340B Covered Entity Report: Frequently Asked Questions

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This document addresses practical approaches to submitting data and speaks to specific circumstances that reporting entities may face. The Minnesota Department of Health (MDH) has heard 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

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 law, MDH expects to receive one report from each covered entity. A single report should include values from the parent entity, as well as any child sites, grantee associated sites, and any other entity associated with the covered entity's 340B identification number (ID).

MDH collects a National Provider Identifier (NPI) number at the time of registration in the online reporting portal. Why does MDH collect this and do reporting entities have to submit all relevant NPIs into the system?

NPI is one of the data elements required by statute. Reporting is required at the 340B ID level and not at the NPI level. MDH recognizes that a single 340B entity may have multiple relevant NPIs. MDH requires that covered entities report an NPI number but does not require them to identify all NPIs associated with their organization. Though voluntary, MDH encourages submitters to also report their 340B ID.

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

Any covered entity that has a physical address in Minnesota is required to report under this initiative. 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 covered entity site is located outside of Minnesota, they do not have an obligation to report under this reporting requirement.

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

Reporting entities are required to report to MDH, regardless of their participation in reporting requirements elsewhere.

Data Definitions and Data Elements

What drugs are subject to reporting under Minnesota's Covered Entity Report?

All drugs that are included in the federal 340B drug pricing program are subject to reporting under Minnesota's initiative. This means reporting includes all outpatient drugs. Drugs administered in inpatient settings are not subject to this reporting.

Is there a difference in how covered entities should report drugs dispensed directly to patients from a pharmacy and drugs dispensed to a provider and administered to the patient in a clinic setting?

The MN 340B Covered Entity Reporting relates to all 340B drugs, which are outpatient drugs obtained under the federal 340B program. MDH understands this to be drugs both dispensed directly from a pharmacy and dispensed to a provider and administered in a clinic setting. MDH acknowledges that while the intent of the statute is clearly to include all 340B drugs, some of the language could be interpreted as ambiguous.

MDH asks that reporting entities include all 340B drugs in their reports. If it is difficult to collect actual values for some of the drugs, such as administered drugs, MDH suggests reporting entities provide their best estimate and include a description of their methodology in the general comments. If it is impossible to submit the full reporting, covered entities should ensure that reporting across all data elements is for the same unit of analysis or grouping of drugs (i.e. if clinic administered drugs are excluded from the payment received data element, they should be excluded from all data elements) and they should provide an explanation of which drugs are included and their methodology in the general comments.

What should a reporting 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 reporting entities must report the information to the best of their ability. Where necessary, reporting entities may submit their best estimates for required data elements; reporting entities may 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 reporting entities reflect this in submitted data?

The required data elements do not require reporting 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.

Does MDH collect data on the types of activities covered entities support with 340B savings?

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

Are some data elements optional?

Yes. While most data elements are required, reporting of certain data elements is optional. Optional data elements are clearly labeled, and reporting entities may leave them blank if desired. Nevertheless, MDH strongly encourages covered entities to report optional data, as it will strengthen Minnesota's empirical understanding of the 340B program in the state. These optional elements were included in response to feedback that certain costs associated with a covered entity's participation in the 340B program were not being collected and should be.

What costs should be included when reporting the optional field on aggregated payments made to any outside organization that is not the covered entity?

Covered entities can work with a number of intermediaries or partners to implement their 340B program. Reporting entities should report the aggregated reimbursement payable amount accrued for payment to any entity that is not the covered entity or a contract pharmacy for managing any aspect of the covered entity's 340B program. This includes, for example, any share of 340B savings retained by third party administrators (TPAs) for 340B program administration tasks.

What costs should be included when reporting the optional field on "all other expenses" related to administering the 340B drug pricing program?

Reporting entities should report the aggregated internal costs—including contract fees, staffing, shipping costs, and operational and administrative expenses—to perform program administration tasks related to the federal 340B program for the past calendar year.

How should reporting entities account for possible differences in the timelines for acquisition, storage, and dispensing drugs associated with the 340B program when preparing their reports?

Reporting entities should report figures as accrued for each reporting period. For example, aggregated acquisition costs should reflect the costs accrued for 340B drugs during the period regardless of whether such drugs were dispensed during the same period.

Does acquisition cost include shipping or other fees?

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

What should entities report if they provide care to patients that does not result in an insurance claim (e.g., entities receive grant payments, cash payments or other)?

Data values related to care for which covered entities do not seek reimbursement from third party payers (grant payments, cash payments, etc.) should be reported with a payer type of "Other." The source(s) of such payments may be specified in the General Comments field.

Data Protection

How will the data elements reported to MDH be protected?

Data submitted by reporting entities are classified as nonpublic data [as defined in section 13.02, subdivision 9 (https://www.revisor.mn.gov/statutes/cite/13.02)]; it is only accessible to the public in summary form.

Reporting entities may have contract terms with third-party administrators, contract pharmacies, or others that include data privacy provisions. How can reporting 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 CE), and reporting entities need report neither 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 report data specific to a reporting entity.

Compliance Enforcement

Will MDH allow deadline extensions in the first year?

Reporting entities may request an extension of the reporting deadline through the portal. An extension request requires demonstrating of good cause; MDH will consider extension requests on a case-by-case basis.

Will MDH implement a hardship waiver or otherwise allow select entities to not report?

Reporting entities may request an extension of the reporting deadline upon demonstrating good cause.

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