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

Enforcement Committee Report

William Powers, Public Member, Chair
Stan Goldenberg, RP.h.
David Fong, Pharm.D.

Report of June 22, 2005

FOR ACTION

ACTION ITEM 1

That the Board of Pharmacy seek clarification of B&P Code § 4186 from counsel regarding the use of automated delivery systems in board licensed clinics and consider the request from UCSF, School of Pharmacy to place an automated system in a board licensed clinic.

Discussion
Dr. Louie, Associate Dean at UCSF School of Pharmacy presented an overview of a telepharmacy network that the school would like to set up in urban center indigent clinics. **(Attachment A)**

These 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 system is called PickPoint.

Kevin Delaney, President of PickPoint presented an overview of the telepharmacy network that will be placed in the clinics. The telepharmacy is designed for the physician (pharmacist or other person authorized by law to dispense dangerous drugs) to dispense medications from the ADDS to the patients. It is proposed that only those prescription medications dedicated to the community clinics' "focused therapeutics" will be stored in the delivery system. A video-consulting link will be connected to network and routed to the school of pharmacy. Patients will receive pharmaceutical care from the pharmacists and pharmacist interns through the teleconferencing system. A vendor such as McKesson will replenish the delivery system. **(Attachment B)**

Mr. Delaney discussed that the use of PickPoint in these clinics is authorized by Business and Professions Code section 4181 and that Business and Professions Code section 4186 does not govern this type of automation unit because the PickPoint system is only automating the manual prescription drug dispensing system currently allowed in clinics. Mr. Delaney stated that he would provide a brief supporting this interpretation. **(Attachment C)**

Business and Professions Code section 4186 authorizes and defines ADDS in licensed clinics. 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 the pharmacist and pharmacist intern through a ADDS video-conferencing link, the issue is whether the PickPoint system must meet all the requirements of B & P Code section 4186 in order for it to be used in board licensed clinics. Dr.Louie requested that if such a telepharmacy system were not authorized, he would like a waiver to perform a demonstration project using the system. The committee advised Dr. Louie that the board does not have the authority to approve such a waiver.

As requested by the committee, counsel reviewed the clinic provisions and advised that the interpretation presented Mr. Delaney is a plausible reading of the law and that B&P 4186 may be interpreted only to apply to those systems controlled remotely by a pharmacist.

ACTION ITEM 2

That the Board of Pharmacy consider a request to repeal 16 CCR § 1717.2 – Notice of Electronic Prescription Files.

Discussion

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. **(Attachment D)**

Paul Riches, former board Chief of Legislation and Regulation, 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.

Dr. Gray spoke before the Enforcement Committee to advocate for the repeal of 1717.2. He argued that the sharing of a patient's prescription information is paramount to good patient care in providing the pharmacy with all the patient's prescription information. He also explained that in some instances, patients who are abusing controlled substances are shielded from detection when they choose not to have their prescription information shared. It was also his position that federal privacy laws [Health Insurance Portability and Accountability Act (HIPAA)] allows for the sharing of patient information and this notice is just duplication of the federal law. It was felt that the regulation was out-of-date and state and federal law protects a patient's privacy and this notice is not longer necessary.

As requested by the Enforcement Committee, counsel reviewed the federal and state laws and advised that a patient's medical information cannot be disclosed without the patient's consent; however, consent is not required when the sharing of the medical information is with other health professionals for the purposes of medical treatment. Therefore, the board's regulation could be considered an additional requirement to current federal and state law and is not mandated.

ACTION ITEM 3 (Not Discussed by the Committee)

That the Board of Pharmacy consider the update on the research study from UCSD, School of Pharmacy related to the use of a self-service automated drug delivery system.

Discussion

At the April board meeting, the Board of Pharmacy approved the request from UCSD for waiver of California Code of Regulations section 1717(e) to install and utilize a self-service drug delivery system in its hospital outpatient pharmacy. The board approved the waiver with the following specified conditions that are required of all approved waivers:

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

Another condition for approving the waiver, the board agreed to the request of the UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) to perform a research study on the impact of this technology to pharmacy and patients. An update on the research study will be presented at the board meeting. **(Attachment E)**

ACTION ITEM 4

That the Board of Pharmacy consider the request to require a pharmacy to submit a "pharmacy service plan" when a waiver is granted pursuant to 16 CCR § 1717(e) to use a self-service drug delivery system for refill medications.

Discussion
The California Pharmacists Association (CPhA) is requesting that the Board of Pharmacy require a pharmacy that is granted a waiver to use a self-service drug delivery system 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.

The committee moved this request to the board meeting in July and requested that CPhA provide in a bullet format the proposal for a pharmacy service plan and a template that would include the requirements. **(Attachment F)**

Since the last board meeting, there have been numerous articles on the self-service drug delivery system for refill medications. **(Attachment G)**

ACTION ITEM 5

That the Board of Pharmacy consider the request from White Cross Drug Store for a waiver of 16 CCR § 1717(e) to install and use a self-service drug delivery system.

Discussion
White Cross Drug Store is requesting a waiver of waiver of California Code of Regulations section 1717(e) to install and utilize a self-service drug delivery system in its pharmacy. White Cross Drug Store plans to install and utilize a self-service drug delivery system, such as the ddn, APM (Automated Product machine). The board considered this request at its April meeting but tabled the discussion until such time the pharmacist-in-charge could be present. Fadi Atiya, R.Ph. from White Cross will be attending the meeting. **(Attachment H)**

At its October meeting, the Board of Pharmacy granted to Longs Drug Stores its request for a waiver of 1717(e) to install and utilize a self-service drug delivery system, such as the Asters ScriptCenter, at various Long Drug Stores in California. At its January meeting, the board granted a similar waiver to Safeway Inc. to install and utilize these same units at its Safeway and Vons pharmacies. At the April meeting, the board granted a waiver to UCSD hospital outpatient pharmacy.

The board granted the waivers to permit the use of a self-service drug delivery system that allows a patient to access his/her filled prescriptions under the following conditions:

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

For UCSD hospital outpatient pharmacy, the waiver included a research study as an additional condition.

These self-use delivery systems are self-contained units that allow patients to access their filled prescriptions. The intent is to install the units in close proximity to the pharmacy area. To improve patient convenience and therapeutic compliance, a patient may access the units during pharmacy hours or during those times when the main store is open, but the pharmacy is closed.

ACTION ITEM 6 (Not Discussed by the Committee)

That the Board of Pharmacy consider the request from Walgreens for a waiver of 16 CCR § 1717(e) to install and use a self-service drug delivery system.

Discussion
The Board of Pharmacy has received a request from Walgreens for waiver of 16 CCR § 1717(e) to install and use a self-service drug delivery system. **(Attachment I)**

ACTION ITEM 7

That the Board of Pharmacy keep its current policy for petitions for reconsideration.

Discussion
The Enforcement Committee was provided with an overview of the process for a petition for reconsideration. This is the legal authority by which a respondent (licensee) can appeal or protest all or part of the decision adopted by the board by filing a request (petition) for reconsideration. Oftentimes, the licensee is contesting part or the entire penalty and is requesting a reduction or modification of the disciplinary action. Petitions are usually in a letter format 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. **(Attachment J)**

The board's current policy for handling petitions for reconsideration of a board- adopted decision issued by an Administrative Law Judge (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 of Pharmacy has delegated to the board president the 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.

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.

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.

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.

Due to the significant resources that are involved in the initial hearing process and are required to process petitions for reconsideration of those decisions and penalties already adopted by the board, and the immediate turn-around time required, the Enforcement Committee was requested to review the board's policy on considering petitions for reconsideration and granting stay orders and some options were provided for consideration such as reducing the effective date from 30 to 15 days and not to reconsider any petitions or to 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.

The committee discussed the options. It was noted that when petitions for reconsideration are submitted, the evaluation of the petitions should be based on whether or not the petitioner has

provided new facts that would support a reconsideration, or whether new laws have been enacted that may impact the decision. When petitions are provided that purportedly argue new facts, the deputy attorney general who represented the board reviews the petition to determine if indeed new facts have been presented. However, the petitions are usually requesting reconsideration of the discipline that has already been adopted by the board.

If a petition for reconsideration is granted, then 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.

NO ACTION

Importation of Prescription Drugs

The importation of prescription drugs has been an ongoing agenda item for the Enforcement Committee and Board of Pharmacy meetings for over the last three years. This has been a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings. The board's mandate is to protect the public, which includes patient access to "safe and affordable" prescription medications.

Attached are articles regarding recent developments on the issue of drug importation. **(Attachment K)**

Clarification of Pharmacy Law Clarification of Pharmacy Law Related to Intern Pharmacists, Orally and Electronically Transmitted Prescriptions and Filling 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 reminded the board that it should refrain from offering

or suggesting a binding interpretation of law, or supplementing the existing law.
(Attachment L)

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 emergency contraception (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.

Counsel 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.

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). 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.

As requested by the Enforcement Committee these pharmacy law clarifications will formatted into questions and answers for the next newsletter.

Implementation of SB 151 (Chapter 406, Statutes of 2003) – Requirements for Controlled Substance Prescriptions to Become Effective January 1, 2005

Over the past year and a half, the Board of Pharmacy has been implementing the changes to prescribing and dispensing laws for controlled substances that resulted from SB 151 (Chapter 406, Statutes of 2003). The board has been working hard at educating pharmacists and prescribers on the new requirements and coordinating its efforts with the Bureau of Narcotic Enforcement, the Medical Board of California, other prescribing boards, and professional associations. Since January 2004, the board has provided more than 50 presentations on SB 151. Some of the presentations were provided by teleconference to reach large numbers of individual prescribers and pharmacists. In addition, the board has included numerous articles in *The Script* newsletters, and a large number of articles and frequently asked questions and answers are provided on the board's website. **(Attachment M)**

In the April 2005*Action Report* publication, Medical Board of California (MBC) cautioned physicians regarding DEA's interim policy statement on prescribing Schedule II controlled substances. The interim policy statement prohibits physicians from issuing multiple prescriptions for Schedule II controlled substances on the same day to the same patient with instructions for the pharmacy to fill some of the prescription on a specific date in the future.

MBC stated in its newsletter that unless DEA changes its position, physicians must see their patients each a prescription for a Schedule II drug is written. In its next newsletter, MBC will be providing the following statement to provide guidance and clarity to physicians who prescribe Schedule II controlled substances their patients:

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

It was noted that Medical Board's position regarding the DEA interim policy statement prohibiting physicians from issuing multiple prescriptions for Schedule II controlled substances on the same day to the same patient with instructions for the pharmacy to fill some of the prescriptions on a specific date in the future will be added to the board's web site and in the next newsletter. It also requested that the board include an article on electronic signatures as well.

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

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

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

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

SupplyScape presented its electronic pedigree software program that enables a safe and secure pharmaceutical supply chain that complies with federal and state regulations to prevent counterfeit drugs.

Acerity Corporation presented its security software program, which is an electronic authentication process. They presented their system at the April board meeting as well. The system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications.

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

The committee was also provided with background articles on counterfeit drugs and efforts to combat the problem. **(Attachment N)**

Implementation of SB 1159 (Chapter 608, Statutes of 2004)

On September 20, 2004, Governor Schwarzenegger signed into law SB 1159, which provides for the pharmacy sale of sterile syringes without a prescription. Cities and counties may elect to authorize a Disease Prevention Demonstration Project, which will permit certified pharmacies to sell ten or fewer syringes to individuals 18 years of age or older. The purpose of the legislation is to further efforts across the state to prevent the spread of HIV, hepatitis and other blood-borne diseases.

SB 1159 mandates, among other provisions, that the State Department of Health Services (DHS) conduct an evaluation of the Disease Prevention Demonstration Project, and that DHS convene an uncompensated advisory panel to design the evaluation. The panel has already met twice. It includes representatives from law enforcement, the waste management industry, pharmacies, chain and independent, community advocates and government, including waste management, the state Board of Pharmacy and the state Office of AIDS (OA). DHS/OA is also encouraged by the bill to seek outside funding for the evaluation of SB 1159; possible funding sources have already been identified and a draft grant proposal is currently under revision.

There are several factors that DHS and the advisory panel has been mandated to examine in the evaluation. These mandates are based on outcomes from studies of other states' experience with expanded syringe access. The preponderance of scientific evidence suggests that California may expect:

- A reduction in the incidence of HIV;
- A reduction in needlestick injuries to both law enforcement personnel and sanitation workers;
- A reduction in needle sharing among injection drug users;
- No increase in improper syringe discard in public spaces;
- Either no change or a reduction in both crime rates and drug use in the communities that elect to participate.

The bill requires DHS to examine these particular measures to determine whether or not California's experience with expanded syringe access matches the evidence that has been accumulated to date. The assumption of the evaluators is that SB 1159 will have a significantly positive impact on public health in California, as prior research indicates.

In addition to conducting the evaluation, the State Office of AIDS is providing technical assistance to local health jurisdictions, which are in the process of implementing SB 1159. Eight counties and 2 cities have already approved a Disease Prevention Demonstration Project. These are:

- Yuba
- Contra Costa
- Alameda
- San Francisco
- Marin
- Santa Cruz
- Yolo
- Los Angeles
- The City of Los Angeles and
- The City of West Hollywood.

More than 20 other county health departments are currently preparing for implementation. Activities include meeting with local stakeholders, weighing different disposal plans for syringes and other potentially hazardous household waste, collaborating with pharmacies and developing health education materials.

Enforcement Committee Meeting Summary of June 22, 2005 (Attachment 0)

Enforcement Team Meeting Summary of June 22, 2005 (Attachment P)

Report on Enforcement Actions (Attachment Q)
Attached is the end of the fiscal year reports on the board's enforcement actions. Included is a workload comparison to the previous two years.

It is important to note that in 2001, the goal was to inspect every pharmacy every three years. At the start of this goal there were 5,530 licensed pharmacies. While the board did not meet this goal within the 3-year period, it was reached within 4 with the completion of approximately 99%. Since July 2001, 2,317 new pharmacies were added for a total 7,847 pharmacies that required inspection. The board has completed 7,482 inspections or 95% of its goal with 365 pharmacies remaining.

It is important to note that the Compliance Team performs the routine inspections in addition to the investigation of consumer complaints. This is a 7 pharmacist-inspector; however, currently there are two vacancies. Throughout the 4 years, other inspectors have assisted with the inspections. However, this team did the core of the routine inspections. In addition, this team implemented and is responsible for the inspection program for the compounding sterile injectable pharmacies.

During this 4 year inspection cycle, inspectors opened 390 complaint investigations (5.2%) as a result of a routine inspection and the top five corrections ordered were: for lack of a self-assessment, no quality assurance program, operational standards and security, requirements for a pharmacy employing pharmacy technicians and sales of outdated drugs.

Final Quarterly Status Report on Committee Strategic Objectives for 2004/2005 (Attachment R)

ATTACHMENT A

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?

Article 13 – Non-Profit or Free Clinics

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of seven years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. Each license shall be issued to a specific clinic and for a specific location.

4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) These policies and procedures shall include a written description of the method used in developing and approving them and any revision thereof.

(c) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing at least twice a year that the clinic is, or is not, operating in compliance with the requirements of this article, and the most recent of those written certifications shall be submitted with the annual application for the renewal of a clinic license.

(c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director.

4183. No clinic dispensing drugs pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

4184. No Schedule II controlled substance shall be dispensed by the clinic. This limitation shall not be construed to prohibit a physician dispensing a Schedule II drug to the extent permitted by law.

4185. The board shall have the authority to inspect a clinic at any time in order to determine whether a clinic is, or is not, operating in compliance with this article.

4186. (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.
(b) Drugs shall be removed from the automated drug delivery system 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. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.
(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.
(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.
(f) The pharmacist operating the automated drug delivery system shall be located in California.
(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.
(h) For purposes of this section, an "automated drug delivery system" means 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. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

Article 14 – Surgical Clinics

4190. (a) Notwithstanding any provision of this chapter, a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic, as provided in subdivision (b). The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of seven years for inspection by all properly authorized personnel.
(b) The drug distribution service of a surgical clinic shall be limited to the use of drugs for administration to the patients of the surgical clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient' s needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.
(c) No surgical clinic shall operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. Each license shall be issued to a specific clinic and for a specific location.

4191. (a) Prior to the issuance of a clinic license authorized under this article the clinic shall comply with all applicable laws and regulations of the State Department of Health Services and the board relating to drug distribution to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. These policies and procedures shall include a written description of the method used to develop, approve, and revise those policies and procedures.
(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4192. Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services.

ATTACHMENT B

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

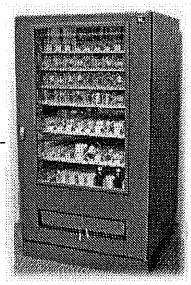
FlexRx™ Secure

After Hours & Remote Outpatient Dispensing

FlexWare™ Secure

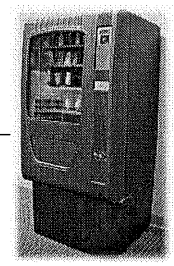
- Real-time monitoring of dispense history, replenishment needs, inventory, lot, and expiration dates from Central Pharmacy
- Dispenses items with bar code verification in less than 10 seconds
- Does not utilize patient data – alleviating HIPPA issues
- Satisfies JCAHO's "Same Standard of Care" Requirement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

LxS



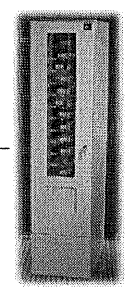
- Securely stores up to 121 rows of prepackaged line items at point of care locations (Avg. 12 items per row)
- Can accommodate nearly every package size available
- Reconfigurable by end users in seconds
- Optimal for ER's, Acute Care Clinics, and other locations that require larger formularies
- 40"W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

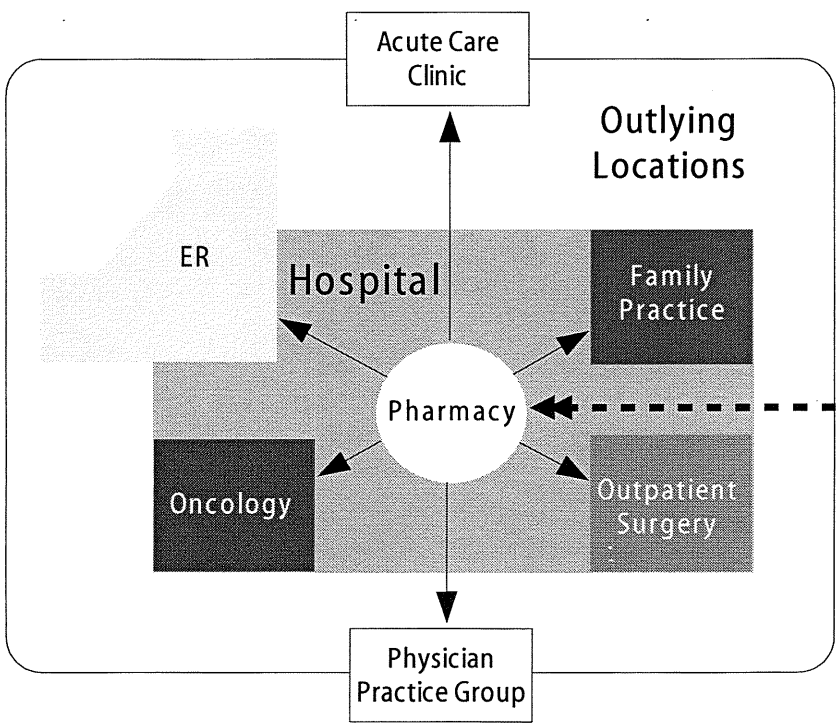
PickPoint™ FlexRx™

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:

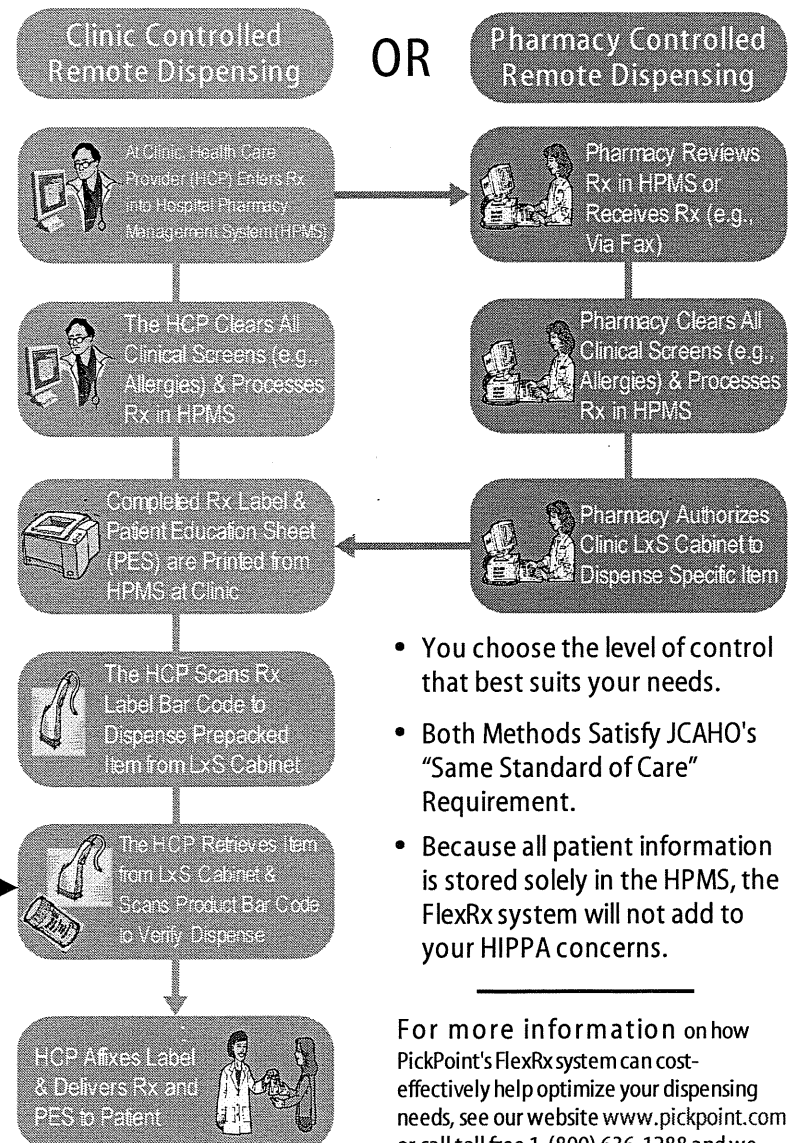
- Labor
- Logistics (Replenishment)
- Patient Safety
- Accountability
- Cost Control

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

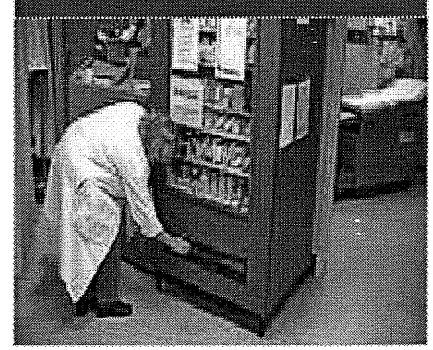
- Approximately 2,000 prescriptions are captured each monthly that were previously unaccounted for
- Patient receives high quality product including typed label and drug monograph
- Process is now at an acceptable safety level with numerous checks to reduce error risk
- Entire process can be safely completed 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 not work must reenter for multiples
ANMC comments: inconsistent on multiple qty to reenter and redo 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.

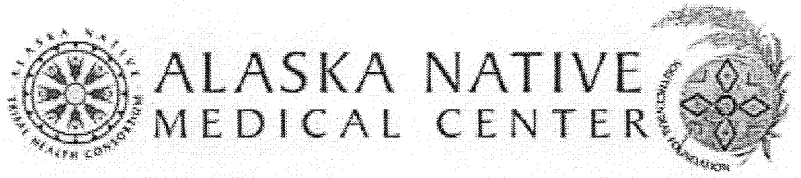
Purpose:

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.



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.

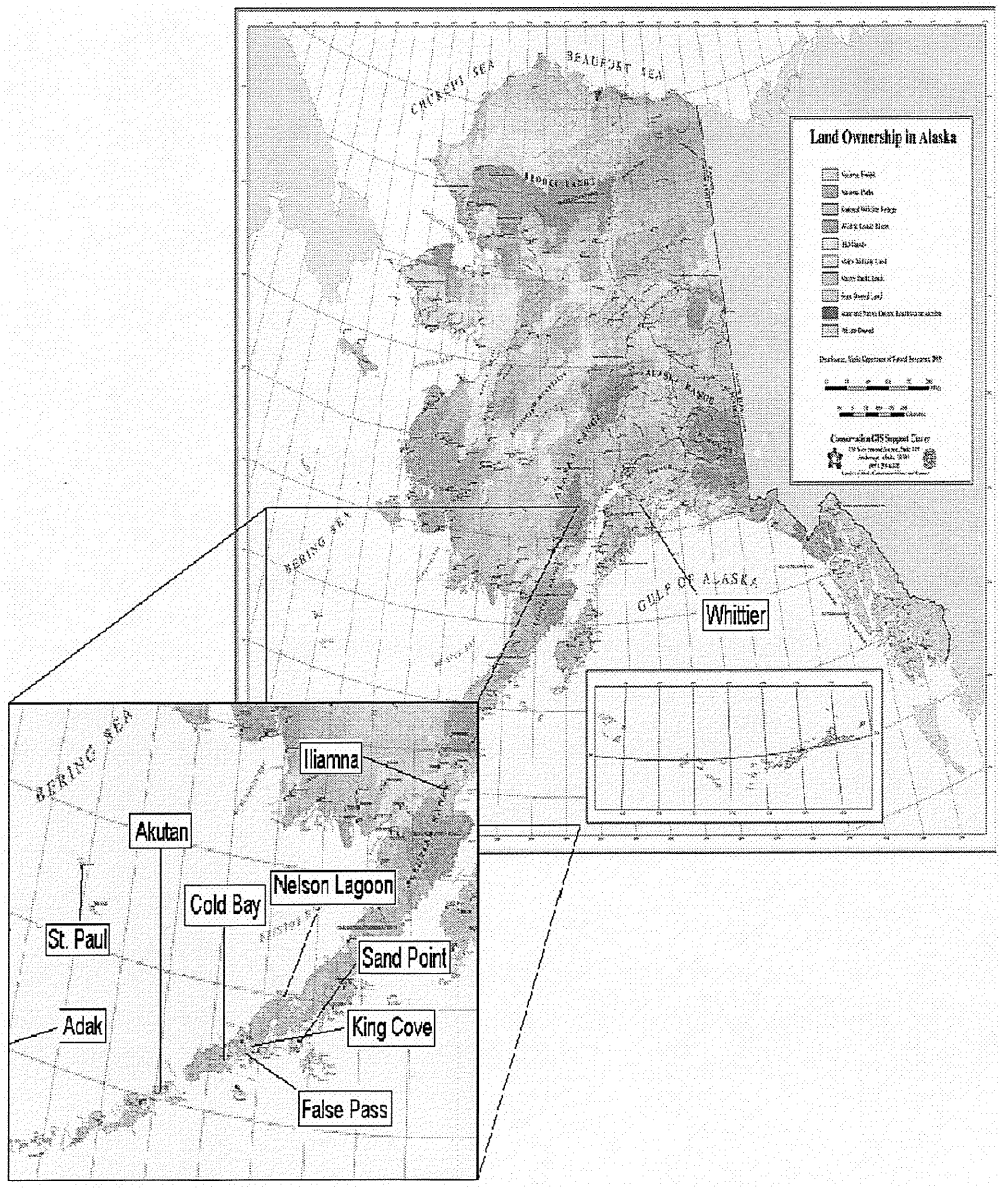
Five automated dispensing units were installed and services initiated in the spring and summer of 2003. An additional seven units have been ordered for installation. The pilot program operated in five sites using two different telepharmacy systems for six months. During the pilot phase, unmet needs were 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

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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

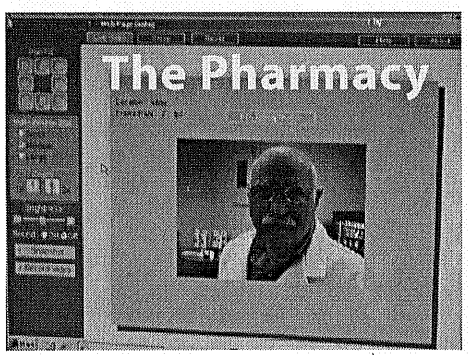
Discussion:

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

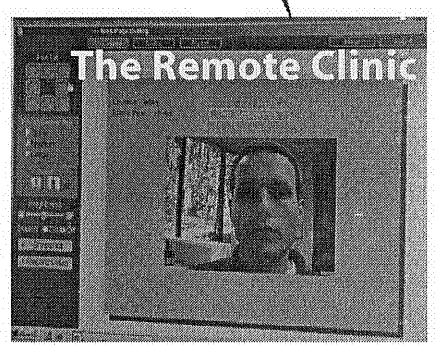


Video Conferencing provides "same standard of care" from miles away, allowing live monitoring of the FlexRx System and real time patient counseling from anywhere in the world.

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

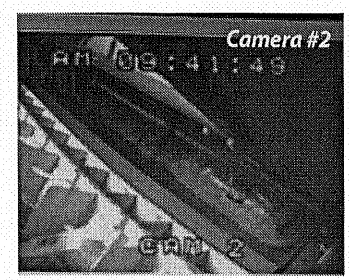
Video Conferencing

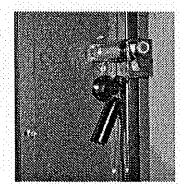


PickPoint Corporation
Simplifying Pharmaceutical Automation

FlexCam

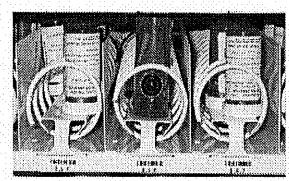
FlexCam, a network-enabled video system for monitoring remote pharmaceutical dispensing environments from any location; it's scalable and can record from up to 16 camera angles, while helping to protect your system integrity using motion-detected video recording.

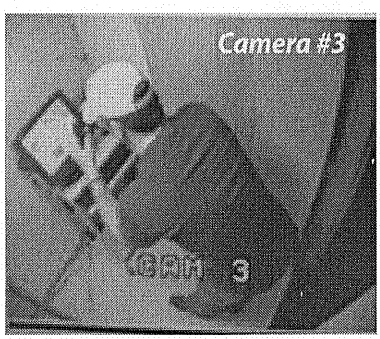




Network Enabled Video
Allows for real time monitoring of the FlexRx

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

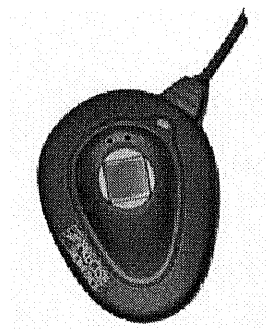
PickPoint Corporation
Simplifying Pharmaceutical Automation

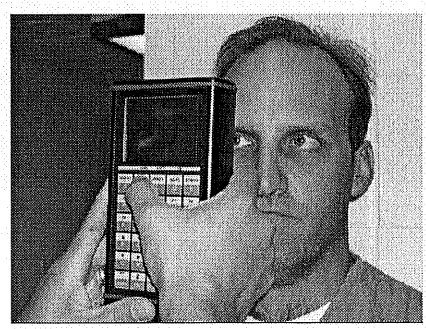
BioFlex

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.

ATTACHMENT C

Brief in Support of the Use of Automated Inventory Management Systems in Community Clinics Licensed Pursuant to Business and Professions Code Section 4180

Presented to

The California State Board of Pharmacy

By

PickPoint Corporation

In conjunction with

Saint Anthony's Community Clinic
and
University of California San Francisco School of Pharmacy

July 20, 2005

I. 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.

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. Among the issues discussed is the need to utilize technology to help improve inventory control and record keeping, so as to free up the time of the health professionals, and ultimately ensure the safe handling of medications dispensed by the clinic.

Pioneered by manufacturers such as Pyxis, Omnicell, and McKesson, automated inventory management systems (AIMS) have long been in use by hospitals and clinics to help control the storage of medications outside of the four walls of a traditional pharmacy. Originally designed to manage floor stock in individual unit dose format, AIMS have evolved to store a variety of dosage formats, including prepackaged, unit of use medications.

PickPoint Corporation manufactures a line of AIMS designed to securely store prepackaged, unit of use medications for eventual dispensing by health care professionals. PickPoint has over one hundred successful installations of its products, located primarily in emergency rooms and clinics operated by all four branches of the United States military. PickPoint's cabinets are constructed of 14-gage steel, with three points of lock, and bullet resistant glass. PickPoint's AIMS restrict access to only authorized users, require all items entering the system to be prepackaged and labeled with a bar codes that identify the National Drug Code (NDC) number for a particular medication, instruct users restocking the cabinet where the place the item within the system, and verify the proper delivery of items to health care professionals via series of bar code scans. PickPoint's software also tracks the lot and expiration date of every item in the system.

Saint Anthony's Clinic, a member of the SFCCC, has been identified by the SFCCC and UCSF to be the first clinic to implement technology provided by PickPoint to help manage Saint Anthony's inventory of prepackaged medications. Prior to implementing this system, however, Saint Anthony's desires clarification from the Board of Pharmacy on the proper use of AIMS in community clinics.

Business and Professions Code Section 4180 – 4186 is a statutory scheme that sets forth the guidelines governing the provision of prescription medications by community clinics to their patient populations. Section 4186 speaks directly to the use

of automated drug delivery systems (ADDS) in these community clinics, and adds additional restrictions over and above those found in the manual clinic prescription dispensing process, such as the direct involvement of a pharmacist in the restocking of the cabinet and authorization of prescriptions.

The clarification Saint Anthony's wishes to receive from the Board is: if Saint Anthony's is currently purchasing drugs, storing them on shelves in a secured room, and dispensing them to patients without the direct intervention of a pharmacist pursuant to their license granted under Section 4180, and Saint Anthony's wishes to further improve the safety, security, and accountability of their drug inventory through the use of an AIM, does Section 4186 require the direct intervention of a pharmacist in the restocking of the AIM and dispensing of the prescription, or may the clinic use the AIM as a safe or closet, utilizing the same personnel (physician) to stock the AIM as it currently uses to stock its shelves and dispense its prescriptions? It is the belief of Saint Anthony's that Section 4186 only restricts the use of remotely controlled AIMS (or ADDS), leaving Saint Anthony's free to use PickPoint's AIMS locally in its clinic with its current personnel and procedures.

II. Business and Professions Code Section 4180 et. seq. Authorizes Saint Anthony's Clinic to Use PickPoint Corporation's AIMS With Its Current Personnel and Procedures.

A. Business and Professions Code Section 4181 Authorizes the Use of AIMS in Clinics Authorized to Dispense Prescriptions Pursuant to Business and Professions Code Section 4180.

Business and Professions Code (B & P Code) Section 4181(a) states in relevant part that any clinic authorized to dispense prescriptions to the public pursuant to B & P Code Section 4180 shall "insure that inventories, security procedures, training, protocol development, record keeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public." Furthermore, Section 4181(a) and 4182(a) leave it to the clinic and its consulting pharmacist to develop policies and procedures to implement these requirements.

It is axiomatic that implicit in any statute is the authorization to perform those activities necessary to fulfill the statute's requirements. Since Section 4181 requires a clinic to properly maintain inventory and security so as to protect the health and safety of the public, it follows that Section 4181 authorizes the clinic to use those tools at its disposal that would enable the clinic to secure its inventory and maintain its records, provided that such the process by which the clinic dispenses prescriptions "promotes and protects the health and safety of the public." Additionally, since Sections 4181(a)

and 4182(a) allow the clinic and the consulting pharmacist to develop the procedures for the clinic, it follows that the statutes allow them to choose among the various tools at their disposal to develop the safest, most effective procedure for the clinic.

Here, Saint Anthony's Clinic is licensed to store and dispense prescriptions pursuant to B & P Code Section 4180. In conjunction with its consulting pharmacist, Saint Anthony's has decided that it needs the use of PickPoint's AIM to better secure its inventory and maintain its records, thereby promoting and protecting the health and safety of the public. Consequently, Section 4181 authorizes Saint Anthony's to utilize PickPoint's AIM in its course of storing and dispensing medications.

B. Although B & P Code Section 4186 Restricts the Use of Automated Drug Delivery Systems (ADDS), It Does Not Restrict the Use of Locally Controlled AIMS.

B & P Code Section 4186(a) states that a clinic authorized to dispense prescriptions to the public pursuant to B & P Code Section 4180 may use an ADDS so long as it complies with restrictions on its use set forth in subsections (b) through (g). Section 4186(h) defines an ADDS for the purpose of that statute 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." Since ADDS have as an essential feature the automatic management of inventory, the issue is whether Section 4186 seeks to restrict the use of all AIMS, or only those remotely controlled by a pharmacist. Plain language and common sense dictate that the proper interpretation is the latter.

As the court stated in *Park Medical Pharmacy v. San Diego Orthopedic Associates Medical Group, Inc.* (2002) 99 Cal.App.4th 247, 250-251, 120 Cal.Rptr.2d 858 (interpreting various provisions of pharmacy law found in B & P Code Section 4170 et. seq.):

> "Our fundamental task in construing a statute is to ascertain the intent of the lawmakers so as to effectuate the purpose of the statute." (*Day v. City of Fontana* (2001) 25 Cal.4th 268, 272 [105 Cal.Rptr.2d 457, 19 P.3d 1196]; *Wilcox v. Birtwhistle* (1999) 21 Cal.4th 973, 977 [90 Cal.Rptr.2d 260, 987 P.2d 727].) "We begin by examining the statutory language, giving the words their usual and ordinary meaning." (*Day*, at p. 272; *People v. Lawrence* (2000) 24 Cal.4th 219, 230 [99 Cal.Rptr.2d 570, 6 P.3d 228].) If the language of a statute is clear, we must follow its plain meaning. (*Torres v. Parkhouse Tire Service, Inc.* (2001) 26 Cal.4th 995, 1003 [111 Cal.Rptr.2d 564, 30 P.3d 57].) "If, however, the language is susceptible to more than one reasonable interpretation, then we look to 'extrinsic aids, including the ostensible objects to be achieved, the evils to

be remedied, the legislative history, public policy, contemporaneous administrative construction, and the statutory scheme of which the statute is a part.' " (*Hoechst Celanese Corp. v. Franchise Tax Bd.* (2001) 25 Cal.4th 508, 519 [106 Cal.Rptr.2d 548, 22 P.3d 324]; *Spanish Speaking Citizens' Foundation, Inc. v. Low* (2000) 85 Cal.App.4th 1179, 1214 [103 Cal.Rptr.2d 75] ["While the ' "final responsibility for the interpretation of the law rests with the courts" ' [citation], 'the construction of a statute by officials charged with its administration ... is entitled to great weight.' "].) " '[W]e do not construe statutes in isolation, but rather read every statute "with reference to the entire scheme of law of which it is part so that the whole may be harmonized and retain effectiveness." [Citation.]' " (*Horwich v. Superior Court* (1999) 21 Cal.4th 272, 276 [87 Cal.Rptr.2d 222, 980 P.2d 927].)

As stated earlier, the purpose of Sections 4180 et. seq., is to allow the effective access to health care, including the provision of prescription medications, to underserved communities through specified clinics so long as the clinics employ procedures that promote and protect the health and safety of the public. Read in this light, the clear and unambiguous language of Section 4186, as well as common sense, dictate that Section 4186 only restricts the use of remotely controlled ADDS and not locally controlled AIMS.

Section 4186(a) plainly states that "Automated drug delivery systems, ***as defined in subdivision (h)***, may be located in any clinic licensed by the board pursuant to Section 4180." (emphasis added). Further, 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." (emphasis added). The clear language limits Section 4186's application to a specific subset of ADDS, specifically those that are controlled remotely by a pharmacist. Thus, the restrictions set forth for the proper use of ADDS set forth in Section 4186 (b) – (g) only apply to those falling under that subset – those that are remotely controlled. Consequently, Section 4186 does not restrict the clinics use of locally controlled AIMS.

Common sense yields the same result. The restrictions set forth in Section 4186 (b) – (g) deal with pharmacist oversight with the dispensing process (e.g., pharmacist stocking the cabinet, pharmacist approving prescriptions, etc.). These restrictions make common sense when speaking about a remotely controlled machine. If the pharmacist is ultimately responsible for a dispensed prescription, and the pharmacist is not physically present at the location where the prescription is to be dispensed, it makes sense to force the pharmacist to review all items going into the machine, and reviewing patient profiles prior to authorizing any dispense. That is the same standard of care required of all pharmacies.

The same cannot be said for holding that 4186 restricts the use of locally controlled AIMS. Community clinics licensed to dispense prescription pursuant to Section 4180 are allowed to purchase drugs, store drugs, and dispense drugs without the direct intervention of a pharmacist. Furthermore, AIMS have been in use in hospitals for many years, and have been shown to be very effective at controlling floor stock and other and other medical devices. To hold that Section 4186 ties pharmacist to the use of all AIMS is counter-intuitive in that it defeats the purpose of Sections 4180 et.seq. Such a holding would force clinics to either forgo AIMS and use lesser effective manual processes for maintaining inventory and records, or, alternatively to employ the services of a pharmacist, which are not be readily available for this patient population, which was the reason for the issuance of Sections 4180 et.seq. in the first place.

Since the plain language of Section 4186 and common sense limit Section 4186's application to ADDS that are remotely controlled, the restrictions found therein do not affect the use of AIMS locally controlled in clinics licensed pursuant to Section 4180.

C. Business and Professions Code Section 4180 et. seq. Authorizes Saint Anthony's Clinic to Use PickPoint Corporation's AIMS.

As stated earlier, Section 4181 authorizes a community clinic licensed pursuant to Section 4180 to use an AIMS to control inventory, etc., to promote and protect the safety of the public, and so long as such AIMS is locally controlled, the restrictions found in Section 4186 do not apply.

Saint Anthony's is a community clinic licensed by the board to dispense prescriptions pursuant to Section 4180. Saint Anthony's wishes to use PickPoint's AIMS as a means of improving its inventory control, record keeping, etc., in the promotion and protection of the safety of the public. Saint Anthony's intends on using the same personnel and procedures it currently uses in stocking shelves and dispensing prescriptions, namely its physicians, in the utilization of the PickPoint AIMS. Since Sections 4181 and 4182 authorize Saint Anthony's to use PickPoint's AIMS, and allow it to decide on the best procedures for how to use it (in conjunction with its consultant pharmacist), and since Section 4186 does not control the use of a locally controlled AIMS; Saint Anthony's is free to use PickPoint's AIMS as a locally controlled method for controlling inventory, stocking the cabinet with the same personnel it currently uses to stock its shelves, and dispensing items from the clinic without the direct intervention of a pharmacist.

ATTACHMENT 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.

ATTACHMENT E

UCSD Medical Center
HILLCREST

July 5, 2005

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

RE: PRESENTATION TO BOARD

Dear Ms. Harris:

The University of California, San Diego Medical Center requests to be included on the agenda of the next Board of Pharmacy meeting on July 20, 2005 if that schedule allows.

It is our intent to provide a short update for the Board on the research study to be conducted by the UC San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences related to our waiver of CCR 1717e on the impact of automated prescription delivery systems on patients and pharmacy.

Please contact me at the address below or directly by phone (619) 543-6194.

Sincerely,

Charles E. Daniels, R.Ph, Ph.D.
Pharmacist-In-Chief

Department of Pharmacy *UCSD Healthcare, University of California, San Diego*
200 WEST ARBOR DRIVE, SUITE ROOM 1-317 SAN DIEGO, CALIFORNIA 92103-8765 TEL: (619) 543-6194 FAX: (619) 543-5829

UCSD Automated Prescription Delivery System (APDS) Evaluation Study

Update for California Board of Pharmacy 7-20-05

J. Hirsch, R.Ph.,Ph.D. C. Daniels, R.Ph.,Ph.D. R. Smith, Pharm.D.
UCSD Skaggs School of Pharmacy & Pharmaceutical Sciences
UCSD Healthcare Department of Pharmacy

1

Key Study Topics

- Study Objectives
- Patient Selection for APDS (ScriptCenter)
  - Flow
  - Criteria
- Study Groups & Data Collection
- Metrics for Assessment
- Timeline

2

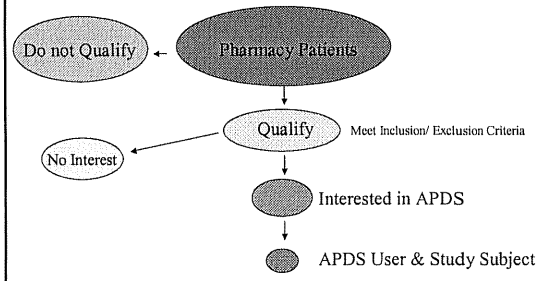
Study Objectives

1. Examine safety, efficiency & quality of pharmaceutical care provided to APDS patients vs. regular pick-up counter patients
2. Explore patient willingness to utilize APDS as means of pharmacist monitoring medication therapy outcomes

NOTE: Longs and Safeway have agreed to participate – details to be determined. Remainder of slides specific to UCSD site.

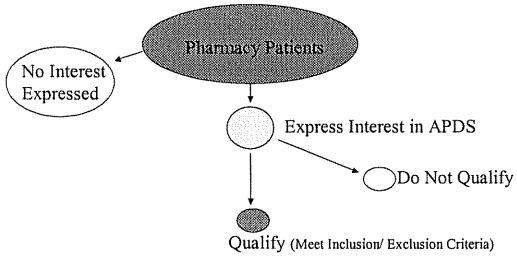
3

Patient Selection Flow - Proactive



4

Patient Selection Flow – In Pharmacy



5

APDS Patient Selection Criteria

- In general, patients with refill prescriptions who are not at high risk of drug related problems
- Inclusion Criteria:
  - Refill Prescription
  - Ability to read and understand written information
  - Ability to understand and utilize ScriptCenter technology
- Exclusion Criteria:
  - More than 3 chronic disease states
  - Five of more chronic medications
  - 12 or more doses per day
  - Medication regimen changed 4 or more times in past year
  - History of non-compliance
  - Drugs requiring therapeutic monitoring
  - Pharmacist judges as unsuitable candidate

Adapted from IMPROVE study criteria for computer-based identification High Risk Pts: Annals Pharmacotherapy, April 1999 6

Study Groups & Data Collection

APDS Patients

Regular Pick-Up Site Patients

- Data Collection
  - •APDS – Operational Metrics & Patient Survey
  - •Regular Pick-Up Site – Observational & Patient Survey

7

	GROUPS		
METRICS	**APDS**	**Regular Pick-Up**	**Matched to APDS**
Patient Descriptors Medication, Gender, Age	X	X	X
APDS Descriptors #: Users, Rxs, Rxs/transaction, Transactions/time period Use patterns (time of day), Attrition rates	X		
Safety: Delivery Accuracy # Patients given wrong bag	X	X	x
Consultations % Patient or Other Picking-up % Request Consultation Refill Rxs Consultation Content (medication, insurance, other) Consultation Medications	X	X	x
% Accept or Refuse consultation Refill & New Rxs		X	x
Patient Assessment Satisfaction with Service & Counseling Willingness to Use as Outcomes Monitoring Mechanism	X X	X	x
RPh Assessment Service & Counseling provided	X	X	
Medication Adherance Rates *(before vs. after APDS)*	X	X	X
Efficiency # Patients given wrong bag Perception of Wait Time	X	X	x

Small x = will have limited ability to make this comparison

8

Study Timeline *(UCSD Estimated)*

	Completed By…
Board of Pharmacy Input	July 20
IRB Submission	August 31
Funding Proposals submitted *(1-4 mo. response)*	August 31
IRB Approval	September 30
APDS Proactive Patient Identification	October 31
UCSD ScriptCenter Installation	November 30
APDS Utilization Starts	December 15
3 month data collection	March 31 2006
Progress – Preliminary Results Report to Board	***April 30***
6 month data collection	June 30
Progress - Results Report to Board	***July 31***
12 month data collection	January 31 2007
Final Results Report to Board	***February 28***

9

Questions?

10

ATTACHMENT F

California Pharmacists Association

RECEIVED BY CALIF
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

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Sacramento, California 95834
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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

RECEIVED BY CALIF
BOARD OF PHARMACY
2005 JUL -8 PM 3:31

July 3, 2005

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Dear Board Members:

I implore the Board to rescind the waiver granted to Long's Drugs allowing them to establish an automatic dispensing kiosk/device.

For many years in the past, the Board and those in the profession of pharmacy have encouraged and even advocated more contact between client and pharmacist. You are now reversing course. I strongly believe that you are doing the citizens of this state a disservice by allowing this type of dispensing to occur just so that a corporation can reduce its labor costs. It goes against the standards of our profession.

I have no personal ax to grind as I am now retired from active employment. I am proud to have been a member of the pharmacy profession these past 49 years and I would hate to see more limitation of personal contact between patient and pharmacist.

Please reconsider your actions.

Sincerely,

Harry Kamian, Jr., BS Pharm
11 Brookdale Ct.
Lafayette, CA 94549

ATTACHMENT G

A New Way to Get Prescriptions: Vending Machines
San Diego Pharmacy Uses Vending Machines to Dispense Prescription Refills
ABC News Internet
Jun. 22, 2005

It seems you can get almost everything out of a vending machine, from soft drinks and sandwiches to umbrellas and sewing kits.

Soon you may even be able to get prescription medicine from a vending machine.

At one drug store in San Diego, pharmacists dispense nearly 1,600 prescriptions a day. The high volume prompted owner Max Atiya to add a drug-dispensing kiosk to his store.

He says customers are buying into this new way of doing business.

"They like the fact that they don't have to deal with anyone," Atiya said. "They go to a machine and they basically dispense their medication."

First-time prescriptions still go through a pharmacist, but the automated pharmacy machine can be used to streamline the refill process.

Bill Homes of the Distributed Delivery Networks Corp. created the machine.

"People who would benefit from the machine are people who need to get in and out without consultation," Homes said.

Customers are still welcome to consult a pharmacist at any time and are encouraged to ask questions, but some in the industry worry that the machines could lead to the misuse of medicine.

"Anything that limits or diminishes the amount of face time between the pharmacist and the patient contributes to that problem," said David Breslow of the California Pharmacists Association.

Steve Fazziola, pharmacy manager, is confident with the technology.

"This machine can do as good a job as I allow it to do," Fazziola said. "And it won't get tired or make mistakes unless we mess up."

Getting Your Drugs: From a Vending Machine
Pharmacies Test Kiosks: That Dispense Refills: Some Regulators Are Leery
By RHONDA L. RUNDLE
THE WALL STREET JOURNAL
June 21, 2005

There's a new antidote for long lines at the drugstore pharmacy: machines that serve up your prescription refills like a can of Coke or a Snickers bar.

The idea behind the machines, which look much like a typical bank ATM, is to expedite a process that is often bogged down by long lines and frustrating waits.

Once customers have filled an initial prescription with the pharmacist, they can register to retrieve and pay for their refills at a vending machine inside the store -- even when the pharmacy counter isn't open. Consumers order their refills in the usual way, either online or by phone. A pharmacist then fills the script and places packaged medicines in the machine. To pick up the order, consumers log on with a user name and password and swipe a credit or debit card. Their pre-wrapped package drops into the bin.

The California and Virginia pharmacy boards have cleared the way for the machines in their states, granting waivers of rules that require a pharmacist be present in order for drugs to be dispensed. And other states are considering allowing the machines.

In California, the State Board of Pharmacy has proposed a permanent rule change that could speed the spread of the technology. Between the stores that already have machines, and the ones that are considering it, "we're getting inundated with waiver requests," says the board's executive officer, Patricia Harris. The state Office of Administrative Law is expected to make a decision early next year.

One of the first drug-dispensing machines, called ScriptCenter, was installed in December at a Longs Drug Stores location in Del Mar, Calif. ScriptCenters are also on their way to an Ahold Giant Food store in Reston, Va., and a Safeway Inc. Vons supermarket in Southern California. Asteres Inc., the closely held Del Mar company that developed the ScriptCenter, says it is discussing sales and leasing deals with a number of large drugstore chains around the country.

A similar, rival kiosk -- the Automated Pharmacy Machine from Distributed Delivery Networks Corp. (DDN) -- is being tested at White Cross Drug Store in San Diego.

Both companies recently made presentations to the Wisconsin Pharmacy Examining Board, which is exploring options for improving access to prescription drugs for people who live in rural areas.

The ATM-like machines are raising questions among pharmacists and state regulators who oversee prescription-drug dispensing. One worry is that patients might end up with the wrong drug. Some pharmacists also don't like the machines because they cut out traditional face-to-face consultations with patients. The concern is that patients might be discouraged from asking pharmacists about such things as whether alcohol should be avoided with a medicine, or possible drug interactions.

"There's lots of leeriness on the part of regulators and the fear that something like this could replace the pharmacist," says Mary Ann Wagner, vice president of pharmacy regulatory affairs for the National Association of Chain Drug Stores, a trade group in Alexandria, Va.

That can be a difficult argument to make given how many drugs are now dispensed by mail order. Indeed, driving this effort is a need by drugstore chains to boost competition against mail-order pharmacies by making pickups faster and easier. Mail order accounted for 14% of prescription drug sales last year, up from 10% in 1999, according to IMS Health Inc., a drug information and consulting firm in Fairfield, Conn. The machines will be particularly attractive to

24-hour supermarkets that want to cut back their pharmacists' working hours to reduce costs, says Christopher Thomsen, a pharmacy consultant in Kansas City, Mo.

"So far, there hasn't been a line at the machine," says Sid Schuman, holding up a sealed plastic bag that he has pulled out of a ScriptCenter machine at the Longs pharmacy on a recent day. The 69-year-old retired garden-supplies distributor says he placed an online order a couple of days earlier and just popped into the store to pick it up. There are no transaction fees for the customer.

A spokeswoman for Longs Drug Stores says the machines will free up pharmacists to spend more time talking with patients who have questions.

Device proponents say that security and accuracy concerns regarding the machines are overblown. Longs says it tested a ScriptCenter prototype for about six months at its corporate headquarters in Walnut Creek, Calif., to be sure that it wouldn't dispense the wrong drug. And Bill Holmes, president of DDN, a unit of Amistar Corp., says its Automated Pharmacy Machines use bar code and other technologies to avoid errors. Each prescription package has a unique bar code that is read when it is put into the machine and again before it is released to the patient. "If there's no match, the door won't open," says Mr. Holmes. "To date they haven't dispensed a single one inaccurately."

The Asteres and DDN systems are very similar. In fact, Asteres has accused DDN and San Marcos, Calif.-based Amistar of "misappropriation of trade secrets" in a lawsuit filed in a California state court last August. Mr. Holmes and Asteres founder Linda Pinney are both alumni of Pyxis, a maker of an inventory-management and drug-dispensing system used by nurses in hospitals that was acquired in 1996 by Cardinal Health Inc., a giant health-care concern in Dublin, Ohio. "We are aggressively defending ourselves against this litigation," Mr. Holmes says. A trial is set for September.

At the University of California at San Diego's medical center, researchers are planning an academic study of drug-dispensing technology's impact on patient care and pharmacy management. The researchers say they aim to have a ScriptCenter machine installed in a clinic building in the next few months.

The drugstore machines are different from another growing drug-dispensing technology called InstyMeds that is used in about 20 urgent-care centers and hospital emergency rooms. The InstyMeds machines, often located in the waiting room, are prestocked with commonly used drugs. Physicians working in those centers can send an electronic order for a prescription to the machines, which print up a label and dispense the drug to the patient.

"We don't have any present plans to move into drugstores," says Ken Rosenblum, founder and chief executive of Minneapolis-based Mendota Healthcare Inc., developer of the InstyMeds machines.

'ATM' for prescription drugs makes debut:" ScriptCenter, the Asteres dispenser of prescription drugs, could be coming to a pharmacy near you.
By Aaron Smith,
CNN/Money

June 21, 2005: 4

NEW YORK (CNN/Money) - In December 2002, Linda Pinney, founder and chief business officer of Asteres Inc., had an epiphany while waiting in line at a pharmacy in Del Mar, Calif.

"I was standing in line thinking there's got to be another way," said Pinney, who was filling a prescription for a drug to treat her Attention Deficit Hyperactivity Disorder. "Make an ADHD person wait in line to pick up a prescription and they're going to come up with a solution."

Thus was born the ScriptCenter, an ATM-style device that dispenses drugs instead of cash.

Three years after Pinney's restless waiting got her thinking, the first ScriptCenter was installed in that very same Del Mar pharmacy, a member of the Longs Drug Stores chain.

"We're always looking for ways to serve our customers, and it seems as though customers are very time constrained," said Longs Drug Stores (down $0.17 to $43.41, Research) spokeswoman Phyllis Proffer. "This is a great example of how we can use technology to save the customers' time."

For the last six months, the first ScriptCenter has served as a test device, delivering prescription refills for hundreds of patients. The California Board of Pharmacy granted a tentative approval for the machine, reserving the right to withdraw it any time. But so far there haven't been any problems, according to the board.

"There seems to be some controversy about the machines," said Patricia Harris, executive officer for the California Board of Pharmacy. "There is concern from the pharmacy profession that you're losing that contact with the patients when they're receiving pharmaceuticals from the machine."

But Harris says the machines are intended to speed up a process, not replace pharmacists. "You still have to go through your checks and balances to make sure it's a legitimate prescription up front," she said. "We see no issues from it, from a staff perspective."

"There is a very strict authentication process to use the machine," said Pinney, who considers it more secure than receiving prescription drugs in the mail.

To guard against fraud, patients use identification cards or passwords to access the drugs and the machines take security photographs of the transactions, like with ATMs.

States start approving

Asteres, a privately-held Del Mar-based company, plans to install two more machines at San Diego pharmacies this month and another machine in San Francisco. In addition to Longs Drug Stores, Safeway Inc. (up $0.93 to $24.47, Research) has agreed to host the ScriptCenters at California locations.

Meanwhile, the Virginia Board of Pharmacy has also granted tentative approval to the ScriptCenter, and one of the machines is in the process of being set up at an Giant Food store in Reston, Va. owned by Ahold USA.

"It's going to be one store and approved for refills only," said Ralph Orr, deputy executive director for the Virginia Board of Pharmacy, "to allow the chance for the technology to be looked at."

The Hawaii Board of Pharmacy on Friday became the first state board to approve the ScriptCenters for accepting new prescriptions, in addition to refills, said Pinney. Also, Asteres has begun the regulatory process in about a half dozen other states.

Some of the ScriptCenters are located inside 24-hour stores. In California and Virginia, the machines can be used even when the pharmacies are closed, Pinney said. Hawaii waived that right by allowing ScriptCenters to accept new prescriptions.

Pinney isn't worried about thieves walking off with drug-laden ScriptCenters.

"The ScriptCenter weighs 1,300 pounds when loaded," said Pinney. "It is drilled down through the cement. I don't think it's going anywhere."

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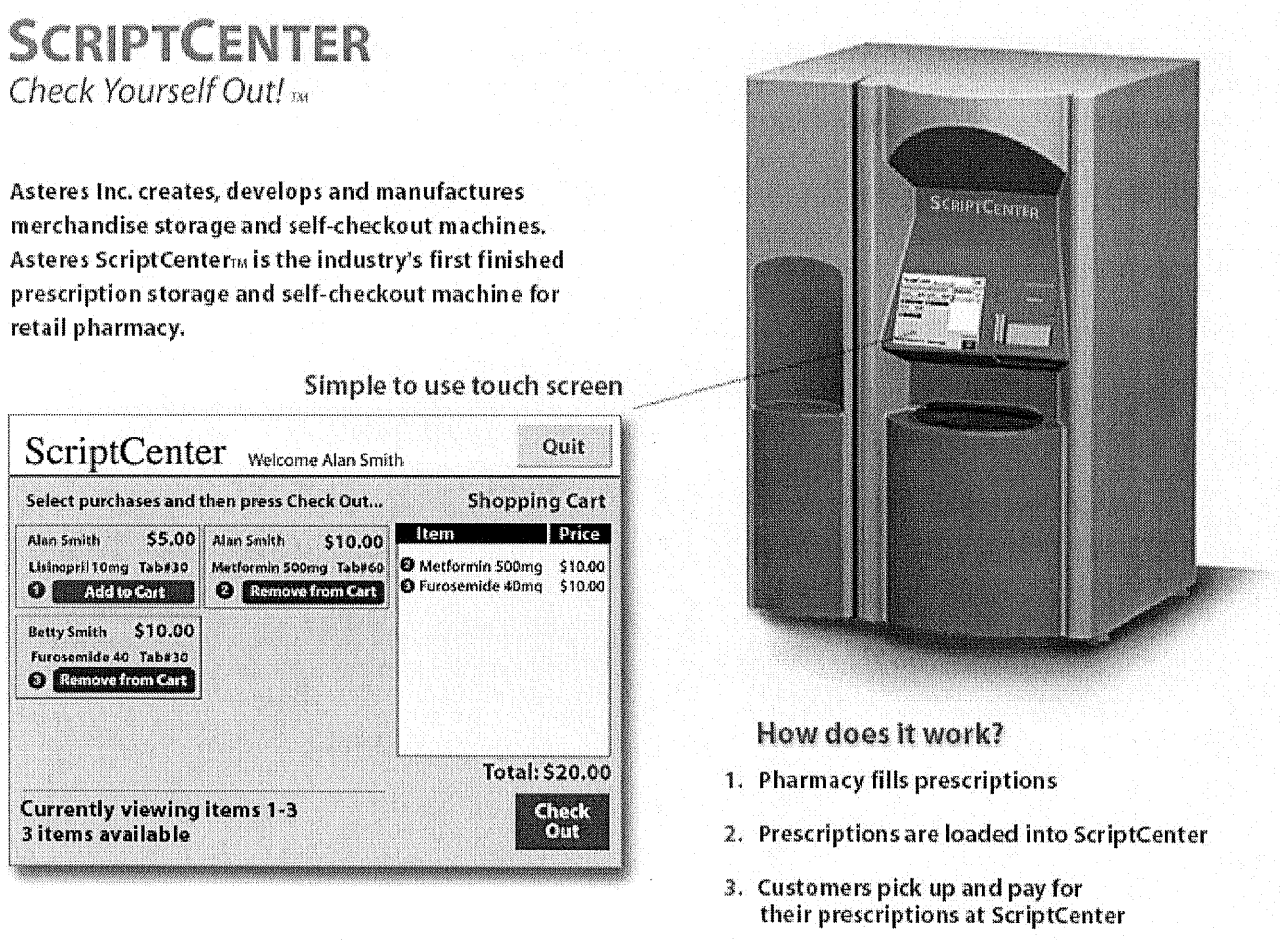
http://www.asteres.com/



"newsletter@ismp.org
"
<R-4-60120-2287159-2
-1287-US2-2767963B

06/29/2005 05:16 PM

To: patricia_harris@dca.ca.gov
cc:
Subject: ISMP Medication Safety Alert! June 30, 2005 Vol. 10, Issue 13

Institute For Safe Medication Practices

Subject: ISMP Medication Safety Alert! June 30, 2005 Vol. 10, Issue 13

Your participation is crucial: computer system safety features in acute care settings - www.ismp.org/s/survey2005_05.asp.

also...

ISMP Medication Safety Self Assessment for Antithrombotic Therapy *in Hospitals.* ***http://www.ismp.org/Survey/Asa/Intro.htm***

ISMP Medication Safety Alert!

June 30, 2005

Volume 10, Issue 13

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Two steps forward and one step back for patient safety?

Two groups focus on improved outcomes, another on Rx "vending" machines

As portrayed in a June 21, 2005, article in *The Wall Street Journal*, surgeons appear to be stepping up to the plate by adopting a focus on patient safety as modeled by anesthesiologists in an attempt to improve patient outcomes and reduce medical malpractice costs. We couldn't agree more that such efforts will pay off impressively in both human and financial terms. However, based on a seemingly unrelated article in the same edition of the newspaper, we are concerned that the profession of pharmacy might be taking a huge step backward in patient safety by embracing a new technology that allows dispensing of prescription medications from "vending" machines.

The first article (entitled *Anesthesiologists Now Offer Model of How to Improve Safety, Lower Premiums. Surgeons Are Following Suit*" by Joseph T. Hallinan) offered irrefutable evidence on how anesthesiologists have largely shielded themselves from rising malpractice insurance costs by focusing on patient safety improvements rather than tort reform to protect them from lawsuits.

The 1999 Institute of Medicine report, *To Err is Human*, identified anesthesiologists as a rare exception to its sweeping criticisms about the lack of professional medical societies or groups that have demonstrated a visible commitment to reducing errors. And the high regard is well deserved. In 1985, the American Society of Anesthesiologists provided $100,000 to launch the Anesthesia Patient Safety Foundation (APSF). Despite some angst, the APSF decided to admit not just physician members, but also nurse anesthetists, insurers, and anesthesia equipment companies, bringing together a broad range of interdisciplinary stakeholders. The risk paid off.

Since then, the APSF has galvanized safety research and prompted significant changes in how anesthesia care is provided. From high-tech simulation mannequins that are used to help anesthesiologists recognize and respond to life-threatening conditions, to pulse oximetry, capnography, non-flammable anesthetics, and other safety features and practices that have been adopted as standards, the APSF has helped reduce anesthesia fatalities from 1 in 5,000 cases to 1 in 200,000-300,000 cases. As anticipated, better patient outcomes have also resulted in fewer lawsuits; anesthesiologists typically pay less for malpractice

insurance today than 20 years ago.

Now, others–particularly surgeons–are praising anesthesiologists for choosing a different and more compelling response to the medical malpractice crisis. Based on the APSF success, the American College of Surgeons recently launched a study of malpractice cases modeled on the one that helped anesthesiologists first recognize many of their safety issues. It's clear that this is a huge step for patient safety, and we hope that others will follow suit, recognizing the enormous return on investment in both saving lives and money that will follow with such an undaunted focus on patient safety.

But now, for the potentially bad news. Another article in same issue of *The Wall Street Journal* (entitled *Pharmacies Test Kiosks That Dispense Refills: Some Regulators are Leery*" by Rhonda L. Rundle) notes, "There's a new antidote for long lines at the pharmacy: machines that serve up your prescription refills like a can of Coke or a Snickers bar." These drug-dispensing machines (e.g., ScriptCenter, Automated Pharmacy Machine) are intended for prescription refills only. After a pharmacist fills and/or verifies the refill, it's placed in the machine so the consumer can pick it up at any time by logging on with a user name and password, swiping a debit or credit card, and removing the medication that has dropped into the bin.

Several state pharmacy boards have already cleared the use of machines that dispense refills, and they're being installed and tested in California and Virginia pharmacies. Of course, the benefits are easy to see: customer convenience, reduced waiting time for prescriptions, and potentially improved access to prescription refills for patients in rural settings, to name a few. Patient and drug accuracy can also be maintained with bar-coding and other advanced technologies. However, there are some significant potential downsides that must be considered.

Like many, we believe patient safety will be compromised if the new technology reduces the patient's interaction with pharmacists. Proponents of the technology believe it will allow pharmacists to spend more time with patients who have questions. Indeed, in several test sites for this technology, it appears that pharmacists *are* readily available to consult with patients who are picking up their prescriptions. However, many pharmacists feel that patients may be discouraged from asking questions about their medications when obtaining their refills from drug-dispensing machines. In fact, a pharmacist may not be available for

questions if the pharmacy counter is closed when patients pick up refills. Detractors of the technology also worry that it will be a short and slippery ride before these kiosks dispense new prescriptions (as currently being explored in Hawaii) or before expanded technology allows physicians to directly send an electronic prescription to a "vending" machine stocked with medications, which in turn dispenses new prescriptions to patients.

The pharmacist's role in post-marketing surveillance of new medications may also be compromised with drug-dispensing machines. Currently, FDA and the Institute of Medicine's Drug Safety Committee are deliberating about ways to improve post-marketing surveillance of medications, perhaps in part through increased involvement of pharmacists. Even the new Medicare legislation acknowledges the value of pharmacist-patient interactions and allows reimbursement for enhanced pharmaceutical care (called Medication Therapy Management in the legislation). Yet, if drug-dispensing machines are used, opportunities to capitalize on these well-grounded initiatives could be missed. Pharmacists may not be able to interact with patients to the degree necessary to identify drug-related problems and offer enhanced pharmaceutical care. They may not be able to question patients about side effects upon refill, and thus will have limited opportunity to detect and report adverse drug reactions.

Proponents of the technology could argue that some community pharmacists currently spend negligible face-to-face time with patients anyway, especially for refills. They could also note that similar concerns have been voiced in response to mail service pharmacies, to no avail. However, it's difficult to shake our apprehension that this technology may be at odds with what we know is optimal for medication safety–ongoing interaction between patients and pharmacists.

Unquestionably, there are steps that can be taken or are currently being tested to increase and improve interaction between pharmacists and patients if drug-dispensing machines (and even mail order services) are employed. Pharmacist-staffed call lines, the consumer's ability to send questions to pharmacists and receive prompt answers by e-mail, the use of prompted questions programmed in dispensing machines about potential side effects that must be answered by patients before receipt of the refill, and many other forms of automated communication are all avenues worth exploring. Another option is to design work in ways that allow pharmacists to realistically increase the amount of face-to-face interaction with patients who do have questions about their medications, even requiring consultation for all new prescriptions and refills of certain identified high-alert medications.

But in the end, with reduced waiting time as the primary impetus for drug-dispensing machines, we still can't help but worry that we are once again sacrificing patient safety. Isn't sacrificing safety for other dimensions of quality and customer convenience what got us into this medical error mess to begin with?

While safe care does not guarantee quality care, it is an absolute prerequisite, and something that may not have been adequately considered with this new technology. To this end, researchers at the University of California San Diego Medical Center are planning to study this technology's impact on both patient care and pharmacy management. Perhaps we will be in a better position to evaluate its impact on patient safety once the research is completed and the findings are presented. Until then, we encourage pharmacists and other healthcare professionals who are testing this new technology to share your thoughts, concerns, and experiences with us so we can update the healthcare community periodically.

Messages in our mailbox

In response to our May 7, 2005 article, End the ice age–Is glacial acetic acid really needed?...

Ohio pharmacist **Paul Witkowski** told us about some medication errors involving acetic acid that happened 25 years ago when he worked in another healthcare facility. In one incident, a medical resident prescribed "acetic acid bladder irrigation 10%." When questioned, the resident assured the pharmacist that a 10% solution was needed. The pharmacist then questioned the chief resident and attending physician, who agreed that the concentration was high, but assured pharmacy that this was what the patient had been using at home. The chief of medicine and vice president of medical affairs were questioned also, but both agreed with the order. Unfortunately, the patient was not consulted and the pharmacist who remained on duty finally agreed to use glacial acetic acid to prepare and dispense several liters of 10% acetic acid irrigation. Two days later, after bright red blood began streaming from the patient's urinary catheter, Mr. Witkowski finally talked to the patient and learned how the error occurred. Apparently, the patient had been making the irrigation himself by mixing "10 teaspoons of vinegar into a quart of water." In the same hospital, less than a year later, an order for 0.5% acetic acid irrigation was received during the night. The