Texas Board of Pharmacy Presentation
February 10, 2009

APM: Results of Test Pilot at Walmart Pharmacy

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SUMMARY OF APM™ PILOT PROJECT

PILOT LOCATION AND DURATION

- Walmart Store 804 – Mineral Wells, TX
- Installation Date – July 20, 2007
- 77 Week Pilot Study

SUMMARY OF APM™ PILOT PROJECT

PILOT DESIGN

- Use of the APM™ is completely voluntary for customers.
- Patients are given the option of participating and are provided a secure PIN number in order to use the system.
- Only allow refills for pickup.
- If a patient selects to be counseled, then they are not given the prescription, but are informed to return when the pharmacy is open to receive their prescription and counseling.
- Security cameras installed to monitor the kiosk.

SUMMARY OF APM™ PILOT PROJECT

REPORTING ELEMENTS

- Number of customers who sign up to use the APM
- Percentage of customers who actually use the APM
- Number of prescriptions delivered through the APM
- Percentage of Refills Delivered through the APM
- After Hour APM Deliveries
  – (Percent of RX deliveries when the pharmacy is closed)
- Accuracy of delivery – any accuracy issues or mis-deliveries

RESULTS
(Walmart Store #804)

- Registered Users (Number signed up to use APM): 1254
  - (Average of 66 New Users Each Month)
- Percentage of Customers using APM vs. Number of Registered Users—15.9%
- Number of Prescriptions delivered through APM since installation: 3866
  - (Average of 50 Prescriptions a Week)
- 4.2% of all refills delivered through APM
- 10% of Prescriptions are dispensed after hours via APM
- Number of Incorrect Rx Dispensed: 0

CONSIDERATIONS

Why are Customers hesitant when first using APM?

- Unfamiliar with the new technology
- Credit card method of payment was a requirement

Confusion has been reduced by:

- Pharmacy staff explaining the ease of use to customers
- Allowing customers to pay at any register

REASONS FOR CHOOSING APM…

CONVENIENCE

- Less than 1 minute to retrieve 1-2 Prescriptions
- Customers can pick up prescriptions after the pharmacy is closed

ACCURACY

- 3,866 refills have been picked up using this system at Store #804

APM PROJECT

CONCLUSION

- APM Pilot was successful for convenience and accuracy.
- Walmart will review ROI based on this program.
- Board may write rules based upon this pilot.

RECOMMENDATION
WAL-MART PHARMACY
AUTOMATED PHARMACY MACHINE (APM) PILOT PROJECT
PRESENTED FOR BOARD CONSIDERATION
February 10, 2009

The pilot project proposed to evaluate the potential benefits of using an automated pharmacy machine (APM) or kiosk allowing for the secure storage, management, and purchase/pick-up of prescription medications during and after pharmacy hours.

SUMMARY

History of the Pilot Project Proposal

March 20, 2006	The proposal for a pilot project was received by the Board.
April 2006	The proposal was reviewed by Allison Benz and found to be appropriate and complete.
June 13, 2006	Board President Brimberry appointed Doyle E. High, R.Ph., Board Member, and Oren M. Peacock, Jr., R.Ph., Board Member, to serve on this Task Force.
July 6, 2006	The Task Force discussed the proposal and developed the following recommendation: It is the recommendation of the Task Force that the proposal for the pilot project be approved with modifications under certain terms and conditions (see APPENDIX A).
December 17, 2008	Wal-Mart submitted a final report regarding the outcomes of the pilot project.
January 2009	Board President Ben Fry appointed Kim Caldwell, R.Ph., Board Member, to serve on this Task Force.
January 12, 2009	The Task Force discussed the final report and results of the pilot project and developed the following recommendation: It is the recommendation of the Task Force that the Board proceed with proposing rules to allow APMs or kiosks in pharmacies for patients to pick-up prescriptions when a pharmacist is not present with specific requirements. (see APPENDIX B).

APPENDIX A

PILOT PROJECT

Goal for the Pilot Project

To evaluate the potential benefits of a kiosk that allows for the controlled storage, management, purchase and pickup of prescriptions during and after pharmacy hours. The kiosk should improve patient ability to access medications by decreasing wait times at the pharmacy during hours and allowing patients access to pickup prescriptions after hours as well.

Person Responsible for the Project

George Polansky, R.Ph.
Pharmacist License #19631
Pharmacist-in-Charge
Wal-Mart Pharmacy #10-0804
601 North FM 1821
Mineral Wells, TX 76067

Location for the Project

Wal-Mart Pharmacy #10-0804
Pharmacy License #21722
601 North FM 1821
Mineral Wells, TX 76067
(940) 325-9401

Rules to be Waived During the Pilot Project

Board Rule 291.33(c)(1)(E)(ii) allows a pharmacy to deliver a prescription drug order to a patient during short periods of time when a pharmacist is not present in the pharmacy as follows:

291.33 Operational Standards.

XXX

(c) Prescription Dispensing and Delivery.

(1) Patient counseling and provision of drug information.

XXX

(E) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient at the pharmacy, the following is applicable.

XXX

(ii) An agent of the pharmacist may deliver a prescription drug order to the patient or his or her agent during short periods of time when a pharmacist is absent from the pharmacy, provided the short periods of time do not exceed two hours in a 24 hour period, and provided a record of the delivery is maintained containing the following information:

(I) date of the delivery;

(II) unique identification number of the prescription drug order;

(III) patient's name;

(IV) patient's phone number or the phone number of the person picking up the prescription; and

(V) signature of the person picking up the prescription.

(iii) Any prescription delivered to a patient when a pharmacist is not in the pharmacy must meet the requirements described in subparagraph (F) of this paragraph.

XXX

Waiving the rule will allow Wal-Mart Pharmacy to provide patients the option of purchasing and picking up prescriptions after the pharmacy's normal business hours.

Summary of the Pilot Project

(1) Patients are giving the option of participating in the program and are provided a secure PIN number in order to use the system.

(2) Patients picking up prescription refills after hours will be given a toll free number to contact a pharmacists for counseling, if desired.

(3) Security cameras will be installed to monitor the kiosk.

Conditions

(1) Unless otherwise stated in this document, the pilot project will operate in accordance with the conditions outlined in the proposed pilot project received March 20, 2006.

(2) The pilot project will be conducted from a licensed pharmacy location.

(3) Patients opting into the program will not be allowed to pick-up new prescriptions at the kiosk.

(4) Adequate safeguards shall be established and maintained to protect a patient's confidential health information from unauthorized access in compliance with rules of the Texas State Board of Pharmacy and HIPAA.

(5) The time frame for the project will be no more than 18 months from the start of the project, which must occur within 120 days of the Board's approval. The Texas State Board of Pharmacy shall be notified in writing within 10 days of the start of the project.

(6) Results must document an improvement in the provision of pharmaceutical care and how this has improved patient safety.

APPENDIX B

TITLE 22. EXAMINING BOARDS
PART 15. TEXAS STATE BOARD OF PHARMACY
CHAPTER 291. PHARMACIES
SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

§291.33. Operational Standards

(a) (No change.)

(b) Environment.

(1) (No change.)

(2) Security.

(A) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drugs, and records for such drugs.

(B) The prescription department shall be locked by key, combination or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site except as provided in subparagraphs (C) and (D) of this paragraph and paragraph (3) of this subsection. The following is applicable:

(i) If the prescription department is closed at any time when the rest of the facility is open, the prescription department must be physically or electronically secured. The security may be accomplished by means such as floor to ceiling walls; walls, partitions, or barriers at least 9 feet 6 inches high; electronically monitored motion detectors; pull down sliders; or other systems or technologies that will secure the pharmacy from unauthorized entrance when the pharmacy is closed. Pharmacies licensed prior to June 1, 2009, shall be exempt from this provision unless the pharmacy changes location. Change of location shall include the relocation of the pharmacy within the licensed address. A pharmacy licensed prior to June 1, 2009 that files a change of ownership but does not change location shall be exempt from the provisions.

(ii) Effective, June 1, 2009, the pharmacy's key, combination, or other mechanical or electronic means of locking the pharmacy may not be duplicated without the authorization of the pharmacist-in-charge or owner.

(iii) Effective, June 1, 2009, at a minimum, the pharmacy must have a basic alarm system with off-site monitoring and perimeter and motion sensors. The pharmacy may have additional security by video surveillance camera systems.

(C) Prior to authorizing individuals to enter the prescription department, the pharmacist-in-charge or owner may designate persons who may enter the prescription department to perform functions, other than dispensing functions or prescription processing, documented

by the pharmacist-in-charge including access to the prescription department by other pharmacists, pharmacy personnel and other individuals. The pharmacy must maintain written documentation of authorized individuals other than individuals employed by the pharmacy who accessed the prescription department when a pharmacist is not on-site.

(D) Only persons designated either by name or by title including such titles as "relief" or "floater" pharmacist, in writing by the pharmacist-in-charge may unlock the prescription department except in emergency situations. An additional key to or instructions on accessing the prescription department may be maintained in a secure location outside the prescription department for use during an emergency or as designated by the pharmacist-in-charge for entry by another pharmacist.

(E) Written policies and procedures for the pharmacy's security shall be developed and implemented by the pharmacist-in-charge and/or the owner of the pharmacy. Such polices and procedures may include quarterly audits of controlled substances commonly abused or diverted; perpetual inventories for the comparison of the receipt, dispensing, and distribution of controlled substances; monthly reports from the pharmacy's wholesaler(s) of controlled substances purchased by the pharmacy; opening and closing procedures; product storage and placement; and central management oversight.

(3) Temporary absence of pharmacist.

(A) (No change.)

(B) Pharmacist is off-site.

(i) The prescription department must be secured with procedures for entry during the time that a pharmacy is not under the continuous on-site supervision of a pharmacist and the pharmacy is not open for pharmacy services.

(ii) Pharmacy technicians and pharmacy technician trainees may not perform any duties of a pharmacy technician or pharmacy technician trainee during the time that the ~~[a]~~ pharmacist is off-site.

(iii) A pharmacy may use an automated storage and distribution device as specified in subsection (i) of this section for pick-up of a previously verified prescription by a patient or patient's agent, provided the following conditions are met:

(I) a notice is posted which includes the following information:

(-a-) the pharmacist is off-site and not present in the pharmacy;

(-b-) no new prescriptions may be prepared at the pharmacy but previously verified prescriptions may be delivered to the patient or the patient's agent; and

(-c-) the date/time when the pharmacist will return.

(II) the pharmacy must maintain documentation of the absences of the pharmacist(s); and

(III) the prescription department is locked and secured to prohibit unauthorized entry.

(iv) ~~[(iii)]~~ An agent of the pharmacist may deliver a previously verified prescription to a patient or patient's agent during short periods of time when a pharmacist is off-site, provided the following conditions are met:

(I) short periods of time may not exceed two consecutive hours in a 24 hour period;

(II) a notice is posted which includes the following information:

(-a-) the pharmacist is off-site and not present in the pharmacy;

(-b-) no new prescriptions may be prepared at the pharmacy but previously verified prescriptions may be delivered to the patient or the patient's agent; and

(-c-) the date/time when the pharmacist will return.

(III) the pharmacy must maintain documentation of the absences of the pharmacist(s); and

(IV) the prescription department is locked and secured to prohibit unauthorized entry.

(v) ~~[(iv)]~~ During the time a pharmacist is absent from the prescription department and is off-site, a record of prescriptions delivered must be maintained and contain the following information:

(I) date and time of the delivery;

(II) unique identification number of the prescription drug order;

(III) patient's name;

(IV) patient's phone number or the phone number of the person picking up the prescription; and

(V) signature of the person picking up the prescription.

(vi) ~~[(v)]~~ Any prescription delivered to a patient when a pharmacist is not on-site at the pharmacy must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(c) – (j) (No change.)

(i) Automated devices and systems.

(1) – (4) (No change.)

(5) Automated storage and distribution device. A pharmacy may use an automated storage and distribution device to deliver a previously verified prescription to a patient or patient's agent provided:

(A) the device is used to deliver refills of prescription drug orders and shall not be used to deliver new prescriptions as defined by §291.31(26) of the title (Relating to Definitions);

(B) the device may not be used to deliver a controlled substance;

(C) drugs stored in the automated storage and distribution device are stored at proper temperatures;

(D) the patient or patient's agent is given the option to use the system;

(E) the patient or patient's agent has access to a pharmacist for questions regarding the prescription either at the pharmacy where the automated storage and distribution device is located or by a telephone available at the pharmacy that connects directly to another pharmacy;

(F) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

(G) the automated storage and distribution device has been tested by the pharmacy and found to dispense prescriptions accurately. The pharmacy shall make the results of such testing available to the board upon request;

(H) the pharmacy will make the automated storage and distribution device available for inspection by the board;

(I) the automated storage and distribution device is located within the pharmacy building whereby pharmacy staff has access to the device from within the prescription department and patients have access to the device from outside the prescription department;

(J) the automated storage and distribution device is secure from access and removal of prescription drug orders by unauthorized individuals;

(K) the automated storage and distribution device has adequate security system to prevent unauthorized access and to maintain patient confidentiality; and

(L) the automated storage and distribution device records a digital image of the individual accessing the device to pick-up a prescription and such record is maintained by the pharmacy for two years.