient time to consider the issues raised in the reconsideration order.