

Questionnaire B – Scope of Practice

Proposal Summary/ Overview

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This proposal is regarding:

- *New or increased regulation of an existing profession/occupation? If so, complete this form, Questionnaire A.*
- *Increased scope of practice or decreased regulation of an existing profession? If so, complete 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

2) *Briefly describe the proposed change.*

Representative is to introduce the companion bill to Senator Dibble's recently introduced: [SF3154](#)

This proposal will increase patient and at-risk population's access in Minnesota to prescription medications that reduce the spread of HIV. The legislation would allow pharmacist to prescribe, dispense and administer preexposure prophylactic antiretroviral therapies and post-exposure prophylactic antiretroviral therapies. This change in law would provide pharmacists in Minnesota with the ability to directly provide PrEP & PEP medications to a patient who is at risk of acquiring HIV or has possibly been exposed to HIV. These miracle medications can dramatically reduce the risk of exposure to HIV and the spread of HIV. In addition, the legislation enhances greater patient access to HIV medications by ensuring HIV medications are a part of every health benefit formulary and that these medications, especially any PEP-post exposure medication, are immediately accessible to patients in Minnesota.

3) *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.*

HF855 a similar bill, was introduced by Representatives Hollins, Keeler, Feist, Frazier, Reyer, Agbaje, Hassan, Her, Xiong, J., Lee, Richardson, Noor, Gomez in 2021. However, the companion to SF3154 will be introduced this year and is the bill language we are asking the Committee/Legislature to consider during the 2022 Minnesota Legislative Session.

Questionnaire B: Change in scope of practice or reduced regulation of a health-

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related profession (adapted from Mn Stat 214.002 subd 2 and MDH Scope of Practice Tools)

This questionnaire is intended to assist the House Health Finance and Policy Committee in deciding which legislative 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?

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

Pharmacists and the practice of pharmacy as well as health benefit providers are directly affected by the proposed legislation.

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

Minnesota Pharmacists Association: just over half of the approximately 8,925 licensed pharmacists in MN.

Minnesota Society of Health-System Pharmacists: approximately 1,250+ of the total licensed pharmacists in MN.

University of Minnesota College of Pharmacy: 300+ students and faculty at the U of M – MPLS & Duluth campuses.

Pharmacists are a trusted healthcare provider that is accessible to most Minnesotans within 5 miles or 5-10 minutes of their home. A majority of patients need no scheduled appointment to have their health needs met at a pharmacy in Minnesota. On average, patients visit their pharmacy about 18 to 25 times per year. There are approximately 21,535 Minnesotans who are comprised of pharmacists, pharmacist technicians and front-of-house pharmacy workers.

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

The pharmacists most impacted by the proposed legislation will be those who work at brick-and-mortar dispensing pharmacies such as chain pharmacies, independent pharmacies, discharge pharmacies, and other community pharmacies. The proposed legislation will also ensure that other pharmacists, such as those located in clinics, can prescribe and administer these medications.

The proposed legislation will also ensure that other pharmacists, such as those located in clinics including

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HIV clinics, will be able to improve access to medications that reduce the spread of HIV.

4. *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.*

Similar to other healthcare providers, pharmacists are able to prescribe and administer certain defined medications and monitor for potential side effects, counsel on medications, administer HIV tests, and recommend over-the-counter medications. Outside of dispensing, prescribing and administering medications, pharmacists are able to recommend to initiate, modify, or discontinue medications; and order and interpret laboratory tests for monitoring purposes in Minnesota. Minnesota pharmacists also work with MN Board of Pharmacy protocols to currently prescribe, dispense and administer to patients Naloxone (Narcan), smoking replacement medication and hormonal contraceptives. This proposal would add prescribing of HIV PrEP & PEP-post exposure FDA approved medications to a pharmacist's authority under the Pharmacy practices act, MN statute Chapter [Chapter 151](#).

5. *Discuss the fiscal impact.*

There is either no cost or a potential savings to the state to implement the proposed scope changes. Making sure those at risk to acquiring HIV will greatly reduce that risk and their chances of getting sick. There are multiple ways this should help save on overall health costs associated with the treatment of a patient/Minnesotan with HIV. Some payers may identify costs associated with the prohibition of a prior authorization requirement or patient/provider step therapy provisions included in the bill language. However, greater access to HIV medications and more immediate access to these medications will reduce the need for treatments, hospitalization and other health associated costs with the disease.

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 licensed in Minnesota are required to have graduated an accredited college with a Bachelors of Science in Pharmacy (phased out in the year 2000) or Doctor of Pharmacy, obtain at least 1600 hours of pharmacy internship experience, and pass the National Pharmacy Licensing Examination. Pharmacists are the medication experts as a result of extensive training in the administration, metabolism, dosing, indications, adverse effects, and interactions of medications. As a result, pharmacists are well-equipped to educate patients on side effects, recognize potential interactions, and perform necessary monitoring of new medications.

Pharmacists would also be trained specifically in providing PrEP & PEP medications. Under the bill, a pharmacist would also work within a protocol written by the Minnesota Board of Pharmacy, much like the protocols written for the other medications Minnesota pharmacists are authorized to prescribe.

- 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 basic training to be a licensed pharmacist in Minnesota (see above). If a pharmacist wishes to provide the proposed patient service, the pharmacist would be required to undergo a Board of Pharmacy sponsored training program on a state-wide protocol for

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prescribing, monitoring, and administration of HIV pre-exposure prophylaxis and post-exposure prophylaxis. The protocol developed by the Board will be based on CDC guidelines regarding safe and effective use of pre-exposure and post-exposure prophylaxis. The pharmacists or their employers would be responsible for the cost of this training program, should a cost be associated with the training.

c. Is there an existing model of this change being implemented in another state? Please list state, originating bill and year of passage?

The following states have enacted laws that allow pharmacist to prescribe, dispense and administer preexposure prophylactic antiretroviral therapies and post-exposure prophylactic antiretroviral therapies.

California | SB 159 | enacted 2019

Colorado | HB 20-1061 | enacted 2020

Oregon | HB 2958 | enacted 2021

Missouri | HB 476 | enacted 2021

Utah | HB 0178 | enacted 2021

Nevada | SB325 | enacted 2021

Maine | LD 1115 | enacted 2021

3) Supervision of practitioners

1. 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 in Minnesota. The Minnesota Commerce Department and the Department of Health have regulatory authority over health insurers, health benefit payors and pharmacy benefit managers (PBMs). The Minnesota Department of Human Services through their Medical Assistance (Medicaid) program and other health benefits they provide could be impacted by the proposed changes.

Pharmacists do not require direct supervision by another health professional in typical activity and would not need additional supervision to provide these medications to patients. This change would not affect the current supervision requirements. Pharmacists who currently operate under a collaborative practice agreement would continue to do work under the supervision of another health provider.

2. If a 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. The Re. Hollins legislation has been discussed with and the MBOP is aware of this proposal (Cody Wiberg, ED of the MBOP).

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

The proposed changes will require pharmacists to complete a training program and continuing education

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as stipulated by the Board of Pharmacy. This training program will ensure that pharmacists who participate in this expanded scope will be aware of the protocol developed by the Board. Continuing education will be accredited by an approved accrediting body such as the Accreditation Council for Pharmacy 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.)

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

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

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

Yes, see MBOP's authorizing and penalties provisions in MN Chapter 151.

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 that prevent the spread of HIV. Pharmacists are the most accessible health professional in Minnesota and are located throughout the state. Pharmacists usually do not require appointments to have patient services provided. Often pharmacists are more accessible than primary care providers, who can have wait times of months and may be less convenient to see. The COVID-19 pandemic has only increased the barriers for patients who would benefit from PrEP/PEP. A recent study estimated that the pandemic resulted in a 22% reduction in PrEP prescriptions from 3/2020-3/2021, and a 25% reduction in new prescriptions for PrEP in the same timeframe.² Increasing access to pre-exposure and post-exposure medications is crucial because timing is crucial in preventing the spread of HIV. This proposal will enable Minnesotans to access life-saving medications in a timely fashion, while also ensuring that a patient's health insurance will cover the medications.

- 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.*

This proposal would have no impact on the supply of practitioners currently working with at-risk and exposed HIV patients. The proposal, as mentioned before, would only increase access to patients across the state.

- 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?*

It is assumed that pharmacists would be reimbursed for the ordering, administration, and interpretation of labs and medications associated with working with a patient taking HIV PrEP & PEP medications at a rate

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equivalent to physician, physician assistant, or advanced practice registered nurse reimbursements for similar services. These would not be duplicative services. Costs to patients are expected to be similar to their current costs for the same services provided by other health care providers. Costs to insurers may initially increase in response to an increased volume of patients requesting such services and not being able to require a prior authorization or have a patient go through step therapy to access these medications, however, over all savings should be realized through cost saving from preventing HIV/AIDS in Minnesota.

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

N/A

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?*

The costs to state government should be similar to commercial insurers and overall savings to health costs in Minnesota should decline.

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 (MDH) reports annually on the number of people living with HIV or AIDS in MN, in addition to detailing new cases of HIV and county breakdown of these cases. As of 2020, there are over 13,000 people living with HIV/AIDS in the state, with over 200 new cases of HIV a year. As of November 2021, MDH had reported 273 new cases of HIV in the state. Current PrEP therapies have been shown to reduce acquisition of HIV by 62-92% compared to placebo, with higher rates of prevention associated with higher rates of adherence ([CDC Guidelines 2021](#)). While there are currently no planned studies for the proposed legislation, we would be happy to collaborate with MDH or another agency to report out on the impacts of the legislation after implementation occurs.

There are no reports from other states that have passed similar legislation since it has only been one year since the first state, California, started implementing changes.

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 Minnesota Pharmacists Association
The Minnesota Society of Health-System Pharmacists
The University of Minnesota College of Pharmacy
The Minnesota Aids Project
Rainbow Health
Rural Aids Action Network
MN Retailer's Association

b. *List organizations, including professional, regulatory boards, consumer advocacy groups, and*

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others, who support the proposal.

The Minnesota Pharmacists Association
The Minnesota Society of Health-System Pharmacists
The University of Minnesota College of Pharmacy
The Minnesota Aids Project
Rainbow Health
Rural Aids Action Network
MN Retailer's Association

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 do not know of any organizations who actively oppose this legislation. The MMA, MNA, APRNs, NNPs, HIV physician community have all said they either do not oppose or are not in opposition to the changes in MN law that this legislation would enact.

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