

Form and Manner for 340B Covered Entity Report - DRAFT

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Overview

This Form and Manner document sets forth provisions for filing prescription drug data sets by 340B Covered Entities with the Minnesota Department of Health (MDH), which was established under Minnesota Statutes, Section 62J.312, subdivision 6.

This document addresses:

- Identification of entities required to register and report.
- Description of statutory requirements for the content and time frame for filing 340B data.
- Establishment of format and manner for the data reported.

Abbreviations

APO – Administrative Penalty Order

HRSA – Health Resources and Services Administration

MDH – The Minnesota Department of Health, the public health agency in Minnesota responsible for implementing the 340B Covered Entity report (www.health.state.mn.us)

NDC – National Drug Code

NPI – National Provider Identification

OPAIS – Office of Pharmacy Affairs Information System

TPA – Third Party Administrator

Definitions

Unless the context indicates otherwise, the following words and phrases shall have the meanings provided below:

“Associated site” is a site that shares a grant number or designation number with a Covered Entity on HRSA’s 340B OPAIS.

“Child site” is an off-site, outpatient facility that is eligible to participate in the 340B program and designated as such on HRSA’s 340B OPAIS.

“Contract Pharmacy” is a pharmacy with whom Covered Entities have arrangements to dispense drugs purchased under the 340B Drug Pricing Program. Covered entities must register the arrangements online and must certify electronically that a fully executed agreement is in effect with the contract pharmacy.

“Covered Entity” means entities that participate in the 340B Drug Pricing Program under Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. § 256b(a)(4)).

“HRSA/340B ID” is a unique identification number provided by HRSA to identify a 340B-eligible entity in 340B Office of Pharmacy Affairs Information System (OPAIS). This 340B ID is used to purchase 340B drugs.

“National Drug Code” or “NDC” means the three-segment code maintained by the federal Food and Drug Administration that includes a labeler code, a product code, and a package code for a drug product and that has been converted to an 11-digit format consisting of five digits in the first segment, four digits in the second segment, and two digits in the third segment. A three-segment code shall be considered converted to an 11-digit format when, as necessary, at least one “0” has been added to the front of each segment containing less than the specified number of digits such that each segment contains the specified number of digits.

“National Provider Identifier” or “NPI” is a unique identification number for covered health care providers.

“**Payer**” is the entity that pays for the care administered by the healthcare provider. The main types of payers include public payers (Medicare, Medicaid, and others), private payers, and commercial payers.

“**Prescription Drug**” means a drug for human use under United States Code, title 21, section 353(b)(1).

“**50 most frequently dispensed drugs/NDCs**” means the top 50 most utilized NDCs in terms of the count of prescription claims in the past calendar year.

Registration

Prior to filing a report as required under Minnesota Statutes, section 62J.312, a Covered Entity must register on the MDH website at <https://rxpt.health.mn.gov>.

Notwithstanding the requirements of Minnesota Statutes, section 62J.312, all Covered Entities are required to register with MDH to enable reception of periodic communications from MDH.

To register, a Covered Entity must provide the following information:

- (1) Covered Entity name
- (2) Business address
- (3) Business phone number
- (4) The name and title of an individual authorized by the Covered Entity to receive communications from MDH regarding compliance with Minnesota Statutes, section 62J.312, and the following information for the authorized individual:
 - (A) Business mailing address
 - (B) Business email address
 - (C) Business phone number
- (5) 340B Classification (Critical Access Hospital, Free Standing Cancer Hospital, etc.)
- (6) National Provider Identification (NPI) number
- (7) HRSA/340B ID (optional field)

A Covered Entity must update the Covered Entity’s registration each time there is a change to any of the information specified above. Covered Entities are strongly encouraged to add two or more individuals when registering to ensure continuity of access and prevent delays.

Submission Requirements

Beginning April 1, 2024, a Covered Entity must submit to MDH timely, accurate, and complete 340B data or data sets in accordance with the requirements of Minnesota Statutes, section 62J.312. Covered Entities must certify the accuracy and completeness of any submissions to MDH, including those made by corporate entities, their subsidiaries, and contractors or other third parties engaged to submit information on the Covered Entity’s behalf. Covered Entities

may also submit additional documentation and information necessary to support the submissions required under Minnesota Statutes, section 62J.312.

340B Covered Entity Reporting

Beginning April 1, 2024, and annually thereafter, a Covered Entity is required to submit information to MDH by 11:59PM Central Time related to its participation in the federal 340B program for the previous calendar year (i.e., the most recent one-year period that begins on January 1 and ends on December 31).

The reporting obligation for Covered Entities is determined by participation in the federal 340B Drug Pricing Program as of April 1 of each reporting year.

Note: the reporting obligation is with the parent/grantee entity and the parent must include an aggregate of all child and associated sites. Child/associated sites are not independently required to report, and their information should be reported as part of the parent/grantee Covered Entity.

Values submitted for items (5) through (10) listed below must be aggregated to include data for the Covered Entity and all child sites, associated sites, contract pharmacies, third-party administrators, and outpatient facilities physically located within the Covered Entity.

Data for items (7) through (10) listed below must be reported by payer type, including commercial insurance, medical assistance and MinnesotaCare, Medicare, or other.

For Covered Entities that are hospitals, data for items (5) through (10) listed below must also be submitted for each of the 50 most frequently dispensed drugs/NDCs under the 340B program.

The data submission must include the following information:

- (1) the National Provider Identification (NPI) number (obtained during registration).
- (2) HRSA/340B ID (optional field) (obtained during registration).
- (3) the name and address of the 340B Covered Entity (obtained during registration).
 - a. Street Address 1
 - b. Street Address 2
 - c. Street City
 - d. Street State
 - e. Street Zip
- (4) 340B Classification (obtained during registration).
- (5) Payer Type: including commercial insurance, medical assistance and MinnesotaCare, Medicare, or other.
- (6) The aggregated acquisition cost for prescription drugs obtained under the federal 340B program for the past calendar year: this is the total acquisition cost obtained under the federal 340B program for the Covered Entity as well as all the agents acting on behalf of

the Covered Entity—including the contract pharmacies and 340B Third Party Administrators (TPAs).

- (7) The aggregated payment amount received for drugs obtained under the federal 340B program and dispensed to patients for the past calendar year: this is the total payment amount received under the federal 340B program by the Covered Entity as well as all the agents acting on behalf of the Covered Entity—including the contract pharmacies and TPAs.
- (8) The aggregated payment made to pharmacies under contract to dispense drugs obtained under the federal 340B program for the past calendar year.
- (9) The aggregated payment made to TPAs under contract to perform program administration tasks related to the federal 340B program for the past calendar year (optional field).
- (10) The number of claims for prescription drugs obtained under the federal 340B program: this is the total claims made under the federal 340B program for the Covered Entity as well as all the agents acting on behalf of the Covered Entity, which includes contract pharmacies and TPAs.

Classification of Data

Data submitted to the commissioner under paragraph (a) is classified as nonpublic data as defined in Minnesota Statutes, section 13.02, subdivision 9.

Method of Submission

Data required under Minnesota Statutes, section 62J.312, shall be submitted to MDH using the Prescription Drug Data Portal at <https://rxpt.health.mn.gov>.

Data must be submitted using one of the following methods:

- (1) Uploading an MDH-provided Excel (.xlsx) template that includes all required information in the format specified in Appendix A or Appendix B (340B Covered Entity Data Specifications). Blank templates should be downloaded from the data submission portal.
- (2) Individually entering each required data field directly into the data submission portal.

Additionally, Covered Entities have the option of uploading any documentation necessary to support data submitted for a drug within the data submission portal.

A user guide will be available to assist users to navigate the data submission portal and will be posted on the Minnesota 340B Drug Pricing Program Reporting website at <https://www.health.state.mn.us/data/340b/index.html>.

Compliance Enforcement

MDH may impose a fine upon a Covered Entity for failure to provide data as required by Minnesota Statutes, section 62J.312.

Any health care entity subject to reporting under this section that fails to provide data in the form and manner prescribed by the commissioner is subject to a fine paid to the commissioner of up to \$500 for each day the data are past due. The commissioner may grant an extension of the reporting deadlines upon a showing of good cause by the entity. Any fine levied against the entity under this subdivision is subject to the contested case and judicial review provisions of Minnesota Statutes, sections 14.57 and 14.69.

Extension Requests

The commissioner may grant an extension of the reporting deadlines upon a showing of good cause by the Covered Entity. To request an extension, the entity must request an extension within the data submission portal and provide any supporting documentation that addresses its good-cause-bases for requesting an extension.

A user guide will be available to assist users to navigate the data submission portal and will be posted on the Minnesota 340B Drug Pricing Program Reporting website at <https://www.health.state.mn.us/data/340b/index.html>.

Appendix A: 340B Covered Entity Report Data Specifications

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Appendix B: Hospital-Only Top 50 NDCs Report Data Specifications

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