Evaluation of Pharmacy Delivery Models

As Required By
House Bill 1, 84th Legislature, Regular Session, 2015
(Article II, Health and Human Services Commission,
Rider 83)

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1. Executive Summary

The 2016-17 General Appropriations Act, House Bill (H.B.) 1, 84th Legislature, Regular Session, 2015 (Article II, Health and Human Services Commission, Rider 83), directed the agency to evaluate new delivery models for cost effectiveness, increased competition, and improved health outcomes and report findings to the Governor, the Legislative Budget Board, and the appropriate standing committees of the legislature.

The report indicates the potential exists to increase the role of licensed pharmacists, within their scope of practice and skillset, to control costs and improve health outcomes for Medicaid members. As the research has demonstrated, pharmacists are vital and cost-effective participants of multi-disciplinary health provider teams positively impacting the quality of care and mitigating costs.

HHSC continues to evaluate delivery models and cost containment strategies which can be feasibly implemented in a cost-effective manner and support improved client outcomes in both managed care and fee-for-service (FFS). Several of the service delivery modalities addressed in this report can also be leveraged as part of Medication Therapy Management (MTM). An MTM pilot performed in response to 2016-17 General Appropriations Act, H.B. 1, 84th Legislature, Regular Session, 2015 (Article II, Health and Human Services Commission, Rider 45), Clinical and Economic Outcomes of the Texas Medicaid Medication Therapy Management (MTM) Pilot: Asthma and Chronic Obstructive Pulmonary Disease (COPD) Report, did show statistical evidence of return-on-investment but did not show savings when based on actual Medicaid claims data.

The need for a Texas Medicaid claims-based review to determine cost-effectiveness can increase the complexity and cost associated with piloting or implementing such evidence-based interventions. HHSC will continue to explore innovative ways of studying evidence-based strategies described in the report within a Texas Medicaid context.

2. Introduction

The HHSC Vendor Drug Program (VDP), in consultation with pharmacy stakeholders, evaluated pharmacist delivered benefits and, where applicable, the supporting evidence of their cost effectiveness and impact on improved health outcomes. The cases evaluated, and discussed in this report, leverage pharmacist expertise in medication management, patient consultation, and, under physician delegation, administration of certain drugs, vaccines and screenings.

At the direction of the legislature, the evaluation included the VDP administered pilot program, which assessed the cost-effectiveness of MTM. A summary of the findings of the pilot are included in this report. A thorough discussion of the MTM pilot and its associated findings can be found in Clinical and Economic Outcomes of the Texas Medicaid Medication Therapy Management (MTM) Pilot: Asthma and Chronic Obstructive Pulmonary Disease (COPD) Report for fiscal year (FY) 2016, as directed by the 2014-15 General Appropriations Act, Senate
Bill 1, 83rd Legislature, Regular Session, 2013 (Article II, Health and Human Services Commission, Rider 45).

3. Overview of Service Delivery Models and Strategies

VDP completed an evaluation of pharmacy delivered benefits, which could result in higher cost-effectiveness, increased competition for market share opportunities, and healthier outcomes for Medicaid clients.

Medication Therapy Management

MTM programs are used to control costs and improve outcomes associated with prescription drug coverage. MTM may include a number of different tools and strategies, depending on the design, and goals. For example, MTM may include or be complemented by comprehensive medication reviews (CMR), a pharmacist’s complete assessment of all prescribed medications to develop a medication management strategy or work plan for the client; other client or provider educational components; retrospective claims reviews and more.

The Medicare Part D Enhanced MTM Program is described by the Centers for Medicare & Medicaid Services (CMS) as "enhanced" in that it is a demonstration pilot being tested by CMS allowing for greater flexibility and payment incentives in its implementation by certain Medicare Part D "Sponsors." The sponsors for the Medicare Enhanced MTM pilot are six insurance providers and/or their pharmacy benefits managers, including Blue Cross and Blue Shield (BC/BS) Northern Plains Alliance, BC/BS of Florida, CVS Health, Humana, United Healthcare and Wellcare Prescription Insurance. These plans provide Part D medications to Medicare beneficiaries.

Research suggests the Medicare Part D Enhanced MTM Program results in increased safety, accuracy, and cost savings when used in a cooperative multidisciplinary approach between the doctor, physician assistant, nurse, and pharmacist working to improve the patient's healthcare.

Associated with their adoption of the Enhanced MTM Pilot, CMS outlined additional MTM-related research findings in a CMS report1 entitled "Enhanced MTM Evidence Base." Those findings, which include research in Medicare, Medicaid and commercial insurers, are:

- Medicare Prescription Drug Plan (PDP) beneficiaries with diabetes or congestive heart failure (CHF), who received CMR, had decreased utilization and costs for Medicare Parts A and B ($399 and $526 reduction in inpatient costs, respectively, after risk-adjustment), although similar results were not statistically significant for those with COPD or for MTM participants who did not receive a CMR.
- Increased medication adherence rates in Medicaid beneficiaries with CHF resulted in fewer hospitalizations and emergency department (ED) visits, leading to a cost savings of $5,910 per year.

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1 "Enhanced MTM Evidence Base," Centers for Medicare and Medicaid Services; Center for Medicare and Medicaid Innovation; retrieved online, October 20, 2016 at https://innovation.cms.gov/initiatives/enhancedmtm/
• Supporting interventions complementing traditional CMR-based MTM, such as reminder packaging, may represent a simple method for improving adherence that could enhance the effect of traditional MTM. One study of MTM among hypertensive patients showed significant improvements in both adherence and persistence.

• Medication self-management programs, including those with pharmacist involvement, appear to improve use, adherence, and clinical outcomes and reduce adverse events and mortality in people self-managing antithrombotic therapy.

• Medicaid programs using MTM in Iowa, Minnesota, and Connecticut have demonstrated increases in appropriate medication use, resolution of drug problems, and cost savings.
  o In Iowa, operators observed a 12.5 percent increase in the medication appropriateness index, and a 24 percent decrease in use of medications considered inappropriate for the age group.
  o In Minnesota, 789 drug therapy problems were resolved and health care expenditures were reduced by $20 per-member, per-month (PMPM).
  o In Connecticut, the program saved an average of $1,123 in drug costs and $472 in medical, hospital, and ED charges per patient. Per-person program costs were estimated at $638, resulting in $912 per patient savings and a final return on investment estimate of 150 percent.

• The Asheville Project, a study examining an MTM program for Medicaid patients enrolled in self-insured health plans, showed a decrease in hospitalization from 4 percent to 1.9 percent for asthma patients, in addition to a decrease in ED visits from 9 percent to 1.3 percent. This resulted in average direct cost savings of $725 per year, even after accounting for drug costs.

• The Pennsylvania Project consisted of a community-based pharmacist intervention targeting five major medication classes. Review of the project’s impact on costs for several plans, offering both commercial and Medicare Part D products, showed significant decreases in overall healthcare costs for patients with diabetes taking oral diabetes medications, as well as patients with hyperlipidemia taking statins.

The results of the recent MTM pilot in Texas Medicaid were more mixed than those of the studies listed above. A study examined whether the MTM pilot improved outcomes and cost-effectiveness for Medicaid clients diagnosed with asthma or COPD.

The pilot included a wellness program to build collaboration between physicians, pharmacists, and patients with asthma or COPD. The patient, pharmacist, and other healthcare providers established goals for proper medication use, effective prescribing, and healthy living, but the program was not intended to replace a physician’s care. MTM providers were pharmacists from various community settings, including independent pharmacies and chain drug stores in Texas.

Throughout the study, 28 pharmacists and 63 patients participated in the program, with a total of 139 interventions (an average of 2.2 interventions per patient). Interventions primarily focused on CMRs and resolving medication-related problems. Of the 139 interventions, the physician/patient acceptance rate was high at 77.7 percent. An "acceptance rate" is the rate at which a pharmacist recommended MTM intervention is adhered to by the patient or MTM team. The acceptance rate percentage is calculated by using the total number of resolved therapeutic issues divided by resolved plus unresolved issues combined. After a CMR encounter with a patient, examples of resolved therapeutic issues included improved adherence, improved
administration technique, and initiation of new or discontinuance of ineffective therapy. Unresolved issues included a patient refusal to follow recommendations, a prescriber refusal to follow pharmacist recommendations, or the inability to reach a patient.

To assess the economic value of the MTM intervention, estimates were based on statistical models like OutcomesMTM® and Medicaid claims data. The study suggested medication adherence improved and some ED visits were diverted, but because of the costs associated with the appropriate, additional dispensing of expensive inhalers for persons receiving MTM, the Medicaid claims data program appears to not have resulted in net savings. Specific findings include:

- OutcomesMTM® showed the asthma/COPD MTM program resulted in cost savings ranging from $37,099 to $48,203 ($589-$765 per patient) and a return on investment (ROI).
- When analyzing Medicaid claims data, post-MTM costs increased from pre-pilot costs by $57,242.86 ($1,244.41/patient). This resulted in a loss of $74,815.86 ($1,626 per patient, or $841 per claim). The largest increase in costs was due to new prescriptions, with over one-third (35 percent) of increases in prescription costs due specifically to increased adherence to long acting inhaled corticosteroid asthma, leading to increased patient utilization and costs to the state. This is not surprising, since pharmacist interventions were mainly focused on either initiating appropriate asthma therapy or enhancing asthma medication adherence, particularly with long acting inhaled corticosteroids.
- One notable finding in both the OutcomesMTM® estimates and the Medicaid claims data analysis was related to ED visits. According to OutcomesMTM® estimates, pharmacists’ interventions potentially helped over 10 percent (N=7) of patients avoid an ED visit. When examining Medicaid claims data, ED visits were reduced from the pre-intervention period having 20 patients with one or more ED visits to zero ED visits in the post-intervention period.

Despite the Texas Medicaid MTM Pilot’s inability to show cost savings across all measurement models, it is clear there are MTM models nationwide having resulted in both cost savings and improved outcomes using the OutcomesMTM® analysis. VDP will continue to work with stakeholders to identify opportunities for changes to client service delivery which may decrease costs while retaining the improved outcomes demonstrated in the MTM Pilot. Currently, MTM is not a reimbursable service for pharmacists participating in Texas Medicaid.

**Long-acting Injectable Anti-psychotic Medications (LAI-AP)**

Research supports patients with certain behavioral health diagnoses can remain stable over a longer time if they receive LAI-AP. One study demonstrated LAI-APs are associated with a decrease in hospitalizations and relapse, as well as improved cost-effectiveness and adherence in psychiatric illnesses.

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2 Although 63 patients were included in the OutcomesMTM® estimates, Medicaid claims data was collected through 9/9/2015 and included only patients up to 63 years of age to avoid including patients who may be dual eligible for Medicaid and Medicare. After employing this additional criteria, the Medicaid claims analysis included 46 of the original 63 patients (N=46).

patients with schizophrenia, as compared with patients only receiving oral antipsychotics. Not only can LAIs decrease relapse rates by improving nonadherence, they can also allow for more predictable and stable serum drug concentrations, reducing the risk of accidental or deliberate overdose. Studies have also shown patients prefer LAI-AP to oral medications and are twice as likely to remain on an LAI-AP. In Texas, a pharmacist may administer certain injections under the direction of a health care provider; however, LAI-AP administration by a pharmacist is not currently a covered Texas Medicaid benefit.

**Immunizations**

Vaccines administered by pharmacists can be a cost-effective, efficient method of delivering vaccines and other immunization products. One study of Walgreens vaccination records from August 2011 to March 2012 concluded states offering pharmacists full vaccination privileges have higher immunization uptake rates than states with restricted or no authorization. Research also suggests allowing pharmacists to vaccinate clients can result in cost savings. In Texas, Medicaid MCOs are not required to offer an influenza vaccine as a pharmacy benefit. Should an MCO choose to offer the vaccine benefit, the MCO may allow its network pharmacies' pharmacists to administer the vaccine and only to Medicaid adults (age 18 and older) and CHIP Perinate mothers. The MCOs are responsible for ensuring immunizing pharmacists are credentialed by the Texas State Board of Pharmacy (TSBP) to administer immunizations and all TSBP immunization protocols are followed. The influenza vaccine is not currently a covered Texas Medicaid FFS pharmacy benefit.

**Pharmacy Act**

Pharmacy stakeholders have proposed legislative changes to the Pharmacy Act, allowing pharmacists to be more involved in a patient's diagnosis and drug therapy, under a doctor's supervision/protocol. A pharmacist’s involvement typically is reserved for non-complex disease management or other extended periods of need for medications, including drug therapies. According to stakeholders, this legislative change would amend the Pharmacy Act to explicitly state pharmacists are health care providers and must be compensated for services consistent with other providers.

**4. Discussion**

**MTM**

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MTM, as documented above, has been shown to improve medication safety, accuracy, and cost savings when accounting for changes in drug expenditures across the range of patient benefits and used in a cooperative multidisciplinary approach to improve the patient's healthcare. The evidence supports pharmacists can be instrumental in identifying and resolving issues such as inappropriate medication use and therapeutics duplication, which can result from a patient seeing multiple prescribing providers or during a patient's transition of care such as discharge from hospital to home. Pharmacists' participation can increase the accuracy of medication administration while improving a patient’s health outcomes and reducing waste. Medication issues range from overuse to underuse of a prescribed medication, as when patients do not pick up initial prescriptions, a circumstance limiting effective management and control of chronic illnesses. MTM can ensure a pharmacist has a substantive face-to-face patient interaction to promote medication adherence. Potential savings from implementation of an MTM program includes reduced ED visits and decreased short and long-term hospitalizations.

**Long Acting Injectable-Antipsychotics**

As noted in the overview, pharmacists have increased the ability of patients with certain behavioral health diagnoses to remain more clinically stable by receiving LAI-AP. Newer LAI-AP are more readily and accurately dosed for optimal patient stabilization, may be better tolerated by the patient, and are more responsive to pharmacological and therapeutic issues. LAI-AP offer a number of advantages over oral medications by reducing the risk of over/under-dosing, providing transparency of medication adherence, and allowing pharmacists to intervene if a dose is missed.

In Texas, pharmacists partner with prescribers (including physicians as well as Advanced Practice Nurses and Physician Assistants under a physician's supervision) to administer antipsychotic LAI-AP under delegation protocols. LAI-AP have proved effective in treatment of schizophrenia and other severe psychotic disorders because they assure stable blood levels, leading to a reduction in relapse. Currently, LAI-AP injections administered by a pharmacist are not a covered benefit under Texas Medicaid, though some community-based pharmacists provide LAI-AP to selected Medicaid patients without receiving additional reimbursement from Texas Medicaid. Pharmacists, along with the prescriber, have coordinated to produce some encouraging medication adherence results.

**Immunizations**

Immunizations administered by pharmacists have proven to be a cost-effective, efficient delivery method. Allowing pharmacists to vaccinate individuals increases public access to immunizations and, thereby, increases the number of individuals getting immunized. Pharmacists have demonstrated a willingness to expand their scope of practice to include providing immunizations; however, implementation requires professional development and certification in vaccine administration. Certified pharmacist immunizers have been vaccinating Texans of all ages under a physician's written protocol for the past 18 years. In Texas, with the exception of flu vaccines, those under 14 years of age must first see a doctor, get a prescription, and present it to the pharmacy before the pharmacist can administer any vaccine. Leveraging the capability for pharmacists to provide vaccinations can be cost-effective by reducing the costs associated with
other professionals who immunize, such as physicians; it can also increase access to vaccinations for the public.

### Pharmacy Act

According to stakeholders, pharmacists are often a patient’s first-line healthcare educator and risk manager because pharmacists are also the most accessible type of healthcare provider. Pharmacy stakeholders have proposed changes to the Pharmacy Act, with the goal of ensuring pharmacists are more involved in a patient's diagnosis and drug therapy and are eligible to be reimbursed by Texas Medicaid for providing services already within the scope of their licensure.

### 5. Conclusion

Research indicates increasing the role of licensed pharmacists, within their scope of practice and skillset, has the potential to control costs and improve health outcomes for Medicaid members. As research has demonstrated, pharmacists are vital and cost-effective participants of multi-disciplinary health provider teams and can positively impact quality of care and mitigate costs.

Patients generally see their pharmacists more frequently face-to-face than their primary care physician, so including pharmacists as reimbursable members of a patient's care team may result in consistent and appropriate use of prescription medications, fewer ED visits, and healthier outcomes for Medicaid beneficiaries. Increased use of pharmacists may lead to better outcomes for patients and lower Medicaid costs for Texas.

The pharmacist delivered benefits below could result in higher cost-effectiveness, increased competition for market share opportunities, and healthier outcomes for Medicaid clients.

- MTM may include a number of different tools and strategies to control costs and improve outcomes associated with prescription drug coverage.
- Use of LAI-APs on patients with certain behavioral health diagnoses is associated with a decrease in hospitalizations and relapse, as well as improved cost-effectiveness and adherence in patients with schizophrenia, as compared with patients only receiving oral antipsychotics.
- Immunizations and vaccines administered by pharmacists can be a cost-effective, efficient method of delivering vaccines and other immunization products.

To allow the increased participation of pharmacists, pharmacy stakeholders have proposed legislative changes to the Pharmacy Act, allowing pharmacists to be more involved in a patient's diagnosis and drug therapy, under a doctor's supervision/protocol.

Discussions with the MCOs regarding how MTM could be incorporated into managed care have already taken place. Many of the MCOs already utilize these different pharmacy benefit programs in various forms to improve care and minimize costs. HHSC will continue to explore,
in coordination with the MCOs, how they may be further incorporated in managed care. The outcome of these discussions may result in required MCO contract amendments.

HHSC will continue to consult with pharmacy stakeholders and other payors to research additional opportunities to incorporate the pharmacist in the patient's care to improve health outcomes and cost effectiveness. HHSC will also monitor any newly effective state laws increasing pharmacists' scope and identify the feasibility of incorporating their expanded scope into the Medicaid pharmacy benefit.
# Appendix: Acronyms

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<tr>
<th>Acronym</th>
<th>Full Name</th>
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<tbody>
<tr>
<td>BC/BS</td>
<td>Blue Cross Blue Shield</td>
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<tr>
<td>CHF</td>
<td>Congestive Heart Failure</td>
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<td>CHIP</td>
<td>Children's Health Insurance Program</td>
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<td>CMR</td>
<td>Comprehensive Medication Reviews</td>
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<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
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<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<td>ED</td>
<td>Emergency Department</td>
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<td>FFS</td>
<td>Fee-for-Service</td>
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<td>FY</td>
<td>Fiscal Year</td>
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<td>Health and Human Services Commission</td>
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<td>H.B.</td>
<td>House Bill</td>
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<tr>
<td>LAI-AP</td>
<td>Long-acting Injectable Antipsychotic Medications</td>
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<td>MCO</td>
<td>Managed Care Organization</td>
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<td>MTM</td>
<td>Medication Therapy Management</td>
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<td>PDP</td>
<td>Prescription Drug Plan</td>
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<td>PMPM</td>
<td>Per Member Per Month</td>
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<td>ROI</td>
<td>Return On Investment</td>
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<td>TSBP</td>
<td>Texas State Board of Pharmacy</td>
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<tr>
<td>VDP</td>
<td>Vendor Drug Program</td>
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