Healthcare Distribution Alliance

HEALTH DELIVERED

Chairwoman Liebling
House Health Finance and Policy Committee
477 State Office Building
St. Paul, MN 55155

On behalf of the Healthcare Distribution Alliance (HDA), the national trade association representing healthcare wholesale distributors, we offer this letter in respectful opposition to House File 2930. While we understand the intent of the legislation, we would like to request the committee consider amendments that more accurately reflect the role of the wholesale distributors within the supply chain.

Each day, wholesale distributors work around the clock to ship roughly 15 million healthcare products to nearly 180,000 pharmacies, hospitals, and other healthcare providers to keep their shelves stocked with the medications and products they need to treat and serve patients. **Their core business is not manufacturing, nor do they prescribe medicines, influence healthcare professionals prescribing patterns, dispense medications to patients, influence patient benefit designs, or set the Wholesale Acquisition Cost (WAC) of medications**.

While we support the state's efforts in seeking a better understanding of the price of prescription drugs. However, the information our members are required to report does not align with their business operations. For example, wholesale distributors are not a part of any negotiations on the "pay side" of the supply chain, rather this is the role of health insurers and pharmacy benefit managers (PBMs). Wholesale distributors have no insight into patient-level data, nor are they privy to how products are dispensed at the patient level.

HDA requests the committee consider limiting the reporting to the top 25 costliest drugs. This will ensure the state is receiving targeted information on the drugs that are specifically concerning to Minnesotans. Rather, the current language will likely result in the state having to analyze an incredibly voluminous amount of data from various supply chain entities. Ultimately preventing the state from efficiently and effectively achieving the legislative intent, while at the same time adding more costs on industry in order to comply with this new and onerous reporting requirements.

We believe it is also important for the committee to understand that the state already has access to publicly available pricing information reported to the Centers for Medicare and Medicaid Services (CMS). The National Average Drug Acquisition Cost (NADAC) data is determined for virtually every drug in the marketplace through a nationwide pharmacy survey process and is the invoice price pharmacies pay wholesalers for their medication products. This information is not proprietary, is updated weekly and can be immediately available to benchmark pharmaceutical prices in Minnesota against national drug pricing trends. In addition to NADAC, each pharmaceutical manufacturer also reports a list price for all products sold in the U.S. This Wholesale Acquisition Cost (WAC), set by the manufacturer of a drug product, is already publicly reported and available to the state.

Amendment Request #1 – Include Definition of "Individual salable unit":
We propose the inclusion of a definition of "individual salable unit."

> *For purposes of this paragraph, an `individual salable unit' is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.*

This definition is already established in Minnesota Statute Section 151.441 pertaining to wholesale distributors and its usage will create uniformity.

Amendment #2 – Include Definition for "Rebate":
We propose including a definition of "rebate."

> *"Rebate is defined as a discount, chargeback, or other price concession that affects the price of a prescription drug product, regardless of whether conferred through regular aggregate payments, on a claim-by-claim basis at the point-of-sale, as part of retrospective financial reconciliations (including reconciliations that also reflect other contractual arrangements), or by any other method. "Rebate" does not mean a "bona fide service fee", as such term is defined in Section 447.502 of Title 42 of the Code of Federal Regulations, published October 1, 2019.*

We propose this definition because it aligns with the Code of Federal Regulations which will ensure uniformity amongst the reporting entities.

Amendment Request #3 – Posting Should Occur on an Annual Basis and Include Only the Top 25 Drugs:

> *Sec. 15. Minnesota Statutes 2022, section 62J.84, is amended by adding a subdivision to read:*
> *Subd. 10. Notice of prescription drugs of substantial public interest.*
> *(a) No later than January 31, 2024, and annually ~~quarterly~~ thereafter, the commissioner shall produce and post on the department's website a list of the top 25 prescription drugs that the department determines to represent a substantial public interest and for which the department intends to request data under subdivisions 9 to 14, subject to paragraph (c).*

Rather than quarterly, annual posting will act as a more accurate benchmark for the Commissioner. Depending on the metric(s) being sought, data requested by the Commissioner in one quarter, may only be available from previous quarters and therefore be shown on a delay. Annual posting of the top 25 drugs will create a much clearer picture for the Commissioner and the Department and depict those drugs that have the most substantial public interest.

Amendment Request #4 - Adjusting the Wholesale Reporting Requirements:

> *Sec. 19. Minnesota Statutes 2022, section 62J.84, is amended by adding a subdivision to read:*
> *Subd. 14. Wholesaler prescription drug substantial public interest reporting.*
> *(a) Beginning January 1, 2024, a wholesaler must submit to the commissioner the information described in paragraph (b) for any prescription drug included in a notification to report issued to the wholesaler by the department under subdivision 10.*
> *(b) For each of the drugs described in paragraph (a), the wholesaler shall submit to the commissioner no later than 90 ~~60~~ days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:*
> *(1) a description of the drug with the following listed separately:*
> *(i) the national drug code;*
> *(ii) the product name;*
> *(iii) the dosage form;*
> *(iv) the strength; and*
> *(v) the package size;*
> *(2) the number of individual salable units of the drug product acquired by the wholesale drug distributor for use in this state during the 12-month period prior to the date of the notification to report;*
> *(3) the total aggregate spent before rebates by the wholesale drug distributor to acquire the drug product for use in this state during the 12-month period prior to the date of the notification to report;*

(4) the total aggregate rebate receivable amount accrued by the wholesale drug distributor for the drug product for use in this state during the 12-month period prior to the date of the notification to report;
(5) the number of units of the drug product sold by the wholesale drug distributor for use in this state during the 12-month period prior to the date of the notification to report;
(6) gross revenue from sales in this state ~~the United States~~ generated by the wholesale drug distributor for this drug product for use in this state during the 12-month period prior to the date of the notification to report; and
(7) total rebate payable amount accrued by the wholesale drug distributor for the drug product used in this state during the 12-month period prior to the date of the notification to report.
(c) The wholesaler may submit any documentation necessary to support the information reported under this subdivision.

This amendment seeks to add additional time for wholesale distributors to report the desired information to the Commissioner. As previously noted, data may not be fully available within 60 days after notification. Therefore, we are asking for a 90-day timeline to submit the requisite information to the Commissioner. In addition, we request to report the data in the aggregate to better align with business operations. Lastly, we believe it is important to report only data related to drugs used in Minnesota which will ensure the state is receiving the most relevant information for its citizens. Compiling data from all states would be unduly burdensome on business operations and prevent distributors from providing information in a timely manner.

Amendment #5 - Request the Removal of Registration:

~~Sec. 20. Minnesota Statutes 2022, section 62J.84, is amended by adding a subdivision to read:~~
~~Subd. 15. Registration requirements. Beginning January 1, 2024, a reporting entity subject to this chapter shall register with the department in a form and manner prescribed by the commissioner.~~

Pharmaceutical wholesale distributors already are required to be licensed and regulated by the State of Minnesota to conduct business. Therefore, additional registration is duplicative and unduly burdensome on our industry.

Amendment #6 – Request for Confidentiality of Reporting:

Data collected under this subdivision are nonpublic data as defined in section 13.02 notwithstanding the definition of summary data in section 13.02, subdivision 19, summary data prepared under this section may be derived from nonpublic data. The commissioner shall establish procedures and safeguards to protect the integrity and confidentiality of any data that it maintains. The Department may share information to the extent necessary so long as: A. prior notice is provided to reporting entities that information will be shared, and any information shared is kept confidential, and B. In the aggregate, as long as it is not released in a manner that allows the identification of an individual drug or manufacturer, wholesale drug distributor, pharmacy or pharmacy benefits manager. The Department may share information in the aggregate, even if it allows the identification of an individual drug, as long as it is not released in a manner that allows the determination of individual prescription drug pricing contract terms covering a manufacturer, wholesale drug distributor, pharmacy or pharmacy benefits manager.

This language is a combination of confidentiality concepts adopted from HF 2930 as introduced as well as existing law in Maine that establishes similar supply chain reporting requirements. Some of the reporting metrics outlined in HF 2930 contain confidential and proprietary information. We propose the aforementioned language to both support the states objective in obtaining the data while also protecting wholesaler's confidentiality.

In order to accurately reflect the role of distributors within the supply chain, we ask the committee adopt our requested amendments to HF 2930. We welcome the opportunity to provide additional information or context to the committee on the wholesale distribution industry and the role our members play within the supply chain, please contact me at (716) 307-4022 or tbutchello@hda.org to discuss this issue further.

Sincerely,

Travis Butchello
Director, State Government Affairs
Healthcare Distribution Alliance