RECOMMENDATION
PETITION FOR A PILOT PROJECT FROM
VIGILANT DEVICES, L.L.C.
REGARDING A WASTE IDENTIFICATION AND DISPOSAL SYSTEM

PRESENTED FOR BOARD CONSIDERATION
August 6, 2013

Report of the Task Force appointed to review a petition for a pilot project presented by Vigilant Devices, L.L.C., allow a device to act as a witness during the wastage process of controlled substances (See Appendix A). The device will adulterate and render the controlled substance unusable and non-retrievable. The pilot project proposes to demonstrate improved pharmaceutical care by: 1) facilitating documentation of the wastage; 2) enabling the detection of wastage discrepancies; 3) preventing controlled substance diversion; 4) eliminating the need for a human witness by providing a precise and reproducible chemical analysis of controlled substance wastage; and 5) rendering the drug non--retrievable in an environmentally sensitive fashion.

SUMMARY OF DELIBERATIONS

Members of the Task Force

Board President Jeanne Waggener appointed the following to serve on this Task Force:

Joyce A. Tipton, R.Ph., Board Member

Allison Benz, R.Ph., M.S., Staff Liaison
Kerstin Arnold, Staff Liaison

Recommendation

It is the recommendation of the Task Force that the proposal for the pilot project be approved under the terms and conditions set forth as follows.

PILOT PROJECT

Goal for the Pilot Project

To improve pharmaceutical care for patients and create positive patient outcomes by 1) facilitating documentation of the wastage; 2) enabling the detection of wastage discrepancies; 3) preventing controlled substance diversion; 4) eliminating the need for a human witness by providing a precise and reproducible chemical analysis of controlled substance wastage; and 5) rendering the drug non--retrievable in an environmentally sensitive fashion.

Person Responsible for the Project

W. Michael Brimberry, R.Ph., MBA

Location for the Project

Reliant Rehabilitation Hospital Central Texas
1400 Hester's Crossing
Round Rock, TX 78681

If a new clinical site is needed to conduct the pilot project, the Texas State Board of Pharmacy will be notified at least 10 days prior to conducting the pilot at any new site.

Rules to be Waived During the Pilot Project

§§291.75 (c)(4)(vii), 291.75 (c)(5)(viii), 291.76 (e)(3)(D)(iii)(VII), and 291.76 (E)(i)(VIII)

This pilot project will require a waiver of the human witness requirement found in §§291.75 (c)(4)(vii), 291.75 (c)(5)(viii), 291.76 (e)(3)(D)(iii)(VII), and 291.76 (E)(i)(VIII). (See Appendix B)

Summary of the Pilot Project

This pilot project will demonstrate that a waste identification and disposal system can automatically verify the identity, approximate concentrations, and volume of wasted controlled substances against which drug was dispensed. The system will use Surface Enhanced Raman Spectroscopy technology. The project will demonstrate that the WID can be used as a substitute for a human witness by accurately identifying the drug, concentration, and volume.

Conditions

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

(2) The pilot project will be conducted at Reliant Rehabilitation Hospital Central Texas.

(3) The time frame for the project will be no more than 18 months from the start of the project, which must occur within 30 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. However, the Board may extend the time frame for the project as deemed appropriate by the Board.

(4) The pilot project may include schedule II – V injectable medications.

June 2, 2013

Ms. Gay Dodson, R.Ph., Executive Director
Texas State Board of Pharmacy
William P. Hobby Bldg., Suite 3-600
333 Guadalupe St.
Austin, Texas 78701

Re: Request for Approval of Pilot Project for Evaluation of a Device for Analysis, Handling and Wastage of Controlled Substances

Dear Ms. Dodson,

Please find the attached Petition for Approval to conduct a pilot study pursuant to Texas Occupations Code § 544.011 and 22 Texas Administrative Code § 291.23 et seq. As described in the petition, we seek permission to allow a device to act as a witness during the wastage process of Controlled Substances. In addition, this device will adulterate and render the Controlled Substance unusable and non-retrievable in accordance with DEA guidelines. This pilot project will require a waiver of the human witness requirement pursuant to 22 Texas Administrative Code § 291.75 (c)(4)(vii), § 291.75 (c)(5)(viii) for Class C Pharmacies as well as 22 Texas Administrative Code § 291.76 (D)(iii)(VII) and 291.76 (E)(i)(VIII) for pharmacies attached to Ambulatory Surgery Centers.

The device described in the following petition will improve Pharmaceutical care by: 1) facilitating documentation of the wastage 2) enabling the detection of wastage discrepancies 3) preventing Controlled Substance diversion 4) eliminating the need for a human witness by providing a precise and reproducible chemical analysis of Controlled Substance wastage and 5) rendering the drug non-retrievable in an environmentally sensitive fashion. Once the waste drug is deposited in the device, it will be accessible to only authorized pharmacy staff and, therefore, unavailable to the clinician for tampering or removal.

We respectfully request the opportunity to present this request for a waiver at the next meeting of the Texas State Board of Pharmacy.

Please feel free to contact me if any additional information is needed or questions arise.

With warm regards,

David A. Nelson, M.D.
Founder/ C.E.O.
Vigilant Devices, L.L.C

Pilot Project for Evaluation of a Device for Analysis, Handling and Wastage of Controlled Substances

Prepared by Dr. David Nelson, CEO Vigilant Devices LLC, for review by
The Texas State Board of Pharmacy

Purpose

The purpose of this document is to present the operational and analytical plan for the proposed Pilot Study of the Waste Identification and Disposal System (WID) for review by Texas State Board of Pharmacy. This document will further serve as the basis for creating the detailed protocol at the study site(s).

Scope

This document outlines the process, personnel, facilities, controlled substances, operational, and analytical plan for the proposed Pilot Study. It contains an outline of the actual test protocol for the initial study site (Reliant Rehabilitation Hospital, Round Rock, Texas). However, it is reasonable to expect that future modifications will need to be made and evaluated for different clinical settings. Pursuant to that, additional protocols, policies, and procedures will have to be created and maintained as part of the pharmacy and hospital internal compliance plan at any new study site. The Board will be notified, well in advance, of any proposed new clinical sites and proposed changes to the protocol.

Objective

The objectives of this Pilot Study will be accomplished in 2 phases. The first objective is to demonstrate that the WID can automatically verify the identity, approximate concentration, and volume of wasted schedule II drugs against the open order under which the drug was dispensed. This will be done using Surface Enhanced Raman Spectroscopy (SERS) technology and comparing the Raman scatter plot of a given substance with a gold standard plot to determine a match.

During the second phase of the study, the objective is to demonstrate that the WID can be used as a substitute for a human witness. This will be done by showing that the WID can accurately identify the drug, approximate concentration, and volume. With the possible exception of volume, a human witness is incapable of achieving these parameters.

Impact

The WID will offload the low-value repetitive tasks associated with wasting drugs from the pharmacist and other clinicians. The WID will perform these tasks more accurately and with better recordkeeping than current manual processes, and will provide immediate detection of diversion. This will allow the pharmacists to focus more attention on recommending and directing patient-specific therapies in consultations with the attending physicians, and allow the clinicians to focus more on direct patient care.

Background

Since the inception of therapeutic pharmaceuticals, the issue of distribution and regulation has been of concern. In 1970 the Controlled Substances Act was passed providing guidelines for identification, distribution and disposal of the now labeled controlled substance category of pharmaceuticals. These drugs are considered to be dangerous by the D.E.A., and require direct physician supervision for administration. As a result of the regulatory documentation requirements, an industry was born to effectively distribute, document and track the utilization of these drugs.

We contend that there are three major components to satisfy the Controlled Substance Act of 1970, one of which has been left to manual adjudication. Commercially available today are

systems for tracking and documenting the distribution and utilization of controlled substances. The last component in the process is wastage, which remains a manual process and is equally prone to abuse, diversion and a host of regulatory and efficiency concerns.

In the absence of technology to assist with controlled substance wastage, medical care providers are required to manually document, countersign and track the heavily regulated process. More frequently than not, there is excess drug during routine administration that must be disposed of under strict guidelines overseen by the D.E.A., State Boards of Pharmacy and state and local law enforcement agencies. The guidelines require:

1. Excess drug from routine administration be disposed of and rendered unusable for human consumption.
2. The wastage process must be witnessed and countersigned by licensed personnel.
3. The witness must visually observe the identity, quantity and disposal of the controlled substance, attesting to the process via handwritten signature or electronic password.
4. The wastage process must be documented with the overseeing authority, which then must reconcile medication administration record with the wastage record.

As the process is primarily manual and adjudicated by those same individuals that are being monitored, it is riddled with inefficiency, opportunity for redirection and theft, compromised by increasing time restraints and creates conflict among those responsible for administration.

The primary objective of Vigilant Devices, L.L.C. is to develop and distribute a controlled substance wastage system that provides the medical care industry an integrated method and device for monitoring drug wastage that is efficient, eliminates the opportunity for redirection and theft, and completes the documentation process required by the D.E.A. as outlined in the Controlled Substances Act of 1970. Another objective is to validate, through the Pilot Study outlined below, that the wastage system will supply a more reliable and accurate alternative to the present requirement that a human witness the wastage process. Further, it is anticipated that this study will provide a method of drug disposal that will adulterate and render drug samples non-retrievable in an ecologically sensitive fashion.

Pilot Study

This study will be conducted in two phases. Phase I will be performed by the facilities and personnel referenced below and will have the limited objective of validating the device within the pharmacy. Only the pharmacy staff will have access to the device in Phase I. Phase II will validate the entire wastage process in the hospital based on the device and including personnel, environmental factors, and real-world situations. This will be done outside the pharmacy on a patient floor. A broad cross section of clinicians will access the device including pharmacists, pharmacy technicians, nurses, and doctors. Phase II will be performed by the same facility and personnel listed below, and additionally may be expanded to a second facility as an ancillary study specific to a patient/provider environment such as an emergency room. The second facility will be presented to the Board for approval well in advance of Phase II.

Facility:
Reliant Rehabilitation Hospital Central Texas
1400 Hester's Crossing
Round Rock, TX 78681
TSBP License Number: 25977
DEA License Number: FR0835869
Texas DPS License Number: G0157335

Pilot Project for Evaluation of a Device for Analysis, Handling and Wastage of Controlled Substances

Prepared by Dr. David Nelson, CEO Vigilant Devices LLC, for review by
The Texas State Board of Pharmacy

Personnel:

W. Michael Brimberry, R.Ph., MBA
Director of Pharmacy
TSBP License Number: 18105
Reliant Rehabilitation Hospital Central Texas
1400 Hester's Crossing
Round Rock, TX 78681
(512) 244-4400 main
(512) 771-1055 cell

Medical Director: Tim Murphree, M.D. (rehab floors)

Medical Director: Teresa Lyson, M.D. (SNU floor)

Vidette Forbes, R.N., C.N.O.
Randi Cruz, L.V.N, Nursing Manager
David Nelson, M.D., Board Certified Anesthesiologist, CEO of Vigilant Devices, L.L.C.
Rafi Baddour, P.E., Consulting Engineer for Vigilant Devices, L.L.C.

Summary of Current Waste Procedure at Facility

The current drug wasting process at Reliant Rehabilitation Center is typical of many organizations. Schedule II medications are dispensed to the nursing staff by accessing a drug dispensal cabinet. At this facility, the AccuDose® system is utilized.

The drug wasting procedure as it currently stands can be summarized by the steps below:

1. The Clinician accesses the AccuDose® cabinet by secure password.

2. The Clinician obtains the Schedule II medication for administration to a patient per physician orders.

3. If there is excess Schedule II medication after administering the ordered dose to the patient, the clinician returns to the AccuDose® cabinet to complete wastage of the excess medication.

4. The Clinician, who originally obtained and administered the medication, logs in with their password and locates the record associated with that transaction. Screen prompts are followed with instructions for the waste process. During the process, another Clinician, who is serving as the waste witness, logs in with their password.

5. The Schedule II medication is wasted by discarding the drug in accordance with the hospital policies and procedures. At this point the transaction is completed and the clinicians can log out of the AccuDose® cabinet.

Phase I Changes to Current Waste Procedures

In Phase I of the pilot study, the changes to the procedure to support this pilot will modify step 5 above; steps 1 through 4 will remain unchanged. Instead of destroying the drug in front of the witness, the clinician will place a patient label, with the date and time noted, on the vial or syringe that contains the Schedule II medication. The drug will be placed in a secure holding bin where it will be periodically collected by members of the Pharmacy Department and returned to the Central Pharmacy.

The rest of the process will be defined, for the purposes of this Phase I pilot, as the specific set of transactions that occur inside the pharmacy during the wastage process. The holding bin will periodically be taken to the pharmacy to be emptied. The WID device will be located inside the pharmacy and accessed only by the pharmacist or a person authorized by the pharmacist. It is assumed that the bin, the WID device computer interface, an AccuDose® terminal interface, and the ultimate waste receptacle (sink, trash, etc.) are all co-located in the pharmacy.

Steps 6-9 will take place in Central Pharmacy and are listed below:

6. The Pharmacist logs on to the WID device and creates a new waste record in the WID. A unique transaction number is automatically assigned to this record by the WID when it is created. The Pharmacist will remove a vial or syringe from the holding bin and enter the type of drug, concentration, and amount using the touch screen on the WID. He/she will also log onto the AccuDose® terminal and identify himself/herself as being in possession of the drugs to be wasted. He/she will next verify the drug by cross referencing the patient label on the vial with the data entries in the AccuDose® transaction log. Once verified, the Pharmacist will enter the WID transaction number in the "Comments" section of the AccuDose® transaction record. This information will be completely extraneous and in addition to all normal recordkeeping for compliance purposes, and will create a cross-reference link between the WID and AccuDose® while ensuring the security of all patient information. No patient information ever will be entered into the WID device.

7. The Pharmacist will follow the on-screen cues and inject the remaining drug into the waste port on the device. A qualified member of the pharmacy staff will witness this step. The Pharmacist will update and reconcile the records previously generated by the AccuDose® cabinet to complete chain of custody documentation and show the drugs have been wasted by the Pharmacist. After the analysis, the drug will be adulterated and converted into a non-retrievable (solid) form.

8. The Pharmacist will periodically empty the adulterated contents of the WID into the waste receptacle and complete any additional documentation required by the facility's policies and procedures.

The WID-generated unique transaction number will serve as the transaction control and identifier for manual reconciliation between the WID data and the AccuDose® data. This number is simply a sequential number entered as a comment in the AccuDose® transaction record and will not guide or affect the chain of custody in any way. There will be no direct information exchange between the AccuDose® records and the WID records.

The device will create a record containing the information outlined in the steps above, as well as the Raman scatter plot created by testing the specific waste sample at the time it is deposited. This plot will be analyzed at the WID server to determine the match and the results stored on the server. Reconciliation and determination of WID accuracy is discussed in the Data Analysis section below.

It is understood that this deviation does not impact any rules nor does it materially change any of the chain of custody controls or policies. No waivers are requested in support of Phase I.

Approval Process to Begin Phase II

The decision to begin Phase II will involve a complete review of all Phase I data, events, and errata, and will be made by all stakeholders identified in the Approval Process at Site section below.

Phase II Changes to Current Waste Procedures

In Phase Two of the Pilot Study, the WID will be placed adjacent to the AccuDose® on one of the patient floors. Steps 1-3 of the Current Waste Procedure will remain unchanged. The rest of the process will implement two key differences:

1. All waste will be deposited by the clinician directly into the WID device

2. The WID device will fill the role of the second human witness

Implementation of the steps outlined below will require a waiver of the human witness requirement pursuant to 22 Texas Administrative Code § 291.75 (c)(4)(vii), § 291.75 (c)(5)(viii) for Class C Pharmacies as well as 22 Texas Administrative Code § 291.76 (D)(iii)(VII) and 291.76 (E)(i)(VIII).

For reference, the unchanged steps 1-3 are shown:

1. The Clinician accesses the AccuDose® cabinet by secure password.

2. The Clinician obtains the Schedule II medication for administration to a patient per physician orders.

3. If there is excess Schedule II medication after administering the ordered dose to the patient, the clinician returns to the AccuDose® cabinet to complete wastage of the excess medication.

The next steps are unique to the Phase II plan and would be implemented only under a grant of the requested waiver:

4. The Clinician, who originally obtained and administered the medication, logs into the AccuDose® with their password and locates the record associated with that transaction. No human witness is present. Instead, the same clinician will log in again, this time as the witness using a separate username and password specific to the WID device. This WID username and password will enable only authorized clinicians to use the WID as the witness.

5. The Clinician then logs on to the WID device and creates a new waste record in the WID. A unique transaction number is automatically assigned to this record by the WID when it is created. The Clinician will enter the WID transaction number in the “Comments” section of the AccuDose® transaction record. The Clinician will then enter the drug type, concentration, and volume in the open transaction record on the WID using pull-down menus. Again, no patient data is entered into the WID.

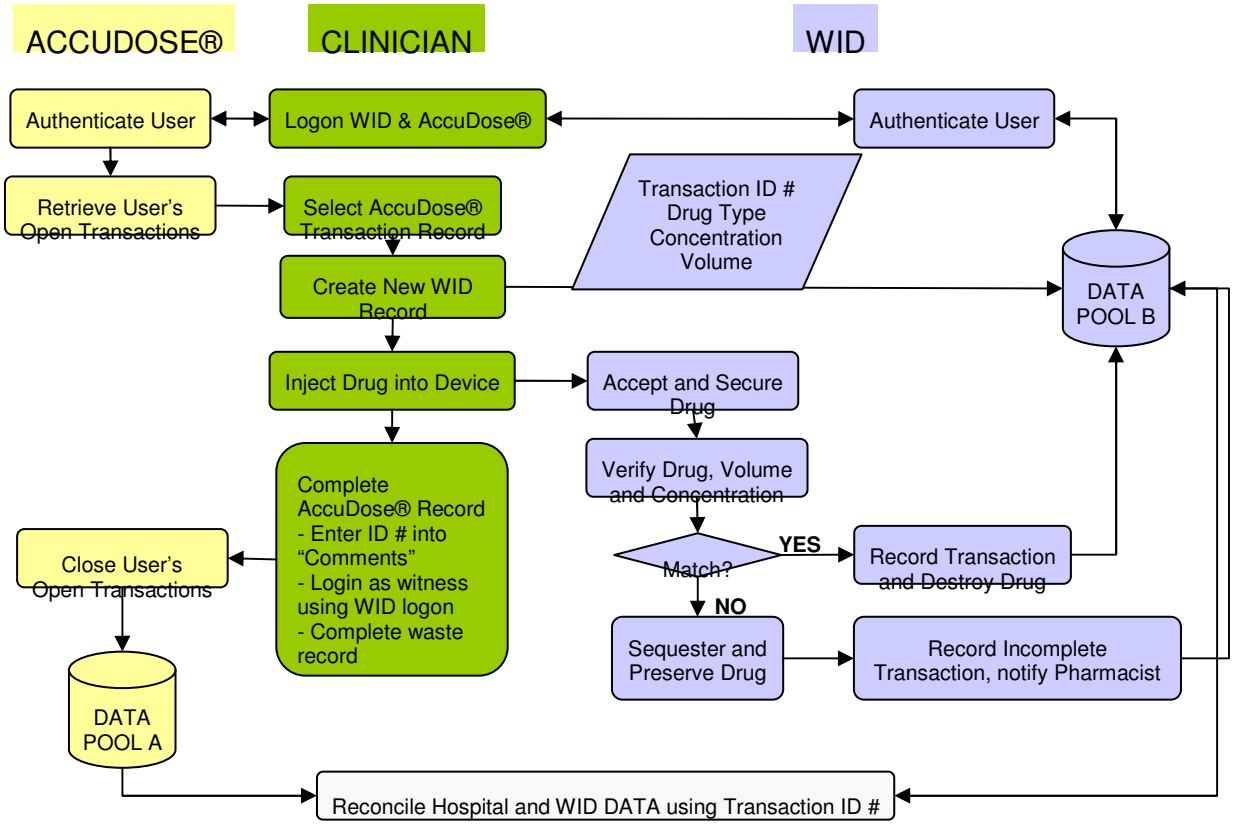
6. The Clinical will follow the on-screen cues and inject the remaining drug into the waste port on the WID device. Once injected, the drug is secured in the device. The clinician will then log out of the WID device. The WID will subsequently analyze the drug. After the analysis, if there are no discrepancies, the drug will be adulterated and converted into a non-retrievable (solid) form. If a discrepancy is noted, the WID will secure, sequester and preserve the drug for subsequent analysis by the Pharmacist. A message will

immediately be sent to the Pharmacist to notify him/her of the discrepancy, either by text, email, or both. No indication will be given to the Clinician who wasted the drug.

7. The Clinician will complete the waste record on the AccuDose® and log out.

8. Waste transaction is now complete.

The flowchart below outlines this process and shows the interactions between the Clinician, AccuDose® and WID.



Test Objectives for WID

The device is expected to integrate easily into the waste operations of the facility. Phase I will validate proper function of the device in a Beta test environment. This includes identifying any errors in the operation of the device when used for an extended period in a controlled Beta test environment. In addition to proper function, the device reliability will be evaluated as well as human interface ease of use.

In Phase II, the device and the associated personnel, environment, and processes will be evaluated as an integrated system to determine overall effectiveness in a real-world patient care

environment. The purpose of Phase II is to demonstrate that the WID device can effectively replace a human witness in an operating patient care facility.

Data Analysis

The records created by the WID will be manually reconciled with the hospital records. The accuracy of the WID will be determined during this reconciliation process, as well as the accuracy of the personnel involved in entering data. Periodically during the pilot waste events will be audited by the pharmacy staff against the hospital transaction records and the device records to determine WID performance. The transaction identifier created by the WID device at the time of wasting will be the only link between the WID-created records and the hospital records.

Outcome Measures

It is expected that the device will verify the drug type according to chemical structure, any changes to expected dilution greater than 25%, and volume to 0.25 ml. How well the device does this will be determined using common statistical methods. Any noted discrepancies will be root caused and a closed loop corrective action plan created to address the discrepancies. Human error, WID machine error, and hospital information system inaccuracies, and diversion are among the possible root causes of discrepancies. Each will involve a thorough analysis of the chain of custody, procedures, and a reconciliation with the original AccuDose® transaction record. Also, third party testing will be used to positively identify any compound of which the drug and dilution can not be ascertained by a review and reconciliation of the records.

Validation

For each specific drug, at least one sample will be retained and sent to an outside laboratory for verification of results of analysis by the device. Also, for any samples that are tagged "incomplete" or have discrepancies, the sample will saved for further analysis. If the discrepancy can't be resolved after review, the sample will be sent to an outside laboratory for analysis. The chain of custody will be maintained by utilizing outside laboratory facilities that have DEA licenses that allow possession of controlled substances. Transfer to these entities will comply with DEA regulations by utilizing Form 222 documentation.

HIPAA Compliance

DATA POOL B shown in the flowchart above will hold all information entered or created by the WID device. The WID device and all its data will be completely isolated from all hospital information systems and will rely on manual input of data. No patient-specific information will be entered, stored, or accessed by the device. It will also be password secured and physically secured.

List of Controlled Substances and Concentrations

The system shall be capable of identifying and disposing the following controlled substances. Each of the substances may or may not be available for testing at a specific test site depending on the facility's formulary and/or clinical usage patterns.

1. Morphine (Morphine Sulfate) 10 mg/cc
2. Versed (Midazolam HCl) 1 mg/cc
3. Demerol (Meperidine HCl) 100 mg/cc
4. Ketalar (Ketamine HCl) 100 mg/cc
5. Ephedrine (Ephedrine Sulfate) 50 mg/cc
6. Valium (Diazepam) 5 mg/cc

7. Ativan (Lorazepam) 2 mg/cc
8. Pentothal (Thiopental) 25 mg/cc
9. Codeine (Codeine Phosphate) 30 mg/cc
10. Barbital (Phenobarbital) 130 mg/cc
11. Dilaudid (Hydromorphone HCl) 2 mg/cc
12. Nubain (Nalbuphine HCl) 10 mg/cc
13. Stadol (Butorphanol Tartrate) 2 mg/cc
14. Sublimaze (Fentanyl Citrate) 50 ug/cc
15. Alfenta (Alfentanil HCl) 500 ug/cc
16. Sufenta (Sufentanil Citrate) 50 ug/cc
17. Ultiva (Remifentanil HCl) 1 mg/cc

Controlled Substance Volume:
Minimum 0.2cc
Maximum 10cc

Approval Process at Site

The following persons at the Site will be responsible for approval and implementation of this Pilot Study at the Site:

- Medical Director: Tim Murphree, MD (rehab floors)
- Medical Director: Teresa Lyson, MD (SNU floor)
- Vidette Forbes, R.N., CNO
- Randi Cruz, L.V.N, Nursing Manager
- Michael Brimberry, R.Ph., M.B.A.

Time Frame

The device will need to be tested in different clinical environments. Therefore, it is anticipated that at least two different beta sites will be utilized for Phase II. For example, testing at a full service acute care hospital and an ambulatory center will be desirable. The Board will be notified well in advance of any proposed additional sites. Phase I study site preparation and protocol development will begin within 30 days following board approval, and only the Reliant site discussed herein will perform Phase I. The time frame required for full evaluation of the device will meet the 18 month requirement specified in 22 Tex. Admin. Code § 291.23 (b)(2).

TITLE 22 EXAMINING BOARDS
PART 15 TEXAS STATE BOARD OF PHARMACY
CHAPTER 291 PHARMACIES
SUBCHAPTER D INSTITUTIONAL PHARMACY (CLASS C)

§291.75 Records

XXX

(c) Patient records.

XXX

(4) Schedule II controlled substances records. Records of controlled substances listed in Schedule II shall be maintained as follows.

(A) Records of controlled substances listed in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records.

(B) An institutional pharmacy shall maintain a perpetual inventory of any controlled substance listed in Schedule II.

(C) Distribution records for controlled substances listed in Schedule II shall bear the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

(iii) name of drug, dosage form, and strength;

(iv) time and date of administration to patient and quantity administered;

(v) name, initials, or electronic signature of the individual administering the controlled substance;

(vi) returns to the pharmacy; and

(vii) waste (waste is required to be witnessed and cosigned, electronically or manually, by another individual).

(5) Floor stock records.

(A) Distribution records for Schedule II - V controlled substances floor stock shall include the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

(iii) name of controlled substance, dosage form, and strength;

(iv) time and date of administration to patient;

(v) quantity administered;

(vi) name, initials, or electronic signature of the individual administering drug;

(vii) returns to the pharmacy; and

(viii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(B) The record required by subparagraph (A) of this paragraph shall be maintained separately from patient records.

(C) A pharmacist shall review distribution records with medication orders on a periodic basis to verify proper usage of drugs, not to exceed 30 days between such reviews.

XXX

§291.76 Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center

XXX

(e) Records.

XXX

(3) Patient records.

XXX

(D) Records of controlled substances listed in Schedule II shall be maintained as follows.

(i) Records of controlled substances listed in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records.

(ii) An ASC pharmacy shall maintain a perpetual inventory of any controlled substance listed in Schedule II.

(iii) Distribution records for Schedule II - V controlled substances floor stock shall include the following information:

(I) patient's name;

(II) practitioner who ordered drug;

(III) name of drug, dosage form, and strength;

(IV) time and date of administration to patient and quantity administered;

(V) signature or electronic signature of individual administering controlled substance;

(VI) returns to the pharmacy; and

(VII) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(E) Floor stock records shall be maintained as follows.

(i) Distribution records for Schedules III - V controlled substances floor stock shall include the following information:

(I) patient's name;

(II) practitioner who ordered controlled substance;

(III) name of controlled substance, dosage form, and strength;

(IV) time and date of administration to patient;

(V) quantity administered;

(VI) signature or electronic signature of individual administering drug;

(VII) returns to the pharmacy; and

(VIII) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(ii) The record required by clause (i) of this subparagraph shall be maintained separately from patient records.

(iii) A pharmacist shall review distribution records with medication orders on a periodic basis to verify proper usage of drugs, not to exceed 30 days between such reviews.

XXX

PART 15 TEXAS STATE BOARD OF PHARMACY
CHAPTER 291 PHARMACIES
SUBCHAPTER A ALL CLASSES OF PHARMACIES

§291.23 Pilot or Demonstration Research Projects for Innovative Applications in the Practice of Pharmacy

(a) Purpose. The purpose of this section is to specify the procedures to be followed in applying for approval of a pilot or demonstration research project for innovative applications in the practice of pharmacy as authorized by §554.011 of the Texas Pharmacy Act (Chapters 551- 566, Texas Occupations Code). In reviewing projects, the board will only consider projects that expand pharmaceutical care services which contribute to positive patient outcomes. The board will not consider any project intended only to provide a competitive advantage.

(b) Scope of pilot or demonstration research projects and the board's approval of such projects.

(1) Pilot or demonstration research projects may not:

(A) expand the definition of the practice of pharmacy as provided in the Act; or

(B) include therapeutic substitution or substitution of medical devices used in patient care.

(2) The board's approval of pilot or demonstration research projects may include the granting of an exception to the rules adopted under the Texas Pharmacy Act, but may not include an exception from any law relating to the practice of pharmacy. Such exception to the rules shall be for a specified period of time and such period may not exceed 18 months.

(3) The board may extend the time an exception to a rule is granted as necessary for the board to adopt an amendment or modification of the rule.

(c) Procedures for applying for approval of pilot or demonstration research projects. A person who wishes the board to consider approval of a pilot or demonstration research project shall submit to the board a petition for approval which contains at least the following information:

(1) name, address, telephone number, and pharmacist's license number of the pharmacist responsible for overseeing the project;

(2) specific location and, if a pharmacy, the pharmacy license number where the proposed pilot or demonstration project will be conducted;

(3) a detailed summary of the proposed pilot or demonstration project which includes:

(A) the goals, hypothesis, and/or objectives of the proposed project;

(B) a full explanation of the project and how it will be conducted;

(C) the time frame for the project including the proposed start date and length of study. Such time frame may not exceed 18 months;

(D) background information and/or literature review to support the proposal;

(E) the rule(s) that will have to be waived in order to complete the project and a request to waive the rule(s);

(F) procedures to be used during the project to ensure that the public's health and safety are not compromised as a result of the rule waiver.

(d) Review and approval or denial of the proposed projects.

(1) On receipt of a petition for approval of a pilot or demonstration research project, board staff shall initially review the petition for completeness and appropriateness. If the petition is incomplete or inappropriate for board consideration for any reason, staff shall return the petition with a letter of explanation. Such review shall be completed within 30 working days of receipt of the petition.

(2) Once board staff has determined that the petition is complete and appropriate, a task force composed of board staff, at least one board member and, if deemed necessary, resource personnel appointed by the board president, shall review the petition and make a written recommendation to the board regarding approval. Such recommendation shall be presented to the board at the next regularly scheduled meeting of the board that occurs at least three weeks after completion of the review and written recommendation.

(3) A copy of the recommendation shall be provided to the petitioner and the board at least two weeks prior to the board meeting.

(4) Both the petitioner and a representative of the task force shall be given equal time for presentations to the board.

(5) Upon hearing the presentations, the board shall either approve or deny the petition. If the board approves the petition, the approval:

(A) shall be specific for that project and for a specific time period; and

(B) may include conditions or qualifications, if deemed appropriate by the board.

(6) The board or its representatives shall be allowed to inspect and review the project documentation and site at any time during the review process and after the project is approved.

(e) Presentation of results to the board.

(1) The pharmacist responsible for overseeing the project shall forward to the board a summary of the results of the project and conclusions drawn from the results within three months after completion of the project.

(2) A task force composed of board staff, at least one board member and, if deemed necessary, resource personnel appointed by the board president, shall review the results and make written recommendations to the board regarding the results of the project.

(3) The board will receive the report of the task force at the next regularly scheduled meeting of the board that occurs at least three weeks after the task force has completed its review and issued written recommendations.

(4) A copy of the task force recommendation shall be provided to the petitioner and the board at least two weeks prior to the board meeting.

(5) Both the petitioner and a representative of the task force shall be given equal time for presentations to the board.