



MIKE ROHRKASTE

STATE REPRESENTATIVE • 55TH ASSEMBLY DISTRICT

Assembly Bill 841:

Relating to: waivers and variances from rules issued by the Pharmacy Examining Board
and authorizations for pilot programs

Testimony of State Representative Mike Rohrkaste

Assembly Committee on Health

February 10, 2016

Thank you, Chair Sanfelippo, and fellow members of the Assembly Committee on Health for holding this public hearing.

Assembly Bill 841 extends the authority of the Pharmacy Examining Board (PEB) to grant a waiver or variance from current rules or to approve a pilot program. Currently, the PEB may only grant a waiver or pilot dependent on the following: in a natural or manmade disaster or emergency; if a pharmacist has requested a variance; or if the board determines it is necessary to protect public health; safety or welfare. This bill allows the PEB to approve pharmacy practice initiatives and waivers to permit pilot programs with the goal of improving the safety, quality, and efficiency of the pharmacy practice in the state of Wisconsin.

The Wisconsin Pharmacy Examining Board (PEB) regulates pharmacists, pharmacy interns, pharmacies, drug or device manufacturers, and wholesale distributors of prescription drugs. The PEB consists of seven members who are appointed by the governor and confirmed by the Senate. Each member can serve up to two four-year terms on the board. The members must include two public members and five pharmacist members. The primary role performed by the PEB is to establish rules which regulate pharmacists to protect the health, safety, and welfare of patients.

The national board with oversight in this area has indicated waiver and pilot granting authority as a best practice for pharmacy legislation and regulation. Senator Moulton and I have worked with the Pharmacy Society of Wisconsin and other stakeholder groups to ensure that this legislation meets standards both nationally and here at the state level. Currently, several other states grant this authority to their state pharmacy boards including Iowa, Michigan, Kansas, Texas, Oklahoma, and Virginia. There are several examples of how this legislation will be helpful right here in Wisconsin and I will let the experts in the pharmacy field discuss those.

Thank you for your time and I'm happy to answer any questions you may have.



From: Senator Terry Moulton

To: Assembly Committee on Health

Re: Testimony on Assembly Bill 841
Relating to: waivers and variances from rules issued by the Pharmacy Examining Board and authorizations for pilot programs.

Date: February 10, 2016

Chairman Sanfelippo and committee members, thank you for the opportunity to testify today about Assembly Bill 841, which would extend the authority of the Wisconsin Pharmacy Examining Board to grant waivers from current rules. Currently, the Pharmacy Examining Board (PEB) can only grant waivers from existing practice in a natural or manmade disaster or emergency. This bill will permit the PEB to approve pharmacy practice initiatives that aim to improve the safety, quality, efficiency of or access to pharmacist services.

The PEB regulates pharmacists, pharmacy interns, pharmacies, drug or device manufacturers and wholesale distributors of prescription drugs. The PEB has seven members - two public members and five pharmacist members. Members are appointed by the Governor, confirmed by the Senate and serve up to two four-year terms. The PEB establishes rules that regulate pharmacists to protect the health, safety and welfare of patients.

This bill will allow the PEB to approve waivers to permit pilot programs that will improve the safety, quality or efficiency of pharmacy practice in Wisconsin. One example of what this bill will permit is known as a 'tech-check-tech,' the checking of a technician's order filling accuracy by another technician rather than a pharmacist. Academic studies demonstrate that this process is just as safe as having a pharmacist check a technician's order filling accuracy. This safe process would streamline the dispensing and verifying of medication. Another type of waiver that the PEB could consider under this bill would be automated distribution systems and telepharmacy services, which could also streamline pharmacy services for patients.

Currently, several other states grant this authority to their state pharmacy boards, including our neighbors in Iowa and Michigan. It is important to note that this bill simply widens the conditions under which the PEB can consider and grant waivers, and does not itself change the regulations governing pharmacy practice or guarantee approval of waiver requests.

Please vote to recommend the passage of Assembly Bill 841. Thank you again for allowing me to testify today.



Date: February 10, 2016

To: Assembly Committee on Health

From: Kyle O'Brien, Senior Vice President Government Relations
Steven Rush, Vice President Workforce and Clinical Practice

Re: Support Assembly Substitute Amendment 1 to Assembly Bill 841

The Wisconsin Hospital Association (WHA) encourages you to support Assembly Substitute Amendment 1 to Assembly Bill 841.

ASA 1, introduced by Representative Mike Rohrkaste, is also supported the Pharmacy Society of Wisconsin (PSW) and would allow the Pharmacy Examining Board (PEB) to grant a variance or waiver to existing rule for the purpose of a licensee to pilot a program, for a time period not to exceed 3 years.

WHA supports the intent of this amendment to enable the PEB to create voluntary, limited term pilots that can enable pharmacists to demonstrate safe and efficient alternatives to existing rules. Through such pilots, Wisconsin can better test emerging pharmacy practice models and help inform future PEB rulemaking.



DATE: Wednesday, February 10, 2016
TO: Representative Joe Sanfelippo, Chair
Members, Assembly Committee on Health
FROM: Pharmacy Society of Wisconsin
SUBJECT: AB841 Substitute Amendment relating to a pilot program authorized by the PEB

Background

The Wisconsin Pharmacy Examining Board (PEB) regulates pharmacists, pharmacy interns, pharmacies, drug or device manufacturers, and wholesale distributors of prescription drugs. The PEB consists of seven members including two public members and five pharmacist members. Members are appointed by the Governor and confirmed by the Senate and serve up to two four-year terms. The primary role of the PEB is to promulgate and adjudicate rules that protect the health, safety, and welfare of patients.

The National Association of Boards of Pharmacy Model State Pharmacy Act and Model Rules document that highlights best practices for pharmacy legislation and regulation. The PEB is responsible for promulgating and enforcing rules outlined in Wisconsin Administrative Code Phar Chapters 1-17. Statute 450.02(3m) authorizes the PEB to grant waivers from existing rules. Currently, the PEB's waiver or pilot granting authority is contingent on all of the following:

1. In the setting of a natural or man-made disaster or emergency
2. A pharmacist has requested the variance
3. The board determines it is necessary to protect public health, safety or welfare

Issue

The National Association of Boards of Pharmacy Model State Pharmacy Act and Model Rules highlights waiver and pilot granting authority as a best practice for pharmacy legislation and regulation. Enabling the PEB to grant waivers, variances, and pilot programs, outside of emergency situations, for matters relating to prescription verification and the practice of pharmacy allows pharmacists to bring forward ideas and initiatives aiming to improve the safety, quality, and efficiency of pharmacist-provided services that currently fall outside the scope of present regulations. For example, this authority would clarify PEB waivers for tech-check-tech, a thoroughly studied program which streamlines medication dispensing and verification in institutional settings. Other states that grant this authority to their state boards of pharmacy include: Iowa, Michigan, Kansas, Texas, Oklahoma, and Virginia.

Solution

Maintain the current statute to continue to allow variances in the setting of emergencies and advance Assembly Bill 841 substitute amendment to authorize the PEB to approve a pilot program by adding the following as 450.02(3r):

The board or its designee may authorize a pilot program and grant waivers or variances under this subsection from a rule promulgated by the board for the authorized pilot program, if all of the following are true:

- (a) The pilot program is related to the practice of pharmacy or prescription verification.
- (b) The board or its designee determines that the pilot program will improve the safety, quality, or efficiency of the practice of pharmacy in this state.

(c) No pilot granted under sub. (3r) may be granted for a period longer than 3 years.



DATE: Wednesday, February 10, 2016

TO: Representative Joe Sanfelippo, Chair
Members, Assembly Committee on Health

FROM: Joe Cesarz, MS, PharmD
Manager, Ambulatory Pharmacy Services
UW Health

SUBJECT: Assembly Bills 841, 865, and 866 relating to the Pharmacy Examining Board and pharmacy practice

Good Morning Chairman Sanfelippo, Vice Chair Rohrkaste, and Committee members.

Thank you for the opportunity to comment on Assembly Bills 841, 865, and 866 relating to the Pharmacy Examining Board and pharmacy practice.

My name is Joe Cesarz, and I am a pharmacy manager at UW Health, a health system in Madison, WI. My primary responsibility within this role is to provide leadership and oversight of our 14 pharmacy dispensing locations, which collectively fill over 2,000 prescriptions per day.

I am here today to express my professional support, as a representative of UW Health, for three of the bills that are up for comment:

- Assembly Bill 841,
- Assembly Bill 865, and
- Assembly Bill 866

Before providing specific details regarding my support for these bills, I wanted to provide the committee with a few global considerations to take into account during the review process.

- The role of pharmacists is becoming increasingly important in the continued evolution of health care and health payment reform. Medications are a cornerstone of therapy for many chronic and complex disease states, and pharmacists have the tools and resources to ensure that medications are:
 - Safe,
 - Cost-effective, and
 - Appropriate for the intended patient and use
- As a result, pharmacists are uniquely positioned to ensure that we achieve the triple aim of healthcare reform:
 - Improving the patient experience
 - Improving population health, and
 - Reducing the per capita cost of health care

- However, current payment models primarily reimburse pharmacies on a product specific basis, and few payers reimburse for pharmacist clinical services or improved patient outcomes.
 - Due to this product-driven payment model, a pharmacy's profitability is directly linked to pushing through high volumes of prescriptions. Combined with decreasing reimbursement to pharmacies for prescription products, the utilization of a high cost labor resource – pharmacists – are kept to a minimum to sustain business.
 - I believe that the true value of a pharmacist is achieved when there is a healthy balance between a pharmacist focusing on a safe and accurate product, as well as improved patient outcomes at a lower cost.
- Therefore, it is necessary to identify methods that allow pharmacies to have flexibility in exploring ways to ensure efficiency and sustainability, while clinically caring for the patient. A few pathways to shifting more pharmacist time to clinical management include advancing the role of lower skill mix employees (pharmacy technicians and pharmacy students) and utilizing technology.

With these considerations in mind, I am putting forth my request to the committee to support the following bills:

Assembly Bill 841 is the bill that I am most passionate about expressing my support for. This bill provides the Pharmacy Examining Board the authority to grant a waiver or variance from a rule promulgated by the board, or authorize a pilot program, if the waiver, variance, or pilot program is related to the practice of pharmacy or prescription verification and if it ensures patient safety.

- In the pharmacies that I oversee, we have been conducting proof of concept models to advance the roles of pharmacy technicians, which would allow the shifting of pharmacist time from product to patient.
- While our pilot project has demonstrated a statistically significant difference that technicians are more accurate than pharmacists at verifying the product in the prescription bottle, the current legislative rules governing pharmacy practice would not allow us to fully enact this practice in our pharmacies. While the Pharmacy Examining Board has been granting variances or licenses for this practice in a hospital pharmacy setting, they have been given legal advice that they should not be providing variances to law when a state of emergency does not exist. As a result, we are inhibited from being able to fully incorporate these safe and more cost-effective practices in our pharmacies.
- Additionally, with the rapid evolution of technology, we have been investigating methods to utilize telepharmacy and telemedicine programs to provide efficient and safe services for our patients. However, there are challenges with interpreting and applying rules as written today and there is not a method to test and validate these care delivery models in a fashion with oversight from the Pharmacy Examining Board.
- This bill would not expand the Pharmacy Examining Board's scope or authorize prescriptive authority. Instead, it would give the Board an opportunity to pilot and evaluate innovative services in a more reliable format, and allow for a standardized approach for considering updates to the pharmacy practice act.

Assembly Bill 865 relates to pharmacist administration of injectable, prescribed products.

- Currently, this practice is limited to the course of teaching self-administration techniques for patients receiving injectable products
- However, there are many situations that occur in hospital pharmacy and dispensing pharmacies where this could negatively impact patient care.
 - Within hospitals, pharmacists serve as key responders for strokes and cardiovascular resuscitation events
 - And in the community pharmacy setting, there may be patients with physical or cognitive impairments that struggle with self-administration.
- In both settings, there are opportunities for pharmacists (or pharmacists in training) to serve as an additional resource for the administration of these injectable products.

Assembly Bill 866 relates to a pharmacist's ability to modify prescription quantity and refill amounts.

- This bill will allow pharmacists the flexibility to meet the needs and preferences of patients, while staying true to the intent of a physician's prescription order.
- Currently, many health plans allow patients who are stable on a given prescription medication to fill up to 3 months of medication at a time. However, if the prescription is only written for a 30-day supply, the pharmacist is unable to modify the prescription to a 90-day supply without contacting the prescriber. Rarely, if ever, is there opposition from the prescriber in response to this request.
- As a result, if passed, this bill would eliminate unnecessary workflow steps and waste in the healthcare system, will maintaining prescriber intent.

Thank you very much for allowing me the opportunity to express my support for these three bills. I am confident that, if approved, these will result in improvements in our healthcare delivery model, without compromising patient safety.

Philip J. Trapskin, PharmD, RPh
2861 Crinkle Root Drive
Fitchburg, WI 53711

DATE: Wednesday, February 10, 2016

TO: The Honorable Joe Sanfelippo, Chairman, Assembly Committee on Health
The Honorable Members, Assembly Committee on Health

FROM: Philip J. Trapskin, Secretary, Pharmacy Examining Board

SUBJECT: Assembly Bills 841, 865, and 866 relating to the Pharmacy Examining Board and pharmacy practice

Good Morning Chairman Sanfelippo, Vice Chair Rohrkaste, and Committee members. Thank you for holding a hearing today on the Pharmacy Examining Board Red Tape Review and Assembly Bills 841, 865, and 866.

My name is Philip Trapskin, I am a pharmacist currently serving on the Wisconsin Pharmacy Examining Board as Secretary and Legislative Liaison.

As the Committee is already aware, the sole responsibility of the Pharmacy Examining Board is protection of public health and welfare. I am here today to express my support for the Pharmacy Examining Board Red Tape Review effort and Assembly Bills 865, 866, and 841.

Assembly Bill 865

Over the last decade, there has been a significant increase in the development of biologic medications that must be administered through and injection. There are times where travel distance or hours of operation are not conducive to for a patient to go to a clinic to receive these medications. This bill will allow pharmacists, who have the necessary training and competency in injection technique, to serve as another access point for patient to receiving these medications.

Assembly Bill 866

Medication non-adherence is estimated to cost the U.S. healthcare system \$300 billion dollars annually. One contributor to non-adherence is the effort it takes to coordinate refills of medications. This bill allows the pharmacist to partner with patients to minimize the number of times refills need to be coordinated. We also know that the workload of clinics continues to increase, and anything that can be done to minimize the tsunami of faxes and phone calls they receive will allow them to focus their resources on more valuable patient care activities. Providing the pharmacist latitude to use their professional judgement to determine when a large days supply without contacting a clinic, and increase medication adherence is a win-win-win for the pharmacy, clinic, and patient.

Assembly Bill 841

The last 5 years have seen significant disruptive innovation in healthcare (e.g. telehealth, delivery models, payment reform). The current regulatory framework for pharmacy practice makes it impossible

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to experiment and study the benefits of disruptive innovation. This bill will allow the Pharmacy Examining Board to pilot innovation in a controlled limited fashion. The Pharmacy Examining Board can then use the lessons learned from these pilots to propose smarter rules and legislation that will promote public health and welfare.

I applaud the efforts of this Committee to take the time to review opportunities that can improve public health, specifically through improved medication use.

Sincerely,



Philip Trapskin, PharmD, BCPS