SOUTHERN NEVADA COMMUNITY HEALTH CENTER
DISTRICT-WIDE POLICY

DIVISION:	FQHC	**NUMBER(s):**	CHC-043
PROGRAM:	Pharmacy	**VERSION:**	1.00
TITLE:	340B Compliance Monitoring and Reporting	**PAGE:**	1 of 3
		EFFECTIVE DATE: Click or tap here to enter text.	
DESCRIPTION:	Click or tap here to enter text.	**ORIGINATION DATE:** NEW	
APPROVED BY: **CHIEF EXECUTIVE OFFICER - FQHC** Randy Smith, MPA Date		**REPLACES:** P-CHC-027 SOP, V1.01	

I. PURPOSE

To maintain the Southern Nevada Health District's (SNHD)/Southern Nevada Community Health Center's (SNCHC) compliance with the 340B Drug Discount Program as specified by the Health Resources and Services Administration (HRSA).

II. SCOPE

Qualified Health Center (FQHC) and Financial Services

III. POLICY

SNHD/SNCHC maintains auditable records demonstrating compliance with 340B Program requirements. SNHD/SNCHC is responsible for monitoring, documenting, and correct instances of noncompliance with any of the 340B Program requirements.

IV. PROCEDURE

A. SNHD/SNCHC performs an internal audit of 340B records annually or more frequently as needed.

B. SNHD/SNCHC reviews the HRSA 340B Database to ensure the accuracy of the information for the parent site, off-site locations, and contract pharmacies (if applicable).

C. SNHD/SNCHC reviews the Medicaid Exclusion File (MEF) to ensure the accuracy of the information for the parent site, off-site locations, and contract pharmacies (if applicable).

D. SNHD/SNCHC reconciles purchasing records and dispensing records monthly to ensure that covered outpatient drugs purchased through the 340B Program are dispensed or administered only to patients eligible to receive 340B drugs and that any variances are not the result of diversion.

E. SNHD/SNCHC reconciles dispensing records to patients' health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B drugs.

F. The SNHD/SNCHC Pharmacy/Finance Committee reviews the internal audit results when criteria thresholds are exceeded or when requested by the auditor.

G. Material Breach Criteria/Review

1. Material Breach indicators include dispenses/administration that involve > 10% of the purchases of a single medication/manufacturer or > 5% of purchases for all 340B medications in a 12-month period.

2. The Pharmacy/Finance Committee reviews audit results for materiality of any breach and makes recommendations to the Authorizing Official (AO) regarding any potential report of a breach to HRSA.

3. The AO reports an identified material breach to HRSA/manufacturers within 30 days.

H. SNHD/SNCHC maintains records of 340B-related transactions, audit results, corrective actions, and reconciliation records for a minimum of three (3) years in a readily retrievable and auditable format.

I. SNHD/SNCHC maintains records of materiality assessments for a minimum of three (3) years.

1. The compliance officer drafts correspondence outlining the suspected breach to HRSA and the affected manufacturers.

2. The AO approves the correspondence and ensures it is transmitted to the

appropriate parties.

ACRONYMS/DEFINITIONS

Not Applicable

REFERENCES

340B Drug Pricing Program: Program Requirements. HRSA.
https://www.hrsa.gov/opa/programrequirements/index.html

DIRECT RELATED INQUIRIES TO

Pharmacy Manager

ATTACHMENTS-FORMS-TEMPLATES

Not Applicable.

HISTORY TABLE

Table 1: History

Version No.	Effective Date	Change Made
Version 0		First issuance

Standing Operating Procedure History

Version	Effective Date	Change Made
Version1.01	06/01/2026	1. Periodic review 2. Updated template
Version 1.00	12/30/2016	First issuance