

**SUBSTITUTE FOR
SENATE BILL NO. 630**

A bill to amend 1978 PA 368, entitled "Public health code," by amending sections 16111, 16333, 17705, 17706, 17707, 17709, 17722, 17742, 17748, 17767, and 17768 (MCL 333.16111, 333.16333, 333.17705, 333.17706, 333.17707, 333.17709, 333.17722, 333.17742, 333.17748, 333.17767, and 333.17768), section 16111 as amended by 2006 PA 392, section 16333 as amended by 2014 PA 285, section 17705 as amended by 1986 PA 304, section 17706 as amended by 2014 PA 280, sections 17707, 17709, 17722, 17742, 17748, and 17768 as amended by 2020 PA 4, and section 17767 as amended by 1993 PA 79, and by adding sections 17748e and 17748f.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 Sec. 16111. (1) This part applies to health professions, but,



1 except for sections 16201, 16261, 16299, 16301, 16303, 16305, and
2 16307, ~~16309, and 16313,~~ does not apply to ~~a~~ **any of the following**
3 **regulated under part 177:**

- 4 (a) A pharmacy. ~~r~~
- 5 (b) A dispensing prescriber. ~~r or~~
- 6 (c) A drug manufacturer. ~~or wholesaler who is regulated by~~
7 ~~part 177.~~
- 8 (d) A wholesale distributor.
- 9 (e) A wholesale distributor-broker.

10 (2) Except as otherwise provided by this article, this part
11 controls over all other parts in this article.

12 (3) A part in this article does not prohibit a licensee under
13 another part or other law of this state from performing activities
14 and using designated titles authorized by a license issued to him
15 or her under that other part or other law of this state.

16 (4) A part in this article does not prohibit a registrant
17 under another part or other state law from using designated titles
18 authorized by a registration issued to him or her under that other
19 part or other state law.

20 (5) This article ~~shall~~ **does** not prohibit a licensee from
21 advising a patient to seek professional services or advice from
22 another person.

23 Sec. 16333. Fees for a person licensed or seeking licensure to
24 engage in the practice of pharmacy or other practices regulated
25 under part 177 are as follows:

26	(a) Application processing fees:	
27	(i) Pharmacist.....	\$ 20.00
28		75.00



1	(ii)	Pharmacy.....	35.00
2			75.00
3	(iii)	Drug control.....	20.00
4			75.00
5	(iv)	Manufacturer, or wholesaler wholesale distributor,	50.00
6		or wholesale distributor-broker.....	75.00
7	(v)	Pharmacy technician.....	25.00
8			75.00
9	(b)	Examination fees:	
10		Jurisprudence examination.....	30.00
11	(c)	License fees, per year:	
12	(i)	Pharmacist.....	30.00
13	(ii)	Pharmacy.....	50.00
14	(iii)	Drug control.....	15.00
15	(iv)	Manufacturer, or wholesaler wholesale distributor,	
16		or wholesale distributor-broker.....	25.00
17	(v)	Pharmacy technician.....	30.00
18	(d)	Temporary license for pharmacist.....	25.00
19	(e)	Limited license for pharmacist, per year...	15.00
20	(f)	Temporary license for pharmacy technician..	15.00
21	(g)	Limited license for pharmacy technician,	
22		per year.....	10.00

23 Sec. 17705. (1) "Label" means a display of written, printed,
24 or graphic matter on the immediate container of a drug or device,
25 but does not include package liners. A requirement made by or under
26 authority of this part that a word, statement, or other information
27 appear on the label is not complied with unless the word,
28 statement, or other information appears on the outside container or
29 wrapper of the retail package of the drug or device as displayed



1 for sale or is easily legible through an outside container or
2 wrapper.

3 (2) "Labeling" means the labels and other written, printed, or
4 graphic matter on a drug or device or its container or wrapper, or
5 accompanying the drug or device.

6 (3) "License" in addition to the definition in section 16106
7 means a pharmacy license, drug control license, or a manufacturer,
8 ~~or~~ wholesale distributor, **or wholesale distributor-broker** of drugs
9 or devices license.

10 Sec. 17706. (1) "Manufacturer" means a person that prepares,
11 produces, derives, propagates, compounds, processes, packages, or
12 repackages a drug or device salable on prescription only, or
13 otherwise changes the container or the labeling of a drug or device
14 salable on prescription only, and that supplies, distributes,
15 sells, offers for sale, barter, or otherwise disposes of that drug
16 or device and any other drug or device salable on prescription
17 only, to another person for resale, compounding, or dispensing.
18 **Manufacturer does not include a pharmacy unless the pharmacy meets**
19 **the requirements described in section 17748f.**

20 (2) "Official compendium" means the United States
21 ~~pharmacopoeia~~ **Pharmacopoeia** and the ~~national formulary,~~ **National**
22 **Formulary**, or the ~~homeopathic pharmacopoeia~~ **Homeopathic**
23 **Pharmacopoeia** of the United States, as applicable. If an official
24 compendium is revised after ~~the effective date of the amendatory~~
25 ~~act that added this sentence,~~ **September 30, 2014**, the department
26 shall officially take notice of the revision. Within 30 days after
27 taking notice of the revision, the department, in consultation with
28 the board, shall decide whether the revision continues to protect
29 the public health as it relates to the manner that the official



1 compendium is used in this act. If the department, in consultation
2 with the board, decides that the revision continues to protect the
3 public health, the department may issue an order to incorporate the
4 revision by reference. If the department issues an order under this
5 subsection to incorporate the revision by reference, the department
6 shall not make any changes to the revision.

7 (3) "Outsourcing facility" means that term as defined in 21
8 USC 353b.

9 Sec. 17707. (1) "Parent pharmacy" means a pharmacy that
10 operates a remote pharmacy through a telepharmacy system.

11 (2) "Personal charge" means the immediate physical presence of
12 a pharmacist or dispensing prescriber.

13 (3) "Pharmacist" means an individual licensed under this
14 article to engage in the practice of pharmacy.

15 (4) "Pharmacist in charge" or "PIC" means the pharmacist who
16 is designated by a pharmacy, manufacturer, ~~or~~ wholesale
17 distributor, **or wholesale distributor-broker** as its pharmacist in
18 charge under section 17748(2).

19 (5) "Pharmacist intern" or "intern" means an individual who
20 satisfactorily completes the requirements set forth in rules
21 promulgated by the department in consultation with the board and is
22 licensed by the board for the purpose of obtaining instruction in
23 the practice of pharmacy from a preceptor approved by the board.

24 (6) "Pharmacy" means a facility or part of a facility that is
25 licensed under this part to dispense prescription drugs or prepare
26 prescription drugs for delivery or distribution. Pharmacy does not
27 include the office of a dispensing prescriber or an automated
28 device. For the purpose of a duty placed on a pharmacy under this
29 part, "pharmacy" means the person to which the pharmacy license is



1 issued, unless otherwise specifically provided.

2 (7) "Pharmacy technician" means an individual who is required
3 to hold a health profession subfield license under this part to
4 serve as a pharmacy technician.

5 (8) "Practice of pharmacy" means a health service, the
6 clinical application of which includes the encouragement of safety
7 and efficacy in the prescribing, dispensing, administering, and use
8 of drugs and related articles for the prevention of illness, and
9 the maintenance and management of health. Practice of pharmacy
10 includes the direct or indirect provision of professional functions
11 and services associated with the practice of pharmacy. Professional
12 functions associated with the practice of pharmacy include the
13 following:

14 (a) The interpretation and evaluation of the prescription.

15 (b) Drug product selection.

16 (c) The compounding, dispensing, safe storage, and
17 distribution of drugs and devices.

18 (d) The maintenance of legally required records.

19 (e) Advising the prescriber and the patient as required as to
20 contents, therapeutic action, utilization, and possible adverse
21 reactions or interactions of drugs.

22 Sec. 17709. (1) "Sign" means to affix one's signature manually
23 to a document or to use an electronic signature when transmitting a
24 prescription electronically.

25 (2) "Sterile pharmaceutical" means a dosage form of a drug
26 that is essentially free from living microbes and chemical or
27 physical contamination to the point at which it poses no present
28 risk to the patient, in accordance with USP standards. As used in
29 this subsection, "dosage form" includes, but is not limited to,



1 parenteral, injectable, and ophthalmic dosage forms.

2 (3) "Substitute" means to dispense, without the prescriber's
3 authorization, a different drug in place of the drug prescribed.

4 (4) "Surveillance system" means a real-time, continuous audio
5 and visual camera system that connects a pharmacist at a parent
6 pharmacy with a remote pharmacy for the purposes of providing
7 oversight and security surveillance.

8 (5) "Telepharmacy system" means an interoperable computer
9 system that meets all of the following requirements:

10 (a) Shares real-time data and uses a real-time audio and video
11 link to connect a pharmacist at a parent pharmacy with a remote
12 pharmacy operated by the parent pharmacy.

13 (b) Uses a camera that is of sufficient quality and resolution
14 to allow a pharmacist at a parent pharmacy who is reviewing a
15 prescription to visually identify the markings on tablets and
16 capsules at the remote pharmacy.

17 (6) "USP standards" means the pharmacopeial standards for drug
18 substances, dosage forms, and compounded preparations based on
19 designated levels of risk as published in the official compendium.

20 (7) "Wholesale distributor" means a person, other than a
21 manufacturer ~~, who~~ **or wholesale distributor-broker, that** supplies,
22 distributes, sells, offers for sale, barter, or otherwise disposes
23 of, to other persons for resale, compounding, or dispensing, a drug
24 or device salable on prescription only that the distributor has not
25 prepared, produced, derived, propagated, compounded, processed,
26 packaged, or repackaged, or otherwise changed the container or the
27 labeling of the drug or device. **A wholesale distributor does not**
28 **include a pharmacy unless the pharmacy meets the requirements of**
29 **section 17748f.**



1 (8) "Wholesale distributor-broker" means a person that meets
2 both of the following:

3 (a) The person facilitates the delivery or trade of a drug or
4 device salable on prescription only, other than a controlled
5 substance, between pharmacies, or between a pharmacy and a
6 qualified pharmacy as that term is defined in section 17748e, for
7 the purpose of filling a prescription for an identified patient.

8 (b) The person does not take possession or ownership of a drug
9 or device salable on prescription only or coordinate warehousing of
10 the drug or device.

11 Sec. 17722. In addition to the functions set forth in part
12 161, except as otherwise provided in this part, the board shall **do**
13 **the following:**

14 (a) Regulate, control, and inspect the character and standard
15 of pharmacy practice and of drugs and devices manufactured,
16 distributed, prescribed, dispensed, administered, or issued in this
17 state and procure samples and limit or prevent the sale of drugs
18 and devices that do not comply with this part.

19 (b) Prescribe minimum criteria for the use of professional and
20 technical equipment and references in the compounding and
21 dispensing of drugs and devices.

22 (c) Grant a pharmacy license for each separate place of
23 practice in which the compounding or dispensing of prescription
24 drugs or devices, or both, or the receiving of prescription orders
25 in this state is to be conducted.

26 (d) Grant a drug control license for the place of practice of
27 a dispensing prescriber who meets the requirements for the license.

28 (e) Grant a license to a manufacturer, ~~or a~~ wholesale
29 distributor, ~~of prescription drugs who~~ **or wholesale distributor-**



1 **broker that** meets the requirements for the license.

2 Sec. 17742. (1) The board may require an applicant or the
3 holder of a pharmacy, manufacturer's, ~~or~~ wholesale distributor's,
4 **or wholesale distributor-broker's** license to fully disclose the
5 identity of each partner, stockholder, officer, or member of the
6 board of directors of the pharmacy, manufacturer, ~~or~~ wholesale
7 distributor, **or wholesale distributor-broker**, as applicable.

8 (2) As used in this section and sections 17742a, 17748,
9 17748a, **17748e**, and 17768, "applicant" means a person applying for
10 a pharmacy, manufacturer's, ~~or~~ wholesale distributor's, **or**
11 **wholesale distributor-broker's** license under this article.

12 Applicant includes only 1 or more of the following:

13 (a) An individual, if the person applying is an individual.

14 (b) All partners, including limited partners, if the person
15 applying is a partnership.

16 (c) All stockholders, officers, and members of the board of
17 directors, if the person applying is a privately held corporation.

18 Sec. 17748. (1) ~~To~~**Except for a qualified pharmacy as that**
19 **term is defined in section 17748e**, to do business in this state, a
20 pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale**
21 **distributor-broker**, whether or not located in this state, must be
22 licensed under this part. To do business in this state, a person
23 that provides compounding services must be licensed as a pharmacy
24 or manufacturer under this part and, if a pharmacy, authorized to
25 provide compounding services under this section and sections 17748a
26 and 17748b. To do business in this state, an outsourcing facility
27 must be licensed as a pharmacy under this part. Licenses are
28 renewable biennially.

29 (2) Except for a remote pharmacy, a pharmacy shall designate a



1 pharmacist licensed in this state as the pharmacist in charge for
 2 the pharmacy. For a remote pharmacy, the pharmacist designated as
 3 the pharmacist in charge of the parent pharmacy shall also serve as
 4 the pharmacist in charge of the remote pharmacy. Except as
 5 otherwise provided in this subsection, a manufacturer shall
 6 designate a pharmacist licensed in or outside of this state as the
 7 pharmacist in charge for the manufacturer or, if the manufacturer
 8 does not hold a license as a pharmacy, shall designate an employee
 9 with the appropriate education or experience, or both, to assume
 10 responsibility for compliance with licensing requirements as
 11 facility manager for the manufacturer. Except as otherwise provided
 12 in this subsection, a wholesale distributor **or wholesale**
 13 **distributor-broker** shall designate a pharmacist licensed in or
 14 outside of this state as the pharmacist in charge for the wholesale
 15 distributor **or wholesale distributor-broker** or shall designate an
 16 employee with the appropriate education or experience, or both, to
 17 assume responsibility for compliance with licensing requirements as
 18 facility manager for the wholesale distributor **or wholesale**
 19 **distributor-broker**. The pharmacy, manufacturer, ~~or~~ wholesale
 20 distributor, **or wholesale distributor-broker** and the individual
 21 designated as the PIC or facility manager under this subsection are
 22 jointly responsible for the pharmacy's, manufacturer's, ~~or~~
 23 wholesale distributor's, **or wholesale distributor-broker's**
 24 compliance with this part and rules promulgated under this part. A
 25 person that is a manufacturer, ~~or~~ wholesale distributor, **or**
 26 **wholesale distributor-broker** with respect to a device salable on
 27 prescription only but not with respect to any drug salable on
 28 prescription only is exempt from this subsection.

29 (3) Subject to this subsection, a pharmacist may be designated



1 as the PIC for not more than 3 pharmacies, including remote
 2 pharmacies. A PIC described in this subsection shall work an
 3 average of at least 8 hours per week at each pharmacy for which he
 4 or she is the PIC unless he or she is serving as the PIC of a
 5 remote pharmacy. The PIC of a remote pharmacy is not required to be
 6 physically present at the remote pharmacy to satisfy the hour
 7 requirement described in this subsection, but may satisfy the
 8 requirement through the use of a telepharmacy system. The pharmacy
 9 and the PIC shall maintain appropriate records and demonstrate
 10 compliance with this subsection ~~upon~~**on** the request of the board or
 11 its designee.

12 (4) A pharmacy, manufacturer, ~~or~~ wholesale distributor, **or**
 13 **wholesale distributor-broker** shall report to the department a
 14 change in ownership, management, location, or its PIC or facility
 15 manager designated under subsection (2) not later than 30 days
 16 after the change occurs.

17 (5) A pharmacist designated as the PIC for a pharmacy shall
 18 supervise the practice of pharmacy for the pharmacy. The duties of
 19 the PIC include, but are not limited to, the following:

20 (a) Supervision of all activities of pharmacy employees as
 21 they relate to the practice of pharmacy including the purchasing,
 22 storage, compounding, repackaging, dispensing, and distribution of
 23 drugs and devices to ensure that those activities are performed in
 24 compliance with this part and the rules promulgated under this
 25 part.

26 (b) Enforcement and oversight of policies and procedures
 27 applicable to the employees of the pharmacy for the procurement,
 28 storage, compounding, and dispensing of drugs and the communication
 29 of information to the patient in relation to drug therapy.



1 (c) Establishment and supervision of the method and manner for
2 storage and safekeeping of pharmaceuticals, including maintenance
3 of security provisions to be used when the pharmacy is closed.

4 (d) Establishment and supervision of the record-keeping system
5 for the purchase, sale, delivery, possession, storage, and
6 safekeeping of drugs and devices.

7 (e) Establishment of policies and procedures for individuals
8 who are delegated responsibilities for any of the tasks described
9 in this subsection by the PIC.

10 (6) Except as otherwise provided in subsection (8),
11 fingerprints for the following individuals must be submitted with
12 an application for a new pharmacy, manufacturer, ~~or~~ wholesale
13 distributor, **or wholesale distributor-broker** license in the same
14 manner as required in section 16174 for the purpose of a criminal
15 history check:

16 (a) If the application is from an individual, who is not a
17 health professional licensed or otherwise authorized to engage in a
18 health profession under this article or who is a health
19 professional but was licensed or otherwise authorized to engage in
20 his or her health profession under this article before October 1,
21 2008, fingerprints for that individual.

22 (b) If the application is from a partnership, fingerprints for
23 all partners and any individual who will manage the day-to-day
24 operations of the new pharmacy, manufacturer, ~~or~~ wholesale
25 distributor, **or wholesale distributor-broker**.

26 (c) If the application is from a privately held corporation,
27 fingerprints for any individual who will manage the day-to-day
28 operations of the new pharmacy, manufacturer, or wholesale
29 distributor. This subdivision only applies to a privately held



1 corporation that in the aggregate owns fewer than 75 pharmacies,
 2 manufacturers, ~~or~~ wholesale distributors, **or wholesale distributor-**
 3 **brokers** on the date the corporation submits its license
 4 application.

5 (7) The board, department, and department of state police
 6 shall conduct the criminal history check on the individuals
 7 described in subsection (6) in the same manner as described in
 8 section 16174.

9 (8) Subsection (6) does not apply if a criminal history check
 10 that meets the requirements of section 16174 has been obtained for
 11 the individuals described in subsection (6) within the 2 years
 12 preceding the date of the application for a new pharmacy,
 13 manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-**
 14 **broker** license under this part. To qualify for the exception under
 15 this subsection, an applicant shall submit proof of the previous
 16 criminal history check for each individual described in subsection
 17 (6), as applicable, with the application for a new pharmacy,
 18 manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-**
 19 **broker** license under this part. If the department or board
 20 determines that a criminal history check for an individual
 21 described in subsection (6) does not meet the requirements of
 22 section 16174 or was not obtained within the time period
 23 prescribed, fingerprints must be submitted for the individual as
 24 required under subsection (6).

25 (9) If, as authorized or required under this article, the
 26 department inspects or investigates an applicant for a new pharmacy
 27 license for a pharmacy that will provide compounding services or a
 28 compounding pharmacy, and the applicant or compounding pharmacy is
 29 located outside of this state, the applicant or compounding



1 pharmacy shall reimburse the department for its expenses incurred
2 in carrying out its authority or duty to inspect or investigate the
3 applicant or licensee under this article.

4 **Sec. 17748e. (1) An out-of-state pharmacy that is not licensed**
5 **under this part as a pharmacy may deliver or trade a drug or device**
6 **salable on prescription only to a person located in this state only**
7 **if the out-of-state pharmacy meets both of the following**
8 **requirements:**

9 (a) The out-of-state pharmacy holds a license in good standing
10 as a pharmacy from the state in which it is located.

11 (b) The out-of-state pharmacy uses a wholesale distributor-
12 broker that is licensed in this state to facilitate the
13 transaction.

14 (2) Except as otherwise provided in this part, a pharmacy that
15 is using a wholesale distributor-broker shall only deliver or trade
16 a drug or device salable on prescription only that it receives from
17 1 or more of the following:

18 (a) A manufacturer.

19 (b) A wholesale distributor.

20 (c) Subject to subsection (3), a pharmacy.

21 (d) Subject to subsection (3), a qualified pharmacy.

22 (3) A drug salable on prescription only must not be delivered
23 or traded between pharmacies, or between a pharmacy and a qualified
24 pharmacy that is using a wholesale distributor-broker, unless all
25 of the following are met:

26 (a) The pharmacy or qualified pharmacy from which the drug is
27 being obtained receives a request for the drug that identifies the
28 drug's brand name or generic name, lot number, expiration date,
29 quality, quantity, and size.



1 (b) The drug is approved by the United States Food and Drug
2 Administration.

3 (c) The drug is not expired at the time of the delivery or
4 trade.

5 (d) The drug is not a controlled substance.

6 (e) Before delivering or trading the drug, the pharmacy or
7 qualified pharmacy from which the drug is being obtained confirms
8 with the pharmacy or qualified pharmacy receiving the drug that the
9 drug is available for delivery or trade.

10 (f) The pharmacy or qualified pharmacy from which the drug is
11 being obtained includes with the drug a packaging checklist,
12 confirming that the drug being delivered or traded matches the
13 information identified on the request described in subdivision (a).

14 (g) The drug is delivered or traded in the original
15 manufacturer's packaging, whether sealed or unsealed, with the
16 drug's national drug code, lot number, and expiration date
17 conspicuously identified on the packaging. If the original
18 manufacturer's packaging is unsealed at the time of the delivery or
19 trade, the delivery or trade may include a quantity of the drug
20 that is less than the quantity contained in the original
21 manufacturer's packaging. However, the pharmacies, or the pharmacy
22 and qualified pharmacy, shall not trade or deliver more than 1
23 unsealed or partial quantity of the drug during any consecutive 90-
24 day period.

25 (h) If 1 of the pharmacies involved in the delivery or trade
26 is a qualified pharmacy, the delivery or trade is intended to fill
27 a prescription for an identified patient.

28 (4) A wholesale distributor-broker is not liable in a civil
29 action for personal injury or death resulting from a drug or device



1 salable on prescription only that was delivered or traded by a
2 pharmacy or qualified pharmacy under this section, regardless of
3 whether the wholesale distributor-broker is subject to disciplinary
4 action under this part, if the wholesale distributor-broker's
5 conduct does not amount to gross negligence as that term is defined
6 in section 7 of 1964 PA 170, MCL 691.1407.

7 (5) To receive a license as a wholesale distributor-broker
8 under this part, an applicant shall meet the requirements for
9 licensure established by the department in consultation with the
10 board by rule. The rules must require the applicant to demonstrate
11 to the satisfaction of the board that, at the time of the
12 application for initial licensure, the applicant facilitates
13 deliveries or trades for at least 50 qualified pharmacies that are
14 each licensed in good standing in their state of licensure. If the
15 number of qualified pharmacies described in this subsection with
16 which a wholesale distributor-broker facilitates deliveries and
17 trades falls below 50, the wholesale distributor-broker may
18 continue to do business in this state. However, a wholesale
19 distributor-broker seeking renewal of its license shall, in
20 addition to meeting any requirements for renewal under section
21 16201, demonstrate to the satisfaction of the board that the
22 wholesale distributor-broker facilitates deliveries and trades for
23 at least 50 qualified pharmacies at the time of license renewal.

24 (6) A wholesale distributor-broker shall provide a transaction
25 history, transaction statement, or transaction information to a
26 pharmacy purchasing a drug or device from a pharmacy or qualified
27 pharmacy through the wholesale distributor-broker under this
28 section if any of the following are met:

29 (a) A transaction history, transaction statement, or



1 transaction information is required under the drug supply chain
2 security act, Public Law 113-54.

3 (b) The qualified pharmacy provided the transaction history,
4 transaction statement, or transaction information to the wholesale
5 distributor-broker, and the wholesale distributor-broker receives a
6 request for the document from the purchasing pharmacy. A wholesale
7 distributor-broker that receives a document described in this
8 subdivision shall retain the document for at least 7 years.

9 (7) A wholesale distributor-broker that receives notification
10 from a pharmacy or qualified pharmacy that a delivery or trade
11 facilitated by the wholesale distributor-broker involved a drug or
12 device salable on prescription only that is a suspect product or
13 illegitimate product shall immediately notify each of the
14 following:

15 (a) The department.

16 (b) The United States Food and Drug Administration.

17 (c) Each pharmacy that received the product from the pharmacy
18 or qualified pharmacy.

19 (8) Before facilitating the delivery or trade of a drug or
20 device salable on prescription only to a pharmacy, the wholesale
21 distributor-broker shall notify the pharmacy, in writing, that the
22 wholesale distributor-broker will not examine the drug or device
23 for quality or accuracy before the pharmacy receives the drug or
24 device.

25 (9) A wholesale distributor-broker shall not facilitate a
26 delivery or trade of a drug or device salable on prescription only
27 between a pharmacy and a qualified pharmacy unless both of the
28 following are met:

29 (a) The pharmacy's or qualified pharmacy's license is in good



1 standing in its state of licensure at the time of the delivery or
 2 trade and the wholesale distributor-broker has no knowledge of
 3 pending disciplinary action against the pharmacy or qualified
 4 pharmacy in its state of licensure.

5 (b) The wholesale distributor-broker has, for the quarter in
 6 which the delivery or trade will occur, received from the pharmacy
 7 and qualified pharmacy a signed attestation that the pharmacy or
 8 qualified pharmacy holds a license in good standing in its state of
 9 licensure and that the pharmacy or qualified pharmacy is in
 10 compliance with all applicable federal and state laws. The
 11 wholesale distributor-broker shall make an attestation received
 12 under this subdivision available to the department on the
 13 department's request.

14 (10) A wholesale distributor-broker shall cooperate with the
 15 department if the department is investigating a transaction
 16 involving the wholesale distributor-broker or a qualified pharmacy
 17 with which the wholesale distributor-broker facilitates
 18 transactions.

19 (11) As used in this section:

20 (a) "Illegitimate product" means that term as defined in 21
 21 USC 360eee.

22 (b) "Out-of-state pharmacy" means a facility or part of a
 23 facility that is located outside of this state and that dispenses
 24 prescription drugs or prepares prescription drugs for delivery or
 25 distribution under the laws of the state in which it is located.

26 (c) "Qualified pharmacy" means an out-of-state pharmacy that
 27 meets the requirements described in subsection (1).

28 (d) "Suspect product" means that term as defined in 21 USC
 29 360eee.



1 (e) "Transaction history" means that term as defined in 21 USC
2 360eee.

3 (f) "Transaction information" means that term as defined in 21
4 USC 360eee.

5 (g) "Transaction statement" means that term as defined in 21
6 USC 360eee.

7 Sec. 17748f. (1) A pharmacy shall obtain a license as a
8 wholesale distributor under this part if the total number of dosage
9 units of all prescription drugs distributed by the pharmacy to a
10 person during any consecutive 12-month period is more than 5% of
11 the total number of dosage units of prescription drugs distributed
12 and dispensed by the pharmacy during the same 12-month period.

13 (2) A pharmacy shall obtain a license as a manufacturer under
14 this part if, during any consecutive 12-month period, the total
15 number of dosage units of all prescription drugs that are prepared
16 or compounded by the pharmacy for the resale, compounding, or
17 dispensing by another person is more than 5% of the total number of
18 dosage units of prescription drugs prepared by the pharmacy during
19 the same 12-month period.

20 Sec. 17767. The board may promulgate rules and make
21 determinations necessary or appropriate to the licensing of
22 pharmacists, drugs, dispensers, manufacturers, and ~~wholesalers~~
23 **wholesale distributors, and wholesale distributor-brokers** under
24 this part.

25 Sec. 17768. (1) In a manner consistent with part 161, the
26 disciplinary subcommittee may fine, reprimand, or place on
27 probation a person licensed under this part, may deny, limit,
28 suspend, or revoke a person's license, or may order restitution or
29 community service for a violation of this part or rules promulgated



1 under this part.

2 (2) In addition to the grounds set forth in subsection (1),
 3 and in a manner consistent with part 161, the board may fine,
 4 reprimand, or place on probation a person licensed under this part,
 5 may deny, limit, suspend, or revoke a license issued under this
 6 part, or may order restitution or community service if the board
 7 finds that any of the following apply to an applicant; a partner,
 8 officer, or member of the board of directors of a pharmacy,
 9 manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-**
 10 **broker** licensed under this part; a stockholder of a pharmacy,
 11 manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-**
 12 **broker** that is a privately held corporation licensed under this
 13 part; or a facility manager for a manufacturer, ~~or~~ wholesale
 14 distributor, **or wholesale distributor-broker** designated under
 15 section 17748(2):

16 (a) The applicant or other person described in this subsection
 17 lacks good moral character.

18 (b) Subject to subsection (3), the applicant or other person
 19 described in this subsection has been convicted of a misdemeanor or
 20 a felony under a state or federal law relating to a controlled
 21 substance or the practice of pharmacy.

22 (c) The applicant or other person described in this subsection
 23 has furnished false or fraudulent material information or has
 24 knowingly omitted material information in an application filed
 25 under this part.

26 (d) The applicant or other person described in this subsection
 27 has maintained a financial interest in a pharmacy, manufacturer, ~~or~~
 28 wholesale distributor, **or wholesale distributor-broker** that has
 29 been denied a license or federal registration, has had its license



1 or federal registration limited, suspended, or revoked, or has been
2 subject to any other criminal, civil, or administrative penalty.

3 (e) The applicant or other person described in this subsection
4 is not in compliance with article 7 or article 8 or the rules
5 promulgated under article 7 or article 8.

6 (f) The applicant or other person described in this subsection
7 has violated section 17748.

8 (3) Except for a conviction for a misdemeanor under section
9 7404(2) (d) or a local ordinance that is substantially similar to
10 section 7404(2) (d), the reference to a misdemeanor in subsection
11 (2) (b) applies only to a conviction for a misdemeanor that is
12 directly related to the manufacture, delivery, possession,
13 possession with intent to manufacture or deliver, use,
14 distribution, prescription, or dispensing of a controlled
15 substance. Subsection (2) (b) does not apply to a conviction for a
16 misdemeanor based on an unintentional error or omission involving a
17 clerical or record-keeping function.

