

To the Executive Commissioner of the Texas Health and Human Services Commission Austin, Texas

Myers and Stauffer LC (Myers and Stauffer) has completed the performance audit of Amber Specialty Pharmacy to determine whether pharmacy claims billed and paid under the state Medicaid program were in accordance with applicable state and federal Medicaid laws, regulations, rules, policies, and contractual requirements. The specific state and federal Medicaid laws, regulations, rules, policies, and contractual requirements to be tested were agreed to by Texas Health and Human Services Commission Office of the Inspector General (HHSC-OIG) in the approved audit test plan.

Our audit was performed under Myers and Stauffer's master contract #529-17-0117-00004, Work Order/Contract #HHS000721400011, Purchase Order #HHSTX-2-0000278647 with HHSC. Our audit covered the period of March 1, 2018, through February 28, 2021.

We conducted this audit in accordance with the performance audit provisions of Generally Accepted Government Auditing Standards issued by the Comptroller General of the United States. Those standards require that we plan and perform the audit to sufficiently obtain appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Management responses from Amber Specialty Pharmacy are included in this report.

This report is intended solely for the information and use of Texas HHSC-OIG and Amber Specialty Pharmacy management and is not intended to be, and should not be, used by anyone other than these specified parties.

If we can be of any assistance to you or if you have any questions concerning this report, please contact us.

Sincerely,

Myers and Stauffer LC

Myers and Stauffer LC

August 9, 2022





Background and Criteria

The Texas Health and Human Services Commission Office of the Inspector General (HHSC-OIG) contracted Myers and Stauffer LC (Myers and Stauffer) to conduct audits of Medicaid claims billed by providers and paid by the state Medicaid program.

Amber Specialty Pharmacy (Provider) was selected in coordination with the Texas HHSC-OIG for Myers and Stauffer to perform a claims audit. The audit will focus on paid fee-for-service (FFS) pharmacy claims having dates of service during the period of March 1, 2018, through February 28, 2021.

The Provider currently conducts pharmacy operations at 1301 E. Arapaho Road, Suite 103, Richardson, TX 75081 and has a headquarters located in Omaha, Nebraska. The Provider has a nationwide presence with 21 pharmacies serving recipients in all 50 states, as well as Puerto Rico. The Provider is a subsidiary of Hy-Vee, Inc. and focuses on multiple specialties including transplant and immunology pharmacy services.

Pharmacies receive, process, and dispense prescription drug or medication orders. Texas pharmacies must enroll with the HHSC Vendor Drug Program (VDP) prior to dispensing outpatient prescriptions to people enrolled in either Medicaid managed care or traditional Medicaid. The HHSC VDP is responsible for outpatient prescriptions of people enrolled in traditional Medicaid.

The HHSC VDP provides statewide access to covered outpatient drugs for people enrolled in Medicaid, the Children's Health Insurance Program (CHIP), the Children with Special Health Care Needs (CSHCN) Services program, the Healthy Texas Women (HTW) Program and the Kidney Health Care (KHC) Program.

Claims for pharmacies enrolled in the HHSC VDP should comply with the HHSC VDP Pharmacy Provider Procedure Manual (PPPM); the Texas Administrative Code (TAC); United States Code, including the False Claims Act and Controlled Substances Act (CSA); Texas Controlled Substances Act; and Texas State Board of Pharmacy Rules, if applicable.

Audit Objective

The objective of the claims audit is to determine whether pharmacy services billed to and paid under the state Medicaid program were in accordance with applicable state and federal Medicaid laws, regulations, rules, policies, and contractual requirements. In addition, this audit serves as a follow up to the audit conducted in 2018 to determine if appropriate actions have been taken to correct previously identified errors. The specific state and federal Medicaid laws, regulations, rules, policies, and contractual requirements to be tested were agreed to by the HHSC-OIG in the approved audit test plan.

Sampling Overview

For the period of March 1, 2018, through February 28, 2021, the HHSC-OIG identified \$3,792,545 at risk of \$16,810,051 total pharmacy service reimbursements for the Provider. HHSC-OIG provided all FFS and



managed care organization (MCO) claims within the total payment population to Myers and Stauffer for review. Upon review of the algorithms and contracting guidelines HHSC-OIG provided, FFS claims with Dispense As Written (DAW) code 1 were identified as outliers to target for audit.

A claims universe was created of FFS single and compound pharmacy claims, only including claims with a DAW code 1 indicating that the prescription dictates to the pharmacist to dispense the brand-name drug. The final claims universe consisted of 406 claim lines for 75 unique recipients with 17 unique National Drug Codes (NDC) for which the provider was reimbursed \$275,725.

A random sample utilizing the RAT-STATS software was selected from the claims universe. The random sample consisted of 131 claim lines for 41 unique recipients, with 13 unique NDCs, for which the Provider was reimbursed \$91,185.

Audit Process

Scope

The scope of this audit included the review of Medicaid FFS pharmacy claims only, due to contracting guidelines, with dates of service during the period of March 1, 2018, through February 28, 2021.

Testing of the HHSC VDP claims processing system is outside the scope of the audit. As such, pursuant to guidance from Texas HHSC-OIG, if the claims adjudicated for payment through the HHSC VDP claims processing system, the following assumptions were made:

- Drug prescribed/dispensed was included in the Texas Drug Code Index.
- Prescribing practitioner was enrolled with the HHSC VDP.

In gaining an understanding of internal controls, Myers and Stauffer limited the review to the Provider's overall internal control structure significant to the audit objectives. Myers and Stauffer determined significant internal controls to the audit objective include:

- **Control Environment:** The foundation for an internal control system. It provides the discipline and structure to help an entity achieve its objectives.
- Control Activities: The actions management establishes through policies and procedures to achieve objectives and respond to risks in the internal control system, which includes the entity's information system.
- Monitoring: Activities management establishes and operates to assess the quality of performance over time and promptly resolve the findings of audits and other reviews.

Methodology

Myers and Stauffer conducted this performance audit in accordance with Generally Accepted Government Auditing Standards (GAGAS) and applicable TAC rules, including 1 TAC §371.1719 and §354.1891, as appropriate. Those standards require that the audit is planned and performed to obtain



sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. Audit testing was performed to verify compliance in the following areas:

- Verify that pharmaceuticals were dispensed by a licensed pharmacist enrolled in Medicaid by obtaining and reviewing licensing documentation for all dispensing pharmacists during the period under review.
- Verify that pharmaceuticals were prescribed by a practitioner licensed to prescribe legend drugs and enrolled as a Texas Medicaid provider by obtaining and reviewing documentation of prescribers' licensing, HHSC VDP status, and original signed prescriptions.
- Verify that claims included the prescriber's correct identification number by obtaining and reviewing the pharmacy claims data and original prescription.
- Verify that the original prescription met documentation requirements by obtaining and reviewing original signed prescriptions and documentation of telephone orders and faxed orders, if applicable.
 - Verify that the original prescription conformed to the Texas State Board of Pharmacy rules concerning the records to be maintained by a pharmacy.
 - Verify that the original prescription was signed.
 - o Verify that the initials or identification code of the transcribing pharmacist was documented if the prescription order was communicated orally or telephonically.
 - Verify that faxed prescriptions included a statement that indicated that the prescription had been faxed (e.g., "Faxed To:").
 - Verify that prescriptions for covered pharmaceuticals submitted to a pharmacy in written form were executed on tamper-resistant prescription paper.
 - Verify that the original prescription included the following information:
 - The name and address of the recipient.
 - The name of the prescriber and their work address.
 - The name and strength of the drug prescribed.
 - The quantity prescribed.
 - Directions for use.
 - Date of issuance.
 - Verify that the pharmacist documents the following on either the original hardcopy prescription or in the pharmacy's data processing system when the prescription is dispensed:
 - The unique identification number of the prescription drug order.
 - The initials or identification number of the dispensing pharmacist.
 - The quantity dispensed (if different from the quantity prescribed).
 - The date of dispensing (if different from the date of issuance).
 - The NDC of the drug actually dispensed.
 - The name of the drug actually dispensed (if different from the one prescribed).



- Verify that refill prescriptions met all requirements by obtaining and reviewing the original prescriptions as well as pharmacy records of refills.
 - o Verify that pharmacist dated the prescription and initialed the refills.
 - Verify that the total amount of prescriptions authorized (up to 11 refills) were dispensed within one year of the original prescription by obtaining and reviewing records of refills dispensed and their corresponding original signed prescription.
 - Verify that the refills were dispensed as authorized by the prescriber by obtaining and reviewing the original signed prescription, record of refill, and other pharmacy records as needed.
- Verify that the pharmacist dispensed and billed drugs safely and accurately, as prescribed, by obtaining and reviewing the original signed prescription and prescriber authorizations as needed.
 - Verify that only authorized drugs were dispensed and billed.
 - Verify that substitutions were authorized by the prescribing physician and the substituted drug was dispensed accurately as prescribed.
 - Verify that prescriptions properly documented when a brand was necessary.
 - Verify that the prescribed and dispensed drug was picked up by the recipient/recipient's guardian by reviewing signed prescription pickup logs.
- Verify that the quantity dispensed was the same as the quantity prescribed and billed, except as limited by HHSC's policies and procedures, by obtaining and reviewing the original signed prescription and pharmacy claims data.
- Verify that the prescription label met documentation requirements by obtaining and reviewing the prescription back tag.

In addition, inquiries; observations; inspection of documents and records; review of other audit reports; and/or direct tests were performed to assess the design, implementation, and/or operating effectiveness of controls determined significant to the audit objectives stated in the scope.

Audit Results

Myers and Stauffer believes the evidence obtained during the course of the claims audit provides a reasonable basis for the findings and conclusions based on the audit objective. The audit was not intended to discover all possible errors and any errors not identified within this report should not lead to a conclusion the practice is acceptable. Due to the limited nature of the review, no inferences should be drawn from this report with respect to the Provider's overall level of performance.

Findings

Myers and Stauffer identified findings on 18 of 131 pharmacy claims. The table below provides a summary of the findings that have been identified in the audit. The findings for the claims universe is listed in detail in Appendix A. The list of findings and supporting policies follows in the table below:



List of Findings and Supporting Policies									
Finding No.	Finding Type	Finding Definition	Number of Claims with Finding	Supporting Policy					
1	Lack of Delivery Record	Delivery confirmation of medication to the correct recipient was not submitted.	17	22 TAC §291.31(1) 22 TAC §291.32 (c)(1)(F) 1 TAC §371.1667					
2	Incorrect Prescriber	The prescriber identified on the prescription record did not match prescriber identified on the claim despite the prescriber on the prescription record holding a valid license and active National Provider Identification (NPI) number.	1	1 TAC §354.1835 HHSC VDP Provider Manual 2019 §4.2					

A lack of internal controls has been identified as a contributing cause of the Lack of Delivery Record findings included in the table above. The Provider has not placed enough emphasis on designing, implementing, and/or effectively operating internal controls, as it does not appear that the Provider had controls in place to adequately document and retain records to support that the billed services were provided in accordance with required regulations. Appropriate internal controls aid in assuring the recipients receive the correct medication(s)/counseling. The Provider's Audit and Quality Improvement Manager indicated during the audit that the United States Postal Service (USPS) does not maintain an archived tracking system and, unfortunately, the Provider's shipping software also failed to archive delivery information for all of the prescriptions shipped via USPS. The Provider expressed that they are currently working to correct this issue.

Although findings were identified during the current audit, it appears that the Provider has made improvements to their internal control system since the previous 2018 audit. Additional instances of missing prescriber signatures or unapproved NDC changes were not identified during this current audit.

Management's Response

A draft copy of this report was sent to the Provider on July 20, 2022. An exit conference was held on July 26, 2022 to discuss the preliminary findings. During the exit conference, the Provider did not contest the findings and stated they do not have any additional documentation to submit.

Final Determination of Overpayment

The Medicaid paid claims with identified findings are listed in detail in Appendix A of this report. The corresponding overpayment amount in Appendix A is only applicable to the sampled claims Myers and Stauffer reviewed during the audit. The overpayment calculated from our sample is \$15,880. The sample



was not confirmed to be representative of the universe; therefore, it would not be appropriate to project the test results to the universe.

The total amount due to the HHSC-OIG is \$15,880 for the claims reviewed. Based on the findings cited in this Final Audit Report, the Provider is directed to:

- Remit the overpayment in the amount of \$15,880, pursuant to 1 TAC §371.1719, Recoupment of Overpayments Identified by Audit, 1 TAC §354.1891, Vendor Drug Providers Subject to Audit, and §354.1892, Exception Notification. Payment is to be made to the Texas HHSC-OIG.
- Comply with all state and federal Medicaid laws, regulations, rules, policies, and contractual requirements.



Appendix A – Detailed Findings Amber Specialty Pharmacy

Amber Specialty Pharmacy Project Number 013

					Original	Claims Information									Audit Determin	ation		
ample Line Number	State Issued Medicald ID	Member Full Name	Claim Number	Prescription Number	Prescribing Provider NPI	Prescribing Provider	Drug Name	National Drug Code	Date of Service	Date Prescribed	Dispensing Fee		Finding Type	Supporting Policy Reference		Adjusted Prescribing	Corrected Claim Payment	Overpaymen Amoun
6							PROGRAF 1 MG CAPSULE				\$42.59	\$1,762.61	LACK OF DELIVERY RECORD	A, B, C	1		\$0.00	\$1,762.6
63							SANDIMMUNE 100 MG CAPSULE				\$24.85	\$857.55	LACK OF DELIVERY RECORD	А, В, С	1		\$0.00	\$857.5
64							SANDIMMUNE 25 MG CAPSULE				\$12.16	\$210.05	LACK OF DELIVERY RECORD	A, B, C	1		\$0.00	\$210.0
67							PROGRAF 0.5 MG CAPSULE				\$11.56	\$179.35	LACK OF DELIVERY RECORD	A, B, C	1		\$0.00	\$179.3
68							PROGRAF 1 MG CAPSULE				\$21.87	\$705.63	LACK OF DELIVERY RECORD	A, B, C	1		\$0.00	\$705.6
71							NEORAL 100 MG GELATIN CAPSU				\$12.86	\$245.77	LACK OF DELIVERY RECORD	А, В, С	1		\$0.00	\$245.77
75							PROGRAF 0.5 MG CAPSULE				\$11.56	\$179.35	LACK OF DELIVERY RECORD	A, B, C	1		\$0.00	\$179.3
76							MYFORTIC 180 MG TABLET				\$14.08	\$307.80	LACK OF DELIVERY RECORD	А, В, С	1		\$0.00	\$307.8
105							MYFORTIC 360 MG TABLET				\$25.97	\$914.83	LACK OF DELIVERY RECORD	А, В, С	1		\$0.00	\$914.8
106							PROGRAF 1 MG CAPSULE				\$21.87	\$705.63	LACK OF DELIVERY RECORD	А, В, С	1		\$0.00	\$705.63
110							PROGRAF 1 MG CAPSULE				\$35.66	\$1,409.18	LACK OF DELIVERY RECORD	А, В, С	1		\$0.00	\$1,409.1
111							MYFORTIC 360 MG TABLET				\$31.94	\$1,219.09	LACK OF DELIVERY RECORD	A, B, C	1		\$0.00	\$1,219.09
112							PROGRAF 0.5 MG CAPSULE				\$11.56	\$179.35	LACK OF DELIVERY RECORD	А, В, С	1		\$0.00	\$179.3
113							MYFORTIC 360 MG TABLET				\$31.94	\$1,219.09	LACK OF DELIVERY RECORD	А, В, С	1		\$0.00	\$1,219.09
114							PROGRAF 1 MG CAPSULE				\$42.56	\$1,760.97	LACK OF DELIVERY RECORD	А, В, С	1		\$0.00	\$1,760.9
117							MYFORTIC 180 MG TABLET				\$26.06	\$919.23	LACK OF DELIVERY RECORD	А, В, С	1		\$0.00	\$919.23
124							PROGRAF 1 MG CAPSULE				\$14.98	\$353.86	LACK OF DELIVERY RECORD	А, В, С	1		\$0.00	\$353.86
128							RAPAMUNE 1 MG TABLET				\$61.84	\$2,750.96	INCORRECT PRESCRIBER	D, E	1		\$0.00	\$2,750.96
Totals				· ·		**					\$455.91	\$15,880.30					\$0.00	\$15,880



Legends

Finding Type	Policy Reference	Definition
LACK OF DELIVERY RECORD	A, B, C	Delivery confirmation of medication to the correct patient was not submitted.
INCORRECT PRESCRIBER	D F	The prescriber identified on the prescription record did not match prescriber identified on the claim despite the prescriber on the prescription record holding a
INCORRECT PRESCRIBER		valid license and active national provider identification (NPI) number.

	Recoupment Type	Recoupment Type Definition
	1	Full
Reference	Supporting Policy	Policy
A	1 TAC §371.1667	A person is subject to administrative actions or sanctions if the person: (1) falls to make, maintain, retain, or produce adequate documentation according to Medicaid or other HHS policy, state or federal law, rule or regulation, or contract for a minimum period of: (A) five years from the date of service or until all audit questions, administrative hearings, investigations, court cases, or appeals are resolved; (3) six years or until all audit questions, administrative hearings, investigations, court cases, or appeals are resolved if the person is a freestanding Rural Health Clinic; and (C) ten years or until all audit questions, administrative hearings, investigations, court cases, or appeals are resolved if the person is a hospital-based Rural Health Clinic; (2) falls to provide originals or complete and correct copies of records or documentation as requested upon reasonable request by a requesting agency; or (3) falls to prain immediate access to the premises, records, documentation, or any terms or equipment determined necessary by the OlG to complete its official functions related to a fraud, waste, or abuse investigation upon request by a requesting agency. Pallure to grant immediate access may include, but is not limited to, the following: (A) failure to allow the OlG or any requesting agency to conduct any duties that are necessary to the performance of inclinal functions; (B) failure to provide to the OlG or a requesting agency to conduct as requested, for the purpose of reviewing, examining, and securing custody of records, access to, disclosure of, and custody of copies or originals of any records, documents, or other requested intens, as determined on securing custody of records upon reasonable request, and the request mined by the OlG or a requesting agency to perform official functions; (C) failure to produce or make available records within 24 hours of a request for production, for the purpose of reviewing, examining, and securing custody of records upon reasonable request, and the request may



Legends

Finding Type	Policy Reference	Definition
LACK OF DELIVERY RECORD	A, B, C	Delivery confirmation of medication to the correct patient was not submitted.
INCORDECT DRESCRIPED	D F	The prescriber identified on the prescription record did not match prescriber identified on the claim despite the prescriber on the prescription record holding a
INCORRECT PRESCRIBER		valid license and active national provider identification (NPI) number.

Recoupment Type	Recoupment Type Definition
1	Full

Reference	Supporting Policy	Policy
В	22 TAC §291.31(1)	 (1) Accurately as prescribedDispensing, delivering, and/or distributing a prescription drug order: (A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed; (B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and (C) with correct labeling (including directions for use) as ordered by the practitioner. Provided, however, that nothing herein shall prohibit pharmacist substitution if substitution is conducted in strict accordance with applicable laws and rules, including Chapter562 of the Texas Pharmacy Act.
С	22 TAC §291.32 (c)(1)(F)	(F) A dispensing pharmacist shall be responsible for and ensure that the drug is dispensed and delivered safely and accurately as prescribed, unless the pharmacy's data processing system can record the identity of each pharmacist involved in a specific portion of the dispensing processing. If the system can track the identity of each pharmacist involved in the dispensing process, each pharmacist involved in the dispensing process shall be responsible for and ensure that the portion of the process the pharmacist is performing results in the safe and accurate dispensing and delivery of the drug as prescribed. The dispensing process shall include, but not be limited to, drug regimen review and verification of accurate prescription data entry, including prescriptions placed on hold, packaging, preparation, compounding, transferring, labeling, and performance of the final check of the dispensed prescription. An intern has the same responsibilities described in this subparagraph as a pharmacist but must perform his or her duties under the supervision of a pharmacist.
D	1 TAC §354.1835	Unless an exception is needed during a disaster, as described in §354.1868 of this subchapter (relating to Exceptions in Disasters), vendors must enter the identification number of the prescriber, as listed with the appropriate medical specialty board, on each claim.
E	HHSC VDP Provider Manual 2019 §4.2	Pharmacy Staff are required to submit claims using the NPI of the prescribing provider or, when applicable, the supervising prescriberthe actual NPI of a physician assistant, advance practice registered nurse (APRN), or prescribing pharmacist is required for prescriptions written by these provider types, which do have prescribing authority as allowed by their respective state boards. For prescriptions written by these provider types that do not have a NPI, the supervising prescriber's NPI will be accepted.