Senate Fiscal Agency
P.O. Box 30036
Lansing, Michigan 48909-7536

BILL ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986

Senate Bill 630 (Substitute S-2)
Sponsor: Senator John Bizon, M.D.
Committee: Health Policy and Human Services

Date Completed: 3-11-20

CONTENT

The bill would amend the Public Health Code to do the following:

- **Require a wholesale distributor-broker doing business in the State to be licensed by the Department of Licensing and Regulatory Affairs (LARA), but specify that licensure would not be required for a qualified pharmacy.**
- **Specify that a pharmacy only could deliver or trade a drug or device salable on prescription only that it received from certain specified entities.**
- **Prohibit a drug salable on prescription only from being delivered or traded between pharmacies, or between a pharmacy and a qualified pharmacy, unless certain requirements were met.**
- **Require an applicant for licensure as a wholesale distributor-broker to demonstrate to the Board of Pharmacy's satisfaction that the applicant facilitated deliveries or trades for at least 500 qualified pharmacies that were each licensed and in good standing in the state of licensure.**
- **Require a wholesale distributor-broker to provide a transaction history, transaction statement, or transaction information to a pharmacy purchasing a drug or device through the wholesale distributor-broker under certain circumstances.**
- **Require a wholesale distributor-broker that received notice that a delivery of trade it facilitated involved a drug or device salable on prescription only that was a suspect or illegitimate product to notify certain specified entities.**
- **Prescribe certain application and license fees for a wholesale distributor-broker.**
- **Require the Board to grant a license to a wholesale distributor-broker that met the requirements for licensure.**
- **Require a wholesale distributor-broker to designate a pharmacist in charge (PIC).**
- **Require an individual who submitted an application for a new wholesale distributor-broker license to provide fingerprints for a criminal history check.**
- **Allow the Department to prescribe grounds for disciplinary action against a licensed wholesale distributor-broker or an applicant for licensure.**
- **Modify certain fees for practices regulated under Part 177 (Pharmacy Practice and Drug Control).**

Wholesale Distributor-Broker Licensure

The Code specifies that in order to do business in Michigan, a pharmacy, manufacturer, or wholesale distributor, whether or not located in the State, must be licensed under Part 177.

Under the bill, this provision also would apply to a wholesale distributor-broker, but would not apply to a qualified pharmacy.

The bill would define "wholesale distributor-broker" as a person that meets both of the following:

-- The person facilitates the delivery or trade of a drug or device salable on prescription only, other than a controlled substance, between pharmacies, or between a pharmacy and a qualified pharmacy as that term is defined in the bill, for the purpose of filling a prescription for an identified patient.
-- The person does not take possession or ownership of a drug or device salable on prescription only or coordinate warehousing of the drug or device.

"Qualified pharmacy" would mean an out-of-State pharmacy that meets the requirement specified below. "Out-of-State pharmacy" would mean a facility or part of a facility that is located outside of Michigan and that dispenses prescription drugs or prepares prescription drugs for delivery or distribution under the laws of the state in which it is located.

Under the bill, an out-of-State pharmacy that was not licensed under Part 177 could deliver or trade a drug or device salable on prescription only to a person located in the State only if the pharmacy met both of the following requirements:

-- It held a license in good standing as a pharmacy from the state in which it was located.
-- It used a wholesale distributor-broker that was licensed in Michigan to facilitate the transaction.

Except as otherwise provided, a pharmacy only could deliver or trade a drug or device salable on prescription only that it received from one or more of the following:

-- A manufacturer.
-- A wholesale distributor.
-- A pharmacy.
-- A qualified pharmacy.

A drug salable on prescription only could not be delivered or traded between pharmacies, or between a pharmacy and a qualified pharmacy, unless all of the following were met:

-- The pharmacy or qualified pharmacy from which the drug was being obtained received a request for the drug that identified its brand name or generic name, lot number, expiration date, quality, quantity, and size.
-- The drug was approved by the U.S. Food and Drug Administration (FDA).
-- The drug was not expired at the time of the delivery or trade.
-- Before delivering or trading the drug, the pharmacy or qualified pharmacy from which the drug was being obtained confirmed with the pharmacy or qualified pharmacy receiving the drug that it was available for delivery or trade.
-- The pharmacy or qualified pharmacy from which the drug was being obtained included with it a packaging checklist, confirming that the drug being delivered or traded matched the information identified on the request for the drug.
-- The delivery or trade was intended to fill a prescription for an identified patient, if one of the pharmacies involved in the delivery or trade were a qualified pharmacy.
-- The drug was delivered or traded in the original manufacturer's packaging, whether sealed or unsealed, with the drug's national drug code, lot number, and expiration date conspicuously identified on the packaging.

If the original manufacturer's packaging were unsealed at the time of the delivery or trade, the delivery or trade could include a quantity of the drug that was less than the quantity contained in the original manufacturer's packaging.

A wholesale distributor-broker would not be subject to disciplinary action under Part 177 or liable in a civil action for personal injury or death resulting from a drug or device salable on prescription only that was delivered or traded by a pharmacy or qualified pharmacy, regardless of whether the wholesale distributor-broker was subject to disciplinary action.

To receive a license as a wholesale distributor-broker, an applicant would have to meet the requirements for licensure established by the Board of Pharmacy by rule under Section 17767. The rules would have to require the applicant to demonstrate to the Board's satisfaction, at the time of the application for initial licensure, the applicant facilitated deliveries or trades for at least 500 qualified pharmacies that each were licensed in good standing in their state of licensure. If the number of qualified pharmacies with which a wholesale distributor-broker facilitated deliveries and trades fell below 500, the wholesale distributor-broker could continue to do business in the State. However, a wholesale distributor-broker seeking renewal of its license would have to, in addition to meeting any requirements for renewal under Section 16201, demonstrate to the Board's satisfaction that the wholesale distributor-broker facilitated deliveries and trades for at least 500 qualified pharmacies at the time of license renewal.

A wholesale distributor-broker would have to provide a transaction history, transaction statement, or transaction information to a pharmacy purchasing a drug or device from a pharmacy or qualified pharmacy through the wholesale distributor-broker if either of the following were met:

-- Federal law required that the transaction history, transaction statement, or transaction information be provided to the pharmacy.
-- If the qualified pharmacy provided the transaction history, transaction statement, or transaction information to the wholesale distributor-broker, and it received a request for the document from the purchasing pharmacy.

"Transaction history", "transaction statement" and "transaction information" would mean those terms as defined under Federal law.

A wholesale distributor-broker that received a document described above would have to retain it for at least seven years.

A wholesale distributor-broker that received notification from a pharmacy or qualified pharmacy that a delivery or trade facilitated by the wholesale distributor-broker involved a drug or device salable on prescription only that was a suspect product or illegitimate product would have to notify each of the following immediately:

-- The Department of Licensing and Regulatory Affairs.
-- The FDA.
-- Each pharmacy that received the product from the pharmacy or qualified pharmacy.

"Suspect product" and "illegitimate product" would mean those terms as defined in 21 USC 360eee. (That section defines "suspect product" as a product for which there is reason to believe that the product: a) is potentially counterfeit, diverted, or stolen; b) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; c) is potentially the subject of fraudulent transaction; or d) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. "Illegitimate product" means a product for which credible evidence shows that the product: a) is counterfeit, diverted, or stolen; b) is

intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; c) is the subject of fraudulent transaction; or d) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.)

Before facilitating the delivery or trade of a drug or device salable on prescription only to a pharmacy, the wholesale distributor-broker would have to notify the pharmacy, in writing, that the wholesale distributor-broker will not examine the drug or device for quality or accuracy before the pharmacy received it.

A wholesale distributor-broker could not facilitate the delivery or trade of a drug or device salable on prescription only between a pharmacy and a qualified pharmacy unless both of the following were met:

-- The pharmacy's or qualified pharmacy's license was in good standing in its state of licensure.
-- The wholesale distributor-broker had, for the year in which the delivery or trade would occur, received from the pharmacy and qualified pharmacy a signed attestation that the pharmacy or qualified pharmacy held a license in good standing in its state of licensure and was in compliance with all applicable Federal and State laws.

The wholesale distributor-broker would have to make an attestation received available to the Department on request.

A wholesale distributor-broker would have to cooperate with LARA if it were investigating a transaction involving the wholesale distributor-broker or a qualified pharmacy with which the wholesale distributor-broker facilitated transactions.

License Fees

Section 16333 of the Code prescribes certain fees for a person licensed or seeking licensure to engage in the practice of pharmacy or other practices regulated under Part 177, including a $20 application fee for drug control and pharmacist and $25 application fee for a pharmacy technician and pharmacy. Under the bill, those fees would increase to $75.

An individual licensed or seeking licensure as a manufacturer or wholesaler must pay a $50 application processing fee and an annual $25 license fee. Under the bill, the application fee would increase to $75. The bill also would refer to "wholesale distributor" instead of "wholesaler".

Additionally, the bill would prescribe a $50 application processing fee and an annual $25 license fee for a wholesale distributor-broker.

Board of Pharmacy

In addition to the functions set forth in Part 161, the Board must, among other things, grant a license to a manufacturer or a wholesale distributor of prescription drugs who meets the requirements for a license. Instead, under the bill, the Board would have to grant a license to a manufacturer, wholesale distributor, or wholesale distributor-broker that met the requirement for a license.

The Code allows the Board to promulgate rules and make determinations necessary or appropriate to the licensing of pharmacists, drugs, dispensers, manufacturers, and wholesalers. The bill would refer to "wholesale distributor" instead of wholesaler. Additionally, under the bill, the Board could promulgate rules and make determinations necessary or appropriate to the licensing of wholesale distributor-brokers.

Disclosure

The Board may require an applicant or the holder of a pharmacy, manufacturer's, or wholesale distributor's license to fully disclose the identity of each partner, stockholder, officer, or member of the board of directors of the pharmacy, manufacturer, or wholesale distributor, as applicable. Under the bill, the Board also could require an applicant or holder of a wholesale distributor-broker license to disclosure the identity of each partner, stockholder, officer, or member of the board of directors.

Pharmacist in Charge

The Code requires, except as otherwise provided, a wholesale distributor to designate a pharmacist licensed in or outside of Michigan as the PIC for the wholesale distributor or must designate an employee with the appropriate education or experience, or both, to assume responsibility for compliance with licensing requirements as facility manager for the wholesale distributor.

The pharmacy, manufacturer, or wholesale distributor, and the individual designated as the PIC or the facility manager are jointly responsible for the pharmacy's manufacturer's, or wholesale distributor's compliance with Part 177 and promulgated rules.

A person that is a manufacturer or wholesale distributor with respect to a device salable on prescription only but not with respect to any drug salable on prescription only is exempt from these requirements.

Under the bill, these requirements also would apply to a wholesale distributor-broker. Also, a person that was a wholesale distributor-broker with respect to a device salable on prescription only but not with respect to any drug salable on prescription only would be exempt from the requirements.

The Code requires a pharmacy, manufacturer, or wholesale distributor to report to LARA a change in ownership, management, location, or it designated PIC or facility within 30 days after the change occurs. Under the bill, this requirement also would apply to a wholesale distributor-broker.

Criminal History Check

Under the Code, except as otherwise provided, fingerprints for the following individuals must be submitted with an application for a new pharmacy, manufacturer, or wholesale distributor license in the same manner as required in Section 16174 for the purpose of a criminal history check:

-- An individual who is not a health professional licensed or otherwise authorized to engage in a health profession, or who is a health professional but was licensed or otherwise authorized to engage in his or her profession before October 1, 2008, if the application is from the individual.
-- All partners and any individual who will manage the day-to-day operations of the new pharmacy, manufacturer, or wholesale distributor, if the application is from a partnership.
-- Any individual who will manage the day-to-day operations of the new pharmacy, manufacturer, or wholesale distributor, if the application is from a privately held corporation that in the aggregate owns fewer than 75 pharmacies, manufacturers, or wholesale distributors on the date the corporation submits its license application.

The fingerprinting requirement does not apply if a criminal history check that meets the requirements of Section 16174 has been obtained for the individuals within the two years preceding the date of the application for a new pharmacy, manufacturer, or wholesale

distributor license. To qualify for this exception, an applicant must submit proof of the previous criminal history check for each individual listed above, as applicable, with the application. If LARA or the Board of Pharmacy determines that a criminal history check for an individual does not meet the requirements of Section 16174 or was not obtained within the prescribed time period, fingerprints must be submitted for that individual.

Under the bill, these provisions also would apply to an individual who submitted an application for a new wholesale distributor-broker license.

(Under Section 16174 of the Public Health Code, an applicant for licensure or registration to engage in a health profession must submit his or her fingerprints to the Michigan Department of State Police (MSP) to have a criminal history check conducted, and request the MSP to forward his or her fingerprints to the Federal Bureau of Investigation to determine the existence of any national criminal history pertaining to the applicant. The MSP must give LARA a written report of the check if it contains any criminal history record information, and must forward the results of the FBI determination to LARA within 30 days after the request is made. The Department of Licensing and Regulatory Affairs must notify the applicable board and the applicant of the type of crime disclosed in the FBI determination without disclosing the details of the crime. The MSP may charge a reasonable fee to cover the cost of conducting the criminal history check.)

Disciplinary Action

Part 161 (General Provisions) of Article 15 (Occupations) of the Code prescribes grounds for disciplinary action against a licensed or registered health professional or an applicant for licensure or registration. The Department must investigate any allegation that one or more of the listed grounds exists. After its investigation, LARA must provide a copy of the administrative complaint to the appropriate disciplinary subcommittee.

In a manner consistent with Part 161, a disciplinary subcommittee may fine, reprimand, or place on probation a person licensed under this part, may deny, limit, suspend, or revoke a person's license, or may order restitution or community service for a violation of Part 161 or rules promulgated under Part 161.

In addition to the grounds set forth above, and in a manner consistent with Part 161, the Board may fine, reprimand, or place on probation a person licensed under Part 177, may deny, limit, suspend, or revoke a license issued under Part 177, or may order restitution or community service if the Board finds that any of the listed grounds apply to an applicant; a partner, officer, or member of the board of directors of a pharmacy, manufacturer, or wholesale distributor licensed under this Part; a stockholder of a pharmacy, manufacturer, or wholesale distributor that is a privately held corporation licensed under this part; or a facility manager for a wholesale distributor.

The Board also could fine, reprimand, or place on probation a person licensed under Part 177, could deny, limit, suspend, or revoke a license issued under Part 177, or could order restitution or community service if the Board found that any of the listed grounds applied to a wholesale distributor-broker.

Applicability

The Code specifies that Part 161 applies to health professions, but, except for 16201, 16261, 16299, 16301, 16303, 16305, and 16307, does not apply to a pharmacy, a dispensing prescriber, a drug manufacturer, or a wholesaler who is regulated by Part 177. The bill would refer to "wholesale distributor" instead of "wholesaler". Additionally, Part 161 would not apply to a wholesale distributor-broker.

(Section 16201 requires a licensee or registrant to renew a license or registration on or before the expiration date, and prescribes the process for renewal. Section 16261 prohibits an individual who is not licensed or registered under the Code from using an insignia, title, or letter, among other things for the purpose of inducing belief that the individual is licensed or registered under the Code. Section 16299 prescribes the penalty for a person who violates or aids or abets another in a violation of the Code. Section 16301 requires fees for licenses and registrations, among other services performed by LARA, to be prescribed in the Code. Section 16303 requires each application for a license or registration under the Code to be accompanied by a nonrefundable application processing fee. Section 16305 provides that an individual who is required to take an examination must pay an examination fee, among other things. Section 16307 requires a person to pay the license or registration fee before issuance of a license or registration.)

MCL 333.16111 et al.

Legislative Analyst: Stephen Jackson

FISCAL IMPACT

The bill would not have a significant fiscal impact on the Department of Licensing and Regulatory Affairs and would have no fiscal impact on local units of government. The Department estimates that fewer than ten wholesalers would be eligible for the proposed license. The fees set in the bill would be sufficient to cover the implementation and administration of the licensing program. Fines resulting from violations of the bill's provisions would be deposited into the Health Professions Regulatory Fund. The magnitude of these fines would depend upon the judgment of the disciplinary board.

Fiscal Analyst: Elizabeth Raczkowski

SAS\S1920\s630sb