MYERS AND STAUFFER LC
CERTIFIED PUBLIC ACCOUNTANTS

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

Myers and Stauffer LC has completed the performance audit of Avita 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 the 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 #HHS000325700001, Purchase Order #HHSTX-9-0000195405 with HHSC. Our audit covered the period of June 1, 2016, through April 30, 2019.

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 Avita Pharmacy are included in this report.

This report is intended solely for the information and use of the HHSC-OIG and Avita 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 27, 2021

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Final Audit Report

Avita Pharmacy
NPI 1841459328

Report Date
August 27, 2021

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Background and Criteria

The Texas Health and Human Services Commission (HHSC) 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. Avita Pharmacy (Provider) was selected by the HHSC-OIG for Myers and Stauffer to perform a claims audit. The audit focused on paid fee-for-service (FFS) pharmacy claims with dates of service during the period of June 1, 2016, through April 30, 2019.

The Provider began operations in 2008 and is a Community Independent Pharmacy. The Provider is owned and operated by 340B Partners Pharmacy which operates more than one pharmacy location in Texas. Although 340B Partners Pharmacy owns the Provider, the pharmacy claims under review are paid through Medicaid FFS.

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.

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 was to determine whether pharmacy claims 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. 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

The HHSC-OIG identified $63,509 dollars in total reimbursements for the Provider during the period of July 1, 2015, through June 30, 2020 for gastroesophageal reflux disease (GERD) drugs and submitted FFS claims for review. The claims data was analyzed and all claims outside the period of review of June 1, 2016, through April 30, 2019 were excluded. Furthermore, only select drugs (e.g., Nexium Delayed-Release 20 mg and Nexium Delayed-Release 40 mg capsules) were included in the final claims universe.

The final claims universe consisted of 50 claims for 10 unique recipients for which the Provider was reimbursed $19,427. The probe sample was created to select every instance of the Provider billing for Nexium Delayed-Release 20 and 40 mg capsules in quantities greater than 30, resulting in 18 selections. In addition, two more claims for the same drugs with a quantity dispensed equal to 30 were selected resulting in a total of 20 claims being selected for the probe sample. The final probe sample included 20 claims for five unique recipients for which the Provider was reimbursed $11,770.

Audit Process

Scope

The scope of this audit includes the review of Medicaid FFS pharmacy claims billed and paid for during the period of June 1, 2016, through April 30, 2019.

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 included:

- **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 1 TAC §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 findings and conclusions based on 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, 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.
    - 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 bared 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.
  - 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.

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 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 a finding on all 20 pharmacy claims. The list of findings and supporting policy follows in the table below.

List of Findings and Supporting Policy

Finding No.	Finding Type	Finding Definition	Number of Claims with Finding	Supporting Policy
1	Lack of Documentation	Delivery confirmation of medication to the correct recipient and prescription labels documenting the directions for use of the medication prescribed were not maintained for the required five years.	20	22 TAC §291.31(1) 22 TAC §291.32 (c)(1)(F) 1 TAC §371.1667

A lack of internal controls has been identified as a contributing cause of the finding noted in the table above. It does not appear that the Provider had controls in place to adequately retain documentation to support that the billed and paid services were provided in accordance with required regulations. A lack of policies and/or oversight of established policies creates an environment in which management or personnel are unable to achieve the applicable control objectives and address related risks.

During the Provider's entrance conference, the Provider stated that they had switched systems since the audit period of review that prevented them from being able to print the requested supporting prescription labels, or equivalent report, from their system. The Provider also explained during the entrance conference that they did not require the signature of the recipient or confirm receipt of delivery for prescriptions dispensed via courier service. During the Provider's exit conference, the

Provider stated that they maintained records for two years and were not aware of the rules for Medicaid. This highlights how the Provider may not have properly designed and implemented this system change for the practice to assure they retain all pharmacy documentation in compliance with applicable policies.

Management's Response

A draft copy of this report was sent to the Provider on July 23, 2021, which included findings on all claims, as no documentation was previously submitted in response to the engagement letter. The Provider responded to the Preliminary Draft Audit Report on August 3, 2021. In its response, the Provider submitted documentation for the claims including copies of the original prescriptions, screen captures from their system, and a spreadsheet detailing specific information for the questioned claims.

An exit conference was held on August 19, 2021, to discuss the preliminary findings after Myers and Stauffer's initial review of the documentation submitted.

During the exit conference, the Provider expressed they felt all of the requested information that they were able to provide in connection with the audit had been submitted. Myers and Stauffer confirmed receipt of the submitted documentation but requested a direct, unaltered report from their system including all information to support the dispensing of the claims under review. The Provider subsequently submitted the requested report in place of the original prescription labels.

Revised Findings Based on Management's Response

After reviewing the Provider's response and the documentation submitted, the findings were revised. However, the resulting number of questioned pharmacy claims remains at 20. Findings were revised as follows:

- The Provider submitted a copy of the original prescription for all 20 pharmacy claims with a finding of original prescription not submitted in the Preliminary Draft Audit Report. Upon review of the submitted documentation, this finding was rescinded for all 20 pharmacy claims.
- Based on the additional documentation submitted by the Provider, a new finding was added to all 20 pharmacy claims for not submitting all required documentation for the prescription label and delivery confirmation that the medication was delivered to the correct recipient.

Final Determination of Overpayment

The Medicaid paid claims with identified findings are listed in detail in Appendix A of this report. Although the finding(s) listed did not result in a corresponding overpayment, audit issues identified in this report may be subject to HHSC-OIG administrative enforcement measures, including administrative penalties, as outlined in 1 TAC §371.1603 and Texas Human Resources Code §32.039.

Appendix A-1 – Detailed Findings

Avita Pharmacy
Project Number 010
NPI 1841459328

Sample Item	Member ID	Member Name	Claim ID	Prescription Number	Drug Name	Date of Service	Date Prescribed	Dispensing Fee Amount	Total Reimbursed Amount	Overpayment Amount	Finding Type	Supporting Policy Reference
1	[redacted]				NEXIUM DR 20 MG CAPSULE	[redacted]		$ 17.76	$ 501.62	$ -	LACK OF DOCUMENTATION	A, B, C
2					NEXIUM DR 20 MG CAPSULE			$ 17.76	$ 501.62	$ -	LACK OF DOCUMENTATION	A, B, C
3					NEXIUM DR 20 MG CAPSULE			$ 22.59	$ 748.38	$ -	LACK OF DOCUMENTATION	A, B, C
4					NEXIUM DR 40 MG CAPSULE			$ 37.28	$ 1,497.64	$ -	LACK OF DOCUMENTATION	A, B, C
5					NEXIUM DR 20 MG CAPSULE			$ 17.76	$ 501.62	$ -	LACK OF DOCUMENTATION	A, B, C
6					NEXIUM DR 20 MG CAPSULE			$ 17.91	$ 501.77	$ -	LACK OF DOCUMENTATION	A, B, C
7					NEXIUM DR 20 MG CAPSULE			$ 13.07	$ 255.00	$ -	LACK OF DOCUMENTATION	A, B, C
8					NEXIUM DR 20 MG CAPSULE			$ 17.91	$ 501.77	$ -	LACK OF DOCUMENTATION	A, B, C
9					NEXIUM DR 40 MG CAPSULE			$ 37.43	$ 1,497.79	$ -	LACK OF DOCUMENTATION	A, B, C
10					NEXIUM DR 20 MG CAPSULE			$ 17.91	$ 501.77	$ -	LACK OF DOCUMENTATION	A, B, C
11					NEXIUM DR 20 MG CAPSULE			$ 17.91	$ 501.77	$ -	LACK OF DOCUMENTATION	A, B, C
12					NEXIUM DR 20 MG CAPSULE			$ 17.91	$ 501.77	$ -	LACK OF DOCUMENTATION	A, B, C
13					NEXIUM DR 20 MG CAPSULE			$ 17.88	$ 500.53	$ -	LACK OF DOCUMENTATION	A, B, C
14					NEXIUM DR 20 MG CAPSULE			$ 17.88	$ 500.53	$ -	LACK OF DOCUMENTATION	A, B, C
15					NEXIUM DR 20 MG CAPSULE			$ 17.88	$ 500.53	$ -	LACK OF DOCUMENTATION	A, B, C
16					NEXIUM DR 20 MG CAPSULE			$ 17.88	$ 500.53	$ -	LACK OF DOCUMENTATION	A, B, C
17					NEXIUM DR 20 MG CAPSULE			$ 17.88	$ 500.53	$ -	LACK OF DOCUMENTATION	A, B, C
18					NEXIUM DR 20 MG CAPSULE			$ 17.88	$ 500.53	$ -	LACK OF DOCUMENTATION	A, B, C
19					NEXIUM DR 20 MG CAPSULE			$ 17.88	$ 500.53	$ -	LACK OF DOCUMENTATION	A, B, C
20					NEXIUM DR 40 MG CAPSULE			$ 13.05	$ 253.95	$ -	LACK OF DOCUMENTATION	A, B, C
Total									$ 11,770.18	$ -		

Appendix A-2 – Detailed Findings Legends

Finding Type	Policy Reference	Definition
LACK OF DOCUMENTATION	A, B, C	Delivery confirmation of medication to the correct recipient and prescription labels documenting the directions for use of the medication prescribed were not maintained for the required five years.

Supporting Policy	Policy	Reference
22 TAC §291.31(1)	(1) Accurately as prescribed--Dispensing, 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.	A
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.	B
1 TAC §371.1667	A person is subject to administrative actions or sanctions if the person (1) fails 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; (B) 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) fails to provide originals or complete and correct copies of records or documentation as requested upon reasonable request by a requesting agency; or (3) fails to grant immediate access to the premises, records, documentation, or any items or equipment determined necessary by the OIG to complete its official functions related to a fraud, waste, or abuse investigation upon request by a requesting agency. Failure to grant immediate access may include, but is not limited to, the following (A) failure to allow the OIG or any requesting agency to conduct any duties that are necessary to the performance of their official functions; (B) failure to provide to the OIG or a requesting agency, upon request and 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 items, as determined necessary by the OIG 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, as determined by the OIG or a requesting agency except where the OIG or a requesting agency reasonably believes that requested documents are about to be altered or destroyed or that the request may be completed at the time of the request and/or in less than 24 hours; (D) failure to grant access to a person's premises at the time of a reasonable request; (E) failure to provide access to records at the time of a request, for the purpose of reviewing, examining, and securing custody of records upon reasonable request, when the OIG or a requesting agency has reason to believe that (i) requested documents are about to be altered or destroyed; or (ii) in the opinion of the OIG or a requesting agency, the request could be met at the time of the request or in less than24 hours; (F) failure to relinquish custody of records and documents as directed by the OIG or a requesting agency; (G) failure to complete a records affidavit, business records affidavit, evidence receipt, or patient record receipt, at the direction of the OIG or a requesting agency and to attach these documents to the records or documentation requested; or (4) fails to make, maintain, retain, or produce documentation sufficient to demonstrate compliance with any federal or state law, rule, regulation, contract, Medicaid or other HHS policy, or professional standard in order to (A) participate in the Medicaid or other HHS program; (B) support a claim for payment; (C) verify delivery of services or items provided; (D) establish medical necessity, medical appropriateness, or adherence to the professional standard of care related to services or items provided; (E) determine appropriate payment for items or services delivered in accordance with established rates; (F) confirm the eligibility of a person to participate in the Medicaid or other HHS program; (G) demonstrate solvency of risk-bearing providers; (H) support a cost or expenditure; (I) verify the purchase and actual cost of products, items, or services; or (J) establish compliance with applicable state and federal regulatory requirements.	C