



21-07

INTERNAL AUDIT REPORT

Lewis Drug—340B Pharmacy Agreement

March 2022

City of Sioux Falls Internal Audit Department
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 **Lewis.**
Your first stop

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Introduction

A compliance audit of the 340B pharmacy agreement with Lewis was included on the 2021 Annual Audit Plan as a carry-over audit from 2020. The purpose of this audit was to review the requirements of Agreement 11-4078 and ensure Lewis's compliance with those requirements. We will also provide assurance that internal controls are in place and functioning properly. Controls are intended to provide reasonable assurance, but cannot guarantee, that fraud and errors will not occur. The audit focuses on compliance with respect to eligibility, duplicate discounts, and diversion, among other requirements.

Background

The development of the 340B drug pricing program (340B program) began in 1990 when Congress formed the Medicaid drug rebate program to reduce the cost of prescription drugs reimbursed by state Medicaid agencies. This program requires drug manufacturers and distributors to enter into a reimbursement agreement with the Department of Health and Human Services in order to receive coverage of their drugs by Medicaid and Medicare Part B. Under the program, a drug company must pay rebates to state Medicaid programs for covered outpatient drugs, as defined in the Medicaid rebate statute. The rebate amount for a covered outpatient drug is based on the "best price" the manufacturer can offer the drug for.

In 1992, Congress extended this assistance with high drug costs to safety-net providers by passing Section 340B of the Public Health Service Act. Section 340B requires pharmaceutical manufacturers to enter into an agreement with the Health and Human Services Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B. Under this agreement, manufacturers agree to provide discounts on covered outpatient drugs purchased by certain hospitals and recipients of federal grants, called covered entities, that serve the most vulnerable patient populations. The purpose of the 340B program is to enable these covered entities to stretch scarce resources as far as possible, reaching more eligible patients and providing more comprehensive services. Participation in the 340B program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities and their patients can realize substantial savings through 340B price discounts, and drug manufacturers must participate in the 340B program to receive Medicaid reimbursement for their drugs. In comparing 340B prices to retail prices, the savings that covered entities and their patients receive range from \$5 to over \$600 per prescription, depending on the medication.

On February 3, 2011, Falls Community Health (FCH) entered into an agreement with Lewis Drug Stores (Lewis) to provide pharmacy services to eligible patients with respect to 340B outpatient drugs. FCH providers write prescriptions for eligible patients and Lewis dispenses the cheaper 340B drugs to those patients. Lewis has to monitor the inventory of 340B drugs, order drugs as needed, and send the invoices to FCH to be paid. Lewis also submits a monthly report and payment to FCH. In order to prevent diversion, which occurs when 340B drugs are dispensed to

patients who are not eligible, Lewis must establish and maintain a tracking system to prevent dispensing covered drugs to non-eligible patients. Lewis and FCH have also agreed to not use 340B drugs for Medicaid patients. This program has benefited many FCH patients since the agreement was made. **See table 1 below.**

Table 1. 340B Prescription & Patient Data

	2019	2020	2021
Prescriptions Filled	3,223	3,173	3,570
Number of Patients	832	788	898

*Data was provided by Lewis’s corporate office.

Objective

Determine if Lewis is compliant with the requirements of Agreement 11-4078 with respect to eligibility status, duplicate discounts, diversion, insurance coverage, and other requirements.

Scope

The audit scope included a review of the 340B process, software utilized, and policies and procedures as they are currently in place. The detailed testing consisted of a sample of 340B drugs dispensed during the twelve-month period of January 1, 2021 through December 31, 2021.

Methodology

To complete this audit, we performed the following steps:

- Review of Agreement 11-4078 and its requirements.
- Review of the federal 340B program and its requirements.
- Review of written policies and procedures over the 340B program.
- Interviews with management and staff.
- Site visits with Lewis pharmacists to observe the 340B process.
- Review of a sample of prescriptions to verify patient eligibility, prescription requirements, and the 340B drugs are not paid for by Medicaid.

Results

Licensed Pharmacy

Section two of the agreement requires Lewis to be duly licensed as a pharmacy in South Dakota. To verify this, we obtained a copy of their license, which is current and active.

Purchase and Shipment of Drugs

In accordance with section four of the agreement, Lewis orders 340B drugs on the FCH formulary directly from the drug manufacturer or wholesaler. After the drugs are shipped to the pharmacy, they verify the shipment matches the invoice and send the invoice to FCH, who is responsible for paying the invoice. Ultimately, this section of the agreement imposes requirements on Lewis for monitoring the inventory of 340B drugs and maintaining enough inventory to meet the needs of eligible patients.

Finding 1 – Inventory Optimization

Section four of the agreement requires Lewis to maintain sufficient supplies to meet the day-to-day needs of eligible patients. In current practice, Lewis's ordering technician or pharmacist physically looks over the 340B inventory, determines what drugs are low based on judgment, and places an order for those drugs as needed.

To be compliant with the agreement requirement to maintain sufficient inventory levels, Lewis should implement a more efficient process for inventorying 340B drugs. **See Recommendation 1 below.**

Tracking System

To comply with section five of the agreement, Lewis must implement a "tracking system" to help ensure 340B drugs are not dispensed to patients who are not eligible. According to the 340B program, such a tracking system may be a periodic sample comparison of eligible patient prescriptions with the dispensing records and a six-month comparison of purchasing and dispensing records.

Finding 2 – Tracking System

Currently, Lewis does not perform any sort of review or reconciliation after 340B drugs have been dispensed to verify patient eligibility. The 340B program provides examples of reconciliation procedures that could be used as a "tracking system," but the agreement maintains this "tracking system" must be in place. **See Recommendation 2 below.**

Prescription Requirements

Per section six of the agreement, Lewis can only dispense 340B drugs when one of the two following conditions are met:

1. They receive a prescription form listing FCH's name, the eligible patient's name, a designation that the patient is eligible, and the signature of a provider affiliated with FCH.
2. They receive a prescription ordered by telephone by a provider affiliated with FCH on behalf of an eligible patient, stating that the patient is eligible for 340B.

Finding 3 – 340B Designation

Section six of the agreement requires Lewis to only dispense 340B drugs upon presentation of a prescription form bearing a designation that the patient is an eligible patient. Typically, providers type a 340B comment on an eligible patient's prescription form. We selected a random sample of 30 prescriptions dispensed in 2021 and found that six of these prescription forms did not have the 340B comment, or any designation that the patient was eligible. **See Recommendation 3 below.**

Pharmacy Services

Section seven of the agreement lists various pharmacy services Lewis is required to provide:

- Maintaining all records and reports; Lewis utilizes PioneerRX to store records and reports. Prior to 2014, they used Condor and still have access to retrieve reports from that system. Beginning in 2019, Lewis now saves all reports in a shared secure folder that FCH also has access to.
- Eligible patient drug utilization review; Lewis uses PioneerRX for drug utilization review. The software will automatically flag certain drugs if there are potential negative drug-drug interactions.
- Maintain eligible patient drug profiles; Lewis stores patient personal information and prescription filling history in PioneerRX.
- Counseling and advising eligible patients; This is done face-to-face and information provided is backed by pharmacists' expertise. Lewis also uses QR codes on prescriptions that patients can scan to receive pertinent drug information.
- Monthly dispensing reports; Lewis provides FCH monthly reports that list patient names, drugs dispensed, and quantity of the drug dispensed. The reports are saved in the shared secure folder.
- Invoices within one business day; Lewis faxes invoices to FCH, and of the 120 invoices sent in 2021, 17 were reviewed and confirmed to have been faxed the same day the 340B drugs were received.

Quarterly Reports

Section 10 of the agreement requires Lewis to provide FCH quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records.

Finding 4 – Quarterly Reports

Lewis is not currently providing the quarterly reports specified above. The only reports Lewis is currently providing are monthly dispensing reports, monthly inventory reports, and expired drug disposal reports; no quarterly reports are currently being sent. **See Recommendation 4 below.**

Prohibition on Resale or Transfer

Lewis and FCH agree to not resell or transfer 340B drugs to individuals who are not eligible patients, per section 11. Of the 1,366 patients who received 340B drugs in 2021, we tested a sample of 30 and verified patient eligibility. We looked up each patient in eClinicalWorks, FCH's electronic health record system, and confirmed they were all eligible FCH patients. Based on this testing, we can provide reasonable assurance Lewis does not resell or transfer covered drugs to non-eligible patients.

Medicaid Prescriptions

In section 12 of the agreement, Lewis and FCH have agreed not to use 340B drugs to cover prescriptions paid for by Medicaid. We also tested the sample of 30 patients above in regards to patient Medicaid eligibility. 29 patients in the sample did not have an active Medicaid status at the time the prescription was filled. For the patient who had active Medicaid status, we verified through PioneerRX the prescription was not billed to Medicaid. We can provide reasonable assurance Lewis does not use 340B drugs to cover prescriptions billed to Medicaid.

Civil Rights

Lewis is subject to the City's Code of Ordinance on discrimination. It is discriminatory for Lewis to fail or refuse to hire, fire an employee, or provide unequal treatment because of race, color, sex, creed, religion, ancestry, national origin, or disability. If Lewis is found guilty of discrimination, the City may terminate the agreement and Lewis would be liable for any costs or expenses incurred by the City. To test for discrimination, we verified with a City attorney who heads the City's Human Relations Department and Lewis corporate that no discrimination or harassment complaints have been made against the Lewis pharmacy. We can provide reasonable assurance Lewis does not engage in discriminatory acts.

Insurance

Section 18 of the agreement lists out insurance requirements for Lewis. They are to secure the insurance specified below and provide certificates to the City:

- Workers' compensation and Employer's Liability Coverage of not less than \$1,000,000 each accident, \$1,000,000 disease – policy limits.
- Commercial general liability insurance with limits of at least \$1,000,000 per occurrence, \$2,000,000 general aggregate, and \$2,000,000 aggregate products and completed operations.
- Automobile liability insurance with limits of not less than \$1,000,000 combined single limit each occurrence.
- Professional liability insurance in the amount of \$1,000,000 each occurrence and \$1,000,000 annual aggregate.

An insurance certificate showing active policies covering the requirements above was found in Munis, providing reasonable assurance Lewis has secured the necessary insurance and provided the certificate to the City. The City's acceptance of the certificate does not establish City assumption of responsibility, and the City assumes no liability.

Recommendations and Management's Response

1 We recommend FCH work with Lewis and utilize PioneerRX, a pharmacy software Lewis currently uses, to establish a more efficient inventory optimization process. We also recommend FCH to develop a process for setting and monitoring product minimum/maximum levels and physically reviewing Lewis's 340B inventory annually.

Management's Response: FCH will review and approve Lewis' inventory optimization process once it is developed.

Management Representative Responding: Alicia Collura, Chief of Health Clinical Services

Date of expected implementation: 7-31-2022

2 We recommend FCH and Lewis work together to develop a reconciling "tracking system" Lewis will utilize to prevent the diversion of 340B drugs to patients who are not eligible. We also recommend FCH to make periodic checks to verify the "tracking system" is in place and working properly.

Management's Response: FCH will work with Lewis to develop a retrospective reconciling tracking system, or periodic audit of sample records, to review patient eligibility. FCH will consider adding this audit report to its quarterly report requirements.

Management Representative Responding: Alicia Collura, Chief of Health Clinical Services

Date of expected implementation: 12-31-2022

3 We recommend FCH utilize eClinicalWorks, their EHR software, to add functionality that allows providers to identify 340B drugs on their prescription forms. We also recommend FCH update their annual provider training to include prescription form requirements for 340B drugs.

Management's Response: FCH will investigate eCW functionality relative to allowing providers to identify 340B drugs on prescription forms. If the functionality exists, FCH will request that the software allow for the identifications of 340B drugs. FCH will update their annual training to include prescription for requirements for 340B drugs.

Management Representative Responding: Alicia Collura, Chief of Health Clinical Services

Date of expected implementation: 8-31-2022

4

We recommend Lewis start providing FCH with the following quarterly reports:

- Quarterly financial statements.
- Detailed status report of collections.
- Summary of receiving and dispensing records.

Management's Response: FCH receives financial statements, however, they have been delayed by a few months from time to time. FCH also receives dispensing records monthly, which is more frequent than required. FCH also has the bill to ship to records, which is an accounting of the medications received by Lewis. The one significant gap in reporting is the detailed status of collections. FCH will work with Lewis to obtain more frequent financial statements and a detailed status of collections.

Management Representative Responding: Alicia Collura, Chief of Health Clinical Services

Date of expected implementation: 12-31-2022

Opportunities for Improvement

1 We recommend FCH update their ePrescription forms to list "Falls Community Health." Section 6 of the agreement requires Lewis to only dispense 340B drugs upon presentation of a prescription form bearing FCH's name.

Management's Response: FCH will consult with prescription vendor to see if FCH facility is a viable option to add. If a viable option, FCH will have the ePrescription forms updated to list "Falls Community Health."

Management Representative Responding: Alicia Collura, Chief of Health Clinical Services

Date of expected implementation: 7-31-2022

2

We recommend FCH review the agreement and update any sections, including section 10, to reflect actual processes and requirements. Currently, section 10 of the agreement requires quarterly reports, however, the Federal 340B program lists these reports merely as examples of reports consistent with customary business practices. They were not meant to be included in agreements as required reports.

Management's Response: FCH will seek legal counsel through our community health association to understand best practices in 340B contractor reporting requirements. FCH will amend contract if appropriate.

Management Representative Responding: Alicia Collura, Chief of Health Clinical Services

Date of expected implementation: 12-31-2022

Conclusion

In conclusion, we determined Lewis is compliant with the majority of requirements outlined in the agreement. However, we believe opportunities exist to improve contract compliance. No evidence of fraud, waste, or abuse was identified, especially regarding transferring 340B drugs to patients who are not eligible and billing 340B prescriptions to Medicaid. The recommendations we have provided will help ensure Lewis is in full compliance with the agreement. We would like to thank Lewis staff, FCH staff, and the City Attorney's Office staff for their assistance provided during this audit.

Authorization

The Sioux Falls City Council approved this audit by resolution and it was included as a compliance audit in the 2020 Annual Audit Plan. The Internal Audit Division operates under the authority of Sections 32.010 through 32.025 of the Sioux Falls Code of Ordinances.

Audit Standards

This audit was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing* issued by the Institute of Internal Auditors.

Statement of Independence

Internal Audit is administratively and operationally independent of the programs and departments it audits, both in appearance and in fact. The Internal Audit Manager is accountable to an Audit Committee appointed by the City Council per Section 32.022 of the Code of Ordinances of Sioux Falls, SD.

Distribution of Report

This report is intended for the information and use of the Mayor and City Council, management, and others within the City of Sioux Falls. However, the report is a matter of public record and its distribution is not limited.

Performed By

Ryan Lauseng
Internal Auditor