MINNESOTA BOARD OF PHARMACY

List any rules or portions of rules that are obsolete, unnecessary, or duplicative of other state or federal statutes or rules. (In compliance with Minnesota Statutes Section 14.05, Subd. 5)

(Obsolete Rules Report)

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COST OF REPORT

Minnesota Statutes §3.197 states that a "report to the legislature must contain, at the beginning of the report, the cost of preparing the report, including any costs incurred by another agency or another level of government". The estimated cost of preparing this report was **$50.00**. That is the approximate value, in terms of salary and benefits, of the time that Board staff spent on preparing the report.

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Obsolete Rules Report

MN Stats. §14.05, subd. 5 states, in part: "By December 1 of each year, an agency must submit to the governor, the Legislative Coordinating Commission, the policy and funding committees and divisions with jurisdiction over the agency, and the revisor of statutes, a list of any rules or portions of rules that are obsolete, unnecessary, or duplicative of other state or federal statutes or rules." This report is being submitted for calendar year 2023. It was reviewed and approved by the Board at its December 13, 2023 meeting.

The Board of Pharmacy regulates both the profession of pharmacy and the distribution of drugs into and within the state of Minnesota. It licenses pharmacists, pharmacies, drug manufacturers and drug wholesale distributors. It registers pharmacy interns and technicians, medical gas distributors and controlled substance researchers. The Board administers the Minnesota Prescription Monitoring Program (PMP), a tool that prescribers and pharmacists can use to help reduce the abuse of prescriptions drugs, such as opiates. It also administers the Opiate Product Registration Fee Program (OPRFP) and a portion of the Minnesota Insulin Safety Net Program (ISNP). The Legislature has also empowered the Board to make certain changes to the state's schedules of controlled substances. The Board has promulgated the rules found in Minnesota Rules Chapter 6800 in order to appropriately exercise its regulatory authority over these complex professions and industries. Note that the Board has not promulgated any rules for the PMP, OPRFP or INSP. The Board strives to protect the health of the public while minimizing regulatory burdens on its licensees and registrants. To that end, the Board often relies on standards established by agencies of the federal government or by professional accrediting and standard-setting organizations.

The Board continuously assesses its rules to determine if any are "obsolete, unnecessary or duplicative of other state or federal statutes or rules". According to the Merriam-Webster Dictionary, one meaning of the word "obsolete" is "no longer in use or no longer useful". It is very rare for any of the Board's rules to be, in their entirety, "no longer in use or no longer useful." However, the Board does routinely update its rules to account for changes in pharmacy practice, professional standards, technology, Minnesota Statutes, and federal statutes and regulations. The Board adopted extensive, general rule changes in 2007 and 2011. During the 2019 Session, the Legislature passed legislation proposed by the Board that brought state statutes concerning the licensing of drug wholesalers into conformance with federal law. The new statutory provision supersedes some of the Board's drug wholesaling rules, effectively rendering them obsolete.

At this time, none of the rule parts found in Chapter 6800 of Minnesota Rules are obsolete in the sense of being, in their entirety, "no longer in use or no longer useful". Nor are any of the rule parts administered by the Board unnecessary. However, since it has been a decade since the Board last engaged in a comprehensive revision of its rules, and since a number of rules could benefit from adjustments, the Board did direct staff to begin complete review of all of its rules. The Board has also authorized the Executive Director to begin the formal rule-making process. During 2018 and 2019, staff reviewed all of Chapter 6800 and identified many rule parts that could use some revision. Staff is now in the process of drafting proposed rule changes. When those drafts are prepared, the Board will use the state's open appointments process to establish two advisory committees to review and make comments on the drafts. One committee will review rules for pharmacy technicians, the second will review all other rules. The goal of this rule-making effort is administrative simplification. For example, some current rules require licensees to have certain policies and procedures approved by the Board. The revised rules may still require the policies and procedures to be in place but will not require them to be approved by the Board. Note that this rule-making effort was delayed by the significant amount of additional work created by the COVID-19 pandemic and the civil unrest that took place during 2020 and 2021.

As alluded to above, among the rule parts that need to be amended are those that address drug wholesaling. Several years ago, Congress passed the Drug Supply Chain Security Act (DSCSA) as part of a larger bill called

the Drug Quality and Security Act. The DSCSA contains language that at least partially pre-empts state drug wholesaling statutes and rules. It also requires states to regulate drug wholesalers in a manner that is consistent with the DSCSA and the regulations promulgated thereunder.

Most of the Board's rules are not duplicative of other state or federal statutes or regulations. One exception involves those rule parts that list the state's controlled substance schedules. (MN Rules Parts 6800.4210 - 6800.4250). Both Minnesota Statutes and federal regulations also contain schedules of controlled substances. However, MN Stats. 152.02, subds. 7, 8, 8b, 9 and 12 empower the Board to engage in the rule-making process to make certain changes to the state's controlled substance schedules. Subdivision 12 is titled "Coordination of controlled substance regulation with federal law and state statute" and contains instructions to the Board for the coordination of the controlled substance schedules found in the Board's rules with the schedules that are found in federal regulations and Minnesota Statutes. The Board issues a report to the Legislature in December of each year that describes any changes made to the Schedules found in the rules. The report also suggests changes to be made to the statutes to align the schedules found in the statutes with those found in state rules and federal regulations.

Some rule parts contain language that is similar to language found in Chapter 151, but those parts also expand upon the statutory language. For example, Minn. Stats. §151.19 contains language that requires pharmacies to be licensed by the Board. Minnesota Rules 6800.0300 also contains language that requires pharmacies to be licensed. However, the rule provides additional requirements for how an application for a pharmacy license must be submitted. That is because Minn. Stats. §151.19 states that an application must be made in a manner specified by the Board. Consequently, the rule helps to “flesh out” the general requirement found in the statutes. So, the rule complements the section of statutes and is not really duplicative.

In summary, none of the rule parts found in Minnesota Rules Chapter 6800 are obsolete or unnecessary, in their entirety. The parts that address drug wholesaling will need to be amended due to changes in federal law. (Probably by repealing them and addressing the regulation of drug wholesaling entirely in the statutes). The parts that list the state's controlled substance schedules are partially duplicative of sections of Minnesota Statutes and the Code of Federal Regulations. However, MN Stats. §152.02, subds. 7, 8, 8b, 9 and 12 actually empower the Board to engage in rule-making to modify the schedules and to coordinate them with the schedules found in the state's statutes and the federal regulations. The Board is currently engaging in the rule-making process in order to comprehensively revise its rules.