

Form and Manner for 340B Covered Entity Reporting

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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) established under [Minnesota Statutes, section 62J.461](https://www.revisor.mn.gov/statutes/cite/62J.461) (<https://www.revisor.mn.gov/statutes/cite/62J.461>).

Reporting for this program concerns the federal 340B Drug Pricing Program of the Public Health Service Act and covers prescription drugs obtained under the 340B program, which are outpatient drugs as defined by the [Social Security Act Section 1927 \(k\)](https://www.ssa.gov/OP_Home/ssact/title19/1927.htm) (https://www.ssa.gov/OP_Home/ssact/title19/1927.htm).

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 form and manner for the data reported

Abbreviations

APO – Administrative Penalty Order

HRSA – Health Resources and Services Administration

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

NDC – National Drug Code

OPAIS – Office of Pharmacy Affairs Information System

Definitions

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

“340B Covered Entity” or “Covered Entity” is a covered entity as defined in United States Code, title 42, section 256b(a)(4), with a service address in Minnesota as of January 1 of the reporting year. 340B covered entity includes all entity types and grantees. All facilities that are identified as child sites or grantee associated sites under the federal 340B Drug Pricing Program are considered part of the 340B covered entity.

“340B Drug Pricing Program” or “340B Program” is the drug discount program established under United States Code, title 42, section 256b.

“340B Entity Type” is the designation of the 340B covered entity according to the entity types specified in United States Code, title 42, section 256b(a)(4).

“340B ID” is a unique identification number provided by HRSA to identify a 340B-eligible entity in 340B OPAIS.

“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 which a 340B Covered Entity has an arrangement to dispense drugs purchased under the 340B Drug Pricing Program.

“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.

“Pricing Unit” means the smallest dispensable amount of a prescription drug product that can be dispensed or administered.

“50 Most Frequently Dispensed or Administered Drugs/NDCs” means the 50 NDCs that were most frequently dispensed or administered to patients under the 340B Program in terms of the count of prescription drug fills in the previous calendar year.

Registration

Each Covered Entity must register and maintain a current registration on the [MDH Rx Data Portal website \(https://rxpt.health.mn.gov\)](https://rxpt.health.mn.gov).

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 and the following information for the authorized individual:
 - (A) Business mailing address
 - (B) Business email address
 - (C) Business phone number
- (5) 340B Entity Type (Critical Access Hospital, Free Standing Cancer Hospital, etc.)
- (6) 340B ID

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

By April 1 of each year, a Covered Entity must annually submit to MDH timely, accurate, and complete 340B data or data sets in accordance with the requirements under Minnesota Statutes. 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 information necessary to support the submissions required under this reporting requirement.

340B Covered Entity Reporting

By April 1 of each year, a Covered Entity is required to submit information to MDH by 11:59 p.m. Central Time related to its participation in the 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).

Values submitted for the items 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.

For Covered Entities that are hospitals, data must also be reported for items (1), (5), and (6) listed below for each of the 50 Most Frequently Dispensed or Administered Drugs/NDCs under the 340B Program.

The data submission must include the following information:

- (1) The **aggregated acquisition cost** for all prescription drugs obtained under the 340B Program during the previous calendar year.
- (2) The **aggregated payments made to Contract Pharmacies** to dispense drugs obtained under the 340B Program during the previous calendar year.
- (3) The **aggregated payments made to any other entity** that is not the Covered Entity, and is not a Contract Pharmacy, for managing any aspect of the Covered Entity's 340B Program during the previous calendar year.
- (4) The **aggregated payments made for other internal, direct expenses** related to administering the 340B Program during the previous calendar year, including staffing, or internal operational and administrative expenses, with a detailed description of the direct costs included.
- (5) The **aggregated payment amount received** for all prescription drugs obtained under the 340B Program and dispensed or administered to patients during the previous calendar year, segregated by payer type, including commercial insurance, medical assistance, MinnesotaCare, Medicare, and other, and encompassing all payments that:
 - a. Are actual payments for insurance claims payments; and
 - b. Reflect the portion of payment received from grants, cash, or other payment types that relate to the dispensing or administering of drugs obtained under the 340B program.

(6) The **number of Pricing Units dispensed or administered** to patients for all prescription drugs obtained under the 340B Program during the previous calendar year, segregated by payer type, including commercial insurance, medical assistance, MinnesotaCare, Medicare, and other.

Classification of Data

Data submitted to the commissioner is classified as nonpublic data as defined in [Minnesota Statutes, section 13.02](https://www.revisor.mn.gov/statutes/cite/13.02) (<https://www.revisor.mn.gov/statutes/cite/13.02>), subdivision 9.

Method of Submission

Data required under Minnesota Statutes must be submitted to MDH using the [Rx Data Portal](https://rxpt.health.mn.gov) (<https://rxpt.health.mn.gov>) by entering each required data field directly into the data portal.

Data that is required to be reported by payer type and/or NDC may also be submitted by uploading an MDH-provided Excel (.xlsx) template that includes all required information in the format specified in Appendices B-D, as applicable. Blank templates are available to download from the data portal.

Supporting materials are available to assist users with navigating the data portal and are posted at MDH's [340B Covered Entity Report](https://www.health.state.mn.us/data/340b/index.html) (<https://www.health.state.mn.us/data/340b/index.html>) and [Rx Data Portal Resources](https://www.health.state.mn.us/data/rxresources/index.html) (<https://www.health.state.mn.us/data/rxresources/index.html>).

Compliance Enforcement

Minnesota statutes specify that MDH may impose a fine upon a Covered Entity for failure to provide data. Any Covered Entity subject to reporting under this section that fails to provide data in the form and manner prescribed by the Commissioner of Health—and has not been granted an extension to or exemption from reporting—is subject to the levy of a fine of up to \$500 for each day the data are past due.

As specified in statute, the Commissioner of Health may grant an extension of the reporting deadlines or exemption from reporting upon a showing of good cause by the Covered Entity. Any fine levied against the Covered Entity under this subdivision is subject to the contested case and judicial review provisions of [Minnesota Statutes, sections 14.57](https://www.revisor.mn.gov/statutes/cite/14.57) (<https://www.revisor.mn.gov/statutes/cite/14.57>) through [14.69](https://www.revisor.mn.gov/statutes/cite/14.69) (<https://www.revisor.mn.gov/statutes/cite/14.69>).

Extension and Exemption Requests

The Commissioner of Health may grant an extension of the reporting deadline or an exemption from reporting upon a demonstration of good cause by the Covered Entity. Covered Entities must request an extension or exemption within the data submission portal and provide any supporting documentation that addresses its good-cause basis.

MDH strongly recommends Covered Entities submit extension and exemption requests at least 20 calendar days in advance of the reporting deadline to be considered.

Supporting materials are available to assist users to navigate the data submission portal and are posted on the [MDH 340B Covered Entity Report](https://www.health.state.mn.us/data/340b/index.html)
(<https://www.health.state.mn.us/data/340b/index.html>).

Appendix A: 340B Covered Entity Totals Report Data Specifications

These are data elements the Covered Entity must manually enter to report totals for the entire Covered Entity.

Data Element	Format	Size	Description	Example
Total 340B Acquisition Cost	Decimal	14,2	The aggregated acquisition cost for all prescription drugs obtained under the 340B Program during the previous calendar year.	1000.00
Total 340B Contract Pharmacy Cost	Decimal	14,2	The aggregated payments made to Contract Pharmacies to dispense drugs obtained under the 340B Program during the previous calendar year.	1000.00
Total 340B Outside Organization Cost	Decimal	14,2	The aggregated payments made to any other entity that is not the Covered Entity, and is not a Contract Pharmacy, for managing any aspect of the Covered Entity's 340B Program during the previous calendar year.	1000.00
Total 340B Internal Direct Expense	Decimal	14,2	The aggregated payments made for other <i>internal, direct</i> expenses related to administering the 340B Program during the previous calendar year, including staffing, or internal operational and administrative expenses.	1000.00
Total 340B Internal Direct Expense Description	Alphanumeric	8000	A description of the internal, direct expenses incurred by your program to administer the 340B program. Responses should include sufficient detail to understand the nature of the costs reported.	“Internal Direct Costs”

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Data Element	Format	Size	Description	Example
General Comments	Alphanumeric	8000	General comments and/or additional information related to the data submitted, if applicable.	"General Comments"

Appendix B: 340B Covered Entity by Payer Type Report Data Specifications

These are data elements the Covered Entity must report either through manual entry or by uploading the data in an MDH-provided Excel (.xlsx) template. Blank templates are available to download from the data portal.

Data Element	Format	Size	Description	Example
Payer Type	Integer	1	Enter Integer Value: 1 – Commercial 2 – Medicare 3 – MinnesotaCare 4 – Medical Assistance 5 – Other/Specify in General Comments	1
Total 340B Payment Received	Decimal	14,2	<p>The aggregated payment receivable amount accrued for all drugs obtained under the 340B Program and dispensed or administered to patients during the previous calendar year, and encompassing all payments that:</p> <ul style="list-style-type: none"> • Are actual payments for insurance claims payments; and • Reflect the portion of payment received from grants, cash, or other payment types that relate to the dispensing or administering of drugs obtained under the 340B program. 	1000.00
Total 340B Pricing Units Dispensed / Administered	Integer	19	The total number pricing units dispensed or administered to patients during the previous calendar year for all drugs obtained under the 340B Program.	1000

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Data Element	Format	Size	Description	Example
General Comments	Alphanumeric	8000	General comments and/or additional information related to the data submitted for the payer type, if applicable.	"General Comments"

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

These are data elements that hospital Covered Entities must report either through manual entry or by uploading the data in an MDH-provided Excel (.xlsx) template. Blank templates are available to download from the data portal.

Data Element	Format	Size	Description	Example
NDC	Alphanumeric	11	NDC of the drug	"000000000000"
Total 340B Acquisition Cost	Decimal	14,2	The aggregated acquisition cost for the NDC purchased under the 340B program during the previous calendar year.	1000.00
General Comments	Alphanumeric	8000	General comments and/or additional information related to the data submitted for the NDC, if applicable.	"General Comments"

Appendix D: Hospital-Only Top 50 NDCs by Payer Type Report

Data Specifications

These are data elements hospital Covered Entities must report either through manual entry or by uploading the data in an MDH-provided Excel (.xlsx) template. Blank templates are available to download from the data portal.

Data Element	Format	Size	Description	Example
NDC	Alphanumeric	11	NDC of the drug	"00000000000"
Payer Type	Integer	1	Enter Integer Value: 1 – Commercial 2 – Medicare 3 – MinnesotaCare 4 – Medical Assistance 5 – Other/Specify in General Comments	1
Total 340B Payment Received	Decimal	14,2	The aggregated payment receivable amount accrued for all drugs obtained under the 340B Program and dispensed or administered to patients during the previous calendar year, and encompassing all payments that: <ul style="list-style-type: none"> Are actual payments for insurance claims payments; and Reflect the portion of payment received from grants, cash, or other payment types that relate to the dispensing or administering of drugs obtained under the 340B program. 	1000.00
Total 340B Pricing Units Dispensed / Administered	Integer	19	The total number pricing units dispensed or administered to patients during the previous calendar year for all drugs obtained under the 340B Program.	1000

340B REPORTING FORM AND MANNER

Data Element	Format	Size	Description	Example
General Comments	Alphanumeric	8000	General comments and/or additional information related to the data submitted for the NDC / payer type, if applicable.	"General Comments"

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