

340B Covered Entity Report: Frequently Asked Questions

APRIL 2025

This document addresses practical approaches to submitting data and speaks to specific circumstances that Covered Entities may face. The Minnesota Department of Health (MDH) has received these questions during the public comment periods, in meetings with stakeholders, as well as through more informal inquiries. MDH will update this document as new questions emerge about implementing the 340B Covered Entity Report in Minnesota.

Contents

Covered Entity Reporting Obligations	3
Why are Covered Entities required to report to MDH?	3
When are Covered Entities required to report?.....	3
For what time period are Covered Entities required to submit data to MDH?.....	3
What is a Covered Entity?.....	3
What is a <i>child site</i> or an <i>associated site</i> ?	3
Is one report required for each Covered Entity, or can one report contain the values that aggregate the activity for multiple Covered Entities?	4
If a Covered Entity has some facilities that are located outside of Minnesota or serves non-Minnesota patients, what are their reporting obligations?	4
If a Covered Entity is located outside of Minnesota, are they required to report?.....	4
Covered Entities may already submit data on their 340B program participation to other entities. How does this affect their reporting obligations to MDH?	4
Data Protection	5
How will the data elements reported to MDH be protected?	5
Covered Entities may have contract terms with third-party administrators, contract pharmacies, or others that include data privacy provisions. How can Covered Entities submit data and adhere to data privacy terms of their contracts?.....	5
Compliance Enforcement	6
Are there penalties for non-reporting?	6
What if I cannot report on time or have a hardship?.....	6
Definitions and Data Elements: <i>General</i>	7

FREQUENTLY ASKED QUESTIONS ON 340B COVERED ENTITY REPORTING

What drugs are subject to reporting under Minnesota’s 340B Covered Entity Report? 7

How should Covered Entities treat “white bagging” and “brown bagging” drugs?..... 7

Are some data elements optional? 7

Does MDH collect data on the activities Covered Entities support with net 340B revenue? 7

Should Covered Entities report actual data or estimates, including data on administered drugs?..... 7

What is a *contract pharmacy*? 8

What should Covered Entities submit for data fields they believe are not applicable to them? 8

How should Covered Entities account for possible differences in the timelines for acquisition, use, and payment for 340B drugs? 8

What sources should Covered Entities use to “pull” data for reporting? 9

Definitions and Data Elements: *Reporting by Payer Type* 10

 What should a Covered Entity do if the payer types used by MDH differ from those in the entity’s billing records? 10

 What should a Covered Entity do when they cannot distinguish between MinnesotaCare and Medicaid/Medical Assistance claims? 11

 What should a Covered Entity do when they cannot collect data elements by payer type from contract pharmacies or other third parties? 11

 When a patient has multiple coverage types over a year, how should Covered Entities reflect this in submitted data? 11

Definitions and Data Elements: *Acquisition Cost*..... 12

 Does *acquisition cost* include shipping or other fees? 12

Definitions and Data Elements: *Payment Amount Received* 13

 What should Covered Entities report if they provide care to patients that does not result in an insurance claim? 13

 What guidance exist to help identify relevant payments for administered drugs?..... 13

Definitions and Data Elements: *Payments Made* 14

 What spending should be included when reporting the field on *aggregated payments made to any other entity*?..... 14

 What costs should be included when reporting on the field *Total 340B All Other Expenses*? 14

Definitions and Data Elements: *Hospital-Only Reporting*..... 15

 If a hospital is not able to report NDC-level data for administered drugs, what should they report on the hospital-only reporting on top 50 NDCs?..... 15

Covered Entity Reporting Obligations

Why are Covered Entities required to report to MDH?

The Minnesota Legislature passed legislation in 2023—and updated it in 2024—that requires Covered Entities participating in the federal 340B Drug Pricing Program to report specific data on their participation in the program to MDH annually. MDH is required by this statute to collect the data and then submit an annual report to the Legislature that summarizes reported data and includes the net 340B revenue of Covered Entities with a significant share of statewide net 340B revenue.

When are Covered Entities required to report?

Per Minnesota statute, Covered Entities are required to annually submit timely, accurate, and complete data on 340B program participation to MDH by April 1 of each year. For this reason, April 1 remains the stated deadline in the Form and Manner for 340B Covered Entity Reporting.

However, 2025 has an extended deadline of May 30, 2025. This is in recognition of the efforts taken by MDH to support Covered Entities and those taken by Covered Entities to transition to new statutory reporting requirements in 2025.

For what time period are Covered Entities required to submit data to MDH?

Covered Entities are required to report on 340B program participation for the prior calendar year. For example, submissions due to MDH in 2025 are for 340B transactions in calendar year 2024.

What is a Covered Entity?

A covered entity is a hospital or clinic that is eligible and approved by HRSA to participate in the 340B drug discount program under Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. § 256b(a)(4)).

What is a *child site* or an *associated site*?

A parent Covered Entity may operate its 340B program using off-site, outpatient facilities that are part of the parent organization, but are physically separate. These sites are known as child sites or associated sites and designated as such on [HRSA OPAIS website](https://340bopais.hrsa.gov/ContractPharmacySearch) (<https://340bopais.hrsa.gov/ContractPharmacySearch>). These sites may also be known as *grantee associated sites*, *hospital outpatient sites*, or *offsite outpatient sites*. Typically, child sites share the same root HRSA 340B ID number with a main “parent” site, but the child site has different suffixes. For example, the parent ID may be DSH12345-00, and the child site’s ID may be DSH12345-01.

Is one report required for each Covered Entity, or can one report contain the values that aggregate the activity for multiple Covered Entities?

As required by Minnesota statute, each Covered Entity must submit one report to MDH. Each report should include data from the parent entity, as well as any child sites, grantee associated sites, hospital outpatient sites, offsite outpatient sites, contract pharmacies, and any other organization associated with the Covered Entity. For example, all 340B transactions for affiliated sites that share the same root HRSA ID (e.g., DSH12345-00) but have different suffixes (e.g., DSH12345-01) must be submitted in a single consolidated report for the parent Covered Entity.

If a Covered Entity has some facilities that are located outside of Minnesota or serves non-Minnesota patients, what are their reporting obligations?

Any parent Covered Entity that has a physical address in Minnesota is required to report under the Minnesota 340B Covered Entity Report. Parent entities with child sites located outside of Minnesota may report either on the activity associated with only the Minnesota sites or report on activity associated with all sites. However, information must be reported using the same method (the same mix of parent and child sites) for all data elements.

If a Covered Entity is located outside of Minnesota, are they required to report?

No. If the physical address of the parent Covered Entity site is located outside of Minnesota, they do not have an obligation to report under this reporting requirement.

Covered Entities may already submit data on their 340B program participation to other entities. How does this affect their reporting obligations to MDH?

Covered Entities are required to report to MDH per Minnesota statute, regardless of their participation in reporting requirements elsewhere.

Data Protection

How will the data elements reported to MDH be protected?

Data submitted by Covered Entities are 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]. Data are only accessible to the public through what is published in the legislative report, which is statutorily defined and includes summary data and net 340B revenue for Covered Entities that earned a significant share of statewide net 340B revenue.

Covered Entities may have contract terms with third-party administrators, contract pharmacies, or others that include data privacy provisions. How can Covered Entities submit data and adhere to data privacy terms of their contracts?

Minnesota statutes and the MDH reporting applications require data to be reported in aggregate (i.e., across all contract pharmacies / TPAs for the Covered Entity), and Covered Entities do not report the number of contracted relationships nor with whom they have contracted relationships. Additionally, data reported to MDH in this report are classified as nonpublic. MDH will not have the ability to discern individual contract terms and is not authorized to publicly release individual data-elements specific to a Covered Entity.

Compliance Enforcement

Are there penalties for non-reporting?

Minnesota statutes authorize MDH to impose a fine on a Covered Entity that fails to provide data in the prescribed form and manner. Direction to Covered Entities is provided in the Form and Manner.

What if I cannot report on time or have a hardship?

MDH established reasonable reporting timelines and developed many guidance documents to support Covered Entities in submitting timely, meaningful data to MDH.

MDH has delayed reporting in 2025 to give Covered Entities additional time to adapt to the new reporting requirements. MDH expects entities to report complete, accurate, and timely reports. As specified in statute, the commissioner may grant an extension of the reporting deadlines or exemption from reporting upon a showing of good cause by the entity.

Definitions and Data Elements: *General*

What drugs are subject to reporting under Minnesota’s 340B Covered Entity Report?

All outpatient drugs purchased under the Federal 340B Drug Pricing Program are subject to reporting under Minnesota’s 340B Covered Entity Report. This means reporting includes all administered and dispensed 340B outpatient drugs. Drugs provided in inpatient settings are not part of the 340B program and are not subject to this reporting.

- **Dispensed drugs** are 340B drugs generally dispensed by a retail pharmacy, mail order, or specialty pharmacy and are generally taken orally or topically by patients themselves. Dispensed drugs include all drugs dispensed through contract pharmacies or in-house pharmacies and are typically billed using National Drug Codes (NDCs) through the pharmacy benefit.
- **Administered drugs** are 340B 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 are typically billed to the medical benefit using procedural codes that include J-, Q-, and certain A-codes.

Covered Entities report the totals for dispensed drugs and administered drugs together.

How should Covered Entities treat “white bagging” and “brown bagging” drugs?

Whether a drug is sent from an outside facility directly to a health care facility or physician for administration (what can be called “white bagging”) or if it is brought in by a patient to a health care facility or clinician for administration (what can be called “brown bagging”), Covered Entities are required to report on the applicable 340B costs and payments for these drugs.

Are some data elements optional?

No. Beginning in 2025, there are no optional data elements.

Does MDH collect data on the activities Covered Entities support with net 340B revenue?

No, that information is not currently part of this reporting requirement.

Should Covered Entities report actual data or estimates, including data on administered drugs?

Covered Entities are required to annually submit timely, accurate, and complete data on 340B program participation. MDH expects Covered Entities to use actual data.

If reporting actual data is not feasible, Covered Entities should report their best estimates and include in their submission:

1. Indication that reported data are an estimate (add in general comments).
2. An explanation why reporting is perceived to be not feasible (add as an attachment).
3. A description of the methodology used and any supporting documentation or explanations (add as an attachment).

Guidance related to administered drugs is outlined in the Reporting Administered 340B Drug Data guidance.

What is a *contract pharmacy*?

Contract pharmacies are generally off-site pharmacies that dispense 340B drugs purchased by the 340B entity. Covered Entities have contractual arrangements with these pharmacies under which 340B drugs are generally billed to the 340B entity but shipped to the pharmacy—either directly from the wholesaler or from the Covered Entity. Examples of contract pharmacies include retail pharmacies like CVS or Walgreens. Covered Entities may also operate in-house wholly or partially owned pharmacies, which in some cases may be registered as contract pharmacies.

To verify the status of a pharmacy, use the Contract Pharmacy Search feature on the [HRSA OPAIS website \(https://340bopais.hrsa.gov/ContractPharmacySearch\)](https://340bopais.hrsa.gov/ContractPharmacySearch).

What should Covered Entities submit for data fields they believe are not applicable to them?

All Covered Entities subject to this reporting are required to report on all data elements required of them in statute. For hospitals, reporting also includes data on their top 50 most dispensed drugs by NDC. If a Covered Entity has not engaged in reportable activity under a given field (e.g. a Covered Entity does not have a contract pharmacy and therefore has no payments made to contract pharmacies to report), the Covered Entity should submit a 0 (zero) for that field and may use the General Comments field to provide further detail.

How should Covered Entities account for possible differences in the timelines for acquisition, use, and payment for 340B drugs?

Covered Entities should report actual data wherever possible.

If actual data are not available, Covered Entities should report based on the following timelines for each data element:

- For total 340B acquisition cost and total 340B pricing units, report on drugs *purchased* in the reporting year regardless of whether they were used in the reporting year.

- For total 340B payments received, report on payments **received** on 340B drugs in the reporting year regardless of whether they were purchased or used in the reporting year.

This guidance also applies entities that use a “replenishment model” to manage and bill for their 340B drugs.

What sources should Covered Entities use to “pull” data for reporting?

Appropriate data sources may vary widely for each Covered Entity. However, actual data should be available to most hospitals and all Covered Entities working with a third-party administrator (TPA) to manage their 340B program. These data should be available in TPA-provided summary reports, which are often sent to finance, billing, and collections departments.

MDH recommends Covered Entities convene representatives from finance, billing, and collections departments prior to beginning reporting. Summary reports shared by TPAs might not be directly shared with Covered Entities’ pharmacy departments; they may instead be available to finance, billing or collections departments.

A Covered Entity may allow a TPA to submit reports on their behalf within the [MN Rx Data Portal \(https://rxpt.health.mn.gov/\)](https://rxpt.health.mn.gov/) by adding the TPA as an affiliate to the Covered Entity’s account. Instructions are available in the MN Rx Data Portal’s [Registration and Account Management Guide \(https://www.health.state.mn.us/data/rxtransparency/docs/rxportalregguide.pdf\)](https://www.health.state.mn.us/data/rxtransparency/docs/rxportalregguide.pdf).

Definitions and Data Elements: *Reporting by Payer Type*

What should a Covered Entity do if the payer types used by MDH differ from those in the entity's billing records?

Please use the additional information below to best fit your data into the payer type options outlined in the Form and Manner.

- The **Commercial** payer type includes all private or commercial insurance plans that act as payers for 340B drugs. Note that some Bank Identification Number (BIN) or Processor Control Number (PCN) numbers may be shared between commercial and non-commercial plans. This data element should include co-payments, coinsurance, or other forms of cost sharing paid by commercially insured patients.
- The **Medicare** payer type includes Medicare Part D, Medicare Part B, or any other Medicare plan (such as Medicare advantage or Medigap) that acts as a payer for 340B drugs. Note that some BIN or PCN numbers may be shared between Medicare and commercial plans. This line should include co-payments, coinsurance, or other forms of cost sharing paid by Medicare patients. For the portion of Medicare-covered patients who are dually eligible for Medicare and Medicaid/Medical Assistance, drugs have multiple payers. Typically, the Medicare Part D plan pays for the plan portion of the claim and Medicaid/Medical Assistance pays for the patient cost-sharing. Please include Medicare's payments for drugs for dually eligible patients on this line and include Medicaid/Medical Assistance coverage of cost-sharing on the Medicaid/Medical Assistance line.
- The **MinnesotaCare** payer type includes any MinnesotaCare plan that acts as payer for 340B drugs. Note that some BIN or PCN numbers may be shared between MinnesotaCare and commercial plans. This line should include co-payments, coinsurance, and other forms of cost sharing paid by MinnesotaCare patients.
- The **Medicaid/Medical Assistance** payer type includes any Medicaid—known as Medical Assistance in Minnesota—plan that acts as payer for 340B drugs. Note that some BIN or PCN numbers may be shared between Medicaid/Medical Assistance and commercial plans. This line should include co-payments, coinsurance, and other forms of cost sharing paid by Medicaid/Medical Assistance patients. Typically, the Medicare Part D plan pays for the plan portion of the claim and Medicaid/Medical Assistance pays for the patient cost-sharing. Please include Medicare's payments for drugs for dually eligible patients on this line and include Medicaid/Medical Assistance coverage of cost-sharing on the Medicaid/Medical Assistance line.
- The **Other** payer type includes payers that are not commercial payers, Medicare, Medicaid (or Medical Assistance), or MinnesotaCare. Examples include but are not limited to workers compensation, auto insurance payments, grant funding, and cash payment. This payer type should *not include cost sharing* (co-pays and or coinsurance, deductible amounts) made by

enrollees of commercial insurance, Medicare, Medicaid/Medical Assistance, or MinnesotaCare.

What should a Covered Entity do when they cannot distinguish between MinnesotaCare and Medicaid/Medical Assistance claims?

Covered Entities that are unable to distinguish between MinnesotaCare and Medicaid/Medical Assistance claims may report aggregated payer type data on *either* payer type line and should note this aggregation in the General Comments.

What should a Covered Entity do when they cannot collect data elements by payer type from contract pharmacies or other third parties?

The distribution of data elements by payer type is statutorily required, and Covered Entities must report the information to the best of their ability. Where necessary, Covered Entities may submit their best estimates for required data elements and use the General Comments field to provide context and detail about the methodology used to develop these estimates.

MDH encourages entities that need to estimate reporting by payer type to distribute the total aggregate amounts based on the Covered Entity's distribution of revenue across each type of payer.

When a patient has multiple coverage types over a year, how should Covered Entities reflect this in submitted data?

The required data elements do not require Covered Entities to assign a single payer type to each patient. For aggregated payments received, this can be broken out by individual payments from each payer type. Similarly, total claims can also be broken out by each claim rather than a single payer type for a patient for a whole year.

Definitions and Data Elements: *Acquisition Cost*

Does *acquisition cost* include shipping or other fees?

No. These costs should be included in the field for “all other expenses,” which is intended to capture costs related to administering the 340B drug pricing program.

Definitions and Data Elements: *Payment Amount Received*

What should Covered Entities report if they provide care to patients that does not result in an insurance claim?

Covered Entities may provide care using drugs acquired through the 340B program to uninsured patients that pay in cash, patients whose care is funded by grants, or another means that does not result in a claim sent to a health insurer. For these scenarios, Covered Entities are still required to include data values related to this care in their report, and these data should be reported with a payer type of "Other." The source(s) of such payments may be specified in the General Comments field.

What guidance exist to help identify relevant payments for administered drugs?

In response to stakeholder requests for support in reporting on administered drugs, MDH developed guidance for Reporting Administered 340B Drug Data in 2025 ([URL](#)) that provides supplemental guidance for reporting on administered drugs. This guidance includes instruction on the commonly used documentation that Covered Entities can reference to collect the required data, as well as guidance on the codes to look for in billing statements to identify 340B drugs.

Definitions and Data Elements: *Payments Made*

What spending should be included when reporting the field on *aggregated payments made to any other entity*?

Covered Entities may work with intermediaries or partners to implement their 340B program. Covered Entities should report the aggregated payment to *any* business organizations for managing any aspect of the Covered Entity's 340B program. This includes all entities that are 1) not the Covered Entity nor a child or associated sites and 2) not a contract pharmacy, which are typically third-party administrators (TPAs). *Payments made* should include any share of net 340B revenue retained by TPAs for 340B program administration tasks.

What costs should be included when reporting on the field *Total 340B All Other Expenses*?

Covered Entities should report the aggregated internal costs—including contract fees (except for contract pharmacy fees, which have a dedicated field), staffing, shipping costs, and operational and administrative expenses—to perform program administration tasks *directly related* to the federal 340B program for the prior calendar year. This data element should not include the fixed costs that are not directly incurred from 340B program administration (e.g. facility costs, provider staffing, etc.).

Definitions and Data Elements: *Hospital-Only Reporting*

If a hospital is not able to report NDC-level data for administered drugs, what should they report on the hospital-only reporting on top 50 NDCs?

Hospital Covered Entities are required to annually submit data on the top 50 NDCs of dispensed and administered 340B drugs.

MDH recognizes there may be challenges in identifying and compiling the required data elements at the NDC level for administered drugs. Therefore, if it not feasible for a hospital to include administered drugs—either actuals or reasonable estimates—MDH will allow hospitals to report only on dispensed drugs and separately payable administered drugs (i.e. exclude administered drugs with bundled payments) for the top 50 NDC reporting fields in reporting year 2025 only. This accommodation is in recognition of the transition to new statutory reporting requirements and future reporting periods likely will not provide this accommodation

- All hospitals must indicate in the general comments field whether their NDC level reporting includes all dispensed and administered drugs, or only dispensed and separately payable administered drugs.
- Any hospital that opts out of submitting data on all administered drugs in their NDC level reporting for reporting year 2025 must include with their submission an explanation for why they are taking this approach. This should be included as a clearly labeled attachment in the submission in the Rx Data Portal.

Guidance related to administered drugs is outlined in the Reporting Administered 340B Drug Data guidance.

FREQUENTLY ASKED QUESTIONS ON 340B COVERED ENTITY REPORTING

Minnesota Department of Health

Health Economics Program

St. Paul, MN 55164-0882

651-201-4520

health.rx@state.mn.us

www.health.state.mn.us/healthconomics

To obtain this information in a different format, call: 651-201-4520