Prescription Drug Price Transparency, Public Interest Reporting: Frequently Asked Questions

June 26, 2024

This Frequently Asked Questions (FAQ) document addresses practical approaches to submitting data and speaks to specific circumstances that reporting entities may face. It specifically focuses on Drugs of Substantial Public Interest reporting and associated changes to the Prescription Drug Price Transparency Act as a result of the 2023 legislative session (Minnesota Statutes, section 62J.84[i], subd. 10-14). For an FAQ regarding New Drug and Price Growth Reporting, please see the Prescription Drug Price Transparency: Frequently Asked Questions (PDF) document.[ii] The Minnesota Department of Health (MDH) has received these questions during public comment periods, in meetings with stakeholders, as well as from more informal inquiries. MDH will update this document as new questions emerge about implementing the Act.

Contents

Reporting Obligations and Options

Is it possible to submit a consolidated report if a reporting entity—a Minnesota-licensed drug manufacturer, wholesaler, pharmacy benefit manager (PBM), or pharmacy—has multiple sites or if multiple organizations fall under a larger organizational umbrella?

There are options for consolidated reporting in some circumstances. If multiple entities are reporting under the same subdivision and have registered in the portal as parent/child or affiliates, then they may submit a single report that aggregates data for multiple entities. Each entity that is obligated to report must still be identified in the organization registration and as contributing to the consolidated report.

Access the Registration Quick Start Guide (PDF) for tips on how best to register your organization to meet your reporting obligations.[iii]

Some wholesalers are not directly involved in rebate transactions. How can wholesalers fulfill the reporting obligations for rebate information?

In instances where an entity does not have any transactions of a certain type, such as rebates, it should enter 0 (zero) in the data field.

Are 503B outsourcing facilities licensed in Minnesota as both a manufacturer and a wholesale distributor required to register and report under the Act?

503B outsourcing facilities licensed in Minnesota as manufacturers and/or wholesale drug distributors are required to register in the RxPT reporting portal and fulfill the reporting obligations. Manufacturers must report under MS 62J.84, subdivision 11 (in addition to subdivisions 3 and 4, as applicable) and wholesalers must report under MS 62J.84, subdivision 14.[iv] If a wholesaler has not acquired or sold a drug included in a notification to report during the 12-month period prior to the date of the notification, the wholesaler should provide 0 (zero) values for all related data fields.

Registration

In managing the registration process on the MN Rx Data Portal, what approach should entities of various sizes and organizational structures adopt, especially regarding contact management?

The Rx data portal provides flexibility for how entities register and affiliate with one another. For example, smaller entities may prefer registering and reporting independently, while larger entities, or those with multiple affiliates, might find it beneficial to register as a parent organization and add child affiliates. It is also possible to add third party administrators (TPAs) in the portal. Regardless of organization structure, MDH recommends having at least two contacts to ensure continuous access to the portal if a contact changes roles or leaves the organization.

The Registration Quick Start Guide (PDF) provides step-by-step instructions for getting started in the portal as well as adding/managing contacts, affiliates, and TPAs.[v]

Data Elements

If information related to some data elements isn't available at the National Drug Code (NDC)-level (e.g., volume-based rebates), what value should be reported?

For data elements not directly attributable to a specific NDC, entities can estimate a value for each NDC using a calculation that is most representative of the entity's operating model. For

example, entities may provide an estimate of the total rebate amount payable for a given NDC based on the total rebates payable for the organization multiplied by the percent of total revenue attributable to each NDC. When estimating values for data elements, entities should indicate the methodology applied in deriving the estimate in the General Comments.

Information related to some data elements is not available until after the reporting deadline (e.g., retroactive rebates), what value should be reported?

Entities should report the most accurate information they can access at the time of reporting. This may include estimates based on historical trends, similar information already calculated, or data from tax filings and other reports. When estimating values for data elements, entities should indicate the methodology applied in deriving the estimate in the General Comments.

What should reporting entities do if they are unable to collect full, exact, and timely data? Some obstacles may include:

- Establishing data collection and reporting processes
- Integrating new technologies and software
- Overcoming unforeseen technical or logistical issues

Entities should aim to provide the most accurate data possible within the given timeframe, balancing the need for timely reporting with the practical challenges faced in compiling required information. MDH understands circumstances may require some submissions to include estimates or partial data based on currently accessible information.

When full, exact, or timely data values are not available, entities should report the best information available. This may be estimates based on historical trends, data derived from other available sources, or other methods that reflect a best effort to comply. Entities should use the General Comments field in the reporting portal for any necessary context or explanations about their data submissions.

How should pharmacies that participate in patient assistance programs and/or dispense medications free-of-charge to patients report?

Pharmacies engaged in patient assistance programs who are dispensing medications at no charge should indicate the number of units acquired and dispensed and indicate 0 (zero) values (as appropriate) for acquisition, rebate, and reimbursement data elements.

International Prices

How should manufacturers proceed when a "Wholesale Acquisition Cost (WAC) Equivalent" is not identifiable or used?

For the international data elements, manufacturers should submit the value that is most equivalent to the WAC value in the United States. This value may be the highest list price in the other country. Where list prices are not maintained, the manufacturer may submit the highest direct cost charged in the other country. All values provided for international price data elements should be expressed in dollars according to the exchange rate on the day the report is submitted. Information about the methodology used to provide international price values may be included in the General Comments for the NDC.

Confidentiality

How can entities address the challenge of maintaining confidentiality agreements while also fulfilling NDC-level reporting requirements?

Reported NDC-level data is assumed to contain information across multiple contractual entities and components, thereby preventing the identification of individual agreements. For example, pharmacy data will include reimbursement values that are aggregated across payers and plans preventing the identification of reimbursement details from any one payer. Manufacturer rebate information will be aggregated across contractual components and may include multiple rebate types which prevent the identification of individual contractual elements with any one entity.

Additionally, MDH will not publish data at a lower level of granularity than what is required under MS 62J.84, subd. 6. [vi] MDH does not intend to associate data elements with named wholesalers, Pharmacy Benefit Managers (PBMs), or pharmacies when publishing data.

The General Comments field in the Rx Data Portal provides an opportunity for entities to add relevant information or context about their data submission as well.

Not Public Data and Trade Secret

For additional FAQs on Not Public Data and Trade Secret, see the Prescription Drug Price Transparency: Frequently Asked Questions (PDF) document.[vii]

How can entities ensure that sensitive information is correctly identified as Not Public when reported?

It is the responsibility of the reporting entity to ensure that all data deemed Not Public Data or Trade Secret is accurately marked as such in the reporting portal. This includes entities that employ third-party administrators for assistance with their reporting obligations.

If a reporting entity is concerned that a third-party reporting on its behalf is not aware of which data elements the reporting entity wants identified as Not Public Data or Trade Secret, MDH suggests that the reporting entity reports directly or clearly communicates with third parties acting on its behalf regarding which data elements are considered Not Public Data or Trade Secret.

List of Drugs of Substantial Public Interest

Will the Drugs of Substantial Public Interest List contain drugs at the National Drug Code (NDC) level?

Yes, the Drugs of Substantial Public Interest list will be communicated at the NDC-level. The reporting template will also be prepopulated with the NDCs for which reporting is required.

How will MDH define and communicate the standards for identifying prescription drugs of substantial public interest?

MDH is charged with the responsibility to identify drugs that represent a substantial public interest for transparency reporting. MDH will share a description of the identification methodology with each list published.

Will MDH repeat lists?

Although MDH aims to explore different aspects of the market with each list, MDH anticipates that there may be reasons to repeat a particular list of drugs over a period of time.

How will public comments be used in the selection of lists?

MDH will share a description of the identification methodology with each list published, including the role that public comments played in the development of the identification methodology.

---

[i] https://www.revisor.mn.gov/statutes/cite/62J.84
[ii] https://www.health.state.mn.us/data/rxtransparency/docs/faq092922.pdf
[iii] https://www.health.state.mn.us/data/rxtransparency/docs/rxportalregquickstart.pdf
[iv] https://www.revisor.mn.gov/statutes/cite/62J.84#stat.62J.84
[v] https://www.health.state.mn.us/data/rxtransparency/docs/rxportalregquickstart.pdf
[vi] https://www.revisor.mn.gov/statutes/cite/62J.84#stat.62J.84.6
[vii] https://www.health.state.mn.us/data/rxtransparency/docs/faq092922.pdf