Proposal Summary/ Overview

To be completed by proposal sponsor. (500 Word Count Limit for this page) Please read the entire questionnaire before completing this page.

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Is this proposal regarding:

- New or increased regulation of an existing profession/occupation? If so, complete Questionnaire A.
- Increased scope of practice or decreased regulation of an existing profession? If so, complete this form, Questionnaire B.
- Any other change to regulation or scope of practice? If so, please contact the Committee Administrator to discuss how to proceed.
- 1) State the profession/occupation that is the subject of the proposal.

Pharmacist and the practice of pharmacy.

2) Briefly describe the proposed change.

This proposed change will enhance Minnesotans' access to HIV prevention and treatment services with the goal of reducing the spread of HIV. The proposed legislation will allow pharmacist to prescribe, dispense and administer preexposure prophylactic (PrEP) antiretroviral therapies and post-exposure prophylactic (PEP) antiretroviral therapies.

This initiative supports Minnesota's 2025 goal to "be a state where new HIV diagnoses are rare and all people living with HIV—and those at high risk of HIV infection—will have access to high quality health care and the resources they need to live long healthy lives, free from stigma and discrimination."

3) If the scope of practice of the profession/occupation has previously been changed, when was the most recent change? Describe the change and provide the bill number if available.

In 2020, the Legislature passed, and the Governor signed SF 13, granting pharmacists the authority to consult with patients and provide/prescribe hormonal contraceptives, nicotine replacement medications, and opioid antagonists under protocols developed by the Minnesota Board of Pharmacy.

4) If the proposal has been introduced, provide the bill number and names of House and Senate sponsors. If the proposal has not been introduced, indicate whether legislative sponsors have been identified. If the bill has been proposed in previous sessions, please list previous bill numbers and years of introduction.

Current 2023-2024:

- HF 2466 (Curran; Reyer; Kozlowski; Keeler; Finke; Frazier; Pérez-Vega; Hollins; Hanson, J.; Jordan; Stephenson; Becker-Finn; Smith; Feist; Fischer; Hornstein; Hassan; Lee, K.; Hussein)
- SF 2320 (Dibble; Oumou Verbeten; Boldon)

2021-2022:

- HF 855 (Hollins; Keeler; Feist; Frazier; Reyer; Agbaje; Hassan; Her; Xiong, J.; Lee; Richardson; Noor; Gomez)
- SF 340 (Dibble)

2019-2020:

- HF 4279 (Cantrell)
- SF 3884 (Dibble; Franzen; Marty; Wiklund)

Questionnaire B: Change in scope of practice or reduced regulation of a health-related profession (adapted from Mn Stat 214.002 subd 2 and MDH Scope of Practice Tools)

This questionnaire is intended to help legislative committees decide which proposals for change in scope of practice or reduced regulation of health professions should receive a hearing and advance through the legislative process. It is also intended to alert the public to these proposals and to narrow the issues for hearing.

This form must be completed by the sponsor of the legislative proposal. The completed form will be posted on the committee's public web page. At any time before the bill is heard in committee, opponents may respond in writing with concerns, questions, or opposition to the information stated and these documents will also be posted. The Chair may request that the sponsor respond in writing to any concerns raised before a hearing will be scheduled.

A response is not required for questions that do not pertain to the profession/occupation (indicate "not applicable"). Please be concise. Refer to supporting evidence and provide citation to the source of the information where appropriate.

While it is often impossible to reach complete agreement with all interested parties, sponsors are advised to try to understand and to address the concerns of any opponents before submitting the form.

1) Who does the proposal impact?

a. Define the occupations, practices, or practitioners who are the subject of this proposal.

Pharmacists and the practice of pharmacy.

b. List any associations or other groups representing the occupation seeking regulation and the approximate number of members of each in Minnesota.

Minnesota Pharmacists Association – approximately 1,200 member pharmacists Minnesota Society of Health-System Pharmacists – approximately 350 member pharmacists University of Minnesota College of Pharmacy - 450+ students and 70+ faculty at the University of Minnesota Twin Cities & Duluth campuses

c. Describe the work settings, and conditions for practitioners of the occupation, including any special geographic areas or populations frequently served.

This proposal will expand patient access across the state in the setting of community pharmacies and health system practices across the state.

d. Describe the work duties or functions typically performed by members of this occupational group and whether they are the same or similar to those performed by any other occupational groups.

Pharmacists are trained to be able to assess the appropriateness, efficacy, safety, and adherence for medications. For prevention of HIV, they have the skills to assess individuals at risk and safely prescribe PrEP & PEP and monitor.

While this is similar to other health care providers, such as NPs and MDs, allowing pharmacists to provide this service will increase access to this underutilized yet powerful therapy.

e. Discuss the fiscal impact.

There is minimal additional cost, and potentially a savings to the state to implement the proposed scope changes. Greater access to PrEP and PEP medications will come at minimal expense and achieve savings with the reduced incidence of HIV and reducing long term morbidity and mortality. Additional costs may relate to the investment in assessments and medications as a result of increased access to prevention and treatment.

2) Specialized training, education, or experience ("preparation") required to engage in the occupation

a. What preparation is required to engage in the occupation? How have current practitioners acquired that preparation?

Pharmacists are the foremost medication experts in the healthcare field. Pharmacists are licensed by the Board of Pharmacy through examination after completing a Doctor of Pharmacy (PharmD) degree at an accredited school or college of pharmacy. Pharmacists who were educated before 2000 may have earned a PharmD or a Bachelor of Science in pharmacy, which also leads to licensing by the Board of Pharmacy. Pharmacists are trained in the pharmacists' patient care process, which includes an assessment of indication, effectiveness, safety, and convenience for all medications. This includes appropriate assessment for vaccinations. Pharmacists are educated to recognize adverse effects and allergic reactions and are trained on how to effectively monitor and respond to allergic reactions. Pharmacists and interns are trained to administer vaccinations and perform basic life support through training programs accredited by the Accreditation Council for Pharmacy Education and the American Heart Association. Additional guidelines and training provisions are called out and specified in the legislation that would be followed by pharmacists, pharmacy interns, and pharmacy technicians. Training may occur as continuing education.

b. Would the proposed scope change or reduction in regulation change the way practitioners become prepared? If so, why and how? Include any change in the cost of entry to the occupation. Who would bear the increase or benefit from reduction in cost of entry? Are current practitioners required to provide evidence of preparation or pass an examination? How, if at all, would this change under the proposal?

Pharmacists will continue to undergo the same training to be a licensed pharmacist in Minnesota. If a pharmacist wishes to provide the proposed patient service, the pharmacist will be required to undergo a training program on HIV pre-exposure prophylaxis and post-exposure prophylaxis. The pharmacy or pharmacists will be responsible for the cost of this training program, should a cost be associated with the training. Related to the 2020 SF 13 scope changes, the University of Minnesota College of Pharmacy offered free training for all interested pharmacists.

c. Is there an existing model of this change being implemented in another state? Please list state,

originating bill and year of passage?

At least eleven states have enacted laws allowing pharmacists to prescribe, dispense and administer preexposure prophylactic antiretroviral therapies and post-exposure prophylactic antiretroviral therapies. They are:

Arkansas, <u>HB 1007</u>, enacted 2023 California, <u>SB 159</u>, enacted 2019 Colorado, <u>HB 20-1061</u>, enacted 2020 Illinois, <u>HB 4430</u>, enacted 2022 Maine, <u>LD 1115</u>, enacted 2021 New Mexico, <u>SB 92</u>, enacted 2023 Nevada, <u>SB 325</u>, enacted 2021 Oregon, <u>HB 2958</u>, enacted 2021 Missouri, <u>HB 476</u>, enacted 2021 Utah, <u>HB 0178</u>, enacted 2021 Virgina, <u>HB 2079</u>, enacted 2021

Additional information is available at <u>https://naspa.us/blog/resource/pharmacist-prescribing-hiv-prep-and-pep/</u>.

3) <u>Supervision of practitioners</u>

a. How are practitioners of the occupation currently supervised, including any supervision within a regulated institution or by a regulated health professional? How would the proposal change the provision of supervision?

The Minnesota Board of Pharmacy regulates the pharmacist profession and the business of pharmacy. This proposal does not require any changes in supervision. Pharmacists do not require direct supervision by another health professional in typical activity and will not have additional supervision to provide these services to patients. Under this proposal, the Board of Pharmacy will develop a protocol for pharmacists.

b. If regulatory entity currently has authority over the occupation, what is the scope of authority of the entity? (For example, does it have authority to develop rules, determine standards for education and training, assess practitioners' competence levels?) How does the proposal change the duties or scope of authority of the regulatory entity? Has the proposal been discussed with the current regulatory authority? If so, please list participants and date.

The Minnesota Board of Pharmacy is the regulatory entity for pharmacists. The Board develops rules, sets baseline requirements for becoming a licensed pharmacist in the state, ensures pharmacists meet continuing education requirements to maintain their license, and ensures compliance with the rules and laws governing pharmacy practice in Minnesota.

c. Do provisions exist to ensure that practitioners maintain competency? Under the proposal, how would competency be ensured?

The proposed changes require pharmacists to complete initial training involving the prescribing of HIV pre-exposure and post-exposure prophylaxis. Pharmacists will continue to meet current requirements for continuing education.

4) Level of regulation (See Mn Stat 214.001, subd. 2, declaring that "no regulations shall be imposed

upon any occupation unless required for the safety and wellbeing of the citizens of the state." The harm must be "recognizable, and not remote." Ibid.)

a. Describe how the safety and wellbeing of Minnesotans can be protected under the expanded scope or reduction in regulation.

The expanded scope will increase the safety of Minnesotans by reducing the spread of HIV. It will also prevent indefinite unsafe use of the medications by ensuring that they are indicated and properly monitored.

b. Can existing civil or criminal laws or procedures be used to prevent or remedy any harm to the public?

Yes, see Board of Pharmacy authorizing and penalties provisions in <u>MN Chapter 151</u>.

5) Implications for Health Care Access, Cost, Quality, and Transformation

a. Describe how the proposal will affect the availability, accessibility, cost, delivery, and quality of health care, including the impact on unmet health care needs and underserved populations. How does the proposal contribute to meeting these needs?

This proposal will increase the accessibility of medications to prevent HIV transmission. Pharmacists are some of the most accessible health professionals in Minnesota and are located throughout the state. Often pharmacists are more accessible than primary care providers. Increasing access to pre-exposure and post-exposure medications is an effective and safe practice to reduce disease. This proposal will enable Minnesotans to access life-saving medications in a timely fashion.

b. Describe the expected impact of the proposal on the supply of practitioners and on the cost of services or goods provided by the occupation. If possible, include the geographic availability of proposed providers/services. Cite any sources used.

As previously mentioned, the pharmacist is one of the most accessible and trained health professionals able to provide this service for patients. Authorizing pharmacists in Minnesota to prescribe, dispense and administer these medications will have no impact on the number of pharmacists in Minnesota. It will also not remove the authority of any other health provider professional who currently serves patients in this area.

c. Does the proposal change how and by whom the services are compensated? What costs and what savings would accrue to patients, insurers, providers, and employers?

Not applicable.

d. Describe any impact of the proposal on an evolving health care delivery and payment system (eg collaborative practice, innovations in technology, ensuring cultural competency, value-based payments)?

Not applicable.

e. What is the expected regulatory cost or savings to state government? How are these amounts accounted for under the proposal? Is there an up-to-date fiscal note for the proposal?

It is anticipated that there is either no cost or potential savings for the state to implement this proposed change. Greater access to HIV medications stands to reduce the need for treatments, hospitalization and other health associated disease-related costs. In addition, we are not aware of additional costs for the Minnesota Board of Pharmacy.

6) Evaluation/Reports

Describe any plans to evaluate and report on the impact of the proposal if it becomes law, including focus and timeline. List the evaluating agency and frequency of reviews.

The Minnesota Department of Health currently reports <u>HIV/AIDS statistics</u> including an annual summary of HIV/Aids in Minnesota.

7) Support for and opposition to the proposal

- a. What organizations are sponsoring the proposal? How many members do these organizations represent in Minnesota?
 - The Aliveness Project Rainbow Health Clare Housing Minnesota Pharmacists Association Minnesota Society of Health-System Pharmacists Minnesota Pharmacy Alliance Minnesota Academy of Physician Assistants National Community Pharmacists Association Minnesota Grocers Association Minnesota Retailers Association National Association of Chain Drug Stores

Collectively these groups represent thousands of members across Minnesota.

b. List organizations, including professional, regulatory boards, consumer advocacy groups, and others, who support the proposal.

Minnesota Pharmacists Association Minnesota Society of Health-System Pharmacists University of Minnesota College of Pharmacy

c. List any organizations, including professional, regulatory boards, consumer advocacy groups, and others, who have indicated concerns/opposition to the proposal or who are likely to have concerns/opposition. Explain the concerns/opposition of each, as the sponsor understands it.

We are unaware of any professional organizations actively opposing this legislation.

d. What actions has the sponsor taken to minimize or resolve disagreement with those opposing or likely to oppose the proposal?

Not applicable.