

Governor's Office of Management and Budget

Alexis Sturm

Director



IL Regulatory Sunset Act Review of The Pharmacy Practice Act

March 22, 2022

**To the Honorable JB Pritzker
Governor of Illinois**

Governor Pritzker:

The Governor's Office of Management and Budget (GOMB), in compliance with the requirements set forth in the Illinois Regulatory Sunset Act (5 ILCS 80), has conducted a review of the Pharmacy Practice Act (225 ILCS 85), which is scheduled to sunset on January 1, 2023. As a result of this review, GOMB makes the following recommendation:

The Pharmacy Practice Act (225 ILCS 85) should be continued with the following modifications to its existing statutory and administrative rule framework:

- Amend the provision pertaining to a pharmacy technician's scope of practice. Currently, a registered pharmacy technician may be delegated to perform any task within the practice of pharmacy if specifically trained for that task, except for patient counseling, drug regimen review, or clinical conflict resolution. The practice of pharmacy includes prescription verification which needs to be verified by a pharmacist before it the prescription drug is dispensed to the patient. The existing provision needs to be amended to clarify the exclusion of the final prescription verification.
- Add a provision requiring pharmacies to report emergency closures of greater than 72 hours to the Department. The Department should be notified of any temporary pharmacy closures as the Department needs to be aware to conduct inspections, handle any complaints, or address any urgent matters related to drugs and patient safety.

GOMB's examination of this Act was conducted considering the nine factors set out in Section 6 of the Illinois Regulatory Sunset Act. The following report details the criteria and data utilized to come to the above recommendation.

Very sincerely and respectfully,

Alexis Sturm
Director
Governor's Office of Management and Budget

Criteria (1) “The extent to which the agency or program has permitted qualified applicants to serve the public.”

As of September 2021, there are 4,389 licensed pharmacists and 32,222 licensed pharmacy technicians in the state of Illinois.

License Type	2017	2018	2019	2020	2021
Registered Pharmacist	4,138	3,924	4,245	4,012	4,389
Pharmacy Technician	35,369	33,512	32,120	39,680	32,222

New Licenses Issued	2017	2018	2019	2020	2021
Registered Pharmacist	809	798	924	903	875
Pharmacy Technician	1,667	1,577	2,104	3,381	8,194

The current licensure fee structure is as follows:

Type	Fee Amount
Application for a license	\$75
Renewal Fee	\$75/year
Restoration After Lapse	\$50 fee, plus all lapsed renewal fees

After prospective pharmacists complete the PharmD program, they must pass two exams to become licensed. These exams are the North American Pharmacist Licensure Exam (NAPLEX) and the Multistate Pharmacy Jurisprudence Exam (MPJE). All 50 states currently license pharmacists. Every state regulates this profession to ensure that pharmacists continue to meet the educational and clinical competencies, as well as continuing education requirements, necessary to provide quality care.

Criteria (2) “The extent to which the trade, business, profession, occupation, or industry being regulated is being administered in a nondiscriminatory manner both in terms of employment and rendering of services.”

IDFPR does not collect information on the gender, race, or ethnicity of licensees. IDFPR has received no complaints citing discrimination in the licensing process, and no external sources have published any information regarding discriminatory practices in licensure.

Criteria (3) “The extent to which the regulatory agency or program has operated in the public interest, and the extent to which its operation has been impeded or enhanced by existing statutes, procedures, and practices of any other department of state government, and any other circumstances, including budgetary resources, and personnel matters.”

IDFPR is tasked with processing applications for licenses and renewal licenses for over one million professionals practicing in the State of Illinois. The Department has adopted internal policies, sought legislative and administrative rule changes, and developed enhanced licensing processes to maintain efficiency and efficacy. Implementation of online, paperless licensing is one example of such a policy that has proved to be successful. While some procedures, such as the disciplinary process for licensees, can be lengthy, this is done to ensure thoroughness and proper due process for complaints against regulated professionals.

Criteria (4) “The extent to which the agency running the program has recommended statutory changes to the General Assembly that would benefit the public as opposed to the persons it regulates.”

P.A. 101-621 (SB 2104 Sen. Jones/Rep. Zalewski) was a comprehensive modernization and 3-year sunset extension of the Pharmacy Practice Act. The legislation contained many provisions seeking to benefit the public, including mandates on pharmacy conditions, access to prescription refills, and advertising and solicitation regulations.

Criteria (5) “The extent to which the agency or program has required the persons it regulates to report to it concerning the impact of rules and decisions of the agency or the impact of the program on the public regarding improved service, economy of service, and availability of service.”

IDFPR establishes rules and makes regulatory decisions through the process established by the Joint Committee on Administrative Rules (JCAR), the administrative body responsible for approving rule proposals by state agencies. This process allows for input from industry and community stakeholders impacted by the Department’s proposed changes. The Department works with lawmakers, community stakeholders and members of industry to ensure that regulations effectively protect Illinois citizens. Rules may be shared with the professional’s boards, associations, and industry prior to being filed. The rulemaking process includes a public comment period after which the Department responds to the comments received during that period.

Criteria (6) “The extent to which persons regulated by the agency or under the program have been required to assess the problems in their industry that affect the public.”

The State Pharmacy Board is composed of licensees and public members and serves in an advisory capacity to the Secretary. The State Board of Pharmacy consists of nine members, seven of whom are licensed pharmacists. Each of those seven members is either a licensed pharmacist in good standing in this State, a graduate of an accredited college of pharmacy, or a Bachelor of Science in Pharmacy with at least five years' experience in the practice of pharmacy after the date of his or her licensure as a pharmacist in the State of Illinois. There are two public members who are not engaged in any way, directly or indirectly, as providers of health care in this State or any other state. Each member is appointed by the governor to serve a five-year term.

Criteria (7) “The extent to which the agency or program has encouraged participation by the public in making its rules and decisions as opposed to participation solely by the persons it regulates and the extent to which such rules and decisions are consistent with statutory authority.”

Promulgated rules are consistent with agency Acts and statutory changes. Decisions made by the agency are based on the Acts and Rules and legislative intent. The Joint Committee on Agency Rule Review reviews rules to ensure that the agency does not exceed their rule-making authority granted to them by the General Assembly. IDFPR adheres to the guidelines and requirements established by the Joint Committee on Administrative Rules (JCAR) and the Illinois General Assembly (ILGA) for approving rule proposals, legislative changes, and internal policies. In addition, the Department adheres to the requirements established in the Illinois Open Meetings Act (5 ILCS 120).

Criteria (8) “The efficiency with which formal public complaints filed with the regulatory agency or under the program concerning persons subject to regulation have been processed to completion, by the executive director of the regulatory agencies or programs, by the Attorney General and by any other applicable department of the State government.”

Complaints made against licensees of IDFPR’s Division of Professional Regulation may be filed via mail, email, or phone to the Division’s Complaint Intake Unit. Complaints are referred to the Division’s Statewide Enforcement Section. After initial review, complaints are assigned to a lead investigator in the Section’s Investigations Unit. The investigator is responsible for determining if IDPR has (1) legal jurisdiction and/or (2) adequate evidence to proceed with any potential violation of a licensing law. After developing facts in cases where there appears to be a

proper legal jurisdiction and adequate evidence, the investigator refers the case to a prosecuting attorney in the Section's Prosecutions Unit. If there is insufficient evidence to indicate a violation of the licensing statute, the investigative file is closed. The investigator also may discover facts that indicate criminal activity which can lead to referral to a county State's Attorney or the Illinois Attorney General.

Complete investigations where there is sufficient evidence of a violation are forwarded to IDPR's prosecuting attorneys' staff for review. After review by a prosecuting attorney, it may be determined that further investigative evidence is needed. If the staff attorney concludes that the matter has been sufficiently investigated and there is evidence supporting the complaint, formal charges are filed. Depending upon the contextual circumstances of the case, IDPR and the licensee may enter into a negotiated agreement regarding the level of discipline to be imposed. Such an agreement would be reduced to writing and presented to the respective professional board or committee for its consideration. The board or committee's recommendation after thorough review is then presented to the Director of Professional Regulation for consideration and approval.

In instances where a formal disciplinary hearing is necessary, a formal complaint is drafted and filed. The hearing is held before the respective professional board or committee and the Department's Administrative Law Judge. The hearing is an administrative law proceeding conducted pursuant to the Illinois Civil Administrative Code and other relevant statutes and rules. After the hearing, the board or committee delivers its findings, conclusions, and recommendations to the Director of Professional Regulation.

Disciplinary action resulting from any enforcement action varies by violation and severity and can include termination of license, revocation, suspension, probation, reprimand, and censure. The license may also be ordered to remain in good standing. In addition, Illinois law allows for the imposition of fines for any of the professions regulated by the Division.

Following a final decision by the Director, the licensee has 35 days to make an appeal in circuit court under the Illinois Administrative Review Act. Investigations referred for criminal prosecution have resulted in numerous criminal convictions. Criminal violations include unlicensed practice of various professions, theft, forgery, unlawful use of weapons, diversions of controlled substances to illegal use and other related offenses.

Between 2016 and 2021, a total of 516 disciplinary actions were taken by the Department involving professions covered by the Pharmacy Practice Act. Some of these disciplines consist of tax problems, child support, continuing education, and unlicensed practice.

Criteria (9) "The extent to which changes are necessary in the enabling laws of the agency or program to adequately comply with the factors listed in this section."

IDFPR recommends the sunset of the Act be extended and that statutory language be modernized to implement more streamlined and efficient regulation of this profession, which will ensure safety and welfare of the public and ease the burden of regulatory compliance. The department's recommendations include:

- Amending the provision pertaining to a pharmacy technician's scope of practice. Currently, a registered pharmacy technician may be delegated to perform any task within the practice of pharmacy if specifically trained for that task, except for patient counseling, drug regimen review, or clinical conflict resolution. The practice of pharmacy includes prescription verification which needs to be verified by a pharmacist before it the prescription drug is dispensed to the patient. The existing provision needs to be amended to clarify the exclusion of the final prescription verification.
- Add a provision requiring pharmacies to report emergency closures of greater than 72 hours to the Department. The Department should be notified of any temporary pharmacy closures as the Department needs to be aware to conduct inspections, handle any complaints, or address any urgent matters related to

drugs and patient safety.

Conclusion:

The practice of pharmacy in the State of Illinois is declared a professional practice affecting the public health, safety and welfare and is subject to regulation and control in the public interest. It is a matter of public interest that only qualified persons be permitted to practice pharmacy in the State of Illinois. GOMB recommends the sunset of the Act be extended and that statutory language modernized to implement more streamlined and efficient regulation of this profession, which will ensure safety and welfare of the public and ease the burden of regulatory compliance. The sunset extension of the Act is necessary to continually ensure that practitioners engage in the practice of pharmacy in a safe and competent manner.