

## Questionnaire B – Scope of Practice

### Proposal Summary/ Overview

#### **To be completed by proposal sponsor. (500 Word Count Limit for this page)**

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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, pharmacy intern, pharmacy technician

2) *Briefly describe the proposed change.*

Minnesota pharmacists and pharmacy technicians have provided at least 37% ([Doses Administered, by Provider](#)) of the millions of COVID-19 vaccinations, millions of flu vaccines and other approved FDA vaccines through injection to patients across the state. Minnesota pharmacists provided hundreds of mental health and substance abuse medication injections a week to patients across Minnesota in 2021. In particular, rural pharmacies are working with providers to help patients with their mental health injectable medication needs.

In 2020 the federal government fortunately recognized the vastness of the problem the pandemic would bring and the logistical challenges that would accompany inoculating an entire population while continuing to provide for the treatment and care for patients in ICUs, clinics, long term care and in other settings as well as ongoing general population health needs. They also were seeing consequences such as immunizations falling at an alarming rate. In order to inoculate/vaccinate the vast majority of Americans, they would need all trained health professionals in the fight. Fortunately, there was a highly qualified resource, pharmacists, interns and pharmacy techs, that could make an enormous impact, right away, safely and trusted in all geographic locations in the country.

Minnesota is a great example of urban, rural and suburban pharmacy stepping into the breach and taking care of Minnesotans. MN pharmacy has administered over 3.4 million COVID-19 vaccines and many of those were administered to children 5 years of age and older (<https://mn.gov/covid19/vaccine/data/index.jsp>) This does not include doses that have been set aside for the CDC's [Pharmacy Partnership Program for vaccination in long-term care settings](#) .

The federal PREP Act has enabled pharmacists, pharmacy technicians, and pharmacy interns to administer indicated immunizations to patients 3 years of age and older. It has also ensured that

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patients are able to receive COVID-19 and other non-lab (FDA approved-CLIA waived) tests in a timely fashion. Currently under Minnesota law, pharmacist are allowed to administer COVID-19 and Flu vaccinations to all patients 6 years and older and inoculate Minnesotans 13 years and older for all other FDA approved vaccines. In order for the state not to go backwards, this bill would make permanent in MN state law pharmacists and pharmacy technicians ability to inoculate Minnesotans 3 years of age and older. In addition, pharmacists would be able to order and pharmacy technicians would be allowed to administer, and interpret any CLIA-waived test (e.g. A1c, influenza, etc.) under the supervision of a pharmacist.

The proposed modifications to the MN pharmacy practice act ([Chapter 151](#)) would provide authority for pharmacists, pharmacist technicians and interns in Minnesota to offer vaccinations and point-of-care testing to individuals in Minnesota that they are currently providing health services and care for. The proposed legislation would put in place, codify their authority to provide these same services for patients after the pandemic is over and the federal PREP act declarations are no longer in effect.

- 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.*

-This proposed pharmacy immunization & point-of-care testing legislation has not been introduced.

-Representative Morrison, Bahner, Huot, Baker, Hamilton, Davids, and other House members have expressed interest and support for this legislation. Senators Duckworth, Klein, Benson and Abeler have also expressed their support for the changes to the pharmacy practice act.

-This bill has not been proposed in the past.

### **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 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.*

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### 1) Who does the proposal impact?

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

Pharmacists, pharmacy interns, and pharmacy technicians, as well as the practice of pharmacy, are directly affected by the proposed legislation.

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: 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.

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

The pharmacists and pharmacy technicians 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 continue to offer these services per their collaborative practice agreements.

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.*

Similar to other healthcare providers, pharmacists are able to administer vaccinations and monitor for potential side effects, counsel on medications, administer CLIA waived tests, and recommend over-the-counter medications. Pharmacy interns and technicians could be delegated these responsibilities under the proposal. Both are currently authorized and have been performing these patient tasks under the federal PREP Act as well as other current state authorities.

Unique work duties for pharmacists include dispensing medications through point-of-sale monetary transactions and identifying potential drug-drug interactions. Pharmacy interns and technicians in Minnesota have many responsibilities, including filling prescriptions, stocking medications, ordering medications, filing prescriptions, vaccinating adults and children when trained and much more. Pharmacists overseeing and responsible for any actions associated with their or the pharmacy tech or interns administering of child vaccinations would comply with all child immunization requirements in Minnesota, including being obligated to inform a child's adult caregiver/parent at the immunization visit of the importance of receiving their "well-child" visit with a pediatrician and reporting

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immunizations of children to the Minnesota Department of Health’s Minnesota Immunization Information Connection (MIIC) (<https://www.health.state.mn.us/people/immunize/miic/index.html>).

*e. Discuss the fiscal impact.*

There is potential savings to both the patient and the healthcare system as a whole. Patients can have access to vaccinations and CLIA-waived tests without the time and costs often required for clinic visits as well as the fee for the visit and/or the 2-6% mark up of medications acquired at the provider’s office, hospital or clinic. Potential savings to the healthcare system present due to the potential for improved access to these preventative measures, potentially increasing vaccination rates and decreasing future primary care visits or hospitalizations. Greater access to vaccinations should reduce the need for disease treatments, hospitalization and other health associated costs that could occur from infection of many preventable diseases. Increased access to CLIA-waived tests can reduce time to therapy initiation and improve outcomes for therapies that are time-dependent. They also can give a patient access to convenient, relatively fast and accredited testing that can often give patients piece of mind or get them to a provider for further therapies and care.

### **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. Except for pharmacists who graduated prior to 1990, all licensed pharmacists in Minnesota have an undergraduate degree and 4 year post-doctorate education with 2 years of residency. As pharmacists do for other medications, assessment of vaccine indication, effectiveness, safety, and convenience would be assessed before any administration allowed under the proposed legislation. Pharmacists are already educated on the recognition of 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 and organized into a protocol.

The bill language will require pharmacists, pharmacy interns and pharmacy technicians to have specific training:

*“...the pharmacist, pharmacy technician or intern has successfully completed a program approved by the Accreditation Council for Pharmacy Education specifically for the administration of immunizations or a program approved by the board;*

*-the pharmacist, pharmacy technician or intern, utilizes the Minnesota Immunization Information Connection to assess the immunization status of individuals prior to the administration of vaccines, except when administering influenza and COVID-19 vaccines to individuals age three and older;*

*-the pharmacist reports the administration of the immunization to the Minnesota Immunization Information Connection;*

*-The pharmacist, pharmacy technician or intern must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider.*

*; and*

*-- In addition, a pharmacy technician may administer vaccinations under this section while being supervised by a licensed pharmacist if:*

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*-the pharmacist is readily and immediately available to the immunizing pharmacy technicians;  
-the pharmacy technician or pharmacy intern has a current certificate in basic cardiopulmonary resuscitation;  
-the pharmacy technician has completed a minimum of two hours of ACPE-approved, immunization-related - continuing pharmacy education as part of their 2 year CE schedule;“*

- 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 (pharmacists in Minnesota have earned a Bachelor’s of Science in Pharmacy or earn a Doctorate of Pharmacy from an accredited school of pharmacy and pass the National Pharmacy Licensing Examination). If a pharmacist or pharmacy technician wishes to provide the proposed patient service, the pharmacist and pharmacy technicians would be required to undergo a Board of Pharmacy sponsored training program that educates about protocols for administering and monitoring vaccinations. They also undergo specific CLIA waived test administration and patient counseling education during their 4 year degree and 2 year residency. The pharmacists or their employers would be responsible for the cost of this training program, should a cost be associated with the training. There are also student loan forgiveness programs for debt reduction associated with the PharmD education.

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

For a deeper understanding of state pharmacy immunization and vaccination laws and policies please see the National Alliance of State Pharmacy Associations (NASPA’s website:

<https://naspaspa.us/resource/pharmacist-authority-to-immunize/>

Every state allows pharmacists and supervised pharmacy technicians to administer immunizations in some way and currently under the federal PREP Act declarations are allowed to provide all services included in this legislation, but laws vary widely in the details surrounding that authorization. The federal government has current guidelines from U.S. HHS that allows pharmacy technicians and interns to give COVID-19 and other vaccinations and tests under the supervision of a pharmacist when training has been completed. This proposal would allow the continuation of these services in Minnesota. (See the above training requirements.)

### **3) Supervision of practitioners**

- 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 of pharmacy and licenses pharmacists in Minnesota. Pharmacy technicians are also regulated by the MBOP. The MN Department of Health runs the Child Immunizations program in Minnesota as well as the MIIC reporting system that pharmacists utilize to comply with State requirements. 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 immunizations. Pharmacy technicians would be

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supervised by a licensed pharmacist. There is currently a 4 to 1 ratio of pharmacy technicians to a supervising pharmacist allowed under Minnesota law. This change would not affect the current supervision requirements or ratio. Pharmacists who currently operate under a collaborative practice agreement would continue to do work under the supervision of another health provider as well as any pharmacy technicians under the pharmacist's supervision.

- 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 that oversees and regulates safety. The MBOP regulates all practice and public safety aspects of the pharmacy practice for pharmacists, pharmacy technicians, and pharmacy interns given to it under MN statute Chapter [Chapter 151](#). The Board develops rules, sets baseline training and educational requirements for becoming licensed in the state, ensures licensees 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 and pharmacy technicians to complete training through a robust training program. Pharmacists are required to take continuous training education on a 2 year schedule. (See the previous listed training and certification requirements.)

Here is an example of one of the immunization/vaccine administration courses offered at the University of Minnesota's College of Pharmacy:

"Immunization Delivery for Pharmacists consists of 20 hours including online self-study and participant live demonstration. Participants will be required to pass (70% or better) two quizzes: one mid-way through the course and a second quiz at the end of the online portion of the course. Participants are required to pass both quizzes prior to attending the live portion of this activity. Information about live demonstration sessions will be communicated in the course Canvas site. "

**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 proposed changes will increase the safety of Minnesotans by decreasing the spread of preventable diseases. It will also prevent indefinite unsafe use of the vaccinations by ensuring that they're indicated and properly monitored. The proposal may also increase overall vaccine adoption by Minnesota patients because they can access their immunizations through a trusted health professional that is convenient to access. Patients will also benefit from reduced flu, COVID-19 and other diseases. They may be able to access treatment more quickly for ailments such as strep throat and the flu if they receive the relevant testing at the pharmacy. Pharmacy plays a vital role with medication education, management, administration and counseling. They are the most accessible trained health professional that Minnesotans will seek services and information about their health from this year.

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- b. *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 vaccinations and CLIA-waived tests by allowing patients to receive them at their local pharmacy, which then increases availability and decreases cost. Pharmacists are the most accessible health professionals in Minnesota and are located throughout the state, often within 5 minutes or five miles of a patient. 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. A pharmacy visit does not charge a patient for an office visit or markup medication ingredient costs. Underserved and/or rural populations often present with barriers to clinic access, which is currently where patients would need to go to receive these vaccination and testing services currently not allowed for by current state statute. This proposal will enable Minnesotans to continue to access preventative care, inoculations and tests in a timely fashion, while also ensuring that a patient's health insurance will cover the vaccinations.

- 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 the most accessible and trained health professional able to provide this service for patients. Authorizing pharmacists, interns, and technicians in Minnesota would have no impact on the number of pharmacists in Minnesota. It will also not impact any other health provider profession, other than to alleviate overburdened hospitals, clinics and provider offices, that currently has the ability to prescribe and work with patients using these medications.

- 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?*

The proposed legislation/change does not require or mention anything about reimbursement. There is another bill being introduced that will require that "pharmacy services" be reimbursed by health carriers in Minnesota. The bill would require pharmacy be reimbursed like any other provider performing the administration or testing services.

- 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. [See earlier mentions of collaborative practice agreements and protocols.]

- 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?*

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There is no additional regulatory cost from implementing this legislation. There is potential savings to both the patient and the healthcare system as a whole. There is no fiscal note at this time for this proposed legislation.

### 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.*

There are no plans to evaluate and report on the impact of the proposal if it becomes law at this time.

### 7) Support for and opposition to the proposal

*a. What organizations are sponsoring the proposal? How many members do these organizations represent in Minnesota?*

Please see the above pharmacy supporting organizations and member information in our answer to question 1-b above. In addition to those organizations, the MN Retailers and MN Grocers support this legislation as well as other patient member organizations.

*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  
The 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 do not know of any organizations who actively oppose 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.