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DECREASING COST ASSOCIATED MEDICATION NONADHERENCE

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DECREASING COST ASSOCIATED MEDICATION NONADHERENCE

A Scholarly Project Submitted to the Graduate School
in Partial Fulfillment of the Requirements for the Degree of
Doctor of Nursing for Practice

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December, 2016

DECREASING COST ASSOCIATED MEDICATION NONADHERENCE

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DECREASING COST ASSOCIATED MEDICATION NONADHERENCE

An Abstract of the Scholarly Project by
Shawn E. Raymond

Medication cost is a major contributor for patient medication nonadherence. Take in the fact that a large population lives in poverty, many cannot afford to pay the retail prices associated with purchasing their medications. By incorporating wholesale medications into a charitable health clinic, the reduced cost of medications for treatment of both acute and chronic illnesses could be passed on to those in need thereby decreasing cost associated medication nonadherence. Nurse Practitioners in the state of Kansas are not afforded the privilege to purchase, repackage and distribute or resell wholesale medications like their physician counterparts. If current legislation were changed to allow this to happen, even if it is only in the setting of the charitable healthcare clinics, those individuals who are uninsured and in poverty would have more affordable access to prescription medications. By increasing the affordability of the medications and decreasing cost associated medication nonadherence, the health status of this population could be greatly improved.

Keywords: wholesale medications, retail medications, medication nonadherence, medication adherence, medication compliance, medication noncompliance, advanced practice nurse, nurse practitioner, charity, charitable health, rural health, cost associated noncompliance, cost associated nonadherence, medication cost, poverty.

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CHAPTER I

INTRODUCTION

Description of the Clinical Problem

Medication costs have always been a barrier to patient medication adherence in the treatment of acute and chronic illnesses throughout the United States and around the World. “Prescription medication costs increase financial burden, often leading individuals to engage in intentional nonadherence” (Martin, Shreffler, Schoster, & Callahan, 2012, p. 236). Medication nonadherence leads to worsening of both acute and chronic illnesses, and at the same time increases the overall cost of treating those illnesses by requiring additional diagnostics, treatments and even hospitalizations. It has been estimated that approximately 125,000 deaths in the United States each year can be attributed to medication nonadherence (Bosworth et al., 2012, p. 2). The total cost estimates for nonadherence range from \$100-\$300 billion each year, and include both direct and indirect costs (Bosworth et al., 2012, p. 2). When taken into account that 1.2 billion people around the world live in extreme poverty, this problem is greatly compounded (Theis, 2013). To show how prevalent the topic is within scholarly literature, Goldberg, DeKoven, Schabert, and Coyle (2009) performed a review of the literature that spanned 40 years, 1967-2007, to show the magnitude in which medication

nonadherence was written about. Results of that review are illustrated in Figure 1 (see Appendix A). In 1977, approximately 300 articles were written on medication adherence that year alone; 30 years later in 2007, there were approximately 4,500 articles written within that same one-year timespan.

Significance

Many individuals often attempt to extend their medication prescriptions by purposefully skipping doses, and in worst case scenarios do not get them filled because they cannot afford them. By showing a definite link between cost of medications and medication adherence by patients, this project will demonstrate that allowing medications to be sold at wholesale cost will increase medication adherence. Medication nonadherence, related to cost, can effectively be decreased by utilizing wholesale medication throughout the United States. Also, by reducing the costs of those medications necessary to treat both acute and chronic illnesses, patients will keep more of the money they earn, effectively helping to increase their financial stability and quality of life.

Purpose

The purpose of this project is to propose a legislative change that will allow Nurse Practitioners (NPs) to incorporate wholesale medications into a NP operated Charitable Health Clinic (CHC) in rural southeast Kansas. By doing this, data can be collected to see if offering medications at wholesale cost will increase medication adherence, based on the reduced cost associated with the purchasing the medications needed for treating the individual's acute or chronic illness. According to Iuga and McGuire (2014), "Reducing

out-of-pocket costs leads to better medication adherence across many diagnoses. There is a linear relationship between the magnitude of patient cost sharing and the level of adherence.” At times, statements are voiced from individuals that directly correlate to the cost associated with the treatment option/s chosen by the provider; statements like “I can’t afford that.” or “we’ll have to wait until payday.” The CHC that will be referenced in this project is run by donations only; there is no cost associated with being seen by the provider. By eliminating the cost associated with being seen by a provider, the hope is that the individuals will be able to afford the medications, at the wholesale price, thus increasing medication adherence for acute and chronic illnesses by those individuals using the CHC.

In the state of Kansas, NPs are required to have a Collaborative Practice Agreement with a Physician to practice. Physicians within the state of Kansas that offer wholesale medications in their clinics are able to buy these medications in bulk, repackage the medications, and resell the medications to their patients; NPs cannot. It is yet to be determined what process it will take to incorporate wholesale medications into the CHC at the time of this writing. This project will be utilized to petition the Kansas state legislators, to seek change within the state giving NPs equal privileges as physicians to purchase, repackage and dispense or resell wholesale medications.

To start, a comparison was made to determine what the cost difference was between wholesale and retail medications. An online medication wholesaler, Andameds.com, was used to collect wholesale prices of a few common medications in the treatment of both acute and chronic illness. These wholesale prices were then

compared to the retail prices for the same medications using GoodRX.com. By comparing the prices of these medications, it was apparent the cost savings that could be passed on to the patients was fairly significant. Table 1 (see Appendix A) lists the medications with breakdown of cost per pill, as well as cost for a standard course of treatment, whether it is a 5-day, 10-day or 30-day course. Prices were taken from each website and compiled into Table 1 on September 15, 2015.

Theoretical Framework/Conceptual Analysis

The theoretical framework used for this specific work is based on the Health Belief Model (HBM). The HBM was originally written in the 1950s by a group of psychologists at the United States Public Health Services (Janz & Becker, 1984). The HBM was utilized as “a conceptual formulation for understanding why individuals did or did not engage in a wide variety of health related actions, and provided considerable support for the model” (Janz & Becker, 1984, p. 1). Initially, the HBM was written in an attempt to understand why people did not undergo preventative care for the early detection of “asymptomatic disease” (Janz & Becker, 1984, p. 2). The HBM later went on to incorporate aspects of how people responded to symptoms of the disease process, as well as medication adherence.

The HBM first addressed Perceived Susceptibility which constitutes an individual’s perception of the risk to contract a disease or illness. Second, the HBM addressed Perceived Severity of the illness if contracted, as well as the physical, emotional, and economic costs of leaving the condition untreated. Next, Perceived Benefits were addressed. This established if there were any benefits to leaving the

condition untreated or obtaining treatment. Finally, Perceived Barriers, defined as anything that hindered the individual from obtaining treatment for the condition, were addressed.

Due to the fact that the CHC sees those patients who are uninsured or underinsured, the total cost associated with the treatment of the acute and chronic illnesses plays a large part in nonadherence. Many patients are denied services when they do not have the monetary means or insurance coverage to pay for the testing or medications up front. By addressing the HBM factors that hinder individuals from getting the diagnostics and treatments they need, this project hopes to show an increase in the health and wellness of this population.

Project Objective

The objective of this project was to petition area senators and legislators to change the current legislation in the state restricting Advanced Practice Nurses (APNs) to purchase, repackage and dispense or resell wholesale medications to the uninsured/underinsured individuals that are cared for at NP run CHCs within the State of Kansas.

Definition of Key Terms

adherence

“The WHO defines *adherence* as ‘the extent to which the persons' behavior (including medication-taking) corresponds with agreed recommendations from a healthcare provider’” (Lam & Fresco, 2015, p. 1).

charitable

1. “Generous in giving money or other help to the needy.”
2. “Mild or tolerant in judging others; lenient.”
3. “Of, for, or concerned with charity: *a charitable organization*” (“Charitable,” 2009).

clinic

“A facility, often associated with a hospital or medical school that is devoted to the diagnosis and care of outpatients” (“Clinic,” 2003).

compliance

“The extent to which the patients' behavior (including medication-taking) coincides with medical or healthcare advice” (Lam and Fresco, 2015, p. 1).

healthcare

“The prevention, treatment, and management of illness and the preservation of mental and physical well-being through the services offered by the medical and allied health professions” (“Healthcare,” 2003).

medication adherence

“The extent to which patients take medication as prescribed by their health care providers”; “the patient’s conformance with the provider’s recommendation with respect to timing, dosage, and frequency of medication taking during the prescribed length of time” (Viswanathan et al., 2012, p. 1).

nurse practitioner

“[Registered] nurses who are prepared, through advanced education and clinical training, to provide a wide range of preventive and acute health care services to

individuals of all ages” (O’Grady, 2008, p. 605). Nurse Practitioners “take health histories and provide complete physical examinations; diagnose and treat many common acute and chronic problems; interpret laboratory results and x-rays; prescribe and manage medications and other therapies; provide health teaching and supportive counseling, with an emphasis on prevention of illness and health maintenance; and refer patients to other health professionals as needed” (O’Grady, 2008, p. 605).

Abbreviations

Advance Practice Nurse/s	APN/APNs
Charitable Health Clinic	CHC
Chronic Care Model	CCM
Centers for Medicare and Medicaid Services	CMS
Doctor of Nursing Practice	DNP
Health Belief Model	HBM
Kansas State Board of Pharmacy	KSBP
Kansas State Board of Nursing	KSBN
Medicare Part D	MPD
Medication Therapy Management	MTM
Nurse Practitioner/s	NP/NPs
Out of Pocket	OOP
Socioeconomic Status	SES
Southeast Kansas	SEK
Verdigris Valley Charitable Health Clinic	VVCHC

Logic Model

The Verdigris Valley Charitable Health Clinic (VVCHC) Logic Model was specifically created for this project. This logic model breaks down factors that were and will need to be addressed prior to initiating, and throughout this evolving project. The logic model is broken down into three separate sections: inputs, outputs and outcomes-impacts. The input section compiles a list of primary issues that face this project overall. Without all of these aspects falling into place, this project will not succeed. The outputs section details what each input's activities and participation level will be within this project. The outcomes-impact section lays out short-, medium- and long-term goals that will need to be achieved for completing and continuing of this project. An example of the logic model would be the following:

- Inputs: Pittsburg State University's Irene Ransom School of Nursing
- Outputs: Activities: Approval and oversight of the DNP Scholarly Project
Participation: Guidance and oversight of the project, peer review project to ensure compliance with evidence based research.
- Outcomes: Short: Project was approved by the DNP advisor and committee.
Medium: Project was validated through peer review.
Long: Scholarly Project was defended successfully.

The complete VVCHC Logic Model can be found in Table 2 (see Appendix A).

Chapter Summary

Cost is a significant factor in medication nonadherence and it leads to worsening of both acute and chronic illnesses. With medication adherence comes a substantial increase in the costs associated with the treatment of worsening illness, both direct and indirect. Cost estimates range from \$100-300 billion each year (Bosworth et al., 2012). A review of the literature by Goldberg, DeKoven, Schabert, and Coyle (2009) shows the vast increase in articles written on the subject matter over the years with approximately 4,500 articles published in 2007 alone (Figure 1, see Appendix A).

The purpose of this project was to not only incorporate wholesale medications into a NP operated CHC in rural southeast Kansas, and to legislate for policy changes through the state government to give NPs the same privileges that physicians have when it comes to buying, repackaging and dispensing or reselling wholesale medications. By offering medications at wholesale cost this project will determine if there is an increase medication adherence, based on the reduced costs associated with purchasing the medications needed to treat an individual's acute or chronic illness.

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

The review of literature will help support the pretense of this project, that cost is a factor to medication adherence. This chapter focuses on the various populations that are affected from the cost of purchasing retail medications, as well as the laws that keep APNs from purchasing, repackaging and dispensing/reselling wholesale medications. The information highlighted in this section was used to educate the legislative representatives on not only the problem that cost association has on medication adherence, but a solution to the problem at hand.

To validate that the costs associated with medication is a factor in adherence, a meta-analysis of the published literature was conducted. The literature was reviewed for validity of subject matter, currency of information, and publication type. Only the work that was published in scholarly, peer reviewed sources within the last five years was included. The information was gathered in a range of various settings, but all information did reveal that, among other variables, cost was a determining factor in medication adherence in the treatment of acute and chronic illnesses.

Literature was gathered from multiple resources using various search criteria. Various online databases were utilized within this review of literature to include CINAHL Plus with Full Text, PubMed, PubMed Central, PubMed Clinical Queries and Proquest Nursing & Allied Health Source; another online resources utilized was Google Scholar. Search sting queries consisted of multiple combinations of the following; medication adherence, medication compliance, cost, costs, afford, affordability, reduced adherence, reduced compliance, wholesale, wholesale medications, charity, charitable, charitable health, charitable health clinic, retail pharmacy, wholesale pharmacy, socioeconomic status, poverty, poor, working poor, uninsured, underinsured, fixed income. Initially very few articles met the criteria for this study, but after extensive research the following literature was chosen to conduct this review.

Medication Adherence

Medication adherence is key to increasing the health status of those who experience acute and chronic illnesses. According to Mackey et al., (2015), the World Health Organization reported medication adherence for those with chronic illnesses only averaged 50% in developed countries (p.2). An estimated 50-60% of those with chronic conditions are noncompliant with medication treatment regimens (Bosworth et al., 2011, p. 2). Medication nonadherence overall drastically reduces the optimal health and wellness of an individual, and also increases the overall costs of individual treatment, possibly requiring more office visits or hospitalizations due to their poor health state. Approximately 1.6 billion prescriptions filled within the Unites States each year are not taken as prescribed (Bosworth et al., 2011, p. 2).

Socioeconomic factors that play into nonadherence include socioeconomic status (SES), whether patients are insured, underinsured, or uninsured, availability to medical care; and availability to pharmaceuticals. Mackey et al (2015, p. 2), found that “patient characteristics such as age, sex, race, and education are associated with medication adherence,” as well as “financial burdens such as low income or socioeconomic status, lack of prescription drug coverage, and high out-of-pocket costs”. In addition, WHO divides the circumstances that lead to nonadherence “into five categories: socioeconomic factors, therapy-related factors, patients-related factors, condition-related factors, and health system/ health care team (HCT) related factors” (Lam & Fresco, 2015, p. 2). Therapy-related factors include various medication reactions such as rash, nausea, vomiting and anaphylaxis. Other therapy-related factors include inability to purchase medications, unavailability of medications or even in rural areas inability to get to where the therapy-related items are sold. Patient-related factors include refusing to take medication or not having the medication available at the time it is to be administered. Condition-related factors include inability to take the medication as prescribed due to disease process or medical condition, inability to take medication due to cognitive function, inability to take the medication due to decreased recall of current treatment plan, and inability to take medications due to pain, blindness, weakness, loss of function of upper extremities, nausea or vomiting. Health care team (HCT) related factors consist of issues such as medical professionals forgetting to inform the patient of changes to the medication plan, forgetting to call new medication in, or forgetting to tell the patient that they had called something in. Other examples could include the provider not taking into

account the individual's SES or insurance information when calling or faxing in a new medication that the individual cannot afford and ineffective communications between the HCT and the individual.

For over 40 years, researchers have used various methods to determine adherence, but none have ever been considered the gold standard (Lam & Fresco, 2015, p. 2). Therefore, multiple techniques must be utilized in studies to enhance the effectiveness of the gathered data. Without testing multiple techniques to measure adherence, researchers could possibly misrepresent the data and show more or less adherence than there actually is. This error in data representation could cause harmful and unnecessary consequences at all levels of the healthcare delivery system.

Uninsured/underinsured. Out of the hundreds of sources reviewed, the article that most specifically related to this project was Alton, March, Mallery, and Fiandt's (2015) "Medication Adherence in a Nurse Practitioner Managed Clinic for Indigent Patients." As the authors themselves state, "Little is published in the literature about medication adherence rates among patients who are medically indigent and patients receiving primary care from nurse practitioners (NPs)" (Alton et al., 2015, p. 433). This study was a cross-sectional analysis that looked at adherence and barriers to treatment plans in the indigent population that were specifically cared for in a NP run health clinic and were deemed to be uninsured or low income. Participants were surveyed on adherence issues and barriers to treatment with "surveys eliciting demographic information, self-report of medication adherence, health literacy, and barriers to adherence" (Alton et al., 2015, p. 433). An unusually large return rate 77% was noted in

this study. Two definitive causes of this return were most frequently identified, and one of those was inability to afford medications (62.5%). The other involved Hispanic patients' inability to understand medication labels. The takeaway point of this project was the need to improve patient access to affordable medications, which could in effect increase rates of medication adherence within that particular clinic and patient population.

A qualitative study published in the journal *Health & Social Work* in 2011 explored various aspects of adherence and nonadherence in low-income individuals with multiple comorbid disease processes. The study accounted for both the physical and mental aspects of chronic illness (Mishra, Giola, Childress, Barnet, & Webster, 2011). They found that various factors played into the adherence level, or lack thereof, of medication treatment plans. Some of those factors that affected medication treatment plans included “medication side effects, fear of harm from medication, fear of dependence on medication, complex instructions, suboptimal communications with doctor, suspicion about doctors’ and pharmaceutical companies’ motives in prescribing medication, and the high cost of medications” (Mishra et al., 2011, p. 249). Also identified were various motivators for medication adherence that actually increased medication adherence in that study; these were “faith, support from family members and doctors, and focused health education and self-management support” (Mishra et al., 2011, p. 249). During the study Mishra et al. also noted financial status as being a large contributor to nonadherence as well; the medications were too expensive and just increased patients’ financial strain. One participant in this study stated, “I was working

and I got laid off and I had to pay for my medications and it cost me \$97 to get all of my prescriptions and I don't have \$97, so I had to choose what medication was the most important" (Mishra et al., 2011, p. 252). This, many times, is what individuals on fixed incomes or low incomes face when they have chronic illnesses. Individuals with acute and chronic illnesses can have every intention of being adherent with their primary provider's medication treatment plans but if they cannot afford the medications there is no way they can be adherent.

Chronically ill/elderly. Medication nonadherence, due to cost can be increasingly influenced by the number of medications an individual is on. This state of taking multiple medications is called polypharmacy. Older adults have vastly unique and challenging barriers, that may not be shared by other age groups. According to Marcum and Gellad (2012), barriers for older adults could include "managing multi-drug regimens, cognitive impairment, functional limitations, financial restraints, use of multiple health care providers, [and/] or transportation limitations" (p. 1). The more chronic illnesses an individual has, the more medications it will take to control the progression of those chronic conditions.

There are multiple stages in which an elderly or chronically ill individual could be nonadherent; these include getting the prescription filled when new medications are prescribed, starting to take the medications as prescribed, continuing to take the medication as prescribed (in those who suffer from chronic conditions), and taking the medication for its intended purpose (Marcum & Gellad, 2012). Multiple studies have been conducted with regard to nonadherence in the elderly; these studies have shown that

approximately 50% of the elderly population are nonadherent on at least one of their medications, whether intentionally or unintentionally (Marcum & Gellad, 2012). Marcum and Gellad (2012) identified three different types of medication nonadherence, nonfulfillment, nonpersistence, and nonconforming (p. 1). Primary nonadherence revolves around not picking up the medication that was prescribed to the individual, nonpersistence is stopping a medication prior to taking the full course of the prescribed medication, and nonconforming relates to not taking the medication as prescribed, whether it is taking doses at the wrong time or skipping doses altogether (Marcum & Gellad, 2012). There are various reasons individuals may be noncompliant, but per Marcum and Gellad (2012). “The most common health-system barrier to medication adherence is cost. Cost is clearly more of a problem for those patients taking more medications, and thus polypharmacy may affect adherence through higher cost-sharing” (p. 4).

Mackey et al. (2012) performed a study using the Chronic Care Model (CCM) to see if this model of treatment would increase medication adherence compared to those who were not treated under this model. They sent out surveys to 40 small community healthcare clinics. Participants in this study were 18 years or older and had at least one chronic illness (mean 2.4). The surveys were based on the Morisky Medication Adherence Scale, the Patient Assessment of Chronic Illness Care, and a set of frequently used items developed by Piette and colleagues (Piette, Heisler, & Wagner, 2004) that helps assess cost-related burdens. A total of 2,634 surveys were given out with 2,392 returned for an astonishing, 90.8% completion rate. Statistical analysis was performed on

the collected data and showed “prescription costs and perceptions of care experiences were significantly associated with medication adherence” and a “high prevalence of poor adherence among chronically ill individuals” (Mackey et al., 2012, p. 5). With regard to the CCM, patients that were treated under this model did show improvement with medication adherence, compared to those who were not treated under it.

Medicare supplemental population. Members of the Medicare supplemental population face unique challenges regarding nonadherence. Mixon, Neal, Bell, Powers, and Kripalani (2015) stated that “Older adults typically take more medications than younger adults due to multimorbidity associated with advanced age” (p. 1). Musich et al. (2015) found that those individuals who were on a Medicare supplemental insurance plan took approximately seven different prescription medications each year, “resulting in substantial out-of-pocket drug copayments, in addition to Medicare Supplement and Medicare Part D (MPD) premiums” (p. 1208). Seniors on Medicare who may have supplemental coverages also fall into the area of being able to not afford certain prescriptions based on cost or many have multiple medications so the cost increases for the amount of medications they may be on. Because many older Americans are on a fixed income and are at or below the poverty line medication costs can tax an already limited budget, based from many older adults being on a fixed income. Per Musich et al. (2015) out of pocket spending (OOP) rates were very sensitive to the rate of medication nonadherence, “OOP spending increases with higher numbers of medications, medication nonadherence increases” (p. 1209). As for Mixon et al. (2015), “before the implementation of MPD (prescription drug insurance) in the USA, 2 million older adults

were nonadherent to their drug regimen due to lack of prescription coverage” (p. 5). Even though MPD came about to give these millions of older adults’ medication coverage, there is still what is known as the donut hole in which the person reverts back to paying full price for medications. The donut hole starts when a person reaches the annual spending limit set by Medicare. Based on the amount of chronic illness and the amount and cost of medications the individual is on, the individual may hit that donut hole midway through the fiscal year while others may hit towards the end of the year. Mixon et al. (2015) showed in their article that the ‘donut hole’ increased medication nonadherence in the Medicare population “with fewer prescriptions filled and more gaps in therapy” (p. 5). The donut hole is currently in the process of phasing out, but this will not take place for another four years (2020). Until that time though, many poor, older adults will continue to hit the donut hole and have to make the decision whether to purchase their medications or purchase food and pay their utilities.

In 2013 a study was done by Carr-Lopez et al. during the MPD open enrollment period. Medication Therapy Management (MTM) teams were dispatched to six different central and northern California cities. Student pharmacists under direct supervision provided the services to the individuals enrolling in MPD. A series of questions were asked by the student pharmacists and answers were recorded. Out of 1,547 individuals showing up for the open enrollment clinic, only 586 of the individuals were provided with MTM. Per Carr-Lopez (2014), inclusion criteria for MTM was established by the Centers for Medicare and Medicaid (CMS) and allowed the MPD organizers to require the participants of this study to take up to eight different medications in order to meet

standardized drug requirement for the provision of MTM services. Data analysis from the 2012 study revealed that “75% of MPD plan sponsors required a beneficiary to be taking seven or eight medications to qualify for MTM” (Carr-Lopez et al., 2014, p. 1282). Out of those 586 that were offered MTM, only 532 (91%) agreed to participate in the study. Data was then taken and processed using various statistical analysis. Only 30% of those who participated in the study admitted to medication nonadherence, but an interestingly higher number (48%) asked questions about missed dosing. Forgetfulness was the most reported factor in nonadherence, but “Cost of medication, even with the MPD prescription drug benefit, was a barrier to adherence” (Carr-Lopez et al., 2014, p. 1281).

Laws Governing the Distribution of Medications

Between the federal government, state government and the Kansas State Board of Pharmacy, the laws that govern how prescription medications are handled within the state are determined. The Pure Food and Drug Act of 1906 is one of the earliest laws that focused on the purity of drugs utilized in interstate commerce (Dusen & Spies, 2006). This act did not address any false advertising or claims to those drugs; it focused on curtailing interstate commerce of those drugs that were mislabeled or contaminated. In 1937, after a compounding error in Tennessee that killed over 100 people, there was a public outcry for the federal government to intervene. In 1938, the Pure Food and Drug Act was replaced by the Food, Drug and Cosmetic Act (Dusen & Spies, 2006). For the first time in history the law mandated that all new drugs be approved prior to entering the market. The companies looking for approval had to show safety and efficacy prior to

being approved. Pharmacist began compounding medications in their pharmacies to be used by the public.

Under the Food, Drug and Cosmetic Act (1938), these compounded medications were considered new drugs and they had to be tested and approved by the FDA prior to dispensing. Because these medicines that were being compounded were in fact a combination of individual medications that had already been approved by the FDA, a new law was enacted. In 1997, the Food and Drug Administration Modernization Act replaced the Food, Drug and Cosmetic Act of 1938 (Dusen & Spies, 2006). The new act would effectively eliminate the FDA's ability to say that compounded drugs were classified as new drugs.

In 1951, the Durham-Humphrey Amendment was established (Dusen & Spies, 2006). This act would cease dispensing medications without a prescription. Up until that time individuals could walk in off the street, tell the clerk what they wanted and get it. In 1970, The Comprehensive Drug Abuse Prevention and Control Act was enacted (Dusen & Spies, 2006). This act would effectively categorize controlled substances into 5 different classes: Schedule I, II, III, IV and V. Also, this act would dictate the storage, dispensing and record keeping of controlled substances.

Also in 1970, the Poison Prevention Packaging Act was enacted (Dusen & Spies, 2006). This act would mandate child-resistant packaging for all medications. Up to that point, poisonings from medications was "considered by pediatricians to be the leading cause of injuries among children under 5 years of age" (Dusen & Spies, 2006, p. 27). In

1987 came along the Prescription Drug Marketing Act. This act would combat the problem of diverting bulk medicines onto the “gray market” (Dusen & Spies, 2006). This act would later be rolled into the Food, Drug and Cosmetic Act (Dusen & Spies, 2006).

The Omnibus Budget Reconciliation Act of 1990 established that pharmacists had to give each individual that picked up a prescription mandatory education on the medication being purchased. The reason this act was initiated was to positively affect therapeutic outcomes, thus saving the federal government money in the process (Dusen & Spies, 2006). 1996 saw the dawning of the Health Insurance Portability and Accountability Act. This act placed limits on individuals protected health information.

Current Laws Affecting APNs in the State of Kansas

Most state in the U.S. allow physicians to dispense medications to some extent (Optum, 2015, para. 1). In many aspects relating to why the author pursued this project, “Physicians perceive drug dispensing as reducing the drug cost to [their] patients, reducing the cost of healthcare [and] improving drug adherence” (Munger, 2014, p. 40). As per Kansas law, medications dispensed by physicians can only be reimbursed at a rate equivalent to that of pharmacies, and also the insurance company may require prior authorization before they will pay for the medication (Optum, 2015, para. 5). Unfortunately, Kansas APNs do not get the same opportunities as physicians with regard to being able to purchase, repackage and dispense or resell wholesale medications without the supervision of a pharmacist. Figures 2 through 6, in Appendix A, show the differentiation of state practices in reference to dispensing medications by non-pharmacist practitioners and physicians’. As these figures show, Kansas does not require

physicians to be licensed to dispense medications. The only restriction is how they charge for the medication.

Kansas Statutes Chapters 65 and 68 provide definitions utilized within the statutes, regarding this topic. The following is a list of the main definitions that are specific to this project:

“‘Dispenser’ means a practitioner or pharmacist who dispenses prescription medication, or a physician assistant who has authority to dispense prescription-only drugs in accordance with subsection (b) of K.S.A. 65-28a08, and amendments thereto” (Kansas Board of Pharmacy, 2014, p. 22).

“‘Mid-level practitioner’ means an advanced practice registered nurse issued a license pursuant to K.S.A. 65-1131, and amendments thereto, who has authority to prescribe drugs pursuant to a written protocol with a responsible physician under K.S.A. 65-1130, and amendments thereto, or a physician assistant licensed pursuant to the physician assistant 25 licensure act who has authority to prescribe drugs pursuant to a written protocol with a responsible supervising physician under K.S.A. 65-28a08, and amendments thereto” (Kansas Board of Pharmacy, 2014, p. 24-25).

“‘Practitioner’ means a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist or scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug” (Kansas Board of Pharmacy, 2014, p.26).

“‘Prescriber’ means a practitioner or a mid-level practitioner” (Kansas Board of Pharmacy, 2014, p. 26).

“‘Wholesale distributor’ means any person, partnership, corporation, or business firm licensed or registered in this state and engaging in the wholesale distribution of prescription-only drugs” (Kansas Board of Pharmacy, 2014, Article 68-14-1, p. 118).

“‘Wholesale distribution’ means distribution of prescription-only drugs to persons other than a consumer or patient, but this term shall not include any of the following: ..., (3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the U.S. internal revenue code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;” (Kansas Board of Pharmacy, 2014, Article 68-14-2, p. 119).

Argument for APNs to Distribute Wholesale Medications

By viewing the definitions above, the prediction could be made that the only difference between the definitions of a mid-level practitioner and practitioner is the supervision aspect for the mid-level practitioners. In rural America, many times these two individuals do not work in the same office, town or even county. So, does the supervisory role take on a more “supervisor on paper” type of roll? Even though some states may have restrictions on which provider can prescribe scheduled (Drug Enforcement Agency, controlled) medications, all can write nonscheduled medication prescriptions. All practitioners (and mid-level practitioners) diagnose, treat and prescribe medications to

their patients and in most cases this is done without any supervision of the mid-level practitioners.

Following the same definitions listed in the statutes, the term “Practitioner” included any person licensed to practice medicine and surgery. Even though APNs are not licensed to perform surgery, they are licensed to practice medicine. The only real piece of legislation standing in the way of APNs being able to purchase, repackage and dispense or resell wholesale medications is the current difference in the definitions of practitioners and mid-level practitioners. Possibly if future legislation were passed to give APNs full practice authority, this may help to sway the influence in favor for APNs being able to purchase, repackage and dispense or resell wholesale medications at their clinics without pharmacy oversight.

Another area that could be debated is a section in Article 1635, of the Kansas Statute Chapter 65, that relates to the dispensing of medications by a duly licensed practitioner in a town where there are no registered pharmacies. This article states nothing in the Kansas Pharmacy Act will inhibit those individuals who are classified as ‘duly licensed practitioners’ from purchasing, repackaging and dispensing or reselling medications to their patients. Following is an excerpt of that statute:

65-1635. Dispensing and administering of drugs by duly licensed practitioners, ... (a) Nothing contained in the pharmacy act of the state of Kansas shall prohibit any duly licensed practitioner from purchasing and keeping drugs, from compounding prescriptions or from administering, supplying or dispensing to such practitioner's patients such drugs as may be fit, proper and necessary.

Except as provided in subsection (b) or (c), such drugs shall be dispensed by such practitioner and shall comply with the Kansas food, drug and cosmetic act and be subject to inspection as provided by law. (Kansas Board of Pharmacy, 2014, p. 40)

Subsection (b) references administering of medications only, and subsection (c) refers to registered nurses being able to dispense medications under the supervision of a practitioner prior to July 1, 1982.

If one could argue that APNs were “practitioners” who are licensed to practice medicine within the state and are located in a town that does not have a registered pharmacy, it may be possible to convince the state to change its regulations and statutes to allow APNs the opportunity to care for their patients the same way that physicians do, with regard to offering wholesale medications to their patients within the clinic setting.

Chapter Summary

The research definitively shows that the costs associated with medications is an undeniable factor in medication adherence. Through this meta-analysis of the published literature, collected from a wide range of various settings did reveal that among all variables cost was definitely a determining factor in medication adherence, in the treatment of both acute and chronic illnesses.

Mackey et al. (2015) showed that approximately half those in developed countries were nonadherent to their medication regimens (p.2). Also, of those with chronic illnesses, the percentage of those who were nonadherent with their medications increased to approximately 50-60% of the population (Bosworth et al., 2011, p. 2). Medication

nonadherence reduces the optimal health and wellness of individuals, increases the overall costs of treatment and increased both direct and indirect costs of medical treatment. Over half of the 3.2 billion prescriptions that are filled within the United States are not taken as prescribed (Bosworth et al., 2011, p. 2). Patient demographics, as well as SES have a great effect on medication adherence as well. Other factors that have been shown to affect medication adherence included financial burdens, lack of prescription drug coverage, and high out-of-pocket costs (Mackey et al., 2015, p. 2).

There is a clear link between the cost of medications and nonadherence. In a study by Alton et al. (2015), which showed a 77% noncompliance rate (p. 433), the two most frequently identified reasons were inability to afford medications (62.5%) and inability to understand medication labels (Alton et al., 2015, p. 433). Mishra et al. (2011) also showed a definitive link between the high cost of medications and nonadherence (p. 249). Marcum and Gellad (2012) showed cost to be the most common health-system barrier to medication; especially in polypharmacy and those who had higher cost-sharing (p. 4).

There is a great disconnect between the current regulations in place denying APNs the ability to dispense wholesale medications and what is best for the patient. When APNs are not allowed the chance to dispense wholesale medications to their patients, especially in the setting of a charitable health clinic, the ones that suffer are the patients. With regard to this project, not allowing wholesale medications into the charitable health clinic may delay the care provided to patients through pharmacotherapy, causing increased illness, increased cost, and possibly other poor outcomes to include

death. Legislation must be changed to incorporate a safety net for those uninsured and underinsured within the State of Kansas.

Within the confines of this project, Kansas Statute Chapter 65, Article 1648 could be used in the meantime to help establish wholesale medications in the charitable health/indigent clinic. The only downfall to Article 1648 is that it would require the assistance of a pharmacist. This article gives authorization for a nurse's or physician's assistant to dispense medications in the absence of the pharmacist in charge (Kansas Board of Pharmacy, 2014). Following is an excerpt of that article:

Kansas statutes Chapter 65, Article 1648 (d) (1) The state department of health and environment, any county, city-county or multicounty health department, indigent health care clinic, federally qualified health center and any private not-for-profit family planning clinic, when registered by the board, may keep drugs for the purpose of distributing drugs to patients being treated by that health department, indigent health care clinic, federally qualified health center or family planning clinic. Distribution and control of prescription medications in a health department, indigent health care clinic, federally qualified health center or family planning clinic shall be under the supervision of a pharmacist in charge. A designated registered nurse or nurses or a licensed physician assistant approved by the pharmacist in charge shall be in charge of distribution and control of drugs in the health department, indigent health care clinic, federally qualified health center or family planning clinic under the supervision of the pharmacist in charge when a pharmacist is not on the premises. Drugs supplied to patients

when a pharmacist is not on the premises shall be limited to the quantity necessary to complete a course of treatment as ordered by the practitioner supervising such treatment. (2) The board shall adopt rules and regulations relating to specific drugs to be used, to recordkeeping and to storage of drugs by a health department, indigent health care clinic, federally qualified health center or family planning clinic as are necessary for proper control of drugs. (Kansas Board of Pharmacy, 2014, p. 53)

Until the laws are changed to allow APNs the authority to dispense medications within the clinic setting without pharmacy or physician oversight, it will take a multidisciplinary team approach to ensure patient care is performed. This multidisciplinary approach will help ensure that there are no delays in the treatment of acute or chronic illnesses in the indigent population. By ensuring there is no delay in treatment, direct and indirect costs associated with patient medication nonadherence can effectively be reduced.

CHAPTER III

PLAN

Introduction

From the literature review, it has been established that cost is a substantial factor in medication adherence/nonadherence. It could be deduced that medication adherence would increase if the cost of medications decreased (Iuga & McGuire, 2014). However, there is some question as to how the cost of medications can be reduced when the prices are set by a free market enterprise, where profitability is the bottom line. The answer lies within offering medications at wholesale cost.

As shown in Table 1 of Appendix A, readers can determine that many retail medications' prices are marked up more than 1000%. These markups allow retail pharmacies to pay for their facilities, salaries and incidentals; all while making profit. Mattingly (2012) wrote a Chain Pharmacy Industry Profile which he stated that "the average cost for retail pharmacy operations is \$11.34 for each prescription [filled]. This means that in order for a pharmacy to earn income beyond the cost of doing business, it must have an average reimbursement that is greater than the cost of the drug plus \$11.34" (para. 10).

In a charitable health clinic, profits are not the driving force, so providing wholesale medications at cost passes the savings onto the patients. To help control the cost, the federal government set up a federal upper limit with regard to medications purchased through Medicaid. Some states have incorporated a maximum allowable cost (MAC) that pharmacies cannot go above; if the pharmacy pays more for the medication than the MAC, they have to take the loss associated with the sale of that medication (Mattingly, 2012, para. 9)

The information gained from this meta-analysis will be utilized to enlighten the state legislators, as well as the Kansas State Board of Pharmacy and the Kansas State Board of Nursing, on not only the problem, but also a solution that will involve changing the current legislation to allow APNs to purchase, repackage and dispense or resell wholesale medications at cost in CHCs across the State. Currently, most of the state legislators are campaigning for the upcoming primary's that will take place in August, 2016. Some of the local legislators have voiced interest in hearing more about the research and proposed solution after the primaries are finished (L. Hibbard, personal communication, July, 2016), (L. Jenkins, personal communication, July, 2016).

A policy analysis was performed on the various alternatives that could be incorporated into the CHC to see what would be the best alternative to pursue. A Practical Guide for Policy Analysis: The Eightfold Path to More Effective Problem Solving, written by Emeritus Professor Eugene Bardach was utilized to perform the policy analysis. The information from this project was placed within the eight steps and the decision to do the legislative presentation was chosen as the most viable alternative to

initiate this project. Chapter five highlights the eight step policy analysis that was used to analyze the alternatives that were available.

The proposal to the state legislators was simple; take out the terminology referring to “mid-level practitioners,” incorporate APNs into the classification of practitioners, this would allow APNs to have the same privileges afforded to the physicians with regard to the purchasing, repackaging and dispensing or reselling of wholesale medications to their patients. During the process of this project, a simple cost analysis was performed to see whether or not it would be feasible to incorporate wholesale medications into the CHC in rural, southeast Kansas. Following is a summary of that feasibility study, which will be incorporated into the presentation to the state legislators.

Market Analysis Research

The current and projected demand for medications across the nation is enormous. With acute and chronic illnesses come the medications to treat those illnesses. Approximately 3.2 billion prescriptions are filled each year within the United States, and approximately 50%, or 1.6 billion, of these prescriptions are not taken as prescribed (Bosworth et al., 2011, p. 2). Common sense affirms that if someone can get the same product for less than one tenth of the cost, they will.

The target market will be those individuals that are uninsured and fall below 200% of the current poverty level. The services will be available to all individuals that utilize the CHC, but in order to avoid taking business away from nearby pharmacies, individuals with insurance will be asked to utilize retail pharmacies. Exceptions will be

made for those individuals who cannot afford the medications from a nearby pharmacy if a delay in treatment would result in rapid deterioration of their current condition.

Currently the CHC is only open on Wednesdays from 1:00 p.m. to 6:00 p.m. The CHC averages 25 patients per half day of operation. The current demand may seem not to justify the initial startup cost, but being able to ensure patients have access to affordable medications for the treatment of chronic illness will be justified through decreasing overall costs associated with medication nonadherence across the board. Initially only small quantities of the most commonly prescribed medications will be purchased. Then, as demand increases, the supply will be increased as well. By starting slow, adjustments can be made in a controlled environment instead of trying to do it when business picks up.

Competition in the area will not be a factor. This service is not being initiated to compete with the nearby pharmacies; it is being established as a safety net for those individuals that cannot afford retail prices at the nearby pharmacies, or those individuals who do not have transportation to the nearest retail pharmacies eight miles away. At the current capacity of the CHC, nearby pharmacies should not be impacted by the initiation of this program.

The location that was selected for this program will help this program to succeed. The clinic is centrally located between four larger communities; individuals travel up to 60 miles to utilize the clinic. At this current time the CHC is housed within a local church, but property has been acquired to build a clinic on in the future. Also the

community where the clinic is located does not have local access to a pharmacy, so this will be an added service for the community.

Key Organizational and Technological Issues

The current organizational structure of the clinic is that it falls under the 501(c)(3) of the cooperating church. Once the new clinic building is completed, the clinic will apply for its own 501(c)(3). The APN provider and receptionist hold positions on the church's Board of Directors to represent the clinic.

The CHC is run by an all-volunteer staff. The current staff is made up of a receptionist, an LPN as office nurse, and a nurse practitioner as primary provider. Under the current state laws, the addition of a pharmacist to the staff is needed because current laws within the state of Kansas do not allow for a nurse practitioner to purchase, repack or redistribute medications without pharmacy oversight. Recruitment for a pharmacist and pharmacy technician to join the all-volunteer staff will be the first step in initiating this program. If a volunteer pharmacist is not found, the next step will be contracting either a local pharmacist or a company that offers ePharmacy oversight. The clinic operates on donation only, so pricing on contracting pharmacy or ePharmacy support will have to be added to the current overhead cost of running the clinic.

The clinic has an electronic medical record (EMR) system that was initially set up for concierge medicine (subscription fee based, medical care practice model). The EMR has a module for inventorying wholesale medications and producing labels based on the medication information within the program. A label printer will have to be purchased which would be a one-time expense. Afterward, labels and pill bottles will need to be

purchased on a routine basis. Cost for the packaging and labels will be added to the price of the medication so that the program sustains itself.

If ePharmacy services are implemented, the equipment for these services will need to be purchased as well. Currently, the CHC has the finances available to initiate the program, but maintaining the program may be a limiting factor. Grant funding is a way to help sustain this program and possibly to buy the equipment needed for the program.

Financial Issues

Currently, while under the covering of the church, 10% of the donations go towards utilities and towards the church secretary handling the finances of the clinic. The clinic's only operating expenses are approximately \$900 per year to pay for the provider's part-time malpractice insurance and \$60 per month for telephone and fax service, which the provider pays. The clinic has substantial funds available in its account to sustain the current program at its current capacity. Once wholesale medications are incorporated, a financial audit will need to be performed so that the budget can be adjusted accordingly for the new expenses associated with this project.

Initially, the clinic will stock some of the most frequent medications the provider prescribes. These will include classes of medications such as antibiotics, antihypertensives, antiemetics, muscle relaxers, anti-inflammatories and cholesterol medications. The initial order will be small enough to ensure that medications will be used before they expire and therefore will not have to be destroyed.

Looking to the future, a stand-alone clinic must be built. The land has already been purchased and donated to the clinic so when the funds become available, the clinic

will be built in stages. One area that will be crucial for the development and continued support of this program is a small room that can be devoted to storing, repackaging and dispensing or reselling the wholesale medication storage room. Depending if grant funding comes in, or not, this project could take a few months to a few years to complete.

Chapter Summary

Throughout this chapter different areas were addressed. First, the plan for presenting this project to attempt to get legislation changed were discussed. Also, items from the feasibility study were discussed including market analysis research, key organizational and technological issues, and financial issues. As far as being a feasible undertaking, the answer lies in the cost of the pharmacist support. If the pharmacist comes on as a volunteer, the program is highly feasible, but as the price for this service increases, the feasibility of this program decreases.

Reasons why retail pharmacies charge more than wholesale drug prices were discussed, and it was determined that the average cost to operate a retail pharmacy was \$11.34 per prescription filled (Mattingly, 2012). Table 1 in the Appendix A shows that many of the most commonly prescribed prescriptions can be had for pennies on the dollar at wholesale prices, and when \$11.34 is added on to each one, price markups near 4,000-5,000%. Whereas profitability is necessary in the retail pharmaceutical industry, this program is about affordability and will be offered to the indigent population, by a nonprofit organization. There may be a slight markup for packaging, but it will not be the \$11.34 per prescription charged by the retail pharmacies.

CHAPTER IV

LEGISLATIVE PRESENTATION

Introduction

As part of this project, a legislative presentation was scheduled. It was imperative that this project be placed in motion so that hopefully legislation change will come. Information gathered in the review of literature was used to validate the argument that cost was a definitive factor in medication adherence in all populations around the world. Building on that, current state laws were reviewed to show APN's do not have the authority to repackage wholesale medications. Various alternatives were discussed at this presentation, but implementing legislation change was the focus.

Legislative Selection

Congresswoman Lynn Jenkins was chosen to be the main guest at this presentation. Congresswoman Jenkins has a long history of supporting rural healthcare. Also, Congresswoman Jenkins is a member of the United States House of Representatives and represents the State of Kansas at the national level. Involving Congresswoman Jenkins in this presentation meant that she would gain direct knowledge of the problems highlighted in this project and be able to convey that knowledge to a national, congressional audience. Other state-level senators and representatives were also

invited to the presentation, but due to business or personal conflicts could not attend. A copy of the letter sent to Congresswoman Jenkins has been included in the Appendix A; Figure 7.

Presentation Layout

The presentation was laid out in a format that would easily be followed. First a review of the literature was highlighted to show that cost was a large barrier to medication adherence in multiple populations. Information highlighted in this portion of the presentation included deaths attributed each year to medication nonadherence, direct and indirect costs associated with medication nonadherence, and the percent of the population that was nonadherent in regards to taking their medications.

Next, the presentation focused on the significance of the problem. Theis (2013) was quoted during the presentation to show that 1.2 billion people around the world were living in extreme poverty. With medication cost being the focus of this project, showing the high number of people living in poverty adds merit to the idea of incorporating wholesale medications into the charitable healthcare setting.

Various ways in which people can be nonadherent with their medications were discussed next. When people cannot afford their medications, they may ignore medical advice regarding dosages. The following are examples of how individuals may be nonadherent with their medication regimens: 1) if they are scheduled to take one pill daily they might take it every other day instead, 2) if a medication is supposed to be taken three times daily, they may only take it twice a day, and 3) they may only take the medication when they identify symptoms caused by not taking the medication, then the

discontinue the medication when the symptoms resolve. Any variation to the written instruction from the provider is classified as being nonadherent with the medication.

After describing the problem and showing the significance of the problem, the focus shifted to the purpose of this project. The purpose of this project was to propose legislative change to allow NPs to purchase, repackage and dispense or resell wholesale medications. The specific legislation to be changed is focused on definitions used to differentiate between practitioners and mid-level practitioners. Kansas statutes chapters 65 and 68 defined practitioner as “a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist or scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug” (Kansas Board of Pharmacy, 2014, p.26). The proposed legislative change would drop the definition of mid-level practitioner and change the wording to the definition of practitioner as follows: a person licensed to practice medicine and/or surgery, with or without a collaborating agreement as determined by state law. If this proposed change to drop the definition of mid-level practitioner and change the definition of practitioner, APNs would achieve authority under K.S.A. 65-1635 to purchase, repackage and dispense or resell wholesale medications.

To validate the cost savings of providing wholesale medications in a charitable health clinic setting a table was presented comparing costs of medications with regard to retail and wholesale pricing. Medications that were commonly prescribed in the charitable health clinic were depicted in this table. This table showed that retail prices

were more than 1000% of wholesale prices in most instances. The slide presentation for this legislation change review has been included in the Appendix A; Table 3.

The Presentation

On October 3, 2016, at 10:30 AM, a delegation from Kansas's second Congressional District, to include the U.S. Representative from Kansas, Congresswoman Lynn Jenkins, met at VVCHC in Altoona, Kansas. Formal introductions were made of persons in attendance. As mentioned before Congresswoman Lynn Jenkins was in attendance with delegates from her office, including William Roe, District Director, and Stephanie Lightle, District Representative. Chief executive officers from two local hospitals were in attendance as well: Dennis Shelby, CEO of Wilson Medical Center in Neodesha, Kansas and Nancy McKenzie, CEO of Greenwood County Hospital in Eureka, Kansas. Dr. Jennifer Harris Ph.D., APRN represented Pittsburg State University, as the advisor to the author's DNP scholarly project. Along with these distinguished guests were representatives from three local area newspapers and an area TV news station.

The presentation garnered support from Congresswoman Jenkins and her delegates, who were in favor of elevating this proposal to legislative change further up in the state government. William Roe stated that he would attempt to connect the author to Kansas lawmakers prior to the next legislative session. Questions from the 2nd Congressional District representatives, as well as the CEOs from the area hospitals were fielded upon completion of the presentation. The presentation concluded with a tour of the facility.

Presentation Results

As a result of the presentation to 2nd Congressional District's Congresswoman, Lynn Jenkins, the importance of the proposed legislative change has Congressional backing, thereby validating the proposal. If the Congresswoman had not been in a position that supported rural health, she may have not elevated this proposal to the next level within the state government. Due to her support of rural health care and comments made during her visit, this legislative change proposal could have a congressional voice at both the state and federal level. Also, when the legislative change proposal is presented to state lawmakers, hopefully support will be garnered. The change that will be sought is to have the current legislation changed in the future to allow APNs to be included in the definition of practitioner, thus giving APNs the lawful ability to purchase, repackage and dispense or resell wholesale medications within the state of Kansas.

After the presentation and questions, Congresswoman Jenkins approached the author for professional insight. Congresswoman Lynn Jenkins had just returned from Washington, D.C. where she proposed legislative change to the Social Security Act to be vetted prior to being resubmitted during the next legislative session in January, 2017. The proposed legislative exchange would include APNs and PAs as practitioners. She asked the author if he would be willing to look at her proposed legislation and make any additional changes as needed, prior to being resubmitted. Without foreknowledge of the Congresswoman's actions, the legislation changes proposed in this project could actually come to fruition in the future.

CHAPTER V

POLICY ANALYSIS

Introduction

Eugene Bardach is an Emeritus Professor of Public Policy at the Goldman School of Public Policy, at the University of California Berkley. He wrote a book on how to conduct an effective policy analysis titled: *A Practical Guide for Policy Analysis: The Eightfold Path to More Effective Problem Solving* (Holquist, 2013). As stated in the title, Professor Bardach broke down policy analysis into eight different steps. Those steps were utilized to analyze the policies that inhibit APNs from being able to purchase, repackage, and dispense or resell wholesale medications. Within the policy analysis, alternatives were brainstormed and evaluated for not only plausibility but also for effectiveness, reliability and ease of implementation. After the analysis was completed it was evident that legislation change would be incorporated into the action plan of implementing this project into rural CHCs throughout the state.

Based on current definitions of practitioners and midlevel practitioners, APNs are not authorized to purchase, repackage and dispense or resell wholesale medications. This chapter was dedicated to analyzing the current definitions and policies using Professor Bardach's eight steps, these steps will be covered in the following sections of this

chapter. This policy analysis made a refutable argument for changing definitions in the current policy and that by doing so APNs will hopefully inherit the same rights as physicians when it comes to the purchasing, repackaging and dispensing/reselling of wholesale medications in rural CHCs.

Define the Problem

The problems associated with this project are twofold. The primary problem is medication nonadherence related to the cost associated with purchasing retail medications. The second problem is that APNs are unable to purchase, repackage and dispense or resell wholesale medications to decrease the cost burden associated with the purchasing of medications for both acute and chronic illnesses.

Assemble Some Evidence - Observations

As outlined in the review of literature, medication costs are a barrier to medication adherence around the world. There are various reasons individuals may be noncompliant, but per Marcum and Gellad (2012) “The most common health-system barrier to medication adherence is cost” (p. 4). Mackey et al. (2015) showed that approximately half of those in developed countries were nonadherent to their medication regimens (p.2). Bosworth et al. (2011) showed that approximately 1.6 billion prescriptions filled within the United States each year are not taken as prescribed (p. 2). Alton et al. (2015), showed 62.5% of individuals they surveyed claimed inability to afford medications as their reason for noncompliance (p. 433).

As far as APNs being able to purchase, repackage and dispense or resell wholesale medications, the problem lies in the purchasing and repackaging of wholesale

medications without pharmacy oversight. Advanced Practice Nurses are classified as mid-level practitioners in the state statutes, therefore they are not afforded the same opportunities as practitioners (“a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist or scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug” (Kansas Board of Pharmacy, 2014, p.26). If there were no differentiation between mid-level practitioners and practitioners, this would not be an issue and there would be no need for legislative change to incorporate wholesale medications in rural CHCs that are run by APNs.

Construct the Alternatives – Future Implications

There are many different alternatives that can be initiated, but all of the alternatives hinge on oversight from a practitioner (physician) or a pharmacist. By utilizing a practitioner to initiate this project it would necessitate that the practitioner actually goes to the clinic in their off hours to repackage the medications themselves. As previously discussed, many times the collaborating practitioners do not live in the same locale as the CHCs, so this would take away from their personal time and some practitioners may be unwilling to do this. Possibly searching out a practitioner that already has this project established in their personal clinic could be an alternative as well. If the practitioner would donate the cost of repackaging or do the repackaging themselves for a nominal fee, it could make the process sustainable while keeping the cost of the wholesale medications low enough that the individuals who utilize the services of the CHC would be able to afford.

Another alternative would be to incorporate a pharmacist into the CHC. Unless one could be found to volunteer for this specific role, an added cost to the CHC would result. If a pharmacist could not be found in the vicinity of the CHC then there are telepharmacists that could be employed by the CHC, but this would also require the CHC to find a pharmacy technician to volunteer or hire to assist with the repackaging of the medications. In the case of the CHC listed in this project, it is run by donation only and this option with an added expense may not be sustainable.

And finally, purchasing medications in a unit dose packing would be another option to explore. With this option the decreased cost of purchasing medications in bulk would be somewhat eliminated, thus increasing the cost of purchasing wholesale medications by the CHC and patient's alike. When cost is the primary reason for incorporating this project into a CHC, this may not be the ideal alternative.

Select the Evaluation Criteria

Evaluation criteria for this project began with the scholarly project proposal. During this phase the review of the literature was utilized to enlighten the project committee of the problem that exists with the cost of retail medications and how it increases patient's medication nonadherence. Also, the committee was shown the cost difference of medications as they relate to wholesale versus retail pricing. By gaining approval from the committee to proceed with the project, the author's opinion of this project was validated.

The Health Belief Model (HBM) was chosen to evaluate and provide a framework for this study and to address the factors associated with nonadherence. The HBM was

written in an attempt to understand why people did not undergo preventative care for the early detection of “asymptomatic disease” along with patient response to medication adherence (Janz & Becker, 1984, p. 2). The proposed legislation change of this project could address the perceived barrier of medication cost by the individual thus effecting the overall outcome of the patient.

A legislative presentation was also used as a measure to evaluate the project. The information was presented to Congresswoman Lynn Jenkins and the staff that accompanied her to the presentation. Congresswoman Lynn Jenkins stated that this project was a great idea and she would get the author in contact with her state senator to further advance the proposal to change legislation regarding this project (L. Jenkins, personal communications, October 3, 2016).

Further evaluation will be performed during the course of this scholarly project and beyond. The project defense will be utilized to evaluate the legitimacy of this project in writing. Advancing the proposed legislative change of including APNs into the definition of practitioner through the state legislature will add another layer of evaluation from a legislative perspective. Finally initiating the wholesale medications into the CHC, regardless of which method is used in compliance with applicable law, will be the final evaluation method used for this project.

Project the Outcomes – Health Policy/Practice Implications

During this phase of the policy analysis, each alternative will be analyzed to address the specifics of this project. This step could possibly help eliminate alternatives

that would not produce the desired effect. Even though it may not determine the most effective alternative, it will narrow down the alternatives available

The primary objective for this project is to propose legislative change, to allow APNs to purchase, repackage and dispense or resell also medications. As a means to an end, this alternative would be the gold standard to incorporating wholesale medications in a NP run, rural charitable health clinic. By getting the current legislation changed there would be no barrier to incorporating this project.

The next option would be to incorporate a pharmacist on staff at the charitable health clinic to perform the function of pharmacy oversight. This alternative could possibly increase costs associated with running a charitable health clinic, unless the pharmacist would volunteer their services to the clinic. Whether this would be a nearby pharmacist or telepharmacist could affect the overall cost associated with their service. Being that the clinic runs on donation only, this cost could inhibit the clinic from incorporating this project into existence.

The final alternative discussed would be to find a practice that already has this project incorporated. Again, there may be cost associated with that facility's employee/s repackaging the wholesale medications unless those individuals volunteered their services to the clinic. Depending on the cost associated with this alternative, it could be a better option than hiring a pharmacist, but again if legislation is passed to allow APNs to purchase, repackage and dispense or resell wholesale medications there would be no additional cost.

Confront the Trade-Offs

When we confront the trade-offs, what we are ultimately doing is evaluating the cost/benefit ratio. The information that was obtained through the alternative analysis is reviewed and a summary statement is developed for each alternative. The summary statements will consist of two to three sentences that verbalize the actual cost of the alternative, as well as the benefit.

With the initial alternative listed above, legislation change would ultimately cost time and effort. Educating members of the state legislation would be key when the proposed legislative change came before them for vote. This would ensure each one knew what was at stake. The benefit would be that APNs would have the authority to purchase, repackage and dispense or resell wholesale medications.

The cost of the next alternative of recruiting a pharmacist would also cost time and effort, but it could also cost a substantial financial obligation; unless one could be found that would be willing to donate their time. The benefit of this alternative would be having additional staff so that one individual would not be responsible for the entire project. Another benefit would be not having to expand the time and energy to educate members of the state legislation.

The cost involved with finding a facility where this project is incorporated would be minimal time and effort to find someone who already has this project up and going. There may be additional costs associated with having individuals from another facility repackage the wholesale medications, unless someone was found who was willing to donate their time and effort. The benefit to this alternative if someone was found who

would donate their time and services, would be saving additional expenses by buying in bulk instead of unit doses. Also, another benefit would be that the repackaged medications would already be labeled thus saving the additional time and resources to do that step.

Tell Your Story

During this phase of the policy analysis it is essential to “consider the three types of audiences, (1) those that will spend 30 seconds reading your analysis, (2) those who will spend three minutes, and (3) those that will spend 30 minutes” (Holquist, 2013). These steps could also be incorporated into various private and corporate level verbal presentations, in various settings. Within the confines of this project, the Congresswoman who attended the presentation allowed for 45 minutes at the facility. In preparing for this meeting 20 minutes was set aside for the actual presentation. The rest of the time was to tour the facility, as well as answer any specific questions raised during the presentation.

Decide – Cost Limitation

During this step of the policy analysis we decide on which alternative is most appropriate for the project. As it has been mentioned in previous times, cost is a definite limiting factor for this project. Above, the alternatives have been laid out and due to cost the legislation change would be the most cost-effective alternative to implementing this project. If this legislation change does not pass a different alternative will be sought. Which alternative would be initiated would depend on the costs associated to implementing that alternative.

Conclusion

Medication costs continue to be an obstacle to patient medication adherence in the treatment of acute and chronic illnesses. “Prescription medication costs increase financial burden, often leading individuals to engage in intentional nonadherence” (Martin, Shreffler, Schoster, & Callahan, 2012, p. 236). It could be deduced that medication adherence would increase if the cost of medications decreased (Iuga & McGuire, 2014). The information gained from through this study can be used to educate state legislators, the Kansas State Board of Pharmacy, and the Kansas State Board of Nursing in an effort to define the problem and identify a solution that may involve changing current legislation in an effort to allow APNs to purchase, repack and dispense or resell wholesale medications at cost in CHCs across the State. By offering medications at wholesale cost, providers can determine if an increase in medication adherence is present and supported by the reduced costs of purchasing medications. This project proposes a legislative change that would amend the definition of practitioner would allow NPs to purchase, repack and dispense or resell wholesale medications.

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APPENDIX

APPENDIX A

Figures and Tables

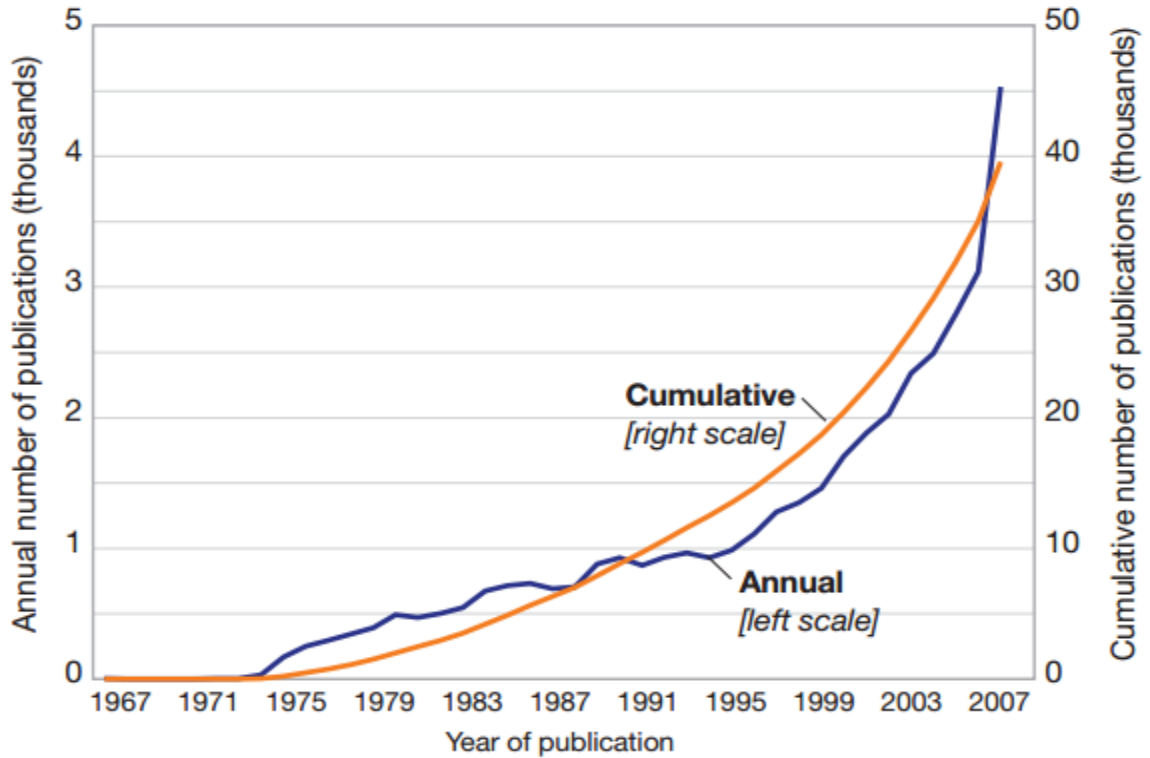


Figure 1. Number of publications on medication adherence over time (Goldberg, DeKoven, Schabert, & Coyle, 2009)

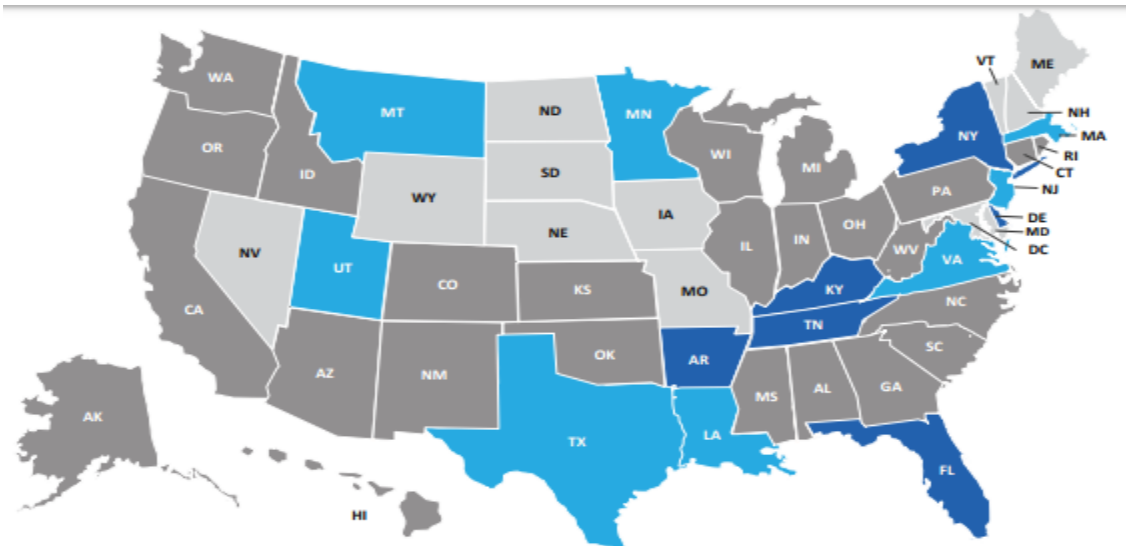


Figure 2. Physician Dispensing Across the Country (Optum, 2015, p. 1)
Note: Light Blue – Legal Restrictions; Light Gray – Nonrestrictive; Dark Gray – Reimbursement Restrictions; Dark Blue Very Restrictive

Non-Pharmacist Dispensing in the US

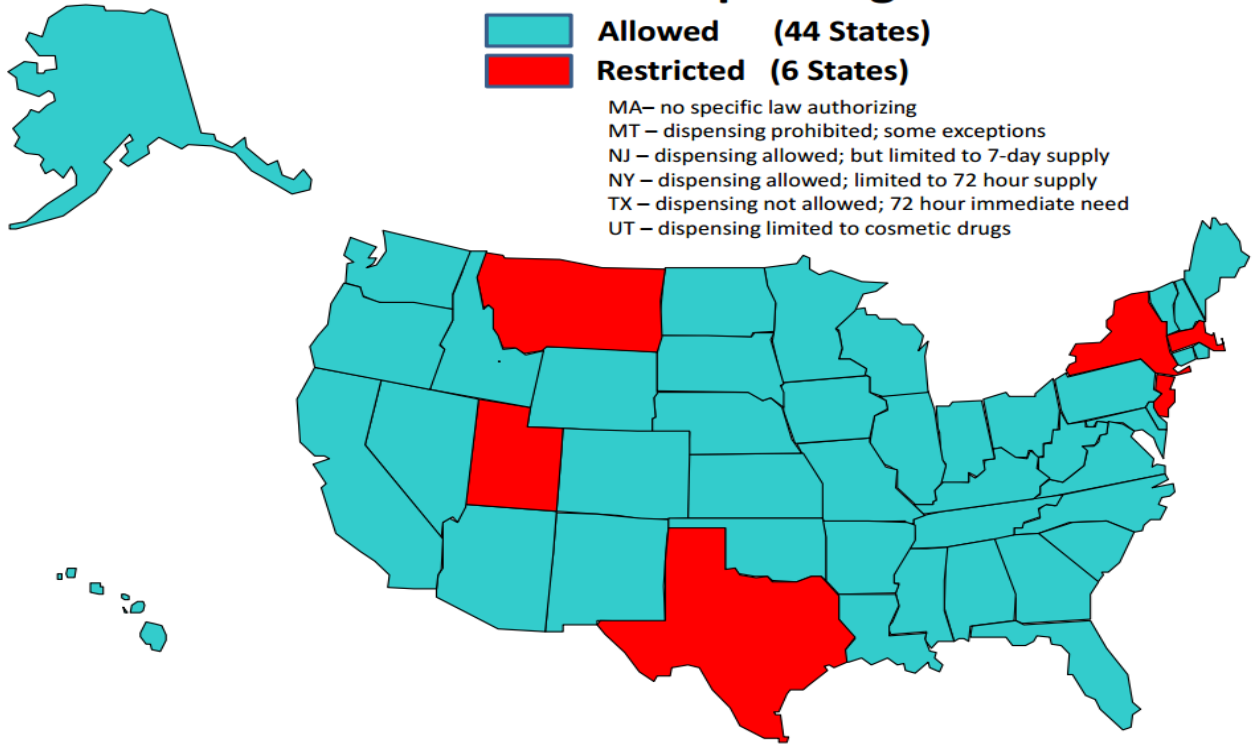


Figure 3. Non Pharmacist Dispensing in the U.S. (Munger, 2014, p. 9)

PRACTITIONERS QUALIFIED TO DISPENSE

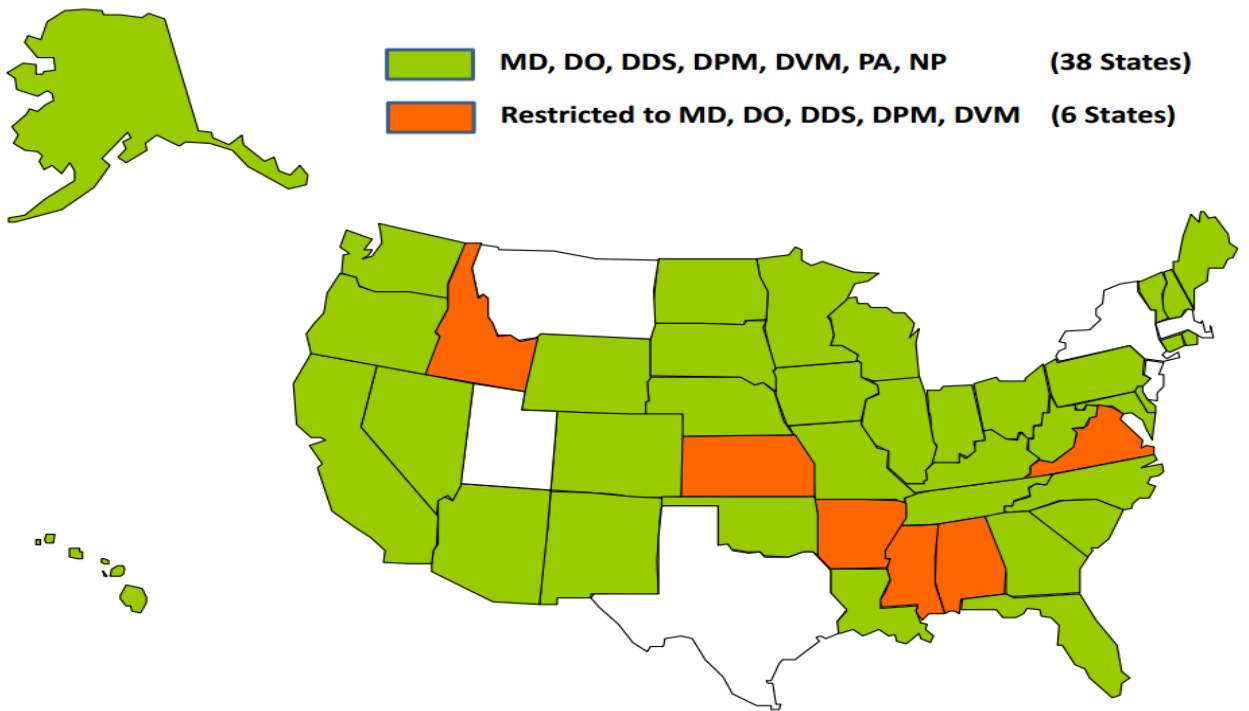


Figure 4. Practitioners Qualified to Dispense (Munger, 2014, p. 10)

DISPENSING PRACTITIONER REGISTRATION

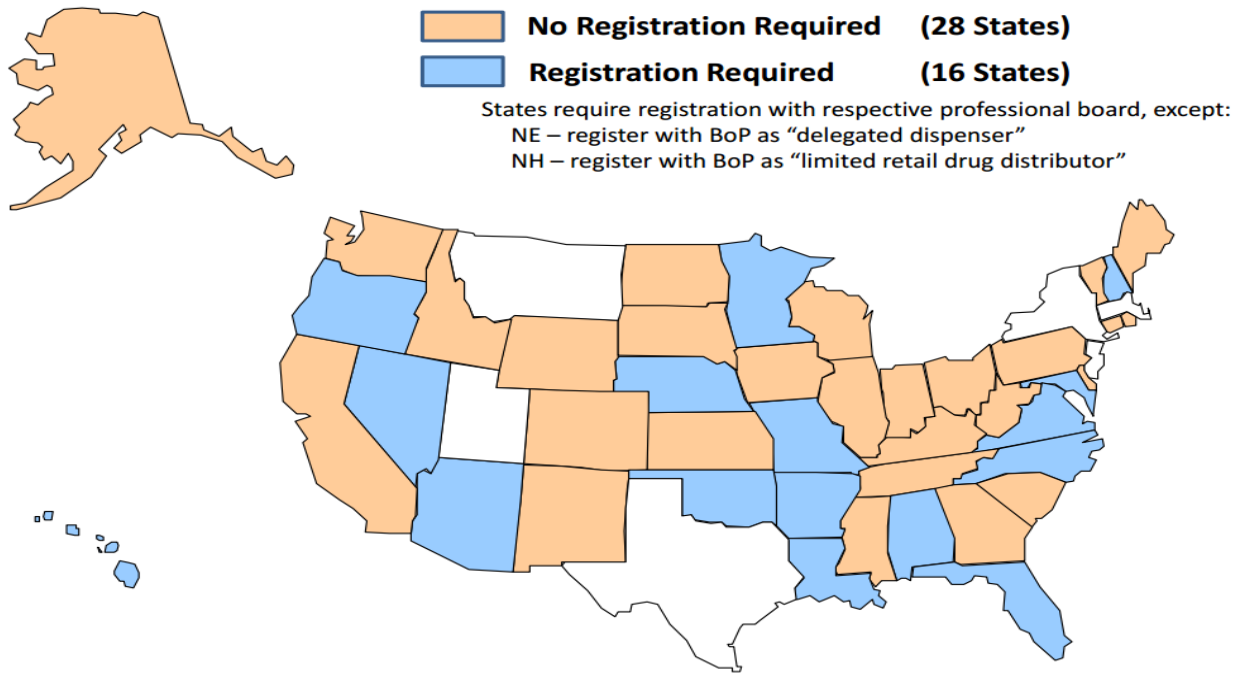


Figure 5. Dispensing Practitioner Registration (Munger, 2014, p. 11)

COMPLIANCE WITH PHARMACY REGULATIONS WHEN NON-PHARMACIST DISPENSING

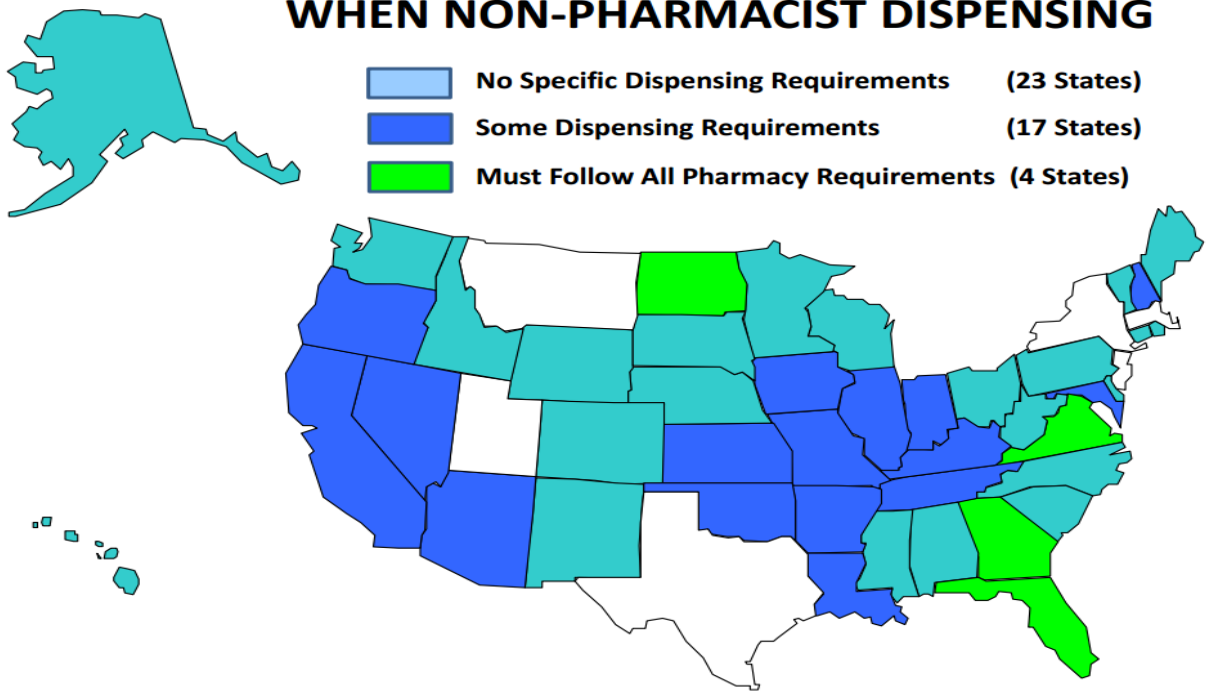


Figure 6. Compliance with Pharmacy Regulations When Non-Pharmacist Dispensing (Munger, 2014, p. 12)

Figure 7. Invitation Letter to Congresswoman Lynn Jenkins

August 23, 2016

Dear Congresswoman Jenkins:

My name is Shawn Raymond and I am a Nurse Practitioner in rural southeast Kansas. I am completing a Doctor of Nursing Practice (DNP) degree at Pittsburg State University (inaugural class). Currently, I am working on a DNP Scholarly Project as part of the requirements for the degree program. The project goal is to educate elected government officials with the potential for legislative changes that would allow nurse practitioners to purchase wholesale medications, then repackage and dispense these medications to the uninsured/underinsured populations within rural communities across the state of Kansas.

After graduating PSU in 2013 with a Master of Science in Nursing degree and becoming certified as a Nurse Practitioner, I petitioned and received approval from the Kansas Department of Health and Environment to open an Indigent Healthcare Clinic. In October 2014, the Charitable Health Clinic (free clinic) was opened in my hometown, Altoona, KS. Currently we have approximately 450 people from a 60-mile radius that utilize the services. A review of the literature shows that cost is a major factor to medication adherence in the treatment of both acute and chronic illness and adds approximately \$100-\$300 billion dollars each year in direct and indirect costs (Bosworth et al., 2011, American Heart Journal). By being able to offer the uninsured/underinsured medications at wholesale cost, the hope is to increase medication adherence in these populations and be able to effectively increase the overall health and wellness of these individuals.

The research of a wholesale supplier's price list, as compared to retail pricing found retail markups up to and greater than 1000%. The state of Kansas currently allows physicians to purchase, repackage and dispense wholesale medications without pharmacy oversight. Since Advanced Practice Nurses are often the available providers in rural communities, it would be desirable to see legislation enacted that would allow nurse practitioners to be able to do the same as physicians, in rural charitable health clinics for the uninsured/underinsured populations that cannot afford the retail costs when purchasing medications.

Currently, I am working to set up meetings with other state officials. As I graduate in December 2016, it would be beneficial to visit with you more in depth about this issue if available anytime between now and the end of September. I can travel anywhere for a meeting, but would be honored to meet in Altoona, KS so you could view the facilities and programs that are offered to the community through the Charitable Health Clinic.

Sincerely,

Shawn Raymond, MSN, APRN, NP-C
Verdigris Valley Charitable Health Clinic
215 E. 13th St.
Altoona, KS 66710
620-xxx-xxxx (Office - Wednesdays 1-6pm)
620-xxx-xxxx (Cell)
Email: sraymond@xxxx.org

Table 1. Wholesale Medication Cost Analysis (Andamed.com and GoodRx.com, 2015)

Medication	Quantity	Andameds Price	Price per pill/ box	Price per prescribed course of medication (5, 10, 30 days) all prices rounded up to the next whole cent.	GoodRx.Com Prices	Savings
Metoprolol Tartrate 25mg	1000 ea.	\$18.55	\$0.01855	\$1.12 BID dosing/30 days	\$4.00	\$2.88 month
Zithromax 250mg Box of 6 (Zpak)	3 box	\$5.64	\$1.88 / box	\$1.88 per box/ 5 day Tx	\$9.95	\$8.07/box
Bactrim DS 800/160mg	500 ea.	\$29.15	\$0.0583	\$1.17 BID dosing/10days	\$4.00	\$2.83
Lisinopril/HCTZ 10/12.5	500 ea.	\$14.85	\$0.0297	\$0.90 Daily dosing/30 days	\$4.00	\$3.10
Amlodipine 10mg	1000 ea.	\$18.15	\$0.01815	\$0.55 Daily dosing/30 days	\$6.94	\$6.39
Losartan 100mg	1000 ea.	\$68.00	\$0.068	\$2.04 Daily dosing/30 days	\$8.53	\$6.49
Metformin 1000mg	1000 ea.	\$24.84	\$0.02484	\$1.50 BID dosing/30 days	\$4.00	\$2.50
HCTZ 25mg	1000 ea.	\$9.98	\$0.00998	\$0.30 Daily dosing/30 days	\$4.00	\$3.70

Table 2. Verdigris Valley Charitable Health Clinic Logic Model

Program: Verdigris Valley Charitable Health Clinic Logic Model
Situation: Doctor of Nursing Practice (DNP) Capstone Project, 2015-2016:
 Attempting to incorporate wholesale medications into a Nurse Practitioner (NP) led, Rural, Charitable Health Clinic (CHC)

Inputs	Outputs		Outcomes -- Impact		
	Activities	Participation	Short	Medium	Long
Kansas Law	Determines legality of the situation	Sets limits and boundaries on what actions are allowable within the State.	See what laws relate to the project.	Establish program in CHC within the established laws.	Petition the State Legislation for changes in the law to ease implementation of the project
Kansas State Board of Nursing (KSBN)	Determines the scope of practice of Nurse Practitioners within the State.	Oversight on legality of project within the scope of the States Nurse Practice Act.	Already stated there was nothing within the States Nurse Practice Act that would prohibit the project.	Continued support for the project.	
Kansas State Board of Pharmacy (KSBP)	Regulates the repackaging and dispensing of medications within the State.	Oversight on legality of project with the laws pertaining to repackaging and dispensing medications within the State.	KSBP has already stated that they would not authorize an NP to repack medications within the State.	Figure out what steps need to be taken to incorporate the project within the CHC.	Petition KSBP for changes in the law to ease implementation of the program in other CHCs within the State.
Pittsburg State University's Irene Ransom School of Nursing	Approval and oversight of the project.	Guidance and oversight of the project, peer review project to ensure compliance with evidence based research.	Approval of the project has been approved by the DNP Advisor and Committee.	Validate project through peer review.	Approve Capstone Project when author defends.
Collaborating Physician	Approval authority of the NPs actions and duties, as overseeing Physician.	Perform any and all tasks necessary for incorporating project into CHC.	Physician has agreed to oversee the program and assist in all capacities needed.	Continued support for the project.	
CHC Budget	Finance the project.	Fund the project	Adequate fund in the account to initiate the project within the CHC	Determine what funds will be necessary to maintain the program in the future.	Initiate a foundation for VVCHC and apply for grant or funding initiatives to help finance the clinic in the future.
Volunteers at the CHC	Perform tasks within the guidelines established in the CHCs protocols	Function within guidelines with regards to logging, handling and storing of medications, within the CHC.	Volunteers have agreed to take on the project to benefit the individuals who utilize the CHC as their source of primary care.	Possibly seek out a Pharmacist and Pharmacy Technician who would donate their time to this worthy, charitable cause.	Continued support in the future.

Assumptions: There will be a work-around that will meet the KSBPs policy on the repackaging and dispensing of wholesale medications within the State of Kansas, within the setting of a CHC.

External Factors: Kansas Law, KSBP, KSBN, Collaborating Physician, VVCHC Budget.

Table 3. Legislative Presentation, October 3, 2017, VVCHC, Altoona, Kansas

"Decreasing Cost Associated Medication Nonadherence"

A Project of Applied Research Submitted to the Graduate School in Partial Fulfillment of the Requirements for the Degree of Doctor of Nursing Practice

Dora Szymanski, MSN, RN-BC
Pharmacist, UMKC
New Director of Pharmacy
October 3, 2017

Significance

- > 1.2 billion people around the world live in extreme poverty (Theis, 2013).
- > Individuals are forced to extend their medications by:
 - Skipping doses
 - Taking reduced doses (cutting pills in half or quarters)
 - Not taking at all
 - Ordering from online pharmacies
 - Stealing medications

Definitions

- > "Practitioner" means a person licensed to practice medicine and surgery. ... (Kansas Board of Pharmacy, 2014, p.16).
- > "Mid-level practitioner" means an advanced practice registered nurse ... who has authority to prescribe drugs pursuant to a written protocol with a responsible physician ... or a physician assistant ... who has authority to prescribe drugs pursuant to a written protocol with a responsible supervising physician. ... (Kansas Board of Pharmacy, 2014, p. 14-15).

References

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Theis, S. (2013). ...
U.S. Kansas Board of Pharmacy. (2014). ...

Description of the Clinical Problem

- > Medication Costs are barriers to adherence
- > Approx. 125,000 deaths in the U.S. each year, attributed to medication nonadherence (Bosworth et al., 2011, p. 2).
- > Total cost estimates for nonadherence, \$ 100- \$300 billion each year direct and indirect costs (Bosworth et al., 2011, p. 2).

Purpose

- > Propose legislative change
- > Incorporate wholesale medications into NP-run charitable health clinics
- > Increase medication adherence
- > Reduce cost associated with purchasing medications
- > Increase wellness in both acute/chronic illness

K.S.A. 65-1635

- > "Dispensing and administering of drugs by duly licensed practitioners, ... (a) Nothing contained in the pharmacy act of the state of Kansas shall prohibit any duly licensed practitioner from purchasing one hearing drug, from compounding prescriptions or from administering, supplying or dispensing to such practitioner's patients such drugs as may be fit, proper and necessary. Except as provided in subsection (a) or (c), such drugs shall be dispensed by such practitioner and shall comply with the Kansas food, drug and cosmetic act and be subject to inspection as provided by law" (Kansas Board of Pharmacy, 2014, p. 40).

REVIEW OF THE LITERATURE

- > WHO reported medication adherence for those with chronic illnesses only averaged 50% in developed countries (Nickey et al., 2012, p.2).
- > Approx. 3.2 billion prescriptions filled within the U.S. each year; 1.6 billion not taken as prescribed (Bosworth et al., 2011, p. 2).
- > Populations affected
 - Uninsured/underinsured.
 - Chronically ill/elderly.
 - Indigent supplemental population.
 - All populations affected due to increased cost of care.

Current Legislation

- > Kansas Statutes Chapters 65 and 68 contain definitions that exclude APNs and PAs from the definition of Practitioners and labels them as Mid-Level Practitioners.

Wholesale vs Retail Price Comparison

Medication	Wholesale Price	Retail Price	Price per patient (wholesale price divided by 30, plus 10% dispensing fee)	Wholesale Price Savings
Atorvastatin 20mg Tablet	\$0.01	\$0.07	\$0.02	\$0.05
Clonidine 0.1mg Tablet	\$0.01	\$0.07	\$0.02	\$0.05
Levamisole 500mg Tablet	\$0.01	\$0.07	\$0.02	\$0.05
Levamisole 500mg Tablet	\$0.01	\$0.07	\$0.02	\$0.05
Levamisole 500mg Tablet	\$0.01	\$0.07	\$0.02	\$0.05
Levamisole 500mg Tablet	\$0.01	\$0.07	\$0.02	\$0.05
Levamisole 500mg Tablet	\$0.01	\$0.07	\$0.02	\$0.05
Levamisole 500mg Tablet	\$0.01	\$0.07	\$0.02	\$0.05
Levamisole 500mg Tablet	\$0.01	\$0.07	\$0.02	\$0.05
Levamisole 500mg Tablet	\$0.01	\$0.07	\$0.02	\$0.05