

WHOLESALE DISTRIBUTOR-BROKERS

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Senate Bill 630 (S-3) as passed by the Senate
Sponsor: Sen. John Bizon, M.D.
House Committee: Health Policy
Senate Committee: Health Policy and Human Services
Complete to 6-1-20

Analysis available at
<http://www.legislature.mi.gov>

SUMMARY:

Senate Bill 630 would amend Part 161 (General Provisions) and Part 177 (Pharmacy Practice and Drug Control) of Article 15 (Occupations) of the Public Health Code to license and regulate *wholesale distributor-brokers* in this state. The bill would extend to wholesale distributor-brokers many of the provisions of Part 177 that apply to wholesale distributors, including disclosure rules, compliance with the code, and certain licensure requirements.

Wholesale distributor-broker would mean a person that meets both of the following:

- The person facilitates the delivery or trade of a drug or device that can be sold only by prescription (other than a controlled substance) between pharmacies, or between a pharmacy and a *qualified pharmacy*, for the purpose of filling a prescription for an identified patient.
- The person does not take possession or ownership of a drug or device that can be sold only by prescription or coordinate warehousing of the drug or device.

Qualified pharmacy would mean an out-of-state pharmacy that is not licensed as a pharmacy under the code and that meets both of the following requirements:

- Holds a license in good standing as a pharmacy from the state in which it is located.
- Uses a wholesale distributor-broker licensed in Michigan to facilitate the delivery or trade to a person in Michigan of a drug or device that can be sold only by prescription.

A qualified pharmacy could deliver or trade a drug or device that can be sold only by prescription to a person in Michigan only in compliance with the above.

Requirements for facilitation of delivery or trade

Generally, a pharmacy using a wholesale distributor-broker could only deliver or trade a drug or device that can be sold only by prescription that was received from a manufacturer, a wholesale distributor, or—as long as it met the following requirements—a pharmacy or qualified pharmacy. Such a drug could be delivered or traded between pharmacies, or between a pharmacy and a qualified pharmacy using a wholesale distributor-broker, only as long as the following conditions are met:

- The pharmacy or qualified pharmacy from which the drug is being obtained receives a request for the drug listing specific information.

- The drug is approved by the U.S. Food and Drug Administration.
- The drug is not expired at the time of delivery or trade.
- The drug is not a controlled substance.
- Before delivery or trade, the pharmacy or qualified pharmacy from which the drug is being obtained confirms with the pharmacy or qualified pharmacy receiving the drug that the drug is available.
- A packaging checklist is included with the drug, confirming that it meets the description in the request.
- The drug is in its original packaging. If the drug is unsealed, the delivery or trade may include a lesser quantity than was in the original packaging. However, there is a limit of one unsealed or partial quantity of the drug during any consecutive 90-day period.
- If one of the pharmacies is a qualified pharmacy, the delivery or trade is intended to fill a prescription for an identified patient.

Additionally, a wholesale distributor-broker could facilitate a delivery or trade of a drug or device that can be sold only by prescription between a pharmacy and a qualified pharmacy only if both of the following conditions are met:

- The pharmacy's or qualified pharmacy's license is in good standing and the wholesale distributor-broker has no knowledge of pending disciplinary action.
- For the quarter in which the delivery or trade will occur, the wholesale distributor-broker has a signed attestation that the pharmacy or qualified pharmacy is in compliance with applicable federal and state laws (to be made available upon request of the Department of Licensing and Regulatory Affairs (LARA)).

Before facilitating the delivery or trade of a drug or device that can be sold only by prescription to a pharmacy, the wholesale broker would have to notify a recipient pharmacy that it will not examine the drug or device for quality or accuracy.

Liability

The bill would exempt a wholesale distributor-broker from civil liability for personal injury or death resulting from a drug or device delivered or traded by a pharmacy or qualified pharmacy as described above, regardless of whether the wholesale distributor-broker was subject to disciplinary action, as long as the wholesale distributor-broker's actions did not amount to gross negligence.

Licensure as a wholesale distributor-broker

To be licensed as a wholesale distributor-broker, an applicant would have to meet the requirements established by LARA in consultation with the Board of Pharmacy by rule. The rules would have to require an applicant to show that it facilitates deliveries or trades with at least 50 licensed qualified pharmacies. That number could fall below 50, but would have to be at least 50 at the time of any renewal.

Required documentation and notice

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 if the Drug Supply Chain Act requires that documentation

or if the qualified pharmacy provided that documentation and the purchasing pharmacy requests it. Wholesale distributor-brokers would have to retain such documents for at least seven years.

Upon notification that a facilitated product is suspect or illegitimate, the bill would require wholesale distributor-brokers to notify state and federal authorities, as well as all pharmacies that received the product.

Additionally, a wholesale distributor-broker would have to cooperate if LARA was investigating a transaction involving the wholesale distributor-broker or a qualified pharmacy with which the wholesale distributor-broker facilitates transactions.

License of a pharmacy as a wholesale distributor or manufacturer

Under the bill, a pharmacy would have to obtain a wholesale distributor license if the total number of dosage units of all prescription drugs distributed by the pharmacy to a person during any consecutive 12-month period was more than 5% of the number of dosage units of prescription drugs it distributed and dispensed during that period.

A pharmacy would have to obtain a manufacturer license if the number of dosage units of all prescription drugs prepared or compounded by the pharmacy for resale, compounding, or dispensing by another person during any consecutive 12-month period was more than 5% of the number of dosage units of prescription drugs it prepared during that period.

Fees

The bill would increase the application processing fees associated with the practice of pharmacy and other related practices as follows:

License	Current fee	Proposed fee
Pharmacist	\$20	\$75
Pharmacy	\$35	\$75
Drug Control	\$20	\$75
Manufacturer, wholesale distributor, or wholesale distributor-broker	\$50	\$75
Pharmacy technician	\$25	\$75

The bill would set the annual license fee for a wholesale distributor-broker at \$25.

Part 161 Applicability

Finally, the bill would provide that the General Provisions part of Article 15 would not, with limited exceptions, apply to wholesale distributor-brokers, as is current law with regard to pharmacies, dispensing prescribers, drug manufacturers, and wholesalers (wholesale distributors) regulated under Part 177.

MCL 333.16111 et seq. and proposed MCL 333.17748e and 333.17748f

FISCAL IMPACT:

Senate Bill 630 would have an indeterminate fiscal impact on the Department of Licensing and Regulatory Affairs (LARA). The bill would increase application processing fees from \$20 to \$75 for pharmacists; from \$35 to \$75 for pharmacies; from \$20 to \$75 for drug control; from \$50 to \$75 for manufacturers, wholesale distributors, and wholesale distributor-brokers; and from \$25 to \$75 for pharmacy technicians. The bill would require LARA to grant licenses to wholesale distributor-brokers and would also set annual license fees for wholesale distributor-brokers at \$25. The net fiscal impact from licensing and regulating wholesale distributor-brokers is presently indeterminate.

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.