
PHARMACY CARE MANAGEMENT SERVICES

Feasibility Study to the Texas Legislature

**As Required by
S.B. 1645, 81st Legislature, Regular Session, 2009**

Texas Health and Human Services Commission

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Executive Summary

Pursuant to S.B. 1645, 81st Legislature, Regular Session, 2009, the Texas Health and Human Services Commission (HHSC) is required to study the feasibility of establishing a separate reimbursement rate under the Texas Medicaid Vendor Drug Program (VDP) for pharmacies that provide pharmacy care management services to patients who are administered specialty pharmacy drugs, including drugs indicated for the prophylaxis of respiratory syncytial virus (RSV), blood factor, or any other biologic or therapy that requires complex care.

Specialty drugs are prescription medications used to treat chronic, complex, or rare medical conditions. Specialty drugs may be injections, infusions, or oral products and typically are high in cost. These products often have special shipping, handling, or storage requirements such as refrigeration and controlled temperature packaging. Most traditional retail pharmacies do not stock or dispense specialty drugs, or do so only on a limited basis, because of the high cost and special shipping and handling these products require.

Specialty drugs are most often provided by specialty pharmacies. Specialty pharmacies are able to provide additional clinical management services to both prescribers and patients that go beyond traditional dispensing activities. They may work closely with the prescribing physician's office and with patients to assist in the coordination of care. Specialty pharmacies provide education and training to patients on drug administration, potential side effects, dosing regimens, and the importance of compliance as well as specialized education on the targeted disease state. In addition, they may also consult with physicians and assist in coordinating other necessary services such as nursing services provided by home health agencies.

The degree of pharmacy care management services differs largely by specialty drug and the pharmacy's treatment model. Treatment models are designed to be drug, disease, and client specific, and the intensity and frequency of the services differs based on clinical need.

The Texas Medicaid program provides coverage for specialty drugs and clinical services for the administration of specialty drugs through two distinct programs: VDP and the home health program. While both the cost of the drug and medical services and supplies are reimbursed in Texas Medicaid, a specific reimbursement model for care management services provided by a pharmacy does not currently exist in Texas Medicaid.

HHSC has studied the feasibility of adding pharmacy care management services as a Texas Medicaid benefit with a separate reimbursement rate and concluded that it is feasible. Approval by the Centers for Medicare & Medicaid Services (CMS) would be needed to add pharmacy care management as a Medicaid benefit. Further program development would also be needed because of the varying levels of care management services available.

Introduction

Pursuant to S.B. 1645, 81st Legislature, Regular Session, 2009, the Texas Health and Human Services Commission (HHSC) is required to study the feasibility of establishing a separate reimbursement rate under the Texas Medicaid Vendor Drug Program (VDP) for pharmacies that provide pharmacy care management services to patients who are administered specialty drugs, including drugs indicated for the prophylaxis of respiratory syncytial virus (RSV), blood factor, or any other biologic or therapy that requires complex care.

In addition, S.B. 1645 requires that HHSC provide a written report on the results of the study to the legislature by September 1, 2010. In conducting the study HHSC is directed to:

- Consult with the Centers for Medicare & Medicaid Services (CMS) and can consider the adoption of pharmacy care management services reimbursement for pharmacy services adopted by other state Medicaid programs.
- Seek information from specialty pharmacy providers or other sources regarding the costs of providing pharmacy care management services.

S.B. 1645 defines pharmacy care management services as services provided by a pharmacy to support patients receiving treatment or therapy through a specialty drug or therapy to maximize adherence to the drug or therapy, including:

- Significant caregiver and provider contact and education regarding the relevant disease, disease prevention, and treatment.
- Counseling related to drug indications, benefits, risks, complications, and appropriate use of the prescribed drug or therapy.
- Patient compliance services including:
 - Coordination of provider visits with delivery of the specialty drug or therapy to the provider.
 - Compliance with the dosing regimen.
 - Patient reminders.
 - Data compilation.
 - Assisting providers in the development of compliance programs.
- Tracking services, including:
 - Developing ordering processes with a provider.
 - Screening and referrals.
 - Tracking a patient's weight for dosing requirements.

Background

Specialty Drugs

Specialty drugs are prescription medications used to treat chronic, complex, or rare medical conditions. Specialty drugs may be injections, infusions, or oral products and typically are high in cost. These products often have special shipping, handling, or storage requirements such as refrigeration and controlled temperature packaging. Most traditional retail pharmacies do not stock or dispense specialty drugs, or do so only on a limited basis, because of the high cost and special shipping and handling these products require.

Historically, specialty medications were used to treat very rare medical conditions. However, specialty drugs are now available in a number of therapeutic categories. There has been an increase in both the number of specialty products available and the indications for which the products are used. Specialty drugs are now available to treat more common chronic disorders such as rheumatoid arthritis, respiratory disorders, multiple sclerosis, and cancer.

Respiratory syncytial virus (RSV) immune globulin vaccine and blood factor are examples of specialty medications. The RSV immune globulin vaccine is used to prevent serious lower respiratory tract infection caused by RSV by increasing immunity to the virus. The vaccine is administered via monthly injections in a physician's office throughout the RSV season to children younger than 24 months who are at increased risk of complications related to RSV. The RSV season varies and can last for six months or longer. RSV immune globulin vaccine is a high-cost biological that is distributed by specialty pharmacies. The dosage is weight based which requires the patient to be weighed each time the vaccine is administered. The effectiveness of the vaccine is dependent on dosing compliance and requires ongoing compliance monitoring to ensure children receiving the vaccine continue to receive the vaccine throughout the RSV season. Proper use of the vaccine can prevent a child from contracting RSV.

Blood factor, or antihemophilia factor, is used to treat and prevent bleeding episodes in individuals with bleeding disorders such as hemophilia. Individuals with bleeding disorders require readily available access to blood factor and ongoing lifetime treatment. Blood factor products are very expensive (e.g. \$800 for one vial of 1,000 units); require specialized storage, refrigeration, and overnight shipping; and patients may require specialized education and assistance with administration of the drug.

Specialty Pharmacies

The increase in the number of specialty drugs has resulted in the evolution of a relatively new type of pharmacy practice devoted exclusively to the distribution of specialty drugs. Specialty pharmacies are able to provide additional clinical management services to both prescribers and patients that go beyond traditional dispensing activities. They may work closely with the prescribing physician's office and with patients to assist in the

coordination of care. Specialty pharmacies provide education and training to patients on drug administration, potential side effects, dosing regimens, and the importance of compliance, as well as specialized education on the targeted disease states. In addition, they may also consult with physicians and assist in coordinating other necessary services such as nursing services provided by home health agencies.

Specialty pharmacies tailor their services to the specific medication that is being dispensed. The therapy and care management services provided by a specialty pharmacy vary by drug, disease state being treated, and the individual client's needs. The services provided to clients may differ, as well as the intensity and frequency in which services are provided. These services are not uniform across all therapies and therefore pharmacy care management services can not be defined by one specific delivery model.

Services and Best Practices

Various models are used by payors to manage the cost of specialty drugs and the provision of pharmacy care management services. The following approaches have been employed by payors in the distribution and management of specialty drugs and care management services: selective contracting with specialty pharmacy providers, medication therapy management, disease management, and drug furnishing fees.

Selective Contracting with Specialty Pharmacy Providers

Some third-party payors directly contract with one or more specialty pharmacies to manage cost and services. These specialty pharmacy providers oversee the distribution and management of the products, and may provide additional pharmacy care management services. These models provide controlled access to medication, as designated specialty drugs must be ordered through the contracted specialty pharmacy provider(s). Specialty pharmacy contracts can include a selected list of products for which drug costs are high and a potential exists for savings, as well as improved health outcomes through clinical and utilization management. Some payors contract with multiple specialty providers in order to achieve a variety of service or treatment options.

Medication Therapy Management

Medication therapy management (MTM) is another approach commercial and government payors have adopted to address specialty care services provided by a pharmacy. MTM has been defined as a "distinct service or group of services that optimize therapeutic outcomes for individual patients [that] are independent of, but can occur in conjunction with, the provision of a drug product".¹ MTM is provided to actively manage overall drug therapy and may consist of medication reviews, pharmacotherapy consults, disease management support, drug therapy management, drug safety surveillance, and health and wellness education.

¹ Bluml BM. Definition of medication therapy management: development of professionwide consensus. J Am Pharm Assoc. 2005;45:566-72.

Medicare Medication Therapy Management

The Medicare Modernization Act (MMA) of 2003 established requirements for MTM programs for Medicare Part D.² The program established in the MMA targets individuals with multiple chronic conditions, who are taking multiple medications, and whose drug cost exceeds a specific cost threshold. The MTM program must be designed to:

- Ensure that prescribed drugs are properly used to optimize therapeutic outcomes.
- Reduce the risk of adverse events (including drug interactions).
- Incorporate licensed physicians and pharmacist in the design and delivery of the program.

Since the adoption of MTM in Medicare, some state Medicaid programs have also added MTM to their state plan as a benefit for eligible enrollees.

Health Care Reform Medication Therapy Management

The Affordable Care Act (ACA) of 2010 establishes a new medication grant program. The program would provide for grants or contracts to eligible entities for the provision of medication management services in the treatment of chronic diseases. Under the new law, services provided under the grants “shall be offered to targeted individuals who:

- Take four or more prescribed medications (including over the counter medications and dietary supplements).
- Take any high-risk medications.
- Have two or more chronic diseases, as identified by the Secretary.
- Have undergone a transition of care, or other factors, as determined by the Secretary, that are likely to create a high risk of medication-related problems.”

The federal provision specifies who may be eligible for the grants or contracts, the required services and providers that must be available under the program and reporting and evaluation requirements for assessing the benefit of providing MTM services.

Disease Management

Other payors manage specialty care services through the adoption of disease management programs. These programs serve individuals with specific medical conditions and diseases that result in high medical cost where more intensive patient management may result in improved patient outcomes. Disease management programs provide enhanced service coordination and tracking for treatment adherence. The goal of disease management is to improve client self management and build positive relationships with providers and payors to reduce medical cost. While individuals receiving treatment with specialty drugs may benefit from a disease management program, not all individuals in a disease management program are being treated with a specialty drug.

² 42 CFR Part 423, Subpart D.

Texas Medicaid Disease Management

Texas Medicaid currently operates a disease management program that serves clients with asthma, chronic obstructive pulmonary disease, diabetes mellitus, coronary artery disease, and congestive heart failure. Plans are underway to expand the existing program. The new health management program will no longer be limited by specific diseases and will identify clients who may benefit from an overall health management program because they are high-cost or at risk of becoming high-cost.

Individuals identified through the program will receive a clinical assessment, and services will be tailored to the individuals' need. The services provided in the disease management program may include but are not limited to:

- Care management visits.
- Phone calls and visits for tracking adherence.
- Education on self management.
- Service coordination including: coordination with primary care, specialty, pharmacy providers; referrals for social services to remove barriers to care; and referrals to community care services.
- Group visits.
- Assisted physician visits.
- Hospital and emergency room discharge interventions.
- Pharmacy care review and consultation.

The anticipated effective date for the expanded disease management program is November 2011.

Drug Furnishing Fees

Drug furnishing fees have also been employed in the reimbursement of specialty drugs. The MMA added provisions to the Social Security Act which required Medicare payment of a furnishing fee for items and services associated with blood clotting factor.³ The 2010 Medicare furnishing fee is currently set at \$0.17 per I.U. (unit) and is reimbursed as a component of the drug product.

Texas Medicaid Blood Clotting Furnishing Fee Initiative

The 2010-11 General Appropriation Act (Article II, Health and Human Services Commission, Rider 69, S.B.1, 81st Legislature, Regular Session, 2009) further directs HHSC, contingent on approval by the Centers for Medicare & Medicaid Services (CMS), to amend the reimbursement methodology for blood factor by adding a \$0.05 furnishing fee for each unit of factor reimbursed on a prescription claim. The legislation directs HHSC to add the reimbursement to the existing dispensing fee methodology. HHSC

³ Section 1842 (o)(5)(c) of the Social Security Act

submitted a State Plan Amendment to CMS to implement the provisions in Rider 69, but it was denied. Per CMS, under federal law the Medicaid pharmacy dispensing fee is composed of basic costs associated with providing medication and does not include care management services or supplies. The addition of services associated with the furnishing of blood factor or other drug products may be appropriate under other sections of the state plan as a service-based fee.

Pharmacy Care Management in Other State Medicaid Programs

Other state Medicaid programs provide reimbursement for pharmacy care management services. The following chart provides a description of the covered benefit and reimbursement amounts for other states.

Examples of Pharmacy Care Management in Other State Medicaid Programs

State	Benefit	Reimbursement Model
Iowa	<p>Pharmaceutical Case Management (PCM) benefit provides care management services to individual identified as being at risk for medication related problems.</p> <p>Services are provided by physicians and pharmacist, who coordinate patient care.</p> <p>Special training is required for pharmacists.⁴</p>	<p>Payable to physicians and pharmacists.</p> <p>Payable at the following reimbursement rates:</p> <p>Initial assessment \$75.00</p> <p>Problem follow-up \$40.00</p> <p>New problem \$40.00</p> <p>Preventive follow-up \$30.00</p>

⁴ <http://www.iarx.org/IowaPharmacy/Foundation/PCM.aspx>

State	Benefit	Reimbursement Model
Florida	<p>Disease Management models that target specific disease states⁵</p> <ul style="list-style-type: none"> • Healthier Florida <ul style="list-style-type: none"> ●● Asthma ●● Diabetes ●● Congestive heart failure ●● Chronic obstructive pulmonary disease ●● Hypertension ●● Renal disease ●● Sickle cell disease • Caremark <ul style="list-style-type: none"> ●● Hemophilia • Hemophilia of the Sunshine State <ul style="list-style-type: none"> ●● Hemophilia • Positive Health Care <ul style="list-style-type: none"> ●● HIV/AIDS • AMI –Alternate Medicine Integration <ul style="list-style-type: none"> ●● Chronic fatigue syndrome ●● Fibromyalgia ●● Chronic neck and back pain 	<p>Payable to contracted disease management providers.</p>

⁵ http://ahca.myflorida.com/Medicaid/Disease_Management/index.shtml

State	Benefit	Reimbursement Model
Minnesota	<p>Medication therapy management services are required under state law and pharmacy providers are reimbursed for therapy management services including:</p> <ul style="list-style-type: none"> • Performing or obtaining necessary assessments of the patient’s health status. • Formulating a medication treatment plan. • Monitoring and evaluating the patient’s response to therapy, including safety and effectiveness. • Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events. • Documenting the care delivered and communicating essential information to the patient’s other primary care providers. • Providing verbal education and training designed to enhance patient understanding and appropriate use of the patient’s medications. • Providing information, support services, and resources designed to enhance patient adherence with therapeutic regimens. • Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient.⁶ 	<p>Payable to licensed pharmacist who meet specific state requirements.</p> <p>Payable at the following reimbursement rates:</p> <p>Initial visit (1st 15 minutes) \$52.00</p> <p>Follow-up visit (1st 15 minutes) \$34.00</p> <p>Each additional 15 minutes \$24.00</p>

State	Benefit	Reimbursement Model
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⁶http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectonMethod=LatestReleased&Redirected=true&dDocName=id_055325

New York

Medication Therapy Management Pilot program provides:

- Patient assessment
- Comprehensive medication therapy review
- Medication action plan
- Patient follow-up for patient adherence

Services are provided by licensed pharmacists. ⁷

Payable to MTM-designated pharmacies that employ or contract with the Medicaid MTM pharmacist(s) who provided the services.

Payable at the following reimbursement rates:

Initial visit (1st 15 minutes)
\$35.00
Follow-up visit (1st 15 minutes)
\$25.00
Each additional 15 minutes
\$15.00

⁷ http://www.health.state.ny.us/health_care/medicaid/program/mtm/index.htm

State	Benefit	Reimbursement Model
North Carolina	<p>Medication Therapy Management program is required for individuals receiving 11 or greater prescriptions per month. Requirements of the program include the following:</p> <ul style="list-style-type: none"> • Services must be provided by licensed pharmacists. • Must include a comprehensive review of medications (including over the counter medication). • Evaluation and assessment of health information. • Evaluate dose optimization. • Provide patient specific education designed to enhance patient understanding and appropriate use of the patient’s medications. • Monitor patient medication regimen adherence. • Providers must document care delivered and communicate essential information to the patient’s primary care provider.⁸ 	<p>Payable to pharmacies that participate in the MTM program. Pharmacies are reimbursed at monthly rate, per client.</p>
Wisconsin	<p>Pharmaceutical Care Program is required under state law and reimburses pharmacy providers an enhanced dispensing fee for providing pharmaceutical care (PC) services that resulted in positive outcomes and increased compliance.⁹</p>	<p>Payable to the pharmacy with documentation of:</p> <ul style="list-style-type: none"> • The reason for the intervention. • The action taken by the pharmacist. • The result of that action. • The level and complexity of the service provided by the pharmacist.

⁸ <http://www.dhhs.state.nc.us/dma//bulletin/Pharmacy.pdf>

⁹ http://familyimpactseminars.org/s_wifis16c04.pdf

Current Texas Medicaid Coverage

The Texas Medicaid program reimburses for acute health-care services (physician, inpatient, outpatient, pharmacy, home health care, lab, and X-ray services), long-term services and supports for aged and disabled clients, and outpatient prescription drugs.

Pharmacy Services and Reimbursement

Reimbursement for pharmacy prescription drug claims includes two components: an amount for the ingredient cost of the drug product and a professional dispensing fee.

Ingredient cost reimbursement:

- A pharmacy's estimated acquisition cost (EAC) is determined by VDP using actual manufacturer reported prices as well as national pricing data services. The EAC is based on the pharmacy's reported source of purchase. This source of purchase could be through a wholesale company, directly from the drug manufacturer, or through a central purchasing entity such as a warehouse.
- Ingredient cost is the product of the EAC times the quantity dispensed.
- Ingredient cost represents an average of 85 to 90 percent of total reimbursement for VDP claims.

Dispensing fee reimbursement:

- Dispensing fees are based on an average pharmacy's cost to dispense a prescription, including costs for staff and overhead. The dispensing fee consists of two separate components, a fixed component plus a variable component. Effective September 2007, the fixed component is \$7.50 per prescription and the variable component is two percent of the ingredient cost plus the fixed component. The dispensing fee component is capped at \$200 per claim.
- Pharmacies that provide no-charge delivery services to Medicaid clients may be eligible for a delivery incentive.

All reimbursement amounts determined by the above methodology are reduced to a pharmacy's reported usual and customary price if that reported price is less than the total reimbursement determined by adding the ingredient cost and the professional dispensing fee.

Medicaid Fee-for-Service Home Health Coverage

Medicaid provides reimbursement for clinical interventions provided by a physician or other recognized practitioner, home health services, and medical supplies. Home Health benefits include coverage for medication administration, equipment, and supplies used in the delivery of intravenous (IV) therapy in addition to other nursing care.

Medicaid policy limits coverage to clients who:

1. Meet the eligibility requirement for Home Health Benefits.
2. Meet the coverage criteria for the requested services, supplies, and equipment.

Covered services include nursing visits for the purpose of administering medication, providing education on self administration, and assisting with the care and/or treatment of clients in home settings. Nursing services as well as the supplies used in IV therapy require prior authorization for coverage. Coverage is limited to providers enrolled in Texas Medicaid as both home health agencies (HHAs) and durable medical equipment (DME) suppliers.

While Texas Medicaid provides reimbursement for nursing services provided in the home, many specialty pharmacies are not enrolled in the Medicaid program as a HHA and, therefore, are not eligible to receive separate reimbursement from Medicaid for services provided in the home. HHAs are required to be certified by Medicare to enroll in Medicaid as a HHA.

Pharmacy Care Management in Texas

HHSC conducted a survey of pharmacies providing pharmacy care management services. The survey’s purpose was to collect information on the pharmacy care management services currently being provided by pharmacies dispensing specialty drugs in Texas Medicaid. The survey was posted on the HHSC Vendor Drug website and notification of the posting was sent to providers through GovDelivery updates. Few pharmacies responded to the survey. However, it is assumed that this is due to the probable low number of specialty pharmacy providers in the state. In addition to conducting the survey, the state also held conference calls with some of the pharmacies that responded to the survey.

In conducting the survey, the state assumed specialty pharmacy drugs included drugs indicated for the prophylaxis of RSV, blood factor, or other biologic or therapy that requires complex care. The following drugs classes were identified as specialty drugs which may require complex care. Information on pharmacy care management services was solicited for medication therapies in the classes below.

Drug Class	Therapeutic Use
Cytokine and CAM Antagonist	Rheumatoid Arthritis (RA) – an autoimmune disorder that causes chronic inflammation of the joints
Growth Hormone	Pituitary Dwarfism – deficiency of growth hormone due to dysfunction of the pituitary gland that results in short stature and other endocrine problems

Drug Class	Therapeutic Use
Hemophilia Agents	Hemophilia – a bleeding disorder that causes abnormal or exaggerated bleeding and poor blood clotting
Hepatitis B and C Agents	Hepatitis – inflammation of the liver
Intravenous immunoglobulin	Immune Deficiencies and Autoimmune and Inflammatory diseases
Multiple Sclerosis Agents	Multiple Sclerosis – a condition resulting in degeneration of the central nervous system
Pulmonary Hypertension	Pulmonary Hypertension – a circulatory condition resulting in elevated pulmonary pressure affecting the flow of blood from the heart to the lungs
Respiratory Syncytial Virus Immunization	Respiratory Syncytial Virus - a virus that causes respiratory infections especially in children borne prematurely and can produce severe pulmonary diseases including bronchiolitis and pneumonia.

Survey Findings

From reviewing the specialty pharmacy survey responses, HHSC found that the degree of pharmacy care management services differed by specialty drug and the pharmacy’s treatment model. Most of the pharmacies who responded to the survey indicated that they provide an initial assessment to evaluate patient compliance and review all drug therapies. Services also included re-fill reminders, coordination of prescription delivery with provider visits, special shipping and handling when necessary, benefit and provider coordination, management of administrative processes (e.g., prior authorization) and patient education. These services are also provided by traditional pharmacies, but may be provided at a different level of intensity or different frequency. Some of the specialty pharmacies noted providing comprehensive high-touch care management services for specific drug therapies. High-touch services included: patient care coordinators who also assisted in resolving issues with barriers to compliance; on-going compliance and utilization management; 24-hour 7 day a week access to clinical support services via phone lines, physician consultation services, monthly client counseling calls, nursing care coordination and direct nursing care in some cases.

Conclusion

The Texas Medicaid program provides coverage for specialty drugs and clinical services for the administration of specialty drugs through two distinct program models: the VDP and home health program. Currently, both the cost of the drug and medical services and supplies are reimbursed in Medicaid. However, a specific reimbursement model for care management services provided by a pharmacy does not currently exist.

HHSC found that the degree of pharmacy care management services differed by specialty drug and the pharmacy's treatment model. Treatment models are designed to be drug, disease and client specific. The intensity and frequency of the services differs based on the client's clinical need.

In conclusion, Texas could feasibly add pharmacy care management as a distinct reimbursable benefit in Texas. There would be a cost to the State to add pharmacy care management as a Medicaid benefit and approval by CMS would be needed. Because of the varying levels of care management services that could be provided, further program development would be necessary to implement this benefit in Texas and determine detailed cost.

To implement a separate reimbursement for pharmacy care management in Medicaid, HHSC would need to:

- Define the services that should be included in a pharmacy care management benefit for a specific drug, as services for distinct drugs and diseases differ.
- Establish reimbursement rates and identify the fiscal impact of providing pharmacy care management services. In 2009, there were over 13,173 clients enrolled in Medicaid that were treated with a specialty drug.
- Amend the Medicaid state plan to include coverage for pharmacy care management as a benefit.
- Develop and adopt program and reimbursement rules.
- Modify existing claims processing and accounting systems to reimburse services and ensure appropriate federal claiming.
- Establish utilization controls to eliminate the potential for duplicate billing with overlapping program benefits (e.g., VDP verse acute care billing; existing home health benefits and disease management services).