

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.

Name:

Organization: Minnesota Pharmacy Alliance (MPA): Minnesota Pharmacists Association (MPhA), Minnesota Society of Health-System Pharmacists (MSHP), University of Minnesota College of Pharmacy (UMN CoP)

Phone: Please contact Buck Humphrey, MPA's Gov Affair rep, with any questions: 612-889-6515

Email Address: hubert4@gmail.com;

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, pharmacy intern, pharmacy technician

2) Briefly describe the proposed change.

Pharmacists have been administering vaccines in Minnesota for over 2 decades. In 2020, immunization authority was expanded to trained pharmacist technicians, and pharmacists, pharmacy technicians, and pharmacy interns were authorized to administer all Advisory Committee on Immunization Practices (ACIP) recommended vaccines to patients ages 3 and up as part to the federal PREP Act during the COVID-19 pandemic. The bill seeks to codify that authorities that have been successfully and safely granted for pharmacists and their teams into Minnesota law. These authorities include:

- A. Allow pharmacists, trained pharmacy technicians, and pharmacy interns to administer indicated immunizations to patients 3 years of age and older. Although the federal PREP Act included all ACIP recommended vaccines to patients 3 and up, and Minnesota pharmacists and trained pharmacy technicians have been working under this authority since 2020, we have modified the proposed language to all ACIP recommended vaccines to ages 6 and up and influenza and COVID-19 vaccines to ages 3 and up in response to concerns raised by other stakeholders in Minnesota.
- B. Allow trained pharmacy technicians in Minnesota to continue to administer immunizations under the supervision of a pharmacist.
- C. Pharmacists would be able to order immunizations, eliminating the need for a protocol. This simplifies the process for everyone, and pharmacists have the clinical training and expertise needed.
- D. Pharmacists would be able to order and administer CLIA-waived tests (e.g. A1C, influenza, etc.) Pharmacy technicians would be allowed to administer, CLIA-waived tests under the supervision of a pharmacist.

In a study recently published by IQVIA, it is clear that pharmacists play a critical role in immunization access. Every year, 60-70% of influenza vaccinations are administered at pharmacies (IQVIA report). This report highlights that minority populations, including Hispanic and Asian America have a higher percent of the population seeking vaccination through pharmacies. (IQVIA, *Trends in Vaccine Administration in the United States*. 2023.) In addition, a survey from the National Association of Chain Drug Stores, **81% of Minnesota adults “believe it’s important for their state to update its policies to ensure that patients permanently have the same access to pharmacy vaccination, testing, and treatment services that were available during the COVID-19 pandemic”.** (Morning Consult, Prepared for NACDS)

The Maryland Department of Health completed a study in July 2023 reviewing the authority of pharmacists to administer children’s vaccines. Their report recommended: **“Given the overall benefit of illness prevention, the documentation that vaccinations are one of the most effective public health tools available, the recognition that lack of easy access to preventive services like vaccinations increases health inequities, and the demonstration that Maryland pharmacists can effectively vaccinate children, MDH strongly recommends making permanent the authority for pharmacists to order and administer CDC recommended vaccinations to children ages 3-18.”** (Maryland Department of Health. Report on Pharmacists Administration of Childrens’ Vaccines – Study and Temporary Authority. July 31, 2023)

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.

The scope of pharmacy in Minnesota and across the US was expanded to include broader immunizations and testing at pharmacies through the federal PREP Act emergency health declarations. Minnesota’s current pharmacy immunizations and testing laws have been in place for more than a decade. More recently, pharmacists were given the authority to give SubQ and IM prescribed injections, and were authorized to prescribe hormonal contraceptives, nicotine replacement therapy, and opioid antagonists.

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.

- This proposed pharmacy immunization & point-of-care testing legislation HF1197 has been introduced by Representative Bahner & SF1176 has been introduced by Senator Hoffman.
- Senators Hoffman, Bolden, Duckworth, Abeler, Nelson are authors of the Senate legislation.
- Representatives Bahner, Reyer, Backer, Lee, Bierman, Fischer, Hussein, Elkins, Finke, Carroll, Hemmingsen-Jaeger, Her, Smith, Acomb, Schultz, Olson have all co-authored the legislation in the Minnesota House.

5) If there is an urgent need for the bill to be heard this year, please explain the urgency.

In 2023, the Biden Administration ended the Presidential Health Emergency. There was an extension for pharmacists, pharmacy technicians, and pharmacy interns to continue to provide COVID-19 and flu vaccines for ages 3 and up until the December 31st of 2024. **After this time, all PREP act authorities will end, and Minnesota will return to the existing Minnesota law.** The MN legislature must act this session to maintain the current access for preventative and public health measures through local pharmacies. Currently pharmacists cannot provide scheduled immunizations to children less than the age of 13 or COVID-19 and flu vaccines to ages less than 6. Therefore, less children have access to

vaccines. Only 50.6% of children have a medical home in Minnesota (*Child and Adolescent Health Measurement Initiative. 2022 National Survey of Children's Health (NSCH) data query. Data Resource Center for Child and Adolescent Health supported by the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB). [www.childhealthdata.org]*); pharmacies serve as hubs for patients to receive their scheduled vaccines and improve public health.

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, pharmacist interns, and pharmacy technicians are directly affected by the proposed legislation. Primary care providers benefit through sharing the workload of public health through vaccination and conducting point-of-care testing.

- 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 1200 member pharmacists

Minnesota Society of Health-System Pharmacists: approximately 350 member pharmacists in MN.

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.

Pharmacists are trusted healthcare providers that are accessible to most Minnesotans within 5 miles or 5- 10 minutes of their home. On average, patients visit their pharmacy about 18 to 25 times per year. Data from July 2023 shows that there are approximately 9,390 active Minnesota pharmacists, 9,551 pharmacy technicians, and 1273 pharmacist interns. (MN Board of Pharmacy)

The pharmacists and pharmacy technicians most impacted by the proposed legislation will be those who work in community pharmacies such as chain pharmacies, independent pharmacies, and health system pharmacies.

As with almost all health care professions, Minnesota is in a tight labor market and this includes pharmacists. Losing the authority for pharmacy technicians to vaccinate patients in Minnesota would have a negative impact on access to critical immunizations across Minnesota. Many Minnesota pharmacies would not be able to continue to maintain the necessary staff and workforce to meet patient immunization and testing demand without the efforts of trained pharmacy technicians.

- 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 provide education on vaccinations, administer vaccinations, and monitor for potential side effects. Pharmacists can also administer CLIA waived tests, interpret test results, and implement appropriate plan of care under collaborative practice agreements. Trained pharmacy technicians can be delegated the responsibilities of administering vaccinations and CLIA-waived tests under the proposal. They have been performing these patient tasks for close to 3 years under the federal PREP Act. Pharmacists are responsible for supervising the work of pharmacy technicians and interns.

- e. Discuss the fiscal impact.

There is potential savings to both the patient and the healthcare system as a whole. While dynamic scoring is not possible, the lives saved and ailments deterred for Minnesota patients by additional convenient access to vaccines cannot be understated.

In addition, patients access to vaccinations and CLIA-waived tests at a pharmacy will occur without the time and costs often required for clinic visits. Greater access to vaccinations is expected to increase vaccination rates and therefore 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 peace of mind or get them to a provider for further therapies and care.

This said, the 2023 fiscal note did state that the Minnesota Department of Human Services and the Minnesota Department of Health would see costs associated with the implementation of this legislation. The vast majority of the fiscal costs are associated with future Vaccine For Children costs to implement the federal program by the Minnesota Department of Health to greatly expand

the VFC program. Minnesota pharmacy has been working with MDH to improve the VFC program, however the access to vaccinations and testing at a pharmacy should not be held up and take access backwards because the VFC program is not currently working. Here is the fiscal analysis from last year:

State Cost (Savings) = 1-2		Biennium		Biennium	
Dollars in Thousands		FY2023	FY2024	FY2025	FY2026
Health Dept					
General Fund	-	864	864	513	513
Human Services Dept					
General Fund	-	130	145	91	73
Total	-	994	1,009	604	586
Biennial Total			2,003		1,190
1 - Expenditures, Absorbed Costs*, Transfers Out*					
Health Dept					
General Fund	-	864	864	513	513
Human Services Dept					
General Fund	-	130	145	91	73
Total	-	994	1,009	604	586
Biennial Total			2,003		1,190

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’s 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?

The proposed scope change does not change current education and training practices.

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, pharmacist intern or pharmacy technician wishes to provide the proposed patient immunizations and testing service, they would all be required to

undergo an ACPE or Board of Pharmacy approved training program for administering and monitoring vaccinations. Pharmacy technicians would be required to complete training and a minimum number of hours on the job as a pharmacy technician. Training on CLIA waived test administration may be completed as part of a degree program, through employer training, or through other continuing education opportunities currently available.

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

Yes, many states have recently passed expansion of the immunization authority for pharmacists, pharmacy technicians and interns as a result of the ending of the PREP Act authorities.

Notably, 19 states allow pharmacists to administer influenza vaccines to any age or ages 6 months and up. Minnesota's current law that limits pharmacists authority to administer ACIP-recommended vaccines to ages 13 and older is more restrictive than most of the country. Surrounding states, Iowa, North Dakota, and Wisconsin, all allow pharmacy technicians to provide immunizations. Wisconsin, Iowa, and South Dakota allow pharmacists to administer immunization to children at least 6 years of age with no restrictions (27 states in total allow this). (NASPA's website: <https://naspa.us/resource/pharmacist-authority-to-immunize/>)

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 (MBOP) regulates the pharmacist profession of pharmacy and grants licenses to pharmacists, pharmacy technicians, and pharmacy interns in Minnesota.

This proposal does not require any changes in supervision. Pharmacists do not require direct supervision by another health professional in typical activity and would not need additional supervision to provide immunizations. Pharmacy technicians and pharmacy interns would be supervised by a licensed pharmacist, as currently described in Minnesota law.

- 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.

This proposal does not include any changes to the regulatory entity of the Minnesota Board of Pharmacy.

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?

All licensed pharmacists and pharmacy technicians must complete continuing education requirements required by the MBOP. For immunizing providers, it is required to maintain current certification in cardiopulmonary resuscitation (CPR).

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, by improving access to care for patients. The proposal may increase overall vaccine adoption by Minnesota patients because they can access their immunizations through a trusted health professional in their local communities around the state. 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. Pharmacists and their teams plays a vital role with medication education, management, and administration.

This proposed change will codify the authorities that were previously granted by the federal government as part of the PREP act. These increased authorities for pharmacists and their teams for vaccinations and testing have been safely implemented. Failure to continue these authorities would create an unnecessary regulation per MN Stat 214.001, as 3 years of experience has shown there is not a recognizable harm from this authority.

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

Yes, see the 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 total health care costs. 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. Urban underserved and rural populations often present with barriers to clinic access, making the community pharmacy an important access point for care. This proposal will enable Minnesotans to continue to access preventative care, vaccinations and tests 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 the most accessible and trained health professional able to provide this service for patients. Increasing the authorities for pharmacists, pharmacist interns, and pharmacy technicians in Minnesota would have no impact on the number of pharmacists in Minnesota. It will not impact any other health provider profession, other than to alleviate overburdened hospitals, clinics and provider offices. However, if Minnesota no longer allows trained pharmacy technicians to vaccinate patients, Minnesota pharmacies could become overwhelmed with patient vaccination administration requests. This could result in decreased vaccine access at community pharmacies.

- 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 anything regarding reimbursement. Vaccination is a service covered by health plans. Both private and public payer reimbursement would not be impacted by this legislation. Overall, providing patient immunizations should reduce healthcare costs for Minnesotans.

- 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?

Please see the discussion points regarding costs and savings noted in the above (1, “Fiscal Impact”) paragraphs. Please also see the House Fiscal note for HF1197 from the 2023 legislative session.

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, however, the data is clear since 2020 that pharmacists and their trained pharmacy technicians have made an extraordinary impact and provided and administered over 5 million vaccinations to patients across Minnesota, old and young, over the past 4 years.

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, the MN APRNs, the MN NNPs 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
The Minnesota Retailers Association
The Minnesota APRN Coalition
The Minnesota Nurse Practitioners
The Minnesota Grocers Association

We also sought technical assistance from the MBOP, MDH and DHS.

- 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. We have and are working with each of the above-mentioned organizations as well as the Minnesota Medical Association to gain consensus for state codification of current federal PREP Act authorities. The MMA has expressed some concern that pediatrician members have with reads to well-child visits being missed at ages 3-5 in particular if those patients can get vaccinated at a pharmacy. The legislative language addresses this concern, however, they still may be opposed to the age provisions of the legislation. We have been working with the Minnesota Board of Pharmacy as well as the Department of Health to address any concerns they may have and may have compromise amendment language to potentially be offered.

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

The sponsor and Minnesota pharmacy organizations have worked over the past year with the MBOP and MDH as well as the MMA to work through any concerns that they may have about authorizing pharmacists and pharmacy technicians to vaccinate (ACIP/FDA approved) Minnesota children down to the age of 3 years old as they are currently authorized to do under the federal emergency authorities granted to them in 2020. The MBOP, MDH and MMA has voiced age related concerns especially as it relates to the 3 – 5 year old patient.

Taking into account all stakeholder concerns and the practical realities and distinction between Flu/COVID-19 children's vaccinations and all other ACIP/FDA approved immunizations, the Sponsor will be bringing forward amendment language that will authorize pharmacists, pharmacy interns and Pharmacy technicians to vaccinate patients down to the age of 6 years old for ACIP/FDA approved vaccines and for flu and COVID-19 vaccine administration, down to the age of 3 years old.

All other provisions and statutory revisions in the bill language have been agreed to by all stakeholders and there are no concerns with those language provisions that we know of. It is critical to have trained pharmacy technicians authorized to administer vaccines under the supervision of a pharmacist in Minnesota. It is also critical that pharmacies are authorized to "order" the tests and ingredient so that they will be reimbursed by payers for the vaccine ingredient and the physical tests (CLIA waived-non laboratory).