



In Opposition to House File 4398: Prescription Drug Reporting

March 22, 2022

Position: The Pharmaceutical Research and Manufacturers of America (“PhRMA”) respectfully opposes House File 4398 (HF 4398), which prematurely adds additional drug reporting requirements for drug manufacturers and other entities. This legislation also creates a disjointedness between triggering products and the scope of products for which reporting would be required with the addition of the term, “drug product family.” The addition of this definition may result in manufacturers being subject to significant pricing component data reporting not due to their actions but rather the pricing decisions of a different manufacturer.

Discussions about cost and affordability of medicines are important. No patient should have to worry about whether they can afford the health care they need. However, the notion that spending on medicines is the primary driver of health care cost growth is false and ignores cost savings that medicines provide to the health care system overall. Medicines lead to fewer physician visits, hospitalizations, surgeries, and other preventable procedures, all of which translate to lower health care costs. Adding burdensome reporting requirements for companies that did not exceed pricing triggers is likely to skew important discussions of policy issues and add unnecessary administrative costs to the healthcare system.

By adding the definition of “drug product family,” HF 4398 may result in manufacturers not identified as a “prescription drug of substantial public interest” to undertake cumbersome reporting requirements.

The new definition of “drug product family” would capture drug manufacturers not identified as a “prescription drug of substantial public interest,” and dramatically expand the scope to manufacturers required to report far beyond 500 prescription drugs. While HF 4398 would require the Department of Health to “consider” certain criteria in selecting prescription drugs of substantial public interest, the Department of Health may rely on “any information the department deems relevant,” and then apply reporting requirements to entire “drug product families.” This provision unfairly burdens manufacturers with expanded reporting requirements based on another manufacturer’s pricing decisions or the broad authority given to the Department of Health. Thus, HF 4398 creates a disconnect between pricing actions and the reasons to file substantial reporting requirements. This is fundamentally unfair given the significant reporting and penalties associated with these requirements.

HF 4398 prematurely makes changes to the 2020 Prescription Drug Price Transparency Act.

In 2020, the Minnesota Legislature passed the Prescription Drug Price Transparency Act, which requires drug manufacturers to report specific information when the price of a medicine increases by a certain percentage over a period of time. PhRMA has worked in good faith with the Minnesota Department of Health during the past year providing comments to the guidance drug manufacturers must follow for reporting. Initial drug

manufacturer reports were not due until March 2022 and it is likely that information from these reports will not be available for review until later in 2022.

HF 4398 dramatically expands the number of prescription drugs and manufacturers impacted by transparency reporting requirements before the current reporting requirements have been evaluated and assessed. We would urge you to pause any additional reporting mandates on drug manufacturers until current reporting requirements have been fully implemented and assessed.

Existing confidentiality protections under the Prescription Drug Price Transparency Act were not amended to cover the new reporting requirements.

Minn. Stat. Section 62J.84, subd. 6 currently provides confidentiality and trade secret protections for drug manufacturers under the Prescription Drug Price Transparency Act. The proposed language introduces the new term “reporting entity”, which includes manufacturers and others required to report information to the Department of Health. However, Minn. Stat. Section 62J.84, subd. 6 was not amended to include “reporting entities” in the process to request the commissioner withhold not public or trade secret data. “Manufacturer” should be changed to “reporting entity” or all the reporting entities under 62J.84 (i.e., manufacturer, pharmacy, PBM, and wholesaler) should be listed in order for any reporting entity to use this process to request withholding of not public or trade section information under subd. 6.

For these reasons, we urge legislators to oppose HF 4368.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than \$1 trillion in the search for new treatments and cures, including an estimated \$83 billion in 2019 alone.