

2023.011 Penicillin G Benzathine (Bicillin) Treatment

Policy Number	2023.011
Effective Date	June 5, 2023
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Subject Matter Expert	340B Program Coordinator
Approval Authority	HIV/STD Section Director
Signed by	<i>D'Andra Luna</i>

1.0 Purpose

The Texas Department of State Health Services (DSHS) purchases Benzathine penicillin G (Bicillin) through the federal 340B drug discount program. Entities participating in the DSHS Central Distribution Model (CDM) prevent violations of the 340B drug discount program, including diversion and duplicate discounts, and follow DSHS policies and procedures under the CDM. Public health entities work to treat occurrences of syphilis and prevent congenital syphilis across Texas. Patients must meet the eligibility criteria in [Policy 2023.004, 340B Patient Eligibility](#).

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 covered entities 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.

340B Program – The federal Health Resources and Service Administration’s (HRSA) 340B drug pricing program, which reduces the cost of covered outpatient drugs for certain federally supported entities and eligible healthcare organizations. The use of the term “340B” throughout this policy refers to the 340B program.

Central Distribution Model (CDM) – An arrangement where CE purchases medications under one account to send to multiple eligible locations; each of the locations has its own 340B ID, except for DSHS regional clinics and pharmacies participating in the Texas HIV Medication Program (THMP).

Contract Pharmacy – A pharmacy contracted by a CE. 340B-covered entities may contract with a pharmacy (or pharmacies) to provide services to the CE’s patients, including the service of dispensing the entity-owned 340B drugs. To engage in a contract pharmacy arrangement, the CE

and pharmacy (or pharmacies) must have a written contract or a memorandum of understanding (MOU) aligning with 340B compliance elements. Typically, a CE or facility uses a bill-to-entity or ship-to-pharmacy arrangement. Covered entities must identify the contract pharmacy on their 340B OPAIS account and can only add or remove the contract pharmacy during a quarterly registration period.

Direct Funding – Funding provided to an organization directly from the federal government. This policy does not consider funding received from DSHS as direct funding.

Local Public Health Entity – A local health authority, local health unit, local health department, or public health district. For this policy, each local public health entity must meet the eligibility criteria listed in 8.0 of [Policy 2023.005, Covered Entity Eligibility and Central Distribution Model Participation](#).

Memorandum of Understanding (MOU) – A written document evidencing the understanding or agreement of two or more parties regarding the subject matter of the agreement. Because the underlying agreement may or may not be legally binding and enforceable in and of itself, a memorandum of understanding may or may not constitute a contract. It is generally considered a less formal way of evidencing an agreement and is ordinarily used in state government only between or among state agencies or other government entities. The term is used interchangeably with "memorandum of agreement."

Office of Pharmacy Affairs (OPA) – The office within the Health Resources and Service Administration (HRSA) responsible for administering the 340B drug pricing program.

Office of Pharmacy Affairs Information System (OPAIS) – The information technology system used to verify entity eligibility. The use of the term "OPAIS database" in this policy refers to this system.

Program – The specific program that awarded a contract or provided in-kind services to an entity.

Registry – A list of entities, maintained at regional headquarters, of providers actively seeking consultation from regional medical directors. Public health regions can keep this list electronically or in paper documentation form.

Uninsured Patient – A patient who experiences circumstances which might influence or restrict access to necessary preventive health care services or medication. These circumstances might include, but are not limited to, a patient concerned about privacy when using insurance or who has a financial burden due to high deductibles or co-pays, a patient whose provider would not be able to provide timely treatment, or a partner of a contact identified through partner services by a Disease Intervention Specialist (DIS).

3.0 Persons Affected

- Programs participating in 340B, including recipients of 340B medication.

4.0 Responsibilities

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

- Ensure agency policies and divisional operational procedures align with:
 - Federal and state statutes, rules, and guidelines
 - DSHS and HHS policies
 - Guidelines defined by external funding sources

4.2 Supervisors

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

4.3 DSHS and CE Employees

- Understand and comply with this policy.
- 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.
- Report instances of violations of this policy to the supervisor

5.0 CE and Provider Procedures

5.1 The provider refers the patient to the local health department, when available.

This should be the primary goal for treatment. If a patient cannot travel to the local health entity or regional clinic, see 5.2.

5.2 Clinics requesting Bicillin from local public health entities must engage in an MOU with the provider and document patient eligibility as follows

5.2.1 The clinic determines patient status.

- Each patient must meet the DSHS uninsured patient definition for STD program patients. The public health entity maintains documentation of the patient's uninsured status.

5.2.2 The clinic maintains records of an individual's health care.

- The local public health entity establishes or shares a patient chart.

- The clinic determines whether the individual receives a health care service or range of services from the CE consistent with the service or range of services for which the DSHS program provided grant funding to the CE.

5.2.3 The program determines TB, STD, HIV, or Ryan White provider eligibility.

- Patient's provider and public health entity both document communication and agreement to the treatment plan in the patient's chart.
- The clinic follows standing delegation orders.

5.2.4 The patient's provider sends documentation of the administration of Bicillin to the public health entity.

5.2.5 The public health entity documents confirmation that the patient received treatment, including the date(s) of administration.

5.2.6 The clinic keeps a copy of the MOU on file.

5.2.7 The clinic determines the patient's Medicaid status. Refer to [Policy 2023.007, Prevention of Duplicate Discounts](#).

5.3 CE seeking support from DSHS to become a part of their care service team

5.3.1 A provider seeking consultation from a regional health department indicates the reason for consultation on the consultation form, and the regional health department maintains a registry of providers and all consultation communication records.

5.3.2 Determine the patient's Medicaid status. Refer to [Policy 2023.007, Prevention of Duplicate Discounts](#).

6.0 Associated Policies

Policy Number	Policy Title
2023.004	340B Patient Eligibility
2023.005	Covered Entity Eligibility and Central Distribution Model Participation
2023.007	Prevention of Duplicate Discounts

7.0 Revision History

Date	Action	Section
11/10/2023	Revisions	1, 2, 5
8/21/2023	Policy revised to allow for a compliance attestation form to be utilized while an entity is seeking MOU during national drug shortages	All

6/5/2023	Policy Issued	All
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