Clinical and Economic Outcomes of Texas Medicaid Medication Therapy Management (MTM) Pilot: Asthma and COPD

Proposal
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BACKGROUND AND SIGNIFICANCE:
Pursuant to the 2012-13 General Appropriations Act (Article II, Health and Human Services Commission (HHSC), Rider 49, H.B. 1, 82nd Legislature, Regular Session, 2011), HHSC contracted with the Texas Pharmacy Foundation (TPF) and The University of Texas College of Pharmacy (UT-COP) to implement a medication therapy management pilot program focusing on high risk patients with hypertension.

Through the Texas Medicaid MTM Pilot, pharmacists identified and intervened with patients who had hypertension and were on 4 or more chronic medications. Interim results (after five months) showed that pharmacists reduced physician visits, unneeded prescriptions, emergency room visits and a hospitalization resulting in an ROI of 3.1:1. Although these are preliminary results, pharmacist interventions have resulted in significant cost savings to the Texas Medicaid program. Other states (e.g., Iowa, Minnesota, Florida, California, and New York) have also had similar positive results with pharmacist-provided MTM.

The current proposal focuses on an expansion of the Texas Medicaid MTM Pilot to include patients with high risk asthma or COPD which is pursuant to 2014-15 General Appropriations Act, Rider 45, S.B. 1, 83rd Legislature, Regular Session, 2013. Studies have documented successful outcomes associated with pharmacist intervention as part of the disease management of chronic conditions; the aim of this pilot is to demonstrate similar positive outcomes among patients suffering from asthma and COPD.

Asthma and chronic obstructive pulmonary disease (COPD) are reactive airway diseases that can result in significant increases in health care costs due to unnecessary emergency department visits or hospitalizations. According to the National Center for Health Statistics, almost 500,000 hospitalizations and approximately 25 percent of all emergency department (ED) visits in the US were due to asthma-related events. COPD is the fourth leading cause of death in the United States, with 125,000 deaths annually. Two groups of pharmacologic agents are primarily used for asthma and COPD management: controller medications (long-term agents (primarily with anti-inflammatory effects) and relievers (long and short term β-agonists). Thus, medication management is central to disease control, which makes these two disease states excellent candidates for MTM programs. For both disease states, medication adherence is suboptimal: approximately 50% in asthma and <50% in COPD. When adherence is poor, exacerbations increase, which can lead to unscheduled and emergent health care visits. Since both disease states are treated using inhaled therapies, it is important that patients use these devices correctly to ensure that medication reaches the lungs. In this pilot, pharmacists will demonstrate and teach appropriate inhaler technique. In addition, since smoking exacerbates both disease states, pharmacists will be encouraged to intervene with patients regarding smoking cessation efforts. Increasing adherence (with both inhaler technique and medication taking behavior) leads to better disease control, less utilization of expensive health care services—all of which translate to cost savings.

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HYPOTHESIS:
Patients suffering from chronic asthma or COPD that receive comprehensive medication therapy management (MTM) services will experience significant clinical improvements, better medication adherence and significantly decreased total medical costs due to a decrease in events associated with costly healthcare resources.

PURPOSE:
To improve patient outcomes and address the burden of rising health care costs in Texas, this study aims to determine the clinical and economic value of a community-based MTM program among Medicaid patients suffering from chronic asthma and COPD who are taking multiple medications.

Objectives:
The primary objective is to determine the degree to which a comprehensive community-based MTM program involving asthma and COPD patients, physicians, and pharmacists can decrease total medical costs within the Texas Medicaid program as compared to similar patients who do not receive consultation services. The secondary objectives are to assess resolution of medication related problems (focusing on medication adherence), effects on total medical and medication costs; and number of hospital and emergency room visits.

The proposal consists of 2 components: MTM Program, which will be implemented by Texas Pharmacy Foundation (p.4) and Program Evaluation, which will be conducted by The University of Texas College of Pharmacy researchers (p.11).
MTM PROGRAM:
Texas Pharmacy Foundation
MTM PROGRAM: Texas Pharmacy Foundation to implement

The program is a wellness program designed to help build collaboration between physicians, pharmacists and patients with asthma and COPD in order to address a spectrum of disease states including asthma, COPD, cardiovascular disease, diabetes, and metabolic syndrome. The most recent clinical guidelines will be used to guide patient care. This study defines the components of medication therapy management as:

- Comprehensive medication review
- Personal patient medication records
- Medication-related action plans
- Intervention including patient education and prescriber recommendations
- Documentation and follow-up

Participants in the program will receive individualized education and counseling on medications, identification and avoidance of triggers, proper peak flow/inhaler use and personalized follow-up tools such as action plans provided and approved by a licensed, trained pharmacist. The patient, pharmacist and other healthcare providers will establish goals for proper medication use, effective prescribing, and healthy living. The program is not intended to replace or substitute for physician care; rather it is intended to be an adjunct to physician office visits.

MTM providers will be pharmacists of various community settings including independent pharmacies, chain drug stores and community health centers in Texas. TPF will provide funding to cover costs of the pharmacists’ time to provide MTM services. A semi-private counseling area will be designated at the pilot sites with emergency facilities located within a reasonable distance from the study setting.

Provider outreach and enrollment methodology

This pilot will utilize regional coordinators to contact, explain, enroll and train (when needed) pharmacists in four broad areas of Texas – Dallas / Fort Worth, Houston, the Rio Grande Valley and San Antonio / Austin. Utilizing past prescription history, regional coordinators will receive a report with a rank order of pharmacies listing those with the highest number of eligible patients so they can best target provider enrollment efforts. The coordinators will act as a primary contact point for enrolled pharmacists within their region as pharmacists redesign work flow and store procedures to support these services.

In addition to this, regionalized provider outreach and support, marketing materials will be sent to managed care organizations throughout the state. Follow-up telephone meetings with appropriate, interested MCO’s will be designed to improve knowledge of the benefits of MTM and hopefully, enable further, individualized discussions to support other, related activities, specific to each MCO.

Human Subject Interactions:

The study sample will consist of up to 300 Texas Medicaid recipients (150 will be enrolled and receive MTM services and 150 will be selected from the database as matched controls) who are between the ages of 5 to 63. Race and gender are not part of the selection criteria. Participants must be diagnosed with chronic asthma and COPD regardless of baseline control or severity and be on a minimum of 4 chronic medications to participate. Participants must also be continuously enrolled for at least 6
months prior to study enrollment and at least 6 months after study enrollment. Participants are not likely to be vulnerable to coercion or undue influence.

Subject enrollment will begin on or shortly after September 1, 2013 and continue until May 31, 2014. Patient interventions will continue for a minimum of 6 consecutive months, though data may be tracked and analyzed for follow-up purposes for a longer period.

Procedures for the Recruitment of the Participants:
Participant enrollment
Tentative components:
• Marketing components:
  o Flyers
  o Regional marketing personnel for outreach and training
• Direct recruitment via pharmacy staff
• Advertising campaign – Press Release Draft

Procedure for Obtaining Informed Consent:
Patients will sign the uploaded consent form at the first pharmacy visit. The provider-pharmacist will offer to explain the study and issue copies of consent forms.

Pilot Design:
Participants will receive at least 5 pharmacy consultations. An initial visit with an estimated duration of 50-60 minutes will focus upon compiling a detailed medication profile/medication history and performing a comprehensive medication review. A 10-20 minute telephone meeting scheduled for a mutually agreeable date within four weeks following the initial visit and will follow up on the discussion and interventions initiated during the initial visit. A second in-person consultation will be conducted to discuss patient education regarding adherence, the importance of proper medication use, and assess initial patient satisfaction. Subsequent follow-ups will be conducted via telephone at one-month intervals. In-person sessions will be conducted in a community pharmacy setting. Summary reports of visits and results as well as recommendations for therapy adjustment may be sent to the patient’s physician.

Below is a step-by-step description of the protocol:

Pre-CMR Visit:
1. Identify eligible patients who are receiving pharmacy services at the study location sites. Medicaid claims information will be used to identify pharmacies with a high potential for qualifying study patients.
2. Recruit patients via direct pharmacy marketing or voluntary enrollment.
3. From patient and physician requests, contact patients by way of phone or email to set up appointments.
4. Contact patients the day before the appointment to remind them of their appointments; remind patient to avoid food, smoking, and caffeine at least 30 minutes prior to appointment.

Live Visit CMR:
1. Obtain written informed consent if the patient agrees to participate in the study and assign unique identifier numbers to participants.
2. Assess initial patient perceptions and understanding of services.
3. Obtain a complete list of prescription and non-prescription medications, drug allergies, adverse drug reactions and relevant clinical lab data from the patients including brief medical, social, and family history.
4. Screen patient for peak flow measurements, smoking status, and proper peak flow/inhaler use.
5. Perform comprehensive medication review with patient; screen for ADRs, drug interactions, and appropriateness of therapy. Assess medication therapy outcomes and target clinical goals.
7. Develop Medication Action Plan (MAP) in conjunction with patient.
8. Discuss MAP with patient and answer patient questions.
9. Discuss basic health and lifestyle education as needed.
10. Assess control level, use of peak flow meters, medication adherence and smoking status. If a current smoker, refer to smoking cessation services. If patient is not well controlled, schedule follow-up patient education and training visit, otherwise, schedule the first follow-up appointment for approximately four weeks later.

Post-CMR Visit:
1. Using the information from the visit, document findings of the visit and determine what items will need follow-up at subsequent visits and to what degree.
2. Make recommendations and provide therapy updates to the physician via faxed MD correspondence form.
3. If therapy adjustments are requested, call physician to let them know fax will be sent and the pharmacist is requesting a response. If the physician does not reply in two days, fax and call office again every two days until a reply is received. Document total time trying to contact physicians.
4. Upon prescriber approval and where therapeutically appropriate, make adjustments to prescriptions; scheduling changes for next refill date to minimize medication waste from prior prescription therapies.
5. Document each Drug Therapy Problem (DTP) identified and steps taken to resolve the problem. Include reason code, action code, observations / assessment.

NOTE: The specific DTP is not finalized until follow-up with documentation has occurred that indicates a resolution to the problem. Follow-up documentation occurs approximately two (2) weeks following the visit. See Telephone Follow-up or Live Visit Follow-up below.

Patient Education and Training Visit:
1. Instruct patient on signs and symptoms, triggers, peak flow meter use, and smoking cessation.
2. Schedule follow-up telephone visit.
3. Document visit reason code, action code, descriptive text, and level code.

Telephone Follow-up:
1. Contact the patient to notify them of changes to therapy and encourage them to pick up new prescriptions, if applicable.
2. Instruct patient to dispose or return old medications, if applicable.
3. Reiterate key discussion topics from CMR visit and Patient Education and Training visit (if applicable).
4. Obtain most current peak flow measurements.
5. Assess current Reactive Airway Disease (RAD) status and determine if live visit follow-up is needed. If live visit is necessary (patient is not well controlled), go to Live Visit Follow-up. If not (patient is well controlled), skip to Telephone Follow-up.

6. Document visit reason code, action code, descriptive text, peak flow measurements and level code.

7. Finalize documentation that was started in Post-CMR Visit, Item 5, above.

Live Follow-up:
1. Obtain and assess most recent peak flow measurements.
2. If well controlled, schedule next Telephone Follow-up for approximately 4 weeks later.
3. If not well controlled, adjust MAP where necessary based on the most recent information, considering patient goals and clinical guidelines.
4. Assess current patient satisfaction with pharmacy service.
5. Record time of MTM visit. The follow-up visit should be approximately 20 minutes, so if the patient needs more help, space it out over 2 visits so patients will remember more of what was presented.
6. Document visit reason code, action code, descriptive text, peak flow measurements and level code.
7. Finalize documentation that was started in Post-Visit #1, Item 5, above. If this visit covered all necessary items, schedule telephone follow-up appointment for approximately 4 weeks later. If not, schedule live follow-up appointment at the soonest convenient time to complete addressing the identified items.

Subsequent Live and Telephone Visits:
1. Live and Telephone Follow-up Visits until the patient has completed 5 post-enrollment CMR Visit dates.

Final Live Visit:
1. Obtain and record most current Peak Flow measurements.
2. Assess final patient satisfaction with pharmacy service.

Procedures for Protecting the Privacy and Confidentiality of Participants:
Pharmacy counseling will take place in a semi-private area. Participants’ names will not be shared with anyone outside of the pharmacist, pharmacy personnel, physician or other authorized healthcare providers.

As part of the program assessment, patients are assigned a Participant ID number that is used to summarize information about participation, such as answers to questionnaires, background information, pharmacist visits, medications and screening tests. The summary reports of general results without PHI will be sent to the pharmacists, TPA staff, and others interested in how and whether the program assists patients in the management of their medication use and in saving healthcare costs associated with chronic asthma and COPD and associated syndromes. Patient names and PHI will not be disclosed.

The data resulting from patients’ participation may be made available to other researchers in the future for research purposes not detailed within the consent form. In these cases, the data will contain no identifying information that could associate the patient with it, or with his or her participation in any study. To make possible future analysis the investigator will retain the records. Throughout the
study, the researchers will notify subjects of new information that may become available and that might affect their decision to remain in the study.

Procedures to Maintain the Confidentiality of the Research Data: The records of this study will be stored securely and kept confidential. Authorized persons from The University of Texas at Austin, members of the Institutional Review Boards, the Texas Health and Human Services Commission, and the Texas Pharmacy Association have the legal right to review research records and will protect the confidentiality of those records to the extent permitted by law. All publications will exclude any information that will make it possible to identify subjects.

When sharing pertinent clinical information with the patients’ physicians, pharmacists will follow HIPAA guidelines. Pharmacists will collect PHI to conduct MTMs on a personal password-protected laptop or desktop computer that is protected by a strong password. Information for data analysis will only use the unique identifier to identify each participant. Encrypted copies of the data may be saved to a secure web-server and computer.

Potential Risks: Risks to participants include psychological risk/mental stress and loss of confidentiality. To reduce these risks, all data will be promptly encrypted and patient consultation will take place in a private setting with a supportive, trained staff. Pharmacists will use only the unique personal identification number on paper questionnaires, and save PHI on a password-protected personal laptop or desktop computer.

There are several unanticipated problems of harmful interventions that could happen. To reduce chances of making a harmful intervention, pharmacists will follow strict clinical guidelines and the IRB approved protocol.

Still the following unanticipated problems may arise:

• **Patients may sue coordinators of the program for lack of action that they deem clinically appropriate.** To minimize this risk, pharmacists must intervene and follow up on recommendations that would reduce patient harm. Also patients must acknowledge in the consent form that they understand and agree that it is their sole responsibility to talk about the program and information about their health conditions with their personal healthcare provider(s). They must agree the Texas Pharmacy Association, including the Texas Pharmacy Foundation, Texas Medicaid, the Texas Health and Human Services Commission and other associated entities are not liable for their failure to discuss the program with their personal healthcare provider(s) or for any other actions that they take which might be inappropriate for their medical condition.

• **Patients may replace their regular physician visits with the Texas Medicaid Medication Therapy Management Pilot.** Therefore, pharmacists will explain that this program is meant to supplement and not replace regular physician care during recruitment and the first appointment. The statement is also bolded in the patient brochure and consent form.
• **Patients may hurt themselves in the course of changing lifestyle behaviors.** Pharmacists will ensure patients know how to correctly use their medications by the end of the first visit. This includes proper training on adherence and compliance to avoid misuse of medication and may also include education on basic dieting and exercise. In addition, patients must acknowledge in consent form that they understand and agree that they are solely responsible for the care and maintenance of any equipment, devices, medications, or supplies given to them during the program and that it is their responsibility to carefully follow instructions and exercise caution regarding the use of any such equipment, device, or supplies. Patients will be strongly encouraged to contact their physician or pharmacists for any questions that arise outside of the consultations.

• **Patients may suffer an adverse drug reaction from a drug the pharmacist recommended.** To minimize the liability of this risk, pharmacists must document drug allergies and adverse events and follow clinical guidelines such as the NHLBI Guidelines (EPR-3), among others. In addition, patients must acknowledge on their consent form that they understand that information about any adverse events (side-effects) associated with a drug or device may be reported to their doctor or the drug manufacturer, who will determine if the information requires reporting to the FDA as part of the federal program to monitor medication safety. In addition, only the patient’s physician can make changes in medications.

If an “unanticipated problem” does occur, the primary investigator will complete an Unanticipated Problem Form and promptly submit to the IRB office and document the event with the study investigators.

**Potential benefits** to be gained by the participants are likely, and include:

- Individualized counseling paid for by Medicaid for 6 months
- Improved management of asthma and COPD and quality of life
- Decreased medical expenditures for physician/emergency department visits/hospital visits
- Increased medication adherence
- Decreased cost of medications used for a wide spectrum of chronic diseases
- Optimized medication therapy
- Individualized medication action plan
- Increased physical activity and healthier lifestyles
- Decreased absenteeism
- Increased productivity

**Potential benefits that may be accrued by society as a result of the planned work are:**

- Decreased overall health care expenditures
- Greater access to valuable healthcare
- Increased collaboration with physicians and community pharmacists that leads to improved patient outcomes

The potential risks of the study are small and unlikely to occur, whereas the anticipated benefits are likely and significant to the participants and to society.
PROGRAM EVALUATION
The University of Texas College of Pharmacy
PROGRAM EVALUATION-The University of Texas College of Pharmacy

OBJECTIVES
1. Describe the number and type of MTM services provided.
2. Describe the frequency of smoking cessation interventions.
3. Describe the frequency of inhaler/peak flow techniques conducted.
4. Determine if patients receiving MTM services (intervention group) have significantly improved resolution of medication-related problems (baseline and 6-months post) compared to patients who did not receive MTM services (control group).
   a. Determine if patients receiving MTM services (intervention group only) have significantly improved resolution of medication-related problems from baseline to 6-months post.
5. Determine if patients receiving MTM services (intervention group) have significantly greater reductions in total health care costs (6-months pre and post) compared to patients who did not receive MTM services (control group).
   a. Determine if patients receiving MTM services (intervention group only) have significant reductions in total health care costs 6-months pre and post.
6. Determine if patients receiving MTM services (intervention group) have significantly better medication adherence (6-months pre and post) compared to patients who did not receive MTM services (control group).
   a. Determine if patients receiving MTM services (intervention group only) have significantly better medication adherence 6-months pre and post.

METHODOLOGY
Data Source and Inclusion Criteria
The proposed study will utilize claims data of Medicaid beneficiaries and community pharmacy records (all de-identified).
Individual member level claims records will be extracted and analyzed using the following criteria:
   1) 5-63 years of age;
   2) High risk asthma and COPD defined as (any one of the following below within the previous 6 months):
      • ASTHMA
         o ≥ 6 short acting beta agonists/year
         o ≥ 2 oral steroid/year
         o ≤ 2 inhaled corticosteroid alone or in combination/year
         o Emergency department visit or hospitalization
      • COPD
         o ≥ 6 short acting beta agonists/year
         o ≤ 2 long acting beta agonists/year
         o ≤ 2 long acting anticholinergics/year
         o ≤ 2 ICS alone or in combination/year
         o Emergency department visit or hospitalization
3) Continuous enrollment 6 months prior and 6 months after study enrollment.

Sample Size
The targeted study enrollment is 150 Medicaid recipients to receive MTM services and 150 will be selected from the database as matched controls.

Study Variables (see Table 1 below)
To determine the impact of MTM services on outcomes, both intervention (received MTM services) and control groups will be utilized in a quasi-experimental design. The control group will be matched on relevant demographic and clinical characteristics. To determine what changes occurred from baseline to follow-up in the intervention group only, a pre-and post-test design will be employed. The data will be collected from Medicaid and community pharmacy records and will include: health care costs, number and type of medication-related problems, adherence, smoking cessation, inhaler/peak flow technique, medical conditions, total number of medications, demographics and pharmacy-related information.

Dependent Variables
- Resolution of medication-related problems (MRPs): Change in number of MRPs from baseline to follow-up.
- Total Health Care Costs: Change in health care costs from baseline to follow-up
- Adherence: Change in adherence from baseline to follow-up

Primary Independent Variable
- Group
  - Intervention group will include beneficiaries who have received MTM services.
  - Control group will include a matched group of beneficiaries selected from the database who have NOT received MTM services.

Covariates
Additional variables will be collected including demographic and pharmacy-related information.
Table 1. Study Variables

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<th>Variable</th>
<th>Categories</th>
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<td>Group</td>
<td>0 = Control; 1 = Intervention</td>
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| Medication-Related Problems (Number and Type) Identified Resolved | 1 = Indication (needs medication, unnecessary medication)  
2 = Effectiveness (suboptimal dose/duration)  
3 = Safety (drug interaction, side effects, allergy, toxicity)  
4 = Adherence (over and under use)  
5 = Cost (formulary adherence, generic conversion) |
| MTM Service Provided             | 1 = Comprehensive medication review  
2 = Prescriber consult  
3 = Patient consult  
4 = Patient education and monitoring |
| Adherence                        | Proportion of Days Covered  
COPD medications  
Asthma medications |
| Smoking Cessation                | 0 = No intervention  
1 = Documented smoking status  
2 = Intervened regarding smoking  
3 = Sent information to the Texas DSHS Quitline [http://www.dshs.state.tx.us/tobacco/](http://www.dshs.state.tx.us/tobacco/) |
| Inhaler and/or Peak Flow Technique | 0 = No intervention  
1 = Inhaler technique  
2 = Peak flow technique |
| Medications                      | Total # of medications (baseline and post)                                |
| Total Health Care Costs          | 1 = MD visits  
2 = Emergency department  
3 = Hospitalization  
4 = Laboratory  
5 = Prescription  
6 = Other |
| Estimated Cost Avoidance OutcomesMTM® categories | 1 = Improved quality of care  
2 = Drug product costs  
3 = Additional physician visit  
4 = Additional prescription order  
5 = Hospital admission  
6 = Emergency room visit  
7 = Life threatening |
| Age                              | Year of birth                                                              |
| Gender                           | 0 = Male; 1 = Female                                                       |
| Race/Ethnicity                   | 0 = White  
1 = African American  
2 = Latino/Hispanic  
3 = Asian  
4 = Other |
| Smoke                            | 0 = No; 1 = Yes                                                            |
| Insurance Group                  | 0 = FFS; 1 = MC                                                             |
| Pharmacist                       | Unique ID for individual pharmacists                                        |
| Pharmacy                         | Unique ID for individual pharmacies                                        |
| Region                           | County                                                                     |
Data Collection and Analysis
Data from Medicaid and participating pharmacies will be extracted from 6 months prior to the intervention date and 6 months after the intervention date.

Means, standard deviations, medians, frequencies will be used to summarize all of the variables and address Objectives 1-3. Unadjusted (bivariate) and adjusted (controlling for covariates) analyses will be used to address Objectives 4-6. An a priori significance level of p<0.05 will be used for all analyses.

TIMELINE

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