Attachment 2

Proposal for placement of an all-in-one automated prescription drug dispensing system combined with virtual pharmacist consultation for licensed-pharmacy dispensing in safety-net clinic setting

I site w NPPA

Primary contact information

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Abstract

The cornerstones of an impactful pharmacy experience include accurate, timely dispensing of medications and pharmacist consultation to improve the incidence of medication adherence (aka, adherence), efficacy, and safety of medication therapy.

MedifriendRx™ is an all-in-one automated prescription drug dispensing system that uses cutting edge robotics and bar-coding technologies to accurately stock, select, label, and dispense commonly prescribed medications to patients, with each step involving the direct participation of a pharmacist. The dispensing system is linked to a real-time live pharmacist who initiates each step of the medication-handling and dispensing process and who is also able to counsel the patients on their medications and assist them with other pharmaceutical care needs.

The purpose of this study is to assess the benefits of implementing this type of system into community clinics. Primary metrics will include a demonstration of process measures (including error rates), and overall utilization. Secondary endpoints measured will include primary non-adherence and patient and provider perception and satisfaction with these services. A mixture of observation, quantitative, and qualitative methods will be employed to achieve these goals.

Legislative Background

California allows the use of automated drug-dispensing systems in free clinics and community clinics (*Section 4186, Business & Professions Code*), but in a manner that limits the participation of pharmacists in the dispensing process. The machines may be operated under the clinic license, making the clinic ultimately responsible for safety, security, operation and maintenance of the machine, and ultimately for the act of dispensing. This places a burden on the limited resources of these non-profit clinics. In addition, there are limitations imposed by Medi-Cal and by the insurance industry that limit the ability of these clinics to recover their costs through billing.

In addition, California expressly allows the use of automated drug-delivery systems, operated by a licensed pharmacy, in skilled nursing facilities and intermediate care facilities (*Section 4119.1, Business & Professions Code*). The conditions under which the machines are operated in these settings allow for pharmacy responsibility for the safety, security, operation and maintenance of the machine, and the act of dispensing. In addition, the pharmacies operating those machines are able to recover their costs through proper billing of insurance providers. While two types of clinics are expressly named, <u>the statute also acknowledges the discretion of the Board of Pharmacy to allow the use of automated drug delivery systems in any licensed health facility</u>. (*Subsection 4119.1(e), Business & Professions Code*)

1

Features of the MedifriendRx Automated Prescription Drug Dispensing System

- Unit of Use Dispensing: The machine is stocked with medications in Unit of Use packaging, which are containers that contain a specific quantity of the medication, matching the recommended prescription run. These packages come direct from the manufacturer/supplier or from a licensed repackager and are not modified, except for labelling. The patient receives his or her full prescription.

- Greater Access to Inexpensive Medications: imgRx proposes to place the MedifriendRx Automated Prescription Drug Dispensing System into low-income, safety-net, community clinics that qualify as Covered Entities under the 340B Drug Program, and to stock the machines with medications purchased under that program. Our experience is that when pharmacy services are brought to the patient at the point of treatment, the patients take advantage of greater access and of the low prices made possible by the 340B Drug Program, dramatically increasing adherence.

- Greater Involvement of Pharmacists in Patient Treatment: imgRx proposes that its pharmacists will periodically visit the clinics that are sites of the MedifriendRx Automated Prescription Drug Dispensing System, to interact with providers on matters such as clinical programming and therapeutic interchange, as well as to interact with patients.

- The Pharmacy Operating the MedifriendRx Automated Prescription Drug Dispensing System takes responsibility for:
  - Compliance with all laws and rules of the Board of Pharmacy.
  - Safety, security, and integrity of the medications stocked in the system.
    - The system is secure to prevent unauthorized access and to limit entry to authorized personnel only.
    - Drugs are placed into the system by the supplier, a pharmacist, or a licensed technician, and the system scans and places each container, and produces a reconciliation of the drugs received against the supplier's invoice, for validation by the pharmacist.
    - The MedifriendRx Automated Prescription Drug Dispensing System has been designed to comply with – or exceed – applicable hazard-mitigation and safety and environmental standards, including those related to fire, shock, electrical irregularities, power loss, liquid intrusion, corrosion, electromagnetic interference, radio frequency interference, and physical stability.
    - The Automated Prescription Drug Dispensing System has been designed to perform self-checks to ensure its readiness for service and includes an error-logging system.
  - Security and confidentiality of patient information.
  - Communication.
    - The MedifriendRx Automated Prescription Drug Dispensing System is connected via computer link and audio/visual link through the information system of the responsible pharmacy. Real-time pharmacist video consultations are requested and encouraged.
  - Stocking and Dispensing.
    - The pharmacist at the responsible pharmacy initiates each step of the stocking and dispensing process. Medications are directly released to the patient by the pharmacist.
    - No medication is dispensed until a pharmacist at the responsible pharmacy has verified the finished prescription.

- Numerous and specific images are captured by the MedifriendRx Automated Prescription Drug Dispensing System, and are checked by the pharmacist, at defined and key points in the machine:
  - Labelling.
    - All prescriptions dispensed at the MedifriendRx Automated Prescription Drug Dispensing System have a label affixed to the drug container that includes the address of the responsible pharmacy.
    - The container label includes all applicable information in both human-readable and machine-readable formats.
  - Inventory Reconciliation.
    - A physical reconciliation of inventory will be conducted annually.
  - Records.
    - Records of drugs received and of prescriptions dispensed at the MedifriendRx Automated Prescription Drug Dispensing System are maintained at the responsible pharmacy and are distinguishable from other records of the responsible pharmacy.
    - Images and transactions of each prescription received and dispensed by the MedifriendRx Automated Prescription Drug Dispensing System are securely maintained by the pharmacy.
    - All records will be maintained in compliance with the rules and regulations of the Board of Pharmacy.

Request for Action of the Board of Pharmacy

We ask the California State Board of Pharmacy to exercise its discretion to allow the use of MedifriendRx automated prescription dispensing machines, operated under a pharmacy license, in safety-net community clinics, for the dispensing of prescription medications in unit of use packaging (e.g., 30 day supply). In addition to establishing that these machines provide a safe and secure method for bringing a pharmacist's care to the point of treatment, this action will provide the mechanism for the study discussed in this paper.

Medication non-adherence is a massive public health problem in the United States. Approximately 33% of patients never pick up their first prescription. Three out of every four persons do not take their medications regularly as directed. Approximately 125,000 deaths annually can be attributed to medication non-adherence. Adherence is a complex phenomenon which is impacted by many items. Patient-related factors, beliefs about medicines, and health-system factors all play an important role in adherence to medications. Something as simple as medication access – having to wait for medicine, or schedule time in one's busy day, may be a deterrent to ever starting a necessary medication. Most ambulatory care systems, particularly non-profit community clinics, are ill-equipped to handle poor adherence due to staffing levels and the intensive follow up that is required to circle between the patient and the pharmacy. There remains a critical need to identify practical and effective ways to bolster clinicians' efforts to improve adherence in patients with chronic diseases.

Pharmacies serve as an important bridge that connects patients to their medicines and their primary care provider. However, even pharmacy systems can be difficult to navigate and require time and energy on the part of the patient to obtain their medicines. In addition, most pharmacies require an extra trip to be made by the patient. An ideal system for medication delivery would: 1) be conveniently located such that it does not require an extra travel step on the part of the patient, 2) provide for minimal waiting time, 3) be accurate so that the right medication is dispensed to the patient, and 4) provide the same higher level, personalized clinical services that pharmacists deliver on a face-to-face basis with their patients every day.

The long-term goals of MedifriendRx are to optimize medication delivery in a way that allows pharmacists to practice "at the top of their license," bring a pharmacist's care to the point of treatment, and improve treatment outcomes for chronic disease by improving medication adherence. We have developed a unique system which combines convenient, rapid, accurate dispensing at the point of medical care with access to all-important pharmacist counseling. The immediate goal of this proposal is to study the MedifriendRx system in the community clinic environment, focusing on measures of feasibility, utilization, and perception of key stakeholders (patients and providers). We seek to immediately place the MedifriendRx machine in two to four community clinics, and to expand the number of machines and clinic settings as we are able and as the results of this study prove positive results. We will achieve these goals by addressing the following study aims:

Aim 1: Describe overall utilization, errors encountered, and error rates associated with implementation of the MedifriendRx system over 90 days

Approach: MedifriendRx will be introduced immediately into two to four non-profit community clinics, in each case to be operated under the license of a remote pharmacy which will be responsible for drug ordering, drug placement into the MedifriendRx machine, the safety and security of the drugs inside the machine, all acts of dispensing such drugs to patients, including patient consultation. We will add machines into other non-profit community clinics as we are able, in each case gleaning data from the machines to enhance the study described in this proposal. Descriptive statistics will be used to track utilization of the machine for prescription processing and utilization of the pharmacist counseling option. Process measures related to operation of the machine, errors in those processes, errors in transmission of prescriptions, verification steps, prescription preparation, dispensing, and payment processes will be tallied. Resolutions and time to resolution will also be documented.

Aim 2: Determine the impact of the MedifriendRx on medication adherence

Approach: Using data from the benefits verification pharmacy and contained within the device, determine rates of primary adherence for prescriptions routed to the MedifriendRx.

Aim 3: Assess the perceptions and experiences of key stakeholders for the MedifriendRx

Approach: Semi-structured interviews with 15 patients and 10 providers to assess their perceptions and experiences regarding the use of this technology and how those perceptions apply to the use of the MedifriendRx machine.

Maintaining high levels of adherence to medications can be challenging. Patients are likely to be most successful when adherence is supported across the spectrum of health care: from the physician's visit through picking up medication refills at the local pharmacy. Pharmacists are ideally positioned to play a larger role in optimizing adherence, yet simple, rapid, and convenient medication access is the very first step in the chain of

interventions. The patient cannot take a drug if they don't have it. This study seeks to determine how well MedifriendRx can assist in this process.

I. Significance & Innovation

Adherence begins with a patient's ability to access a prescription medication. The more complex the system required to obtain medications is, the higher the risk of non-adherence. Primary non-adherence is an important health challenge, and existing literature does not cite a lot of evidence-based interventions. However, contributors to non-adherence can include delays in prescription processing, medication errors, time required to determine insurances status, distance to the home/work, and hours of pharmacy operation. All of these steps merit careful consideration. **MedifriendRx is a modern dispensing system which helps free pharmacist time to speak with the patients and brings the presence of the pharmacist into the treatment zone or clinic waiting room.**

By leveraging technology, pharmacists can buy the time needed to extend one's reach. Changes in health care place community pharmacists in a promising position to improve the patient health through individual and population-based interventions. A shortage of primary care physicians plus these changes in the health care system will result in an opportunity for community pharmacists to become an integral part of enhancing the efficiency of care delivery.[1] Existing models demonstrate the value of pharmacists in ambulatory care settings such as the U.S. Department of Veterans Affairs and Kaiser Permanente.[2] Models of care such as the Asheville Project, where community pharmacists collaboratively managed chronic conditions such as asthma, hypertension, dyslipidemia, and diabetes will likely be needed to broaden the reach and impact of clinicians.[3-8] While all of these opportunities exist within the current healthcare system, There must either be a parallel increase in the pharmacy workforce or significant improvements in efficiency of health care delivery (eg MedifriendRx) to serve as many patients as possible, safely and effectively.

II. Approach

A. Overview of experimental design

This protocol describes a study, enabled by the placement of the MedifriendRx automated prescription dispensing machine in clinic settings and operated under a pharmacy license, with three aims described above.

Aim 1 -- _Describe overall utilization, errors encountered, and error rates associated with implementation of the MediFriendRx system over 90 days._

1.a: Study Design Overview: This portion of the study will focus on feasibility measures. Upon the placement of each machine, the 90-day study period will commence.

1.b: Study Population: Initially, two to four devices located in community clinics, with the potential of additional devices and locations to be added.

1.c: Data Acquisition: Participants will be asked questions about the sciences as well as to public art. Multiple items will be measured (*see Table 1*). The two primary measures will include 1) total number of errors incurred during MedifriendRx use and the time it took to resolve them and 2) utilization of

Table 1: Proposed feasibility measures – MediFriendRx
Primary Measures
1. Overall error rate   2. Utilization of pharmacist consultation services   3. Rates of primary adherence to prescriptions routed to MediFriend
Secondary/other measures

1. Error types
    - Transmission of prescription to pharmacy
    - Transcription error at pharmacy
    - Error in benefits adjudication
    - Transmission to MediFriendRx
    - Drug selection
    - Drug labeling process
    - Dispensing of drug
    - Payment processing
    - Connecting for pharmacist consultation
    - Other error
 2. Error resolution
    - Time to correct each error
    - How resolved
 3. Pharmacist consultation
    - Primary requests
    - Time spent
 4. Adherence/prescriptions
    - Primary adherence (% = # MediFriendRx prescriptions dispensed/prescriptions routed to MediFriendRx)
    - % primary adherence by types of prescriptions (medication class)
    - Number of 1st prescriptions
    - Number of refill prescriptions

pharmacist consult services.

1.d: <u>Human Subjects</u>: Not applicable as this portion of the project only studies the device.

1.e: <u>Data Analysis</u>: Errors will be recorded in real time by the pharmacy technician who is on –site at each clinic. Errors will be compiled across clinics/devices on a bi-weekly basis, by the clinical research coordinator. Errors will be categorized and entered into an Excel spreadsheet in order to facilitate references.

Aim 2 -- *Determine the impact of the MedifriendRx on medication adherence*

2.a: <u>Study Design Overview</u>: We hypothesize that prescriptions routed to the MedifriendRx device will provide an effective method of prescriptions to be picked up by the patient due to the convenience, speed, and service that the device offers.

2.b: <u>Study Population</u>: Prescriptions for community clinic patients will be routed to MediFriendRx over the period of six months. The human subjects portion of data collection will stop after six months for each machine, so as not to burden the patient, but other data will continue to be collected and provided for this study.

2.c: <u>Data Acquisition</u>: Descriptive statistics, counts, and proportions will be used to analyze these data. Data for this portion of the project are housed in the pharmacy that will perform the insurance benefits review step and in the MedifriendRx device. The study facilitator will, on a bi-weekly basis, obtain data on the total number of prescriptions routed to the MedifriendRx (denominator). He/she will compare these data with MedifriendRx utilization reports to assess how the device impacts the patient for new prescriptions (primary adherence). Reports will also be generated to determine the proportion of patients who also "return" to the device for subsequent refills.

2.d: <u>Human Subjects</u>: Although the numerator and denominator for this measure is prescriptions, Human Subjects ethical research approval for this measure may be required. Expedited approval is expected for this portion of the project because subjects will be de-identified with use of a data key. This portion of the research will be submitted to BioMed Institutional Review Board (San Diego, CA) for approval.

Table 2: DRAFT Semi-structured interview guide
Patients
1. How do you usually get your prescriptions?
2. What problems do you typically run into when trying to get your prescriptions?
3. What was your experience like using the MediFriendRx?
4. What would you change about your experience?
5. What do you usually talk with the pharmacist about when you are at the pharmacy?
6. If a pharmacist was available at the clinic where you see your doctor, what would you like for them to help you with?
7. Would you see a pharmacist for any of the following: medication review, smoking cessation, immunizations, travel medicine, obtaining birth control?
8. Anything else I left out that would be important for me to know?
Providers
1. What problems do you usually run in to when prescribing medicines for your patients?
2. What was your experience like using the MediFriendRx?
3. What would you change about your experience?
4. If a pharmacist was available at your clinic, what services would you like them to provide for you? What services should they provide for your patients?
5. Should a pharmacist provide any of the following services: medication review, smoking cessation, immunizations, travel medicine, providing birth control?
6. Anything else I left out that would be important for me to know?

2.e: <u>Data Analysis</u>: Prescription data will be extracted from the community pharmacy record by the study facilitator or designee. Records will contain a keyed patient ID, clinic site, dates, medications, quantity/days supply, refills, and whether new or ongoing prescription. Prescriptions will be compiled across clinics/devices on a bi-weekly basis, by the study facilitator. Data will be transferred into a database spreadsheet for analysis.

Aim 3: -- *Assess the perceptions and experiences of key stakeholders of the MediFriendRx*

3.a: <u>Study Design Overview</u>: In addition to capturing quantitative data to describe the utility of the device, we also employ individual interviews with patients and providers to better understand the positive aspects (and any potentially negative), challenges, and attitudes from the perspectives of end-users.

3.b: <u>Study Population</u>: Patients and providers of community clinics where MedifriendRx will be housed.

> *Inclusion criteria:* Patients > 18 years of age who are seen for primary care at community clinics who speak English fluently, who opted to have a prescription sent to the MedifriendRx, and who agree to participate. Prescribers at community clinics who have routed at least one prescription to the MedifriendRx device.

3.c: <u>Data Acquisition</u>: One-on-one face-to-face interviews will be conducted on site at each clinic using a semi-structured interview guide (*see Table 2*). Each participant will be asked to fill out a brief demographic form. The purpose of the interview will be explained to each participant using an information sheet as a guide. Written informed consent will be obtained. Interviews will be audio-recorded and transcribed verbatim. Each participant will be asked to refrain from using names (including their own) during the interview, in order to maintain privacy. Clinical research coordinator will conduct the interviews and will briefly review transcripts versus their audio files for accuracy. Upon verification of accuracy, audio files will be destroyed.

3.d: <u>Human Subjects</u>: Human Subjects ethical research approval for this portion of the project will be required. Expedited approval is expected because subjects will be de-identified.

3.e: <u>Data Analysis:</u> Transcripts will be reviewed upon completion. A thematic analysis will be performed using both inductive and deductive methods. A codebook will be developed using an iterative process. Codes will be added and refined as new transcripts become available until no new themes appear to emerge from the data.

III. Conclusion

At the conclusion of this project we will have become better versed in the feasibility and challenges associated with implementing the MedifriendRx device in a community clinic. This data will serve as a baseline reference for anyone interested in utilizing this tool to help improve adherence in their patient population.

REFERENCES

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California State Senate

SENATOR
JEFF STONE, PHARM.D.
TWENTY-EIGHTH SENATE DISTRICT

November 1, 2016

Ms. Virginia Herold
Executive Director, California State Board of Pharmacy
1625 N. Market Blvd, Suite N219
Sacramento, CA 95834

Dear Ms. Herold:

 For approximately two years, my office has been following the progress in development of what is now known as MedifriendRx™, an automated prescription dispensing system using cutting-edge robotics to serve as the arms and legs of the pharmacist. Placed in a clinic setting and remotely operated at every step of stocking and dispensing medications in unit-of-use containers, I believe this system will bring a pharmacist's care and responsibility to underserved populations.
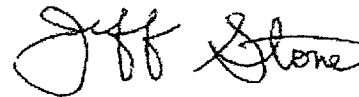
 California expressly allows the use of automated drug-dispensing systems in free clinics and community clinics but limits the responsibility, and thus the participation, of pharmacists in the dispensing process. Under Section 4186 of the Business and Professions Code, automated drug-dispensing systems may be operated under the clinic license, making the clinic ultimately responsible for safety, security, the operation and maintenance of the machine, and ultimately the act of dispensing. This places a burden on the limited resources of these non-profit clinics. In addition, there are limitations imposed by Medi-Cal and by the insurance industry that limit the ability of these clinics to recover their costs through billing.

 In addition, California expressly allows the use of automated drug-delivery systems, operated by a licensed pharmacy, in skilled nursing facilities and intermediate care facilities (*Section 4119.1, Business and Professions Code*). The conditions under which the machines are operated in these settings allow for pharmacy responsibility for the safety, security, operation and maintenance of the machine, and the act of dispensing. In addition, the pharmacies operating those machines are able to recover their costs through proper billing of insurance providers. While two types of clinics are expressly named, the statute also acknowledges the discretion of the Board of Pharmacy to allow the use of automated drug delivery systems in any licensed health facility. (*4119.1(e), Business and Professions Code*)

I encourage you to use the Board's discretionary authority to grant ImgRx and its pharmacies licenses to place their MedifriendRx machines in licensed, non-profit community clinics, as requested in their proposal. imgRx is a small, start-up company, founded by a retired California pharmacist. They have proven themselves as valuable contributors to California health care, having established 21 on-site contract pharmacies in safety-net, non-profit, community clinics in the state. With the amount of time and energy already spent in developing the MedifriendRx machine and system to bring a pharmacist's care into clinic settings where currently there is none, I encourage an immediate grant of the permissions sought in their proposal, which will allow them to bring their services to many clinics and will provide the Board with meaningful data on the study topics outlined by their proposal.

I look forward to working with the Board during the next legislative term to fashion legislation, if necessary, to make this kind of pharmacy service a permanent reality in California.

Sincerely,

Jeff Stone
State Senator, 28th District