

Governor's Office of Management and Budget

Alexis Sturm

Director



IL Regulatory Sunset Act Review of The Wholesale Drug Distribution Licensing 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 Wholesale Drug Distribution Licensing Act (225 ILCS 120), which is scheduled to sunset on January 1, 2023. As a result of this review, GOMB makes the following recommendation:

The Wholesale Drug Distribution Licensing Act (225 ILCS 120) should be continued with the following modifications to its existing statutory and administrative rule framework:

- Require licensees to provide an email address of record with the Department.
- Allow notice of hearing to be served by mail or email, rather than registered or certified mail.
- Add "virtual distributor" to the definition of Wholesale drug distributor to include a virtual distributor who has title but does not take physical possession of prescription drugs. Make conforming changes to the designated representative requirements and other provisions of the Act. This is proposed in order to identify virtual distributors and specially include them in the Act as virtual distributors are part of the wholesale distribution channel of prescription drugs.
- Make a technical change to the term "third party logistics provider" and change to "third-party logistic provider" throughout the Act for consistency.
- Remove outdated provisions of the Act which do not reflect Department practice.
- Amend the board recommendation process to conform to standardized language and Department practice.
- Add language clarifying the renewal and restoration process.
- Add provisions requiring reports of suspicions orders per the Drug Enforcement Agency's reporting requirements in order to promote patient safety and opioid recovery and treatment for patients.

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 June 2021, there are 1,344 wholesale drug distributors licensed to conduct business in Illinois.

Type	2017	2018	2019	2020	2021
Licensed Wholesale Drug Distributors	1,332	1,471	1,360	1,479	1,344

New Licenses Issued	2017	2018	2019	2020	2021
Licensed Wholesale Distributor	150	139	133	119	99

The current licensure fee structure is as follows:

Type	Fee Amount
Initial Application	\$200
Renewal Fee	\$200/year
Restoration After Lapse	\$230 fee, plus all lapsed renewal fees

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.”

Wholesale Drug Distributor licenses are issued to entities and not individuals, making demographic information not applicable. 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. Further, IDFPR has not received any complaints alleging discrimination by wholesale drug distributors.

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.”

N/A

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.

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."

IDFPR works with stakeholders and members of the industry to provide direct feedback.

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."

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. 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. JCAR reviews rules to ensure that the agency does not exceed their rule-making authority granted to them by the General Assembly. 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 DPR 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 particular 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.

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 in order to implement more streamlined and efficient regulation of this profession. This will ensure safety and welfare of the general public and ease the burden of regulatory compliance.

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- Allow notice of hearing to be served by mail or email, rather than registered or certified mail.
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Conclusion:

Wholesale Distributors are regulated so that no person or entity can make or distribute prescription drugs in any state unless that person or entity is licensed by the state in accordance with federally prescribed minimum standards, terms, and conditions as set forth in guidelines issued by the United States Food and Drug Administration. If the Wholesale Distributor Act were to sunset and become deregulated, any person or entity would be able to distribute/sell prescription drugs to anyone without any oversight or regulation. This would pose a threat to public health and safety as the drugs could be misused, expired, or abused.