

Reporting Administered 340B Drug Data in 2025 – DRAFT

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Minnesota providers that participate in the federal 340B Drug Pricing Program as Covered Entities must report statutorily required data elements to the Minnesota Department of Health (MDH) ([Minnesota Statutes, section 62J.461](#)). The [Form and Manner for 340B Covered Entity Report](#) provides guidance to Covered Entities for reporting. Beginning in 2025, Covered Entities are explicitly required to report data on all dispensed *and* administered 340B drugs. In response to stakeholder feedback, this document provides supplemental guidance for reporting on administered drugs, which is a subset of the broader reporting requirements.

- **Dispensed drugs** are drugs generally dispensed by a retail pharmacy, mail order, or specialty pharmacy and are generally taken orally or topically by patients themselves. These drugs include all drugs dispensed through contract pharmacies or in-house pharmacies and typically are billed using National Drug Codes (NDCs) through the pharmacy benefit (e.g. Medicare Part D plan). Stock drugs may be dispensed drugs, even if given to patients by a clinician.
- **Administered drugs** are drugs administered in an outpatient setting, such as a clinic or outpatient surgery center, and are primarily injected or infused by a clinician. These drugs may also be known as infusion drugs, injectable drugs, physician administered drugs (or PADs), and “buy and bill.” These drugs are typically billed to the medical benefit using procedural codes called “J-codes.”

This document only applies to entities that have 340B transactions for administered drugs.

Table 1: When this guidance is required

The guidance is required for:	This guidance is NOT for:
Covered Entities that handle any administered drugs	Covered Entities that handle only dispensed 340B drugs
Determining the following required data elements: <ul style="list-style-type: none"> ▪ Total 340B Acquisition Costs for administered 340B drugs ▪ Total 340B Pricing Units by Payer Type for administered 340B drugs ▪ Total 340B Payments Received by Payer Type for administered 340B drugs 	Determining the following required data elements: <ul style="list-style-type: none"> ▪ Total 340B Contract Pharmacy Costs ▪ Total 340B Outside Organization Costs ▪ Total 340B All Other Expenses ▪ Data elements in the lefthand column for dispensed 340B drugs

Requirement for reporting on administered drugs in 2025

Covered Entities that handle any administered 340B drugs must submit their actual administered drug data when reporting in 2025. If this is not feasible, Covered Entities must use one of the alternate approaches below and include with their submission supporting documentation and a justification for using an alternative approach.

Every reporting entity must indicate in the General Comments which approach was taken.

Actual data reporting: Reporting entities must report their actual data, which in most cases is included in summary reports from third-party administrators (TPAs) that contain the complete data for their 340B program, including administered drugs. TPA reports include all 340B transactions for invoices on eligible claims. These reports should be aggregated for 2024, summed with the corresponding data on dispensed 340B drugs, and submitted to the Rx Data Portal as required in the [Form and Manner](#).

- Note: TPA summary reports may be available to covered entity finance, billing, and collections departments; these reports might not be directly shared with Covered Entities' pharmacy departments.

Alternative 1: MDH recommended alternative approach If reporting entities are unable to access actual data for administered 340B drugs, they must first attempt to use the approach outlined in this document to obtain the relevant data elements and provide an explanation for why they are unable to report actual data.

Alternative 2: individualized method If reporting entities document they are unable to report actual data or data consistent with Alternative 1, reporting entities should employ their own methodology or approach and include a *detailed* explanation of their approach in the General Comments fields of their data submission as well as an explanation for why they are unable to report actual data.

Alternative 1: MDH recommended alternative approach

When actual data are not available—which the Covered Entity must be able to demonstrate to MDH—reporting entities should use the approach outlined here to derive values for:

- *Total 340B Acquisition Costs* for **administered 340B drugs**
- *Total 340B Pricing Units by Payer Type* for **administered 340B drugs**
- *Total 340B Payments Received by Payer Type* for **administered 340B drugs**

Acquisition costs for administered 340B drugs

Inputs:

- Purchasing documentation. For audit purposes, Covered Entities are expected to maintain records of quantities ordered and prices paid for each NDC and purchase account (e.g. 340B accounts, Group Purchasing Organization [GPO] accounts, etc.). These data should be available from Covered Entities' TPAs or directly from wholesalers.

Step 1: Determine the acquisition cost for all administered 340B drugs *purchased* in the 2024 calendar year, regardless of whether they were *used* in the 2024 calendar year.

Step 2: Add the amount from Step 1 to the *Total 340B Acquisition Cost* for **dispensed drugs** and report the grand total for both administered and dispensed drugs in the *Total 340B Acquisition Cost* field in the Rx Data Portal.

Number of pricing units for administered 340B drugs

Inputs:

- Purchasing documentation—same as for Acquisition Costs above.

Step 1: Determine the total number of units of administered 340B drugs that were *purchased* in the 2024 calendar year by payer type, regardless of whether they were *used* in the 2024 calendar year.

Step 2: Add the amount from Step 1 to the *Total 340B Pricing Units by Payer Type* for dispensed drugs. Enter the grand total in the *Total 340B Pricing Units Dispensed/Administered* field for the corresponding *Payer Type* in the Rx Data Portal.

Total 340B payment received by payer type

Inputs:

- HCPCS J-codes: HCPCS codes are a system for recording medical procedures, with J codes indicating specific types of administered drugs.
- Separately payable administered drugs: These can be identified by selecting claims with J-codes in the HCPCS field and a payment value on the claim line for the drug.

- Note: These drugs may also be called drugs with separately identifiable payment, or “payment line” drugs.

Step 1: Retrieve the payment received amounts (\$) of all J-codes that have service line payment amounts for the drugs (i.e. separately payable).

- Note: This step excludes any drugs paid through a bundled payment, including inpatient Diagnosis-Related Groups (DRGs) or bundled outpatient procedures.

Step 2: Using the results from Step 1, sum the service line payment amounts (\$) and group by payer type as described in the [Form and Manner](#).

Step 3: Sum your results from Step 2 with the corresponding *Total 340B Payment Received by Payer Type* for dispensed drugs. Submit your result in the Rx Data Portal. When submitting, add the following to the general comments:

- The administered drug methodology was Alternative 1.
- An estimate of what percentage of 340B payments collected (\$) are likely missing.