

## 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.*

Pharmacists and the practice of pharmacy

2) *Briefly describe the proposed change.*

Representative Morrison's: [HF2768](#)

Minnesota pharmacists and pharmacy technicians have provided at least 37% ([Doses Administered, by Provider](#)) of the millions of COVID-19 injectable (subcutaneous and intramuscular) 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. This legislation would authorize pharmacists to work with provider/patient prescribed FDA injectable medications through IM or SubCu. And to help patients with external health monitoring device placement and counsel such as a Continuous Glucose Monitor (CGM).

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 who are specifically trained in SubCu and IM medications administration that could make an enormous impact, right away, safely and trusted in all geographic locations in the country.

Patients also often need help with external health monitoring devices such as Continuous Glucose Monitors that are placed on the skin and do need patient assistance and counsel when placing and working with these devices. The proposed legislation will expand the definition of the practice of

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pharmacy. This will be done in two ways: by allowing pharmacists to administer any prescribed intramuscular or subcutaneous medication, rather than merely those to treat alcohol or opioid dependence; and by adding the placement of drug monitoring devices.

Additionally, some needle-phobic patients may have their quality of life improved if someone else, like their friendly neighborhood pharmacist, can inject their medication for them. Examples of injectable medications include COVID-19 vaccine and boosters, long-acting antipsychotics for patients with mental health conditions, Prolia for osteoporosis, Makena for women at risk of delivering pre-term infants, vaccinations, and medications used in oncology, psoriasis, rheumatoid arthritis, multiple sclerosis, hormone deficiency, HIV, and fertility among others.

Allowing pharmacists to administer medications would allow patients to avoid numerous challenges such as scheduling conflicts with prescribers, difficulty with medication adherence, issues with medication access, and a lack of knowledge of the medication or administration. It would also help with the health care system's workload and is where patients are now used to getting these health/medication administration services. 93% of Americans live within five miles of a community pharmacy, pharmacists are one of the most accessible healthcare professionals and can support closing this gap. 33 states currently allow pharmacists to provide medication administration and injection services, including all of Minnesota border states and Canada – Wisconsin, Iowa, South Dakota and North Dakota. (See the attached National Alliance of Pharmacists Associations (NASPA) <https://naspa.us/wp-content/uploads/2017/07/Pharmacists-Authority-to-Administer-Medications.pdf>)

The proposed amendment of this statute would enable more comprehensive medication administration services for patient's provider prescribed medication administration. These patient-centered services would improve patient-access to medications, increase patient-adherence, reduce negative stigma, decrease health care costs and enhance patient-pharmacist relationships.

*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.*

[HF2768](#) - Representative Morrison

[SF2678](#) - Senator Duckworth

-A version of broad pharmacists' authority for prescribed injectable medication administration through SubCu and IM was introduced in 2019 by Rep. Mann, Cantrell, Morrison, Tabke, Acomb and Bahner ([HF3208](#)).

-A limited version of pharmacists SubCu/IM administration authority was passed in 2019 in the Minnesota Legislature's Opioid Stewardship Legislation ([HF0400](#)) (Rep. Olson & Baker's legislation as well as Senator Rosen's bill.) It provided that pharmacists could administer mental health, psychiatric and substance abuse injectable medications through SubCu/IM administration. This language was agreed upon with all stakeholders, including the Minnesota Medical Association, MN-APRN's & NNPs National Alliance for Mental Illness (NAMI) and the Minnesota Psychiatric Society. Legislators recognized that pharmacists are accessible and important partners in addressing substance abuse disorder. This language change allowed Minnesota to join over 44 states that allow pharmacists to administer long-acting injectable antipsychotic medications.<sup>1</sup>

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### 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.*

#### 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*

8,925+ actively licensed pharmacists in Minnesota  
1242 of intern pharmacists in Minnesota  
2076 total licensed pharmacies in Minnesota

*c. 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 continue to offer these services per their collaborative practice agreements.

According to the Center for Disease Control and Prevention (CDC), 25% of influenza immunizations are administered by pharmacists in the community setting, reinforcing that patients are comfortable visiting the community pharmacy and can easily access their pharmacists' expertise and utilize available services.<sup>3</sup> Pharmacists were charged to fill a public health gap in the "immunization neighborhood" and contributed to improved outcomes.

Similarly, to the benefits reaped from pharmacy services in the "immunization neighborhood," Pharmacists are willing and have the expertise to be part of the solution for many other medical conditions, both chronic and acute. This solution includes comprehensive pharmacist medication

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administration services. Patients are often limited to certain medication therapy plans based on the route of administration or dosage form (i.e. oral, nasal, subcutaneous, intramuscular). This barrier may arise due to patients' initial fear of injectables (i.e. needle-phobia), limited access to another health care professional for administration (i.e. residence distance from clinic), physiologic limitations (i.e. arthritis, psoriasis, dexterity limitations) or other challenges. Pharmacist medication administration could allow for enhanced therapy plans with the ability to administer these alternative dosage forms. Particular examples include antipsychotic medications, diabetes medications, antirheumatic medication, hematopoietic medications and many more.

- 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 through SubCu and IM and monitor for potential side effects, counsel on medications, administer COVID-19 tests, and recommend over-the-counter medications. These prescribed injections are currently administered by physicians as well as nurses and their assistants that have been trained to administer injections.

- e. Discuss the fiscal impact.*

There are no costs to the state as this change would result in pharmacist reimbursement for medication administration services that is equivalent to administration fees charged by other healthcare providers. There is also no "office visit" charge and no potential medication markup. It may improve access and adherence to medications or devices, which could reduce the need for hospitalizations or other costs associated with poorly controlled 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 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 long acting injectables, other vaccinations and perform basic life support through training programs accredited by the Accreditation Council for Pharmacy Education and the American Heart Association.

Many pharmacists in Minnesota are currently certified to administer intramuscular or subcutaneous medications through the American Pharmacists Association or equivalent program. Any pharmacist administering prescribed injectable medications for patients under this legislation would need to

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successfully complete a program approved by the Accreditation Council for Pharmacy Education. Pharmacists are trained in pharmacy school in administering intramuscular or subcutaneous injections during their 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> years and continue to learn through experience during their 5<sup>th</sup> and 6<sup>th</sup> year of education during their residency. Pharmacists are able to place monitoring devices through product and representative demonstration and instruction. Pharmacists in turn educate patients on placement.

- 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). Additional training is not required for the scope expansion.

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

Fairly recent adoption of similar authorities for pharmacists licensed in other states:

-North Carolina | HB 96 | enacted 2021

-Kentucky | Board of Pharmacy 315.010 (22) | updated 2017

-33 states currently allow pharmacists to provide medication administration and injection services for their patients at a pharmacy, including all of Minnesota border states and Canada – Wisconsin, Iowa, South Dakota and North Dakota. (See the attached National Alliance of Pharmacists Associations (NASPA) <https://naspa.us/wp-content/uploads/2017/07/Pharmacists-Authority-to-Administer-Medications.pdf>)

### **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 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.

Pharmacists currently administer SubCu and IM injectables as defined by Minnesota Pharmacy Statute 151.01 Subd. 27. Practice of Pharmacy and have policies and procedures in place that align with the Advisory Committee on Immunization Practices (ACIP) national recommendations for patient assessment, administration and monitoring, including contraindications and special populations. Pharmacies have also developed processes for reacting to medication allergy or adverse reaction. Pharmacists would provide similar assessment, administration and monitoring as outlined by national practice guidelines, drug references and US Food and Drug Administration (FDA) package labeling for other administered medications. Pharmacies already have access to these references as outlined by Minnesota Pharmacy administrative rules 6800.1050: Required Reference Books and Equipment.

In addition to drug reference resources and knowledge, pharmacists have a standard patient care

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practice model endorsed by the Joint Commission of Pharmacy Practitioners (JCPP) that optimizes medication efficacy and patient safety.<sup>6</sup> This process includes collecting information about/from the patient, assessing medication therapy, optimizing the medication plan, implementation, and a continuous follow-up of monitoring and evaluating the patient and outcomes.



- b. *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.

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

There is currently no requirement or proposal to maintain competency in medication administration or device placement. However, pharmacists are required to complete continuing education on a 2-year schedule that requires several hours of updated training and curriculum. In addition, any other required certifications must be maintained on their individual schedules.

**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.*

Three state agencies primarily regulate and/or affect the practice of pharmacy:

- 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.
- 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. MDH also helps

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regulate and ensure pharmacy benefits and medical benefits network adequacy.

Safety is regulated also by federal agencies such as the FDA, HHS and the consumer product safety board. For SubCu and IM injectable immunizations, the pharmacist has to complete ACPE-approved immunization-related- pharmacy education.

- 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 improve the availability of medication administration services to patients, allowing for decreased cost and time spent traveling to and from clinics, where many of these medications currently need to be administered. When patient injectable medications are administered at a clinic, primary care provider's office or hospital, patients and insurance are often charged for an "office visit" and/or medication markup fees. These charges/fees would not occur when a patient receives their injection at a pharmacy. They would only be charged for the medication, dispensing and an administration fees. This should save health plans and their members money.

Pharmacists are the most accessible health professionals 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. Increasing availability, accessibility and medication adherence while often decreasing costs of administration, this proposal would also improve healthcare needs, particularly in patients where cost and/or transportation may be a barrier to care.

- 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. This proposal would not impact the supply of pharmacists or other administering practitioners.

- 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?*

This proposal does not change how or by whom the services are compensated and importantly, does not add another service or provide a duplicative service for patients. Patients would likely see cost savings by decreasing transportation costs to and from clinics and by avoiding an office visit charge on top of the administration fees. Insurers may also see cost savings as there are fewer office visits needing to be covered for patients to come in for medication administration alone. Providers may see decreased revenue through the possible reduction in medication administration visits but would still see patients for regular follow-up visits for prescribing of these medications. Patients would still have the option to see their primary care providers for these administrations, but pharmacists can offer an alternative when patients face barriers to these visits, often due to long travel times or booked out schedules of primary care providers.

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- 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)?*

This proposal could improve the rate at which technology innovations are adopted into practice. With an expanded definition of the practice of pharmacy, pharmacists will be more likely to assist patients with innovative medication monitoring devices such as those being currently for blood sugar monitoring in patients with diabetes.

Also see this pre-pandemic article in Pharmacy Times:

<https://www.pharmacytoday.org/action/showPdf?pii=S1042-0991%2818%2930146-4>

- 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?*

There is potential savings to both the patient and the healthcare system as a whole. Patients can have access to medication administration services without the time and costs often required for clinic visits. We believe that accessing subcu and IM injections services at a pharmacy should reflect save the MN DHS-MA and MNCare budgets based on lower reimbursement of costs associated with injectable services at a pharmacy. Potential savings to the healthcare system are present due to the potential for improved access to these measures that are often preventing worsened disease states, potentially decreasing future hospitalizations. Greater access to medication administration services should reduce the need for additional treatment, hospitalization and other health associated costs that could occur from worsened disease states that may be uncontrolled due to lack of availability or affordability of medication administrative services.

### 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?*

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

- 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

\*MN APRN's & NNPs supported this almost identical legislation in 2019 and 2020. The MMA was supportive as well.



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- 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?*

The Minnesota Pharmacy Alliance has reached out to and engaged most other provider trade organizations including the MMA, the APRN's & NNPs and the MNA.

### Citations:

<sup>1</sup> New Frontiers for Pharmacists: Administration of Long-Acting Injectable Antipsychotics. Pharmacy Times. 2019-07-18 15:58:44. <https://www.pharmacytimes.com/publications/specialty-pharmacy-times/2019/2019-Asembia-Recap/New-Frontiers-for-Pharmacists-Administration-of-Long-Acting-Injectable-Antipsychotics>

<sup>2</sup> Skelton JB, Rothholz MC, Vatanka P. Report of the APhA Stakeholder Conference on Improving Patient Access to Injectable Medications. *JAPhA* 2017;57:e1-e12. Available at: <http://dx.doi.org/10.1016/j.japh.2017.04.001>.

<sup>3</sup>Centers for Disease Control and Prevention. Health Care Personnel and Flu Vaccination, Internet Panel Survey, United States, November 2015. Available at: <https://www.cdc.gov/flu/fluview/hcp-ips-nov2015.htm>.