

2023.007 Prevention of Duplicate Discounts

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Revision Date	
Subject Matter Expert	340B Program Coordinator
Approval Authority	Associate Commissioner of Laboratory and Infectious Disease Services
Signed by	<i>Josh Hutchison</i>

1.0 Purpose

To ensure the Texas Department of State Health Services (DSHS) and its partner covered entities (CEs) prevent duplicate discounts.

The DSHS Central Pharmacy participates in a Central Distribution Model (CDM) for distributing 340B medications. CEs receiving medications from the DSHS Central Pharmacy are by default participating in the CDM and must meet the requirements outlined in this procedure. CEs adhere to and uphold the requirement set forth in 42 USC §256b(a)(5)(A)(i), which prohibits duplicate discounts; manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. CEs must have mechanisms in place to prevent duplicate discounts.

To avoid duplicate discounts, A CE must determine if it will carve in Medicaid fee-for-service or carve it out. DSHS does not allow for the billing of any 340B medications. All CEs under the DSHS Central Distribution Model umbrella automatically opt to carve out Medicaid billing. A carve-in means that the CE can bill Medicaid for 340B medications. A carve-out is when a CE cannot bill Medicaid for 340B medications. Each CE participating in the CDM carves out a space for patients enrolled in Medicaid. Participation in the DSHS CDM includes entities ordering medication, supplies, or both from the DSHS Central Pharmacy.

CEs using a DSHS grant number but not participating in the DSHS CDM make the decision to carve out or carve in any medications or supplies provided or administered to patients at the clinic. Entities follow [federal requirements](#) to prevent duplicate discounts.

CE cannot provide 340B drugs to Medicaid patients at a contract pharmacy absent an arrangement between the contract pharmacy, CE, and the state Medicaid agency to prevent duplicate discounts. DSHS notifies the Health Resources and Services Administration (HRSA) of this arrangement. This means the CE must carve out prescriptions filled by a contracted pharmacy.

CE reports each instance of duplicate discounts to DSHS and the affected manufacturer. Each entity is responsible for payback associated with duplicate discount violations and must work in

good faith with manufacturers. DSHS reports violations meeting the material breach threshold as defined in [Policy 2023.009, 340B Material Breach Policy](#), to the Health Resources and Services Administration (HRSA) as well.

DSHS clinics report violations of duplicate discounts to 340B Pharmacy Unit staff at 340B@dshs.texas.gov as soon as they identify them. 340B Pharmacy Unit staff handle reporting instances of duplicate discounts to affected manufacturers.

Summary of Carve-in/Carve-out Options

How the CE receives medication or supplies	Where the CE dispenses or administers medication	Carve-in or Carve-out
Ordered through PIOS	N/A	Carve-out
Paid for by CE	At Clinic	Option to Carve-in or Carve-out
	Contract Pharmacy	Carve-out

2.0 Definitions

340B Covered Entity (CE) – A program or facility participating in the 340B medication program. This includes DSHS as a direct recipient of federal funds as well as DSHS’s CEs receiving federal funds or in-kind services from DSHS and utilizing a DSHS grant number for registering their program in the 340B Office of Pharmacy Affairs Information System (OPAIS) database.

Administer – The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by: (A) a practitioner or an authorized agent under his supervision; or (B) the patient at the direction of a practitioner.

Carve-In – 340B entities may elect to use drugs purchased at 340B prices and bill Medicaid for Medicaid fee-for-service patients. HRSA terms this activity a “Medicaid Carve-In.” If an entity chooses to use 340B drugs for fee-for-service patients and bill Medicaid, it must indicate this on the Medicaid Exclusion File (MEF) and list the appropriate Medicaid Provider Numbers (MPNs), National Provider Identifiers (NPIs), or both. Entities must inform HRSA whether they are carving in or out.

Carve-Out – 340B entities may elect to use non-340B drugs for Medicaid fee-for-service patients. HRSA terms this activity a “Medicaid Carve-Out.” Entities may choose to do this so they can receive Medicaid reimbursement. Entities must inform HRSA whether they are carving in or out through the Medicaid Exclusion File.

Contract Pharmacy – A pharmacy or pharmacies providing services to the covered entity’s patients, including the service of dispensing the entity-owned 340B drugs. The entity and pharmacy (or pharmacies) must have a written contract and list the contract pharmacy on 340B OPAIS during a quarterly registration period.

Diversion – When CE provides a 340B medication to an ineligible patient or entity. Examples (this is not an exhaustive list):

- Providing medication to an ineligible patient or covered entity
- Undocumented medication (e.g., failure to track or document)
- Sharing or transferring medication to another location or clinic

Duplicate Discount – Prohibited by the 340B statute, a duplicate discount occurs when a covered entity obtains a 340B discount on a medication and a Medicaid agency obtains a discount in the form of a rebate from the manufacturer for the same medication.

Eligible Patient – An individual is a patient of a 340B covered entity (except for state-operated or state-funded AIDS drug purchasing assistance programs) only if: the covered entity established a relationship with the individual, such that the covered entity maintains records of the individual's health care. The individual receives health care services from a health care professional who either the CE employs or who provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity. The individual receives a health care service or range of services from the covered entity consistent with the service or range of services for which grant funding or DSHS provided federally qualified health center look-alike status to the entity. HRSA does not consider an individual a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting. Exception: HRSA does consider individuals registered in a state-operated or funded AIDS Drug Assistance Program (ADAP) receiving federal Ryan White funding patients of the participant ADAP if registered as eligible by the state program.

Entity-Owned Pharmacy – A pharmacy owned by, and a legal part of, the 340B entity. Also called "in-house" pharmacy.

Prescribe – Provide a prescription for a medication to an individual filled at an outpatient or retail pharmacy.

Provide – To supply one or more units of use of a nonprescription drug or dangerous drug to a patient.

3.0 Persons Affected

- DSHS and covered entity employees.

4.0 Responsibilities

4.1 Division Heads (Laboratory and Infectious Disease Services and Regional and Local Health Operations Division Heads)

- Ensure agency policies and division operation procedures are in alignment with:
 - Federal and state statutes, rules, and guidelines;
 - DSHS and HHS policies; and

- ▶ Guidelines defined by external funding sources.

4.2 Supervisors

- Ensure the implementation of this procedure;
- Ensure they communicate policies and procedures to employees; and
- Document instances of violations of this procedure and report them to the director and 340B coordinator.

4.3 DSHS and CE employees

- Understand and comply with this procedure;
- Ask the supervisor to clarify responsibilities for complying with policies and procedures as necessary;
- Report perceived conflicts or discrepancies between different DSHS policies and procedures to the supervisor; and
- Report instances of violations of this procedure to the supervisor.

5.0 Procedures

5.1 Medicaid Carve-Out

5.1.1 Medications procured using CDM or dispensed or administered at clinics

5.1.1.1 CE dispenses or administers 340B-purchased drugs to Medicaid patients and does not bill Medicaid for those 340B drugs (carve-out)

5.1.1.2 CE answered “no” to the Medicaid question on 340B OPAIS. The DSHS Central Office reviews OPAIS selections quarterly.

5.1.2 Medications dispensed at contract pharmacies

5.1.2.1 Contract pharmacies dispense non-340B-purchased drugs to Medicaid patients and subsequently bill Medicaid for those non-340B drugs (carve-out).

5.2 Medicaid Carve-In

CEs, including entity-owned, in-house pharmacies opting to Carve-in, follow the procedures for both the MEF (5.2.1) and Texas-required billing (5.2.2) to prevent duplicate discounts

5.2.1 Medicaid Exclusion File (MEF) on OPAIS:

5.2.1.1 CE dispenses or administers 340B-purchased drugs to Medicaid patients (carve-in).

5.2.1.1.1 CE answered “yes” to the Medicaid question on 340B OPAIS.

5.2.1.2 On the MEF for 340B OPAIS, list MPNs for state Medicaid agencies billed and applicable NPIs.

5.2.1.3 CE informs HRSA immediately of changes in its MEF information by updating 340B OPAIS before the 15th of the month before the quarter when the change takes effect (note: this is a different timeframe than quarterly registration). For example, changes made to 340B OPAIS before March 15 would become effective on April 1.

5.2.1.4 CE regularly reviews its [340B OPAIS Medicaid Exclusion File records](#). Update this information in OPAIS anytime there are changes to MPNs or NPIs.

5.2.1.5 CE bills Medicaid per Texas Medicaid reimbursement requirements; see Section 5.2.2.

5.2.1.6 Medicaid reimburses the CE for 340B drugs per state policy and does not seek rebates on drug claims submitted by the CE.

5.2.2 Texas-required billing

5.2.2.1 For clinic-administered or clinic-provided medications purchased at the 340B discounted price, the claim identifier field must include the “U8” modifier when billing Medicaid.

5.2.2.2 For in-house retail pharmacy claims, the procedure requires the “Submission Clarification Code (SCC) 20” when billing Medicaid.

5.2.3 Procedures for Handling and Reporting Violations of Diversion

5.2.3.1 Report violations of duplicate discounts to DSHS 340B Pharmacy Unit staff in writing. Include the following information with the notification:

- Entity name
- Entity’s 340B ID number
- Name of Medication and National Drug Code (NDC)
- Quantity of medications reported as violations of duplicate discounts
- Description of Violation—do not include Personally Identifiable Information (PII) in the description

5.2.3.2 Report violations of duplicate discounts to the affected manufacturer(s).

- Refer to Apexus for the reporting template: 340bpvp.com/education/340b-tools/.
- Notify DSHS 340B Pharmacy Unit staff once you submit the report to the manufacturer(s).
- Work with manufacturers to determine the cost associated with violations.

5.2.3.3 DSHS 340B Pharmacy Unit staff determine if a corrective action plan is necessary after receiving any reported incidents of duplicate discounts.

If instances of duplicate discount reach or exceed the material breach defined in [Policy 2023.009, 340B Material Breach Policy](#), Section 7.0, for reporting.

6.0 Associated Policies

Policy Number	Policy Title
2023.009	340B Material Breach Policy

7.0 Revision History

Date	Action	Section
7/27/2023	Policy Issued	All