Illinois Department of Financial and Professional Regulation

Division of Professional Regulation

J.B. Pritzker
Governor

Deborah A. Hagan

Secretary

CECILIA ABUNDIS
Acting Director
Division of Professional Regulation

October 30, 2020

MEMORANDUM

TO: **The Illinois General Assembly**

FROM: **The Illinois Collaborative Pharmaceutical Task Force**
Philip P. Burgess, MBA, DPh, RPh, Chairperson
Hunter Wiggins, General Counsel, Department of Financial & Professional Regulation
Scott Meyers, MS, RPh
Helga Brake, PharmD
Brian H. Kramer, RPh, MBA
Jerry L. Bauman, PharmD
Adam Bursua, PharmD
Scott A. Reimers
Garth Reynolds, RPh
Thomas Stiede
Rob Karr
Jayna Brown
Representative Randy E. Frese
Representative Michael J. Zalewski
Senator Jennifer Bertino-Tarrant's
Lemrey Al Carter, RPh*
Ryan McCann, PharmD *

*Lemrey Al Carter resigned from the Task Force and Ryann McCann was appointed to replace Lemrey Al Carter on 3/13/20.

Illinois Collaborative Pharmaceutical Task Force Report and Recommendations

Mandated by 225 ILCS 85/4.5

November 1, 2020

Table of Contents

Collaborative Pharmaceutical Task Force Authorizing Statute:

For the purposes of continuing dialogue on best practices for pharmacy in the State of Illinois, the Task Force shall be reconvened beginning January 1, 2020. Members who served on the Task Force before January 1, 2020 shall continue to serve. The following additional voting members shall be appointed to the Task Force as follows:

(A) one representative of a statewide organization exclusively representing retailers, including pharmacies, who shall be appointed by the Governor;

(B) one representative of a statewide organization representing unionized pharmacy employees who shall be appointed by the Governor;

(C) one member of the General Assembly who shall be appointed by the Speaker of the House of Representatives;

(D) one member of the General Assembly who shall be appointed by the Minority Leader of the House of Representatives;

(E) one member of the General Assembly who shall be appointed by the President of the Senate; and

(F) one member of the General Assembly who shall be appointed by the Minority Leader of the Senate.

All provisions relating to the operation and meeting of the Task Force shall continue to apply during the extended period beginning January 1, 2020.

No later than October 1, 2020, the voting members of the Task Force shall vote on recommendations that are in addition to those voted on, on or before September 1, 2019.

No later than November 1, 2020, the Department, in direct consultation with the Task Force, shall propose rules for adoption that are consistent with the Task Force's recommendations, or recommend legislation to the General Assembly, concerning the items considered by the Task Force.

Task Force Votes and Rationales Regarding Recommended Standards:

The Collaborative Pharmaceutical Task Force made the following recommendations regarding the standards delineated in Section 4.5 of the Act, as well as other recommendations regarding changes to the Pharmacy Practice Act and the rules promulgated thereunder.

Maintaining Error Records

Regarding the standard contained in Section 4.5 of the Act, which involved a consideration whether to require a pharmacy "to retain records of any errors in the receiving, filling, or dispensing of prescriptions of any kind," by modifying this standard to establish a Continuous Quality Improvement ("CQI") Program and recommending that the legislature enact a provision in the Pharmacy Practice Act under a new Section entitled "Continuous Quality Improvement Program," which states the following:

Each pharmacy shall implement a program for continuous quality improvement, for the purpose of detecting, documenting, assessing, and preventing Quality-Related Events (QREs). At a minimum, a CQI Program shall include provisions to:

(i) designate an individual or individuals responsible for implementing, maintaining, and monitoring the CQI Program, which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;

(ii) initiate documentation of QREs as soon as possible, but no more than seven days, after determining their occurrence;

(iii) analyze data collected in response to QREs to assess causes and any contributing factors;

(iv) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients;

(v) provide ongoing CQI education at least annually to all pharmacy personnel

Any pharmacy that contracts with a federally-listed Patient Safety Organization (PSO) and has developed and implemented a Patient Safety Evaluation System in order to advance the goal of continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) shall be deemed in compliance with this Section.

All information, communication, data, reports, deliberations and analyses of any pharmacy which satisfies the CQI Program requirements set forth that have the potential to improve quality and/or patient safety and are maintained as a component of a pharmacy CQI Program are privileged and confidential and shall not be subject to discovery or admissible into evidence in a state or federal proceeding nor subject to a judicial subpoena.

These protections shall not prevent the review of a pharmacy's CQI Program materials, policies, procedures and corrective actions taken pursuant to their Program. In addition, the Department may collect information of any adverse event or error that is maintained outside of a PSO's Patient Safety Evaluation System or outside of a CQI program, in response to a subpoena. The disclosure of documents or information under subpoena does not constitute a waiver of the privilege or confidentiality protections associated with a CQI Program.

The 2019 Pharmaceutical Task Force determined that in order to maintain effective error records, there must be continuous quality improvement ("CQI") to build a "just" culture and improve overall safety and quality of patient care. The Task Force believed that this proposal provides the Department and other oversight authorities with access to pharmacies' processes in monitoring and preventing quality-related events, while protecting the documentation of the errors from discovery in litigation and disciplinary actions – which discourage addressing errors. The Task Force believed that this provision gives pharmacies and pharmacists an incentive to strive toward providing accurate prescriptions and reports of adverse incidents without fear of litigation. The Task Force determined that the amendments would open any CQI process to review, but not the documentation involving the specific incident. Documentation of specific adverse events are intended to be used to improve systems and processes for the purpose of better patient safety.

The 2020 Pharmaceutical Task Force adopted the same CQI language that was proposed by the previous Pharmaceutical Task Force in 2019.

> The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder with the following votes:
> **Motion passed. Task Force members voted as follows:**
> **Ayes:** Philip P. Burgess, Helga Brake, Brian H. Kramer, Scott Meyers, Lemrey Al Carter, Garth Reynolds, Rob Karr, Jayna Brown
> **Nays:** None reported.
> **Abstains:** Scott A. Reimers

Rationale provided by Task Force member Helga Brake:

This recommendation more than any other addresses the Task Force's charge to optimize the safety of Illinois' pharmacy patients. Continuous Quality Improvement (CQI) is a systematic approach to identifying errors, investigating to understand their cause, and implementing effective strategies to prevent their reoccurrence. Its objective is to learn from mistakes in order to prevent future error. Incorporating CQI into the medication-use process leads to safer patient outcomes. Numerous studies validate the success of CQI programs to reduce mistakes and patient harm when thoughtfully executed.

It is a fact that human beings are fallible; however, the vast majority do not wake up in the morning with the intention of making a mistake. Pharmacists are human beings as well and unwillingly contribute to the occurrence of error. To avoid committing mistakes, reporting them is fundamental to error prevention as underreporting eliminates opportunities to better serve patients.

The key to increasing the reporting rate is to build trust by promoting a proactive approach rather than responding with discipline after an error has occurred. Reporting will result only in a safe environment. People underreport their errors out of embarrassment and fear of consequences and are wary about providing information that may be subsequently used against them. Therefore, the promise of confidentiality and legal protections for committing an unintended error is a substantial

deterrent to underreporting. Protecting this information encourages disclosure which, with the help of a CQI program, leads directly to prevention of error.

The National Association of Boards of Pharmacy (NABP) strongly recommends that "States…continue efforts to develop and implement requirements for CQI Programs in pharmacies, recognizing that CQI Programs enhance patient safety and operate most effectively when privilege of discovery laws and/or regulations protecting CQI data and information are enacted and included as a component of the CQI process." Discovery protections are not new or unique. Their inclusion is not only supported by the NABP but also written into the pharmacy practice acts and rules of more and more states, including Arizona, Indiana, Iowa, Florida, Kansas, Maryland, New Hampshire, New Jersey, North Dakota, and Virginia, among others.

Finally, it is vital we pay attention to the safety demands of patients and provide assurances that effective quality improvement efforts are implemented that support shared learning to prevent similar future errors. The approval of the CQI recommendation is the necessary first step to ensure this occurs. If we are to optimize patient safety, the implementation of an effective Pharmacy CQI program must be the highest priority.

Pharmacy Resident Exemption

Proposed Amendment to the Pharmacy Rules:

A pharmacy resident participating in a nationally accredited residency program is exempt from Section 15.1(a) of the Act to the extent the provision conflicts with the requirements of the nationally accredited residency program.

> The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder with the following votes:
> **Motion passed. Task Force members voted as follows:**
> **Ayes:** Philip P. Burgess, Helga Brake, Brian H. Kramer, Scott Meyers, Rob Karr, Jayna Brown
> **Nays:** None reported.
> **Abstains:** Scott A. Reimers and Garth Reynolds

Rationale provided by Task Force member Adam Bursua:

This exemption was necessary in order to ensure that the Pharmacy Practice Act fully considered unique aspects of pharmacy residency training as compared to the roles of other retail and hospital pharmacists. Pharmacy residencies are overseen by an accrediting body, the American Society of Health-System Pharmacists (ASHP). This body enforces guidelines and procedures meant to ensure a safe environment for pharmacy residents and patients, while also allowing for intense and comprehensive experiences required for residency training. The overseeing body has published "Duty-Hour Requirements for Pharmacy Residencies" that address many of the same

provisions included in this section of the act, but tailors the requirements to the needs of the pharmacy residents and residency programs.

This exemption was necessary to allow Illinois to continue recruiting the most talented pharmacy residents and trainees to our state, to ensure a safe, effective, and innovative pharmacy practice for the future.

Mandatory Breaks and Lunch Period

Proposed Amendments to the Pharmacy Practice Act:

225 ILCS 85/15.1: Pharmacy working conditions.

(a) A pharmacy licensed under this Act shall not require a pharmacist, student pharmacist, or pharmacy technician to work longer than 12 continuous hours per day, inclusive of the breaks required under subsection (b).

(b) A pharmacist who works 6 continuous hours or longer per day shall be allowed to take, at a minimum, one 30-minute uninterrupted meal break and one 15-minute break during that 6-hour period. **The breaks shall be provided no earlier than 3 hours after the pharmacist begins work unless otherwise requested by the pharmacist.** If such pharmacist is required to work 12 continuous hours per day, at a minimum, he or she qualifies for an additional 15-minute break. **The additional 15-minute break shall be provided no earlier than 6 hours after the pharmacist begins work unless otherwise requested by the pharmacist.** A pharmacist who is entitled to take such breaks shall not be required to work more than 5 continuous hours, excluding a 15-minute break, before being given the opportunity to take a 30-minute uninterrupted meal break. If the pharmacy has a private break room available, or if there is a private break room in the establishment or business in which the pharmacy is located, a pharmacist who is entitled to breaks must be given access to that private break room and allowed to spend his or her break time in that room.

> The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder with the following votes:
> **Motion passed. Task Force members voted as follows:**
> **Ayes:** Philip P. Burgess, Helga Brake, Brian H. Kramer, Jayna Brown
> **Nays:** Scott Meyers, Garth Reynolds, Ryan McCann
> **Abstains:** Scott A. Reimers

225 ILCS 85/15.1: Pharmacy working conditions.

(c) A pharmacy may, but is not required to, close when a pharmacist is allowed to take a break under subsection (b). If the pharmacy does not close, the pharmacist shall either remain within the licensed pharmacy or within the establishment in which the licensed pharmacy is located in order to be available for emergencies. In addition, the following applies:

> (1) pharmacy technicians, student pharmacists, and
> other supportive staff authorized by the pharmacist on duty may continue to perform duties as allowed under this Act;

(2) no duties reserved to pharmacists and student pharmacists under this Act, or that require the professional judgment of a pharmacist, may be performed by pharmacy technicians or other supportive staff; and

(3) only prescriptions that have received final verification by a pharmacist may be dispensed while the pharmacist is on break, except those prescriptions that require counseling by a pharmacist, including all new prescriptions and those refill prescriptions for which a pharmacist has determined that counseling is necessary, may be dispensed only if the following conditions are met:

(i) the patient or other individual who is picking up the prescription on behalf of the patient is told that the pharmacist is on a break and is offered the chance to wait until the pharmacist returns from break in order to receive counseling;

(ii) if the patient or other individual who is picking up the prescription on behalf of the patient declines to wait, a telephone number at which the patient or other individual who is picking up the prescription on behalf of the patient can be reached is obtained;

(iii) after returning from the break, the pharmacist makes a reasonable effort to contact the patient or other individual who is picking up the prescription on behalf of the patient and provide counseling; and

(iv) the pharmacist documents the counseling that was provided or documents why counseling was not provided after a minimum of 2 attempts, including a description of the efforts made to contact the patient or other individual who is picking up the prescription on behalf of the patient; the documentation shall be retained by the pharmacy and made available for inspection by the Board or its authorized representatives for at least 2 years.

(d) In a pharmacy staffed by 2 or more pharmacists, the pharmacists shall stagger breaks so that at least one pharmacist remains on duty during all times that the pharmacy remains open for the transaction of business.

(e) A pharmacy shall keep and maintain a complete and accurate record showing its pharmacists' daily break periods.

(f) Subsections (a) and (b) shall not apply when an emergency, as deemed by the professional judgment of the pharmacist, necessitates that a pharmacist, student pharmacist, or pharmacy technician work longer than 12 continuous hours, work without taking required meal breaks, or have a break interrupted in order to minimize immediate health risks for patients.

(g) Subsections (a), (b), and (e) shall not apply to pharmacists who do not "dispense" during their shift as defined in Sec. 3.

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder with the following votes:

Motion passed. Task Force members voted as follows:

Ayes: Philip P. Burgess, Helga Brake, Brian H. Kramer, Jayna Brown, Scott Meyers, Tom Stiede

Nays: Garth Reynolds, Ryan McCann

Abstains: Scott A. Reimers

Expansion of Standing Orders

The Pharmaceutical Task Force strongly recommends continued efforts to enable pharmacists to maximize the use of their training and expertise to improve patient care. Expansion of the use of standing orders is one example that would greatly benefit the citizens in the State of Illinois. It is our opinion that Illinois lags many states in allowing pharmacists these functions and the provision of such (though already permitted in the current Pharmacy Practice Act) will improve the public health of Illinois citizens and improve access to care. The provision of self-administered contraception and nicotine replacement products by pharmacists are clear examples where standing orders could be expanded. Moreover, the literature is replete with studies demonstrating the capabilities and benefits of pharmacists to provide these functions in cooperation with the patient's primary care provider. The Task Force believes that the State of Illinois, through its Department of Public Health can and should facilitate these processes and more as opportunities are identified.

> The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder with the following votes:
> **Motion passed. Task Force members voted as follows:**
> **Ayes:** Philip P. Burgess, Helga Brake, Brian H. Kramer, Scott Meyers, Garth Reynolds, Rob Karr, Ryan McCann
> **Nays:**
> **Abstains:** Scott A. Reimers, Tom Stiede, Jayna Brown

Rationale provided by Task Force member Scott Meyers:

The majority of the Task Force believes that moving the responsibility of identifying and establishing specific standing orders that enable pharmacists to provide care, including initiation of specific medications for specific conditions is better accomplished using the expertise of the Illinois Department of Public Health staff with sign-off of the Department's Medical Director. This process has been used before with the standing order that allows pharmacists to dispense naloxone without a prescription. This particular standing order has been broadly implemented across the State and has helped save multiple lives from opioid overdoses. Not to mention raise awareness of the public to this important antidote. Rather than placing specific standing orders within the Pharmacy Practice Act, placing a statement in the Act that places the responsibility of the process on the Department of Public Health and encourages implementation of additional appropriate standing orders, the process becomes extremely responsive to day-to-day needs of the citizens of Illinois. This process is anticipated to include input from and discussion with all interested health-care related parties but would make standing orders much easier to implement, revise and cancel, should the need arise. These standing orders are anticipated to include only services that pharmacists are trained to provide through their formal pharmacy education or with programming that is appropriately accredited for post-graduate training. Participation by pharmacists in these standing orders would be voluntary.

Pharmacy Reimbursement and Pharmacist Remuneration

Task Force Recommendation to appoint a new Task Force on Pharmacy Reimbursement and Pharmacist Remuneration to Improve Patient Care Outcomes and Enhance Patient Safety:

Since 2005, pharmacists must obtain the Doctor of Pharmacy Degree from an accredited College or School of Pharmacy. This education provides the most comprehensive education on the proper use of medications of any type of health care provider in our nation. And yet, pharmacists continue to be reimbursed based on the quantity and sometimes the overall cost of the product they dispense, regardless of the level of services they provide. Pharmacists, as well-trained medication-use experts provide services that have been proven to improve patient care outcomes and enhance patient safety to a greater extent if allowed to practice at their high level of training and education. Compensation for those services will increase the opportunities to provide additional and important services. The Collaborative Pharmaceutical Task Force recommends that the Illinois General Assembly appoint a new Task Force representing Pharmacy, Medicine, insurance providers, and State agencies involved in the provision of and payment for health care services to the citizens of Illinois. This Task Force should discuss revisions to the pharmacy payment model and produce recommendations that include remuneration for services distinct from reimbursement for sales of drug products. Payment for patient care services distinct from payment for products will improve patient care and safety. We have compiled a recommended charge below for this new Task Force.

This new Task Force shall:

1. Identify and review other current and proposed models from State, Federal and private payers, for pharmacist remuneration and pharmacy reimbursement for patient care services consistent with contemporary pharmacist training and education.
2. Identify and recommend necessary legislative and regulatory changes that are needed to ensure that the Illinois Departments of Insurance and Healthcare and Family Services (hereafter referred to as "the Departments") have the authority to assure that the citizens of Illinois have equal and equitable access to patient care services provided by pharmacists and pharmacies.
3. Identify and recommend necessary legislative and regulatory changes that will provide the Departments with the authority to combat medication spread pricing and establish pricing and claim transparency by insurance companies and pharmacy benefit managers (PBMs).
4. Identify and recommend necessary legislative and regulatory changes that will allow the Departments to establish equal and equitable remuneration to pharmacists for the provision of medication-related patient care services currently provided by nurse practitioners and physician assistants.
5. Identify and recommend legislative, regulatory and funding changes needed by the Departments in order to ensure that the existing "any willing provider" provisions of the Insurance Code and Public Aid Code are enforced and ensuring that a patient's right to equal and equitable access to pharmacist and pharmacy services are available across Illinois.

6. Identify and recommend legislative, regulatory, and funding changes necessary so that the Departments are able to investigate and take appropriate action on complaints from the public and the profession in relation to pharmacy benefit managers.
7. Identify and recommend legislative, regulatory, and funding changes that will enable pharmacists and pharmacy providers to maximize medication-related patient safety for the citizens of Illinois.
8. Identify legislative and regulatory changes necessary to facilitate the provision of pharmacist and pharmacy-based services in communities with recognized health disparities, especially those communities that currently have pharmacy and medical deserts.
9. Identify and recommend a new Illinois model for pharmacy reimbursement and pharmacist remuneration that will improve patient outcomes and enhance patient safety for the citizens of Illinois.

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder with the following votes:
Motion passed. Task Force members voted as follows:
Ayes: Philip P. Burgess, Scott Meyers, Helga Brake, Brian H. Kramer, Garth Reynolds, Robb Karr, and Ryan McCann
Nays:
Abstains: Scott A. Reimers, Jayna Brown, and Tom Stiede

Rationale provided by Task Force member Garth Reynolds:

The majority of the Task Force agreed in the recommendation that a new Taskforce is required to examine pharmacist remuneration of services that improve patient care outcomes and enhance patient safety. Most current benefit designs for pharmacy services are solely focused on reimbursement of the dispensing of medication product to the patient. There are many concerns with the current models used to reimburse pharmacies for medication dispensing. Some of the current models jeopardize access to pharmacies in communities throughout Illinois and especially in communities with established health disparities. These models also do not generally recognize the direct patient care services that pharmacists provide patients under their care. The National Governor's Association paper titled, *The Expanding Role of Pharmacists in a Transformed Health Care System*, identifies the role of pharmacists in team-based care and the barriers that need to be addressed.

"The critical role that medication management plays in treating chronic diseases suggests that the integration of pharmacists into chronic-care delivery teams has the potential to improve health outcomes. Studies of pharmacists providing medication therapy management (MTM) services to improve therapeutic outcomes indicate that such services can improve outcomes and reduce costs. Pharmacists typically provide those services in interdisciplinary teams through collaborative practice agreements (CPAs). Such agreements with other health care providers allow a licensed provider to refer patients to a pharmacist and delegate the delivery of clinical services under supervision. Several key challenges and barriers, however, prevent the full integration of pharmacists into health care delivery teams: restrictive laws and regulations governing CPAs, lack of provider recognition in

federal and state law governing compensation of pharmacists who provide direct patient-care services, and limitations on pharmacists' ability to access health information systems."

Studies continue to exhibit the value that pharmacists provide in a team-based health care design beyond the safe dispensing of medication. Pharmacists are highly trained health care providers that are not used to their full potential and scope of practice. A new Taskforce based on the recommendation will enable a needed further discussion and look at models of care that exhibit how pharmacists can improve patient safety and health outcomes.