MINNESOTA BOARD OF PHARMACY
Obsolete Rules Report

Report to the Legislature on rules or portions of rules that are obsolete, unnecessary, or duplicative of other state or federal statutes or rules. (In accordance with Minnesota Statutes Section 14.05, Subd. 5)

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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 $200.00. That is the approximate value, in terms of salary and benefits, of the time that Board staff spent compiling and preparing the report.

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Introduction

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 2025. It was reviewed and approved by the Board at its October 22, 2025, meeting.

The Board of Pharmacy regulates both the profession of pharmacy and the distribution of drugs within and into the state of Minnesota by:

- Licensing pharmacists;
- Licensing pharmacies, drug manufacturers, drug wholesale distributors, and third-party logistics firms;
- Registering pharmacy interns and technicians;
- Registering medical gas dispensers and controlled substance researchers;
- Administering 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.
- Administering the Opiate Product Registration Fee Program (OPRFP)
- Administering a portion of the Minnesota Insulin Safety Net Program (ISNP).

The Board has promulgated the rules found in Minnesota Rules Chapter 6800 in order to effectively regulate these diverse and complex professionals and areas of practice as well as the drug supply chain industry. Note that the Board has not promulgated any rules for the Prescription Monitoring Program (PMP), Opioid Registration Fee Program (OPRFP), Insulin Safety Net Program (INSP), or Insulin Manufacturer Registration programs. The Legislature has also empowered the Board to make certain changes to the state's schedules of controlled substances.

Hurdles and Opportunities

The Board strives to protect the health and wellbeing of the public and achieve its mission. Complexities associated with rapid development of automation and technology have contributed to difficulty with clarity and understanding for licensees in the application of the Board's rules. Because of this and other factors, the Board has issued guidance on numerous occasions, and a significant number of variances to rules. Each of those strategies is burdensome for the agency and for its licensees.

The board recognizes potential value in minimized regulatory burden on licensees and registrants while ensuring it meets its mission. Because of the complexities associated with regulating both individual and facility licensees and the scope of the board, the Board's rules are extensive. The current Chapter 6800 constitutes over 120 pages of regulation. The board recognizes the complexity and thoroughness of its rules and the difficulties and challenges in healthcare which contribute to licensees seeking more creative

and flexible solutions.

Many of these rules reference other federal law citations, incorporation of standards or guidance established by agencies of the federal government, or standards established by professional accrediting and standard-setting organizations within the healthcare sector. While this has traditionally been a common and reliable strategy for states and agencies, recent changes in the landscape have created additional considerations which may need to be addressed by the Board and its licensees.

Lessons learned by the Board and licensees regarding public health emergencies have not been incorporated into practice or rules. The ability for sectors of healthcare regulated by the board to be involved in mounting public health and disaster response is an important consideration. There are still opportunities to evaluate where measured use of enforcement discretion and the need for practice flexibilities utilized during the state's proclaimed emergency period may be beneficial to Minnesotans.

This Board is using all these factors and others which are considered hurdles as an opportunity to incorporate solutions to those issues as part of a more comprehensive and strategic effort to consider and address Rules it is empowered to enforce, certain statutory conflicts, and the standards and safety parameters the citizens of Minnesota can rely on.

Assessment

One area of opportunity involves those rule parts that list the state's controlled substance schedules. (MN Rules Parts 6800.4210 - 6800.4250). Both Minnesota Statutes Chapter 152 and federal regulations also contain schedules of controlled substances. It is the Board's intent to remove the state's controlled substance schedules from rule because it is duplicative with MN Stat. 152. It is also inefficient and burdensome for the Board to try and maintain timely changes to the lists in both rule and statute. The Board will continue to consider the removal of such items during its upcoming rulemaking initiatives. The Board also continues to consider other strategies for this section which may be beneficial for those parties which rely on those portions of rule and statute.

Areas of significant interest to the board and its licensees and stakeholders include:

- the use of support personnel,
- the use of technology,
- the use of automation, robotics, and unmanned arial vehicles,
- the application of Artificial Intelligence (AI),
- flexibility in remote work considerations,
- and pharmacy workflow and practice considerations.

The Board continues to assess its rules to determine which if any are obsolete, unnecessary, or duplicative of other state or federal statutes or rules. The Board adopted extensive general rule changes in 2007 and 2011. 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. Staff of the board continue to assess rule status and contemplate necessary changes, particularly since it has been more than a decade since the Board last engaged in a comprehensive revision of its rules, and a number of rules could benefit from contemporary adjustments.

Action

The Board recently authorized the Executive Director to convene advisory task force committees to evaluate several relevant pharmacy practice topics and provide information and policy recommendations to the Board for consideration.

The committees are made up of diverse groups of licensees of the board which represent broad sectors in which the practice of pharmacy occurs. The utilization of an Advisory Committee to the board allows for increased stakeholder involvement in policy discussion, consideration, and evaluation prior to the ultimate drafting of rules and notice and commentary processes.

The use of Advisory Committees in this fashion may lead to additional insight and innovation. Obtaining important stakeholder feedback early in the drafting process for rulemaking is crucial for understanding what stakeholders desire. It also allows for more opportunities for engaging discussion and deliberation of policy perspectives. The use of Advisory committees by the board may also provide new means for a more unique and meaningful stakeholder input process. The opportunity for stakeholders to engage in this process has been well received, and has provided opinions from participants which the board has not encountered in the recent past. Other benefits may include the development of a better final rule product than entering directly into the notice and comment periods, which requires less revision and ultimately, a more efficient rule making process.

Through the compilation of recommendations from the advisory task force committees and board staff subject matter experts, the Board will be able to critically consider and update its rules for a beneficial rules package both for the agency, its licensees and stakeholders, and all affected Minnesotans.