

HOUSE SUBSTITUTE FOR
SENATE BILL NO. 704

A bill to amend 1978 PA 368, entitled "Public health code," by amending sections 16233, 16241, 17702, 17704, 17706, 17707, 17709, 17742, and 17748 (MCL 333.16233, 333.16241, 333.17702, 333.17704, 333.17706, 333.17707, 333.17709, 333.17742, and 333.17748), sections 16233 and 16241 as amended by 2013 PA 268, section 17702 as amended by 2012 PA 209, section 17706 as amended by 1986 PA 304, section 17707 as amended by 1990 PA 333, section 17709 as amended by 2006 PA 672, section 17742 as added by 1987 PA 250, and section 17748 as amended by 1988 PA 462, and by adding sections 17748a, 17748b, 17748c, and 17748d.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 Sec. 16233. (1) The department may conduct an investigation
2 necessary to administer and enforce this article. Investigations

1 may include written, oral, or practical tests of a licensee's or
2 registrant's competency. The department may establish a special
3 paralegal unit to assist the department.

4 (2) The department may order an individual to cease and desist
5 from a violation of this article, article 7, or article 8 or a rule
6 promulgated under this article, article 7, or article 8.

7 (3) An individual ordered to cease and desist under subsection
8 (2) is entitled to a hearing before a hearings examiner if the
9 individual files a written request for a hearing within 30 days
10 after the effective date of the cease and desist order. The
11 department shall subsequently present the notice, if any, of the
12 individual's failure to respond to a complaint, or attend or be
13 represented at a hearing as described in sections 16231 and 16231a,
14 or the recommended findings of fact and conclusions of law to the
15 appropriate disciplinary subcommittee to determine whether the
16 order is to remain in effect or be dissolved.

17 (4) Upon a violation of a cease and desist order issued under
18 subsection (2), the department of attorney general may apply in the
19 circuit court to restrain and enjoin, temporarily or permanently,
20 an individual from further violating the cease and desist order.

21 (5) After consultation with the chair of the appropriate board
22 or task force or his or her designee, the department may summarily
23 suspend a license or registration if the public health, safety, or
24 welfare requires emergency action in accordance with section 92 of
25 the administrative procedures act of 1969, MCL 24.292. If a
26 licensee or registrant is convicted of a felony; a misdemeanor
27 punishable by imprisonment for a maximum term of 2 years; or a

1 misdemeanor involving the illegal delivery, possession, or use of a
2 controlled substance, the department shall find that the public
3 health, safety, or welfare requires emergency action and, in
4 accordance with section 92 of the administrative procedures act of
5 1969, MCL 24.292, shall summarily suspend the licensee's license or
6 the registrant's registration. If a licensee or registrant is
7 convicted of a misdemeanor involving the illegal delivery,
8 possession, or use of alcohol that adversely affects the licensee's
9 ability to practice in a safe and competent manner, the department
10 may find that the public health, safety, or welfare requires
11 emergency action and, in accordance with section 92 of the
12 administrative procedures act of 1969, MCL 24.292, may summarily
13 suspend the licensee's license or the registrant's registration.

14 **(6) THE DEPARTMENT MAY SUMMARILY SUSPEND A PHARMACY LICENSE IF**
15 **THE DEPARTMENT HAS RECEIVED A NOTICE FROM THE UNITED STATES FOOD**
16 **AND DRUG ADMINISTRATION OR THE CENTERS FOR DISEASE CONTROL AND**
17 **PREVENTION THAT THERE IS AN IMMINENT RISK TO THE PUBLIC HEALTH,**
18 **SAFETY, OR WELFARE AND EMERGENCY ACTION IN ACCORDANCE WITH SECTION**
19 **92 OF THE ADMINISTRATIVE PROCEDURES ACT OF 1969, MCL 24.292, IS**
20 **APPROPRIATE. A SUSPENSION UNDER THIS SUBSECTION REMAINS IN EFFECT**
21 **FOR THE DURATION OF THE EMERGENCY SITUATION THAT POSES A RISK TO**
22 **THE PUBLIC HEALTH, SAFETY, OR WELFARE. NOTWITHSTANDING ANY**
23 **PROVISION OF THIS ACT TO THE CONTRARY, THE DEPARTMENT IS NOT**
24 **REQUIRED TO CONDUCT AN INVESTIGATION OR CONSULT WITH THE BOARD OF**
25 **PHARMACY TO TAKE EMERGENCY ACTION UNDER THIS SUBSECTION.**

26 Sec. 16241. (1) After administrative disciplinary action is
27 final, the department shall publish a list of the names and

1 addresses of disciplined individuals. The department ~~of commerce~~
2 shall indicate on the list that a final administrative disciplinary
3 action is subject to judicial review. The department shall report
4 disciplinary action to the department of ~~public~~**COMMUNITY** health,
5 the ~~director of the~~ department of insurance and financial services,
6 the state and federal agencies responsible for fiscal
7 administration of federal health care programs, and the appropriate
8 professional association.

9 (2) Once each calendar year, the department shall transmit to
10 the library of Michigan sufficient copies of a compilation of the
11 lists required under subsection (1) for the immediately preceding 3
12 calendar years. The library of Michigan shall distribute the
13 compilation to each depository library in this state. The
14 department shall also transmit the compilation to each county clerk
15 in this state once each calendar year.

16 (3) The department of community health shall report the
17 disciplinary actions to appropriate licensed health facilities and
18 agencies. The ~~director of the~~ department of insurance and financial
19 services shall report the disciplinary actions received from the
20 department to insurance carriers providing professional liability
21 insurance.

22 (4) In case of a summary suspension of a license under section
23 16233(5), the department shall report the name and address of the
24 individual whose license has been suspended to the department of
25 community health, the ~~director of the~~ department of insurance and
26 financial services, the state and federal agencies responsible for
27 fiscal administration of federal health care programs, and the

1 appropriate professional association. **IN CASE OF A SUMMARY**
2 **SUSPENSION OF A LICENSE UNDER SECTION 16233(6), THE DEPARTMENT**
3 **SHALL REPORT THE NAME AND ADDRESS OF THE PHARMACY LICENSE THAT HAS**
4 **BEEN SUSPENDED TO THE DEPARTMENT OF COMMUNITY HEALTH, THE**
5 **DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES, THE STATE AND**
6 **FEDERAL AGENCIES RESPONSIBLE FOR FISCAL ADMINISTRATION OF FEDERAL**
7 **HEALTH CARE PROGRAMS, AND THE APPROPRIATE PROFESSIONAL ASSOCIATION.**

8 (5) A licensee or registrant whose license or registration is
9 revoked or suspended under this article shall give notice of the
10 revocation or suspension to each patient who contacts the licensee
11 or registrant for professional services during the term of the
12 revocation or suspension. The **LICENSEE OR REGISTRANT MAY GIVE THE**
13 notice required under this subsection ~~may be given orally~~ and shall
14 ~~be given~~ **GIVE THE NOTICE REQUIRED UNDER THIS SUBSECTION** at the time
15 of contact.

16 (6) A licensee or registrant whose license or registration is
17 revoked or is suspended for more than 60 days under this article
18 shall notify in writing each patient or client to whom the licensee
19 or registrant rendered professional services in the licensee's or
20 registrant's private practice during the 120 days immediately
21 preceding the date of the final order imposing the revocation or
22 suspension and to each individual who is already scheduled for
23 professional services during the first 120 days after the date of
24 the final order imposing the revocation or suspension. The notice
25 ~~shall~~ **MUST** be on a form provided by the licensee's or registrant's
26 board or task force and ~~shall~~ state, at a minimum, the name,
27 address, and license or registration number of the licensee or

1 registrant, the fact that his or her license or registration has
2 been revoked or suspended, the effective date of the revocation or
3 suspension, and the term of the revocation or suspension. Each
4 board or task force shall develop a notice form that meets at least
5 the minimum requirements of this subsection. The licensee or
6 registrant shall send the notice to each patient or client to whom
7 the licensee or registrant rendered professional services in the
8 licensee's or registrant's private practice during the 120 days
9 immediately preceding the date of the final order imposing the
10 revocation or suspension within 30 days after the date of the final
11 order imposing the revocation or suspension and shall
12 simultaneously transmit a copy of the notice to the department. The
13 licensee or registrant orally shall notify each individual who
14 contacts the licensee or registrant for professional services
15 during the first 120 days after the date of the final order
16 imposing the revocation or suspension. The licensee or registrant
17 shall also provide a copy of the notice within 10 days after the
18 date of the final order imposing the revocation or suspension to
19 his or her employer, if any, and to each hospital, if any, in which
20 the licensee or registrant is admitted to practice.

21 (7) A licensee or registrant who is reprimanded, fined, placed
22 on probation, or ordered to pay restitution under this article or
23 an applicant whose application for licensure or registration is
24 denied under this article shall notify his or her employer, if any,
25 and each hospital, if any, in which he or she is admitted to
26 practice, in the same manner as provided for notice of revocation
27 or suspension to an employer or hospital under subsection (6),

1 within 10 days after the date of the final order imposing the
2 sanction.

3 (8) The department shall annually report to the legislature
4 and to each board and task force on disciplinary actions taken
5 under this article, article 7, and article 8. The ~~report~~ **DEPARTMENT**
6 shall ~~contain~~, **INCLUDE**, at a minimum, all of the following
7 information **IN THE REPORT REQUIRED UNDER THIS SUBSECTION:**

8 (a) Investigations conducted, complaints issued, and
9 settlements reached by the department, separated out by type of
10 complaint and health profession.

11 (b) Investigations and complaints closed or dismissed.

12 (c) Actions taken by each disciplinary subcommittee, separated
13 out by type of complaint, health profession, and final order
14 issued.

15 (d) Recommendations by boards and task forces.

16 (e) The number of extensions and delays granted by the
17 department that were in excess of the time limits required under
18 this article for each phase of the disciplinary process, and the
19 types of cases for which the extensions and delays were granted.

20 Sec. 17702. (1) "Agent" means an individual designated by a
21 prescriber to act on behalf of or at the discretion of that
22 prescriber as provided in section 17744.

23 (2) "Brand name" means the registered trademark name given to
24 a drug product by its manufacturer.

25 (3) **EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION (4),**
26 **"COMPOUNDING" MEANS THE PREPARATION, MIXING, ASSEMBLING, PACKAGING,**
27 **AND LABELING OF A DRUG OR DEVICE BY A PHARMACIST UNDER THE**

1 FOLLOWING CIRCUMSTANCES:

2 (A) UPON THE RECEIPT OF A PRESCRIPTION FOR A SPECIFIC PATIENT.

3 (B) UPON THE RECEIPT OF A MEDICAL OR DENTAL ORDER FROM A
4 PRESCRIBER OR AGENT FOR USE IN THE TREATMENT OF PATIENTS WITHIN THE
5 COURSE OF THE PRESCRIBER'S PROFESSIONAL PRACTICE.

6 (C) IN ANTICIPATION OF THE RECEIPT OF A PRESCRIPTION OR
7 MEDICAL OR DENTAL ORDER BASED ON ROUTINE, REGULARLY OBSERVED
8 PRESCRIPTION OR MEDICAL OR DENTAL ORDER PATTERNS.

9 (D) FOR THE PURPOSE OF OR INCIDENTAL TO RESEARCH, TEACHING, OR
10 CHEMICAL ANALYSIS AND NOT FOR THE PURPOSE OF SALE OR DISPENSING.

11 (4) "COMPOUNDING" DOES NOT INCLUDE ANY OF THE FOLLOWING:

12 (A) EXCEPT AS PROVIDED IN SECTION 17748C, THE COMPOUNDING OF A
13 DRUG PRODUCT THAT IS ESSENTIALLY A COPY OF A COMMERCIALY AVAILABLE
14 PRODUCT.

15 (B) THE RECONSTITUTION, MIXING, OR OTHER SIMILAR ACT THAT IS
16 PERFORMED PURSUANT TO THE DIRECTIONS CONTAINED IN APPROVED LABELING
17 PROVIDED BY THE MANUFACTURER OF A COMMERCIALY AVAILABLE PRODUCT.

18 (C) THE COMPOUNDING OF ALLERGENIC EXTRACTS OR BIOLOGIC
19 PRODUCTS.

20 (5) "COMPOUNDING PHARMACY" MEANS A PHARMACY THAT IS LICENSED
21 UNDER THIS PART AND IS AUTHORIZED TO OFFER COMPOUNDING SERVICES
22 UNDER SECTIONS 17748, 17748A, AND 17748B.

23 (6) ~~(3)~~ "Current selling price" means the retail price for a
24 prescription drug that is available for sale from a pharmacy.

25 Sec. 17704. (1) "Federal act" means the federal food, drug,
26 and cosmetic act, ~~of 1938, 21 U.S.C. 301 to 392.~~ 21 USC 301 TO 399F.

27 (2) "FOOD AND DRUG ADMINISTRATION" OR "FDA" MEANS THE UNITED

1 STATES FOOD AND DRUG ADMINISTRATION.

2 (3) ~~(2)~~—"Generic name" means the established or official name
3 of a drug or drug product.

4 (4) ~~(3)~~—"Harmful drug" means a drug intended for use by human
5 beings ~~which~~ **THAT** is harmful because of its toxicity, habit-forming
6 nature, or other potential adverse effect; ~~the~~ method of its use;
7 ~~or~~ the collateral measures necessary to its safe and effective
8 use ~~and~~ ~~which~~ **THAT** is designated as harmful by ~~the board~~
9 ~~according to~~ **A rule PROMULGATED UNDER THIS PART.**

10 (5) ~~(4)~~—"Internship" means an educational program of
11 professional and practical experience for an intern.

12 Sec. 17706. (1) "Manufacturer" means a person ~~who~~ **THAT**
13 prepares, produces, derives, propagates, compounds, processes,
14 packages, or repackages a drug or device salable on prescription
15 only, or otherwise changes the container or the labeling of a drug
16 or device salable on prescription only, and ~~who~~ **THAT** supplies,
17 distributes, sells, offers for sale, barter, or otherwise disposes
18 of that drug or device and any other drug or device salable on
19 prescription only, to another person for resale, compounding, or
20 dispensing.

21 (2) "Official compendium" means the United States
22 pharmacopoeia and **THE** national formulary, **OR THE** homeopathic
23 pharmacopoeia of the United States, ~~or a supplement thereof~~
24 ~~existing on July 1, 1983.~~ **AS APPLICABLE. IF AN OFFICIAL COMPENDIUM**
25 **IS REVISED AFTER THE EFFECTIVE DATE OF THE AMENDATORY ACT THAT**
26 **ADDED THIS SENTENCE, THE DEPARTMENT SHALL OFFICIALLY TAKE NOTICE OF**
27 **THE REVISION. WITHIN 30 DAYS AFTER TAKING NOTICE OF THE REVISION,**

1 THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, SHALL DECIDE
2 WHETHER THE REVISION CONTINUES TO PROTECT THE PUBLIC HEALTH AS IT
3 RELATES TO THE MANNER THAT THE OFFICIAL COMPENDIUM IS USED IN THIS
4 ACT. IF THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, DECIDES
5 THAT THE REVISION CONTINUES TO PROTECT THE PUBLIC HEALTH, THE
6 DEPARTMENT MAY ISSUE AN ORDER TO INCORPORATE THE REVISION BY
7 REFERENCE. IF THE DEPARTMENT ISSUES AN ORDER UNDER THIS SUBSECTION
8 TO INCORPORATE THE REVISION BY REFERENCE, THE DEPARTMENT SHALL NOT
9 MAKE ANY CHANGES TO THE REVISION.

10 (3) "OUTSOURCING FACILITY" MEANS THAT TERM AS DEFINED IN 21
11 USC 353B.

12 Sec. 17707. (1) "Personal charge" means the immediate physical
13 presence of a pharmacist or dispensing prescriber.

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

16 (3) "PHARMACIST IN CHARGE" OR "PIC" MEANS THE PHARMACIST WHO
17 IS DESIGNATED BY A PHARMACY, MANUFACTURER, OR WHOLESALE DISTRIBUTOR
18 AS ITS PHARMACIST IN CHARGE UNDER SECTION 17748(2).

19 (4) ~~(3)~~ "Pharmacist intern" or "intern" means an individual
20 who satisfactorily completes the requirements set forth in rules
21 promulgated ~~by the board~~ **UNDER THIS PART** and is licensed by the
22 board for the purpose of obtaining instruction in the practice of
23 pharmacy from a preceptor approved by the board.

24 (5) ~~(4)~~ "Pharmacy" means a building or part of a building in
25 which the practice of pharmacy is conducted. **FOR THE PURPOSE OF A**
26 **DUTY PLACED ON A PHARMACY UNDER THIS PART, "PHARMACY" MEANS THE**
27 **PERSON TO WHICH THE PHARMACY LICENSE IS ISSUED, UNLESS OTHERWISE**

1 **SPECIFICALLY PROVIDED.**

2 (6) ~~(5)~~—"Practice of pharmacy" means a health service, the
3 clinical application of which includes the encouragement of safety
4 and efficacy in the prescribing, dispensing, administering, and use
5 of drugs and related articles for the prevention of illness, and
6 the maintenance and management of health. Professional functions
7 associated with the practice of pharmacy include:

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

9 (b) Drug product selection.

10 (c) The compounding, dispensing, safe storage, and
11 distribution of drugs and devices.

12 (d) The maintenance of legally required records.

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

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

19 (2) **"STERILE PHARMACEUTICAL" MEANS A DOSAGE FORM OF A DRUG**
20 **THAT IS ESSENTIALLY FREE FROM LIVING MICROBES AND CHEMICAL OR**
21 **PHYSICAL CONTAMINATION TO THE POINT AT WHICH IT POSES NO PRESENT**
22 **RISK TO THE PATIENT, IN ACCORDANCE WITH USP STANDARDS. AS USED IN**
23 **THIS SUBSECTION, "DOSAGE FORM" INCLUDES, BUT IS NOT LIMITED TO,**
24 **PARENTERAL, INJECTABLE, AND OPHTHALMIC DOSAGE FORMS.**

25 (3) ~~(2)~~—"Substitute" means to dispense, without the
26 prescriber's authorization, a different drug in place of the drug
27 prescribed.

1 (4) "USP STANDARDS" MEANS THE PHARMACOPEIAL STANDARDS FOR DRUG
2 SUBSTANCES, DOSAGE FORMS, AND COMPOUNDED PREPARATIONS BASED ON
3 DESIGNATED LEVELS OF RISK AS PUBLISHED IN THE OFFICIAL COMPENDIUM.

4 (5) ~~(3)~~—"Wholesale distributor" means a person, other than a
5 manufacturer, who supplies, distributes, sells, offers for sale,
6 barter, or otherwise disposes of, to other persons for resale,
7 compounding, or dispensing, a drug or device salable on
8 prescription only that the distributor has not prepared, produced,
9 derived, propagated, compounded, processed, packaged, or
10 repackaged, or otherwise changed the container or the labeling
11 thereof. **OF THE DRUG OR DEVICE.**

12 Sec. 17742. (1) The board may require an applicant or the
13 holder of a pharmacy, manufacturer's, or wholesale distributor's
14 license to fully disclose the identity of each partner,
15 stockholder, officer, or member of the board of directors of the
16 pharmacy, manufacturer, or wholesale distributor, as applicable.

17 (2) As used in this section and ~~section~~ **SECTIONS 17748,**
18 **17748A, AND** 17768, "applicant" means a person applying for a
19 pharmacy, manufacturer's, or wholesale distributor's license under
20 this article. Applicant includes only 1 or more of the following:

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

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

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

26 Sec. 17748. (1) ~~A~~ **TO DO BUSINESS IN THIS STATE, A** pharmacy,
27 manufacturer, or wholesale distributor, ~~of prescription drugs,~~

1 whether or not located in this state, ~~but doing business in this~~
2 ~~state, shall MUST~~ be licensed by the board in accordance with ~~UNDER~~
3 this part. **TO DO BUSINESS IN THIS STATE, A PERSON THAT PROVIDES**
4 **COMPOUNDING SERVICES MUST BE LICENSED AS A PHARMACY OR MANUFACTURER**
5 **UNDER THIS PART AND, IF A PHARMACY, AUTHORIZED TO PROVIDE**
6 **COMPOUNDING SERVICES UNDER THIS SECTION AND SECTIONS 17748A AND**
7 **17748B. TO DO BUSINESS IN THIS STATE, AN OUTSOURCING FACILITY MUST**
8 **BE LICENSED AS A PHARMACY UNDER THIS PART.** Licenses ~~shall be~~
9 ~~renewed~~ **ARE RENEWABLE** biennially.

10 (2) A pharmacy, ~~manufacturer, or wholesale distributor~~ may
11 **SHALL** designate ~~an individual to be~~ **A PHARMACIST LICENSED IN THIS**
12 **STATE AS** the licensee ~~PHARMACIST IN CHARGE~~ for the pharmacy. ~~7~~
13 ~~manufacturer, or wholesale distributor and the licensee is~~ **A**
14 **MANUFACTURER OR WHOLESALE DISTRIBUTOR SHALL DESIGNATE A PHARMACIST**
15 **LICENSED IN OR OUTSIDE OF THIS STATE AS THE PHARMACIST IN CHARGE**
16 **FOR THE MANUFACTURER OR WHOLESALE DISTRIBUTOR. THE PHARMACY,**
17 **MANUFACTURER, OR WHOLESALE DISTRIBUTOR AND THE INDIVIDUAL**
18 **DESIGNATED AS THE PIC UNDER THIS SUBSECTION ARE JOINTLY** responsible
19 **for THE PHARMACY'S, MANUFACTURER'S, OR WHOLESALE DISTRIBUTOR'S**
20 **compliance with this part AND RULES PROMULGATED UNDER THIS PART.**

21 (3) **SUBJECT TO THIS SUBSECTION, A PHARMACIST MAY BE DESIGNATED**
22 **AS THE PIC FOR MORE THAN 1 PHARMACY. A PIC DESCRIBED IN THIS**
23 **SUBSECTION SHALL WORK AN AVERAGE OF AT LEAST 8 HOURS PER WEEK AT**
24 **EACH PHARMACY FOR WHICH HE OR SHE IS THE PIC. THE PHARMACY AND THE**
25 **PIC SHALL MAINTAIN APPROPRIATE RECORDS AND DEMONSTRATE COMPLIANCE**
26 **WITH THIS SUBSECTION UPON THE REQUEST OF THE BOARD OR ITS DESIGNEE.**

27 (4) **A PHARMACY, MANUFACTURER, OR WHOLESALE DISTRIBUTOR SHALL**

1 REPORT TO THE DEPARTMENT A CHANGE IN OWNERSHIP, MANAGEMENT,
2 LOCATION, OR DESIGNATED PIC NOT LATER THAN 30 DAYS AFTER THE CHANGE
3 OCCURS.

4 (5) A PHARMACIST IN CHARGE SHALL SUPERVISE THE PRACTICE OF
5 PHARMACY FOR THE PHARMACY IN WHICH HE OR SHE HAS BEEN DESIGNATED
6 THE PIC. THE DUTIES OF THE PIC INCLUDE, BUT ARE NOT LIMITED TO, THE
7 FOLLOWING:

8 (A) SUPERVISION OF ALL ACTIVITIES OF PHARMACY EMPLOYEES AS
9 THEY RELATE TO THE PRACTICE OF PHARMACY INCLUDING THE PURCHASING,
10 STORAGE, COMPOUNDING, REPACKAGING, DISPENSING, AND DISTRIBUTION OF
11 DRUGS AND DEVICES TO ENSURE THAT THOSE ACTIVITIES ARE PERFORMED IN
12 COMPLIANCE WITH THIS PART AND THE RULES PROMULGATED UNDER THIS
13 PART.

14 (B) ENFORCEMENT AND OVERSIGHT OF POLICIES AND PROCEDURES
15 APPLICABLE TO THE EMPLOYEES OF THE PHARMACY FOR THE PROCUREMENT,
16 STORAGE, COMPOUNDING, AND DISPENSING OF DRUGS AND THE COMMUNICATION
17 OF INFORMATION TO THE PATIENT IN RELATION TO DRUG THERAPY.

18 (C) ESTABLISHMENT AND SUPERVISION OF THE METHOD AND MANNER FOR
19 STORAGE AND SAFEKEEPING OF PHARMACEUTICALS, INCLUDING MAINTENANCE
20 OF SECURITY PROVISIONS TO BE USED WHEN THE PHARMACY IS CLOSED.

21 (D) ESTABLISHMENT AND SUPERVISION OF THE RECORD-KEEPING SYSTEM
22 FOR THE PURCHASE, SALE, DELIVERY, POSSESSION, STORAGE, AND
23 SAFEKEEPING OF DRUGS AND DEVICES.

24 (E) ESTABLISHMENT OF POLICIES AND PROCEDURES FOR INDIVIDUALS
25 WHO ARE DELEGATED RESPONSIBILITIES FOR ANY OF THE TASKS DESCRIBED
26 IN THIS SUBSECTION BY THE PIC.

27 (6) EXCEPT AS OTHERWISE PROVIDED IN THIS SUBSECTION, AN

1 APPLICANT FOR A NEW PHARMACY, MANUFACTURER, OR WHOLESALE
2 DISTRIBUTOR LICENSE UNDER THIS PART WHO IS NOT A HEALTH
3 PROFESSIONAL LICENSED OR OTHERWISE AUTHORIZED TO ENGAGE IN A HEALTH
4 PROFESSION UNDER THIS ARTICLE OR WHO IS A HEALTH PROFESSIONAL BUT
5 WAS LICENSED OR OTHERWISE AUTHORIZED TO ENGAGE IN HIS OR HER HEALTH
6 PROFESSION UNDER THIS ARTICLE BEFORE OCTOBER 1, 2008 SHALL SUBMIT
7 FINGERPRINTS IN THE SAME MANNER AS REQUIRED IN SECTION 16174 FOR
8 THE PURPOSE OF A CRIMINAL HISTORY CHECK. THE BOARD, DEPARTMENT, AND
9 DEPARTMENT OF STATE POLICE SHALL COMPLY WITH SECTION 16174 FOR THE
10 PURPOSE OF A CRIMINAL HISTORY CHECK ON AN APPLICANT DESCRIBED IN
11 THIS SUBSECTION. THIS SUBSECTION DOES NOT APPLY IF A CRIMINAL
12 HISTORY CHECK THAT MEETS THE REQUIREMENTS OF SECTION 16174 HAS BEEN
13 OBTAINED FOR THE APPLICANT WITHIN THE 2 YEARS PRECEDING THE DATE OF
14 THE APPLICATION. TO QUALIFY FOR THE EXCEPTION UNDER THIS
15 SUBSECTION, THE APPLICANT SHALL SUBMIT PROOF OF THE PREVIOUS
16 CRIMINAL HISTORY CHECK WITH HIS OR HER APPLICATION FOR A NEW
17 PHARMACY, MANUFACTURER, OR WHOLESALE DISTRIBUTOR LICENSE UNDER THIS
18 PART. IF THE DEPARTMENT OR BOARD DETERMINES THAT THE CRIMINAL
19 HISTORY CHECK DOES NOT MEET THE REQUIREMENTS OF SECTION 16174 OR
20 WAS NOT OBTAINED WITHIN THE TIME PERIOD PRESCRIBED, THE APPLICANT
21 SHALL COMPLY WITH THIS SUBSECTION.

22 (7) IF, AS AUTHORIZED OR REQUIRED UNDER THIS ARTICLE, THE
23 DEPARTMENT INSPECTS OR INVESTIGATES AN APPLICANT FOR A NEW PHARMACY
24 LICENSE FOR A PHARMACY THAT WILL PROVIDE COMPOUNDING SERVICES OR A
25 COMPOUNDING PHARMACY, WHICH APPLICANT OR COMPOUNDING PHARMACY IS
26 LOCATED OUTSIDE OF THIS STATE, THE APPLICANT OR COMPOUNDING
27 PHARMACY SHALL REIMBURSE THE DEPARTMENT FOR ITS EXPENSES INCURRED

1 IN CARRYING OUT ITS AUTHORITY OR DUTY TO INSPECT OR INVESTIGATE THE
2 APPLICANT OR LICENSEE UNDER THIS ARTICLE.

3 SEC. 17748A. (1) BEGINNING ON THE EFFECTIVE DATE OF THIS
4 SECTION, AN APPLICANT FOR A NEW PHARMACY LICENSE FOR A PHARMACY
5 THAT WILL PROVIDE COMPOUNDING SERVICES FOR STERILE PHARMACEUTICALS
6 SHALL SUBMIT VERIFICATION OF CURRENT ACCREDITATION THROUGH A
7 NATIONAL ACCREDITING ORGANIZATION APPROVED BY THE BOARD OR VERIFY
8 THE PHARMACY IS IN THE ACCREDITATION PROCESS. THE DEPARTMENT SHALL
9 NOT ISSUE A LICENSE TO A PHARMACY DESCRIBED IN THIS SUBSECTION THAT
10 IS NOT ACCREDITED UNLESS THE APPLICANT DEMONSTRATES COMPLIANCE WITH
11 USP STANDARDS IN A MANNER DETERMINED BY THE BOARD.

12 (2) BY 1 YEAR AFTER THE EFFECTIVE DATE OF THIS SECTION, A
13 PHARMACY THAT IS LICENSED ON THE EFFECTIVE DATE OF THIS SECTION AND
14 THAT PROVIDES COMPOUNDING SERVICES FOR STERILE PHARMACEUTICALS MUST
15 BE ACCREDITED BY A NATIONAL ACCREDITING ORGANIZATION APPROVED BY
16 THE BOARD, BE VERIFIED BY THE BOARD AS BEING IN THE ACCREDITATION
17 PROCESS, OR BE IN COMPLIANCE WITH USP STANDARDS IN A MANNER
18 DETERMINED BY THE BOARD.

19 (3) NOTWITHSTANDING ANY PROVISION OF PART 161 TO THE CONTRARY,
20 A PHARMACY THAT PROVIDES COMPOUNDING SERVICES FOR STERILE
21 PHARMACEUTICALS SHALL SUBMIT WITH A LICENSE RENEWAL APPLICATION
22 VERIFICATION OF CURRENT ACCREDITATION OR COMPLIANCE WITH USP
23 STANDARDS, AS APPLICABLE.

24 (4) A PERSON THAT PROVIDES SERVICES CONSISTENT WITH AN
25 OUTSOURCING FACILITY SHALL COMPLY WITH REQUIREMENTS OF THE FDA
26 APPLICABLE TO COMPOUNDING SERVICES FOR STERILE PHARMACEUTICALS.

27 (5) A PHARMACY SHALL NOTIFY THE DEPARTMENT OF A COMPLAINT

1 FILED BY ANOTHER STATE IN WHICH THE PHARMACY IS LICENSED FOR
2 VIOLATIONS OF THAT STATE'S PHARMACY LAWS, AN INVESTIGATION BY
3 FEDERAL AUTHORITIES REGARDING VIOLATIONS OF FEDERAL LAW, OR AN
4 INVESTIGATION BY ANY AGENCY INTO VIOLATIONS OF ACCREDITATION
5 STANDARDS REGARDING COMPOUNDING ACTIVITIES WITHIN 30 DAYS OF
6 KNOWLEDGE OF THE COMPLAINT OR INVESTIGATION.

7 (6) EXCEPT FOR DISTRIBUTION WITHIN A HOSPITAL OR ANOTHER
8 HEALTH CARE ENTITY UNDER COMMON CONTROL WHEN REGULATED BY FEDERAL
9 LAW, A PHARMACIST SHALL MAINTAIN A RECORD OF A COMPOUNDED STERILE
10 PHARMACEUTICAL IN THE SAME MANNER AND FOR THE SAME RETENTION PERIOD
11 AS PRESCRIBED IN RULES FOR OTHER PRESCRIPTION RECORDS. THE
12 PHARMACIST SHALL INCLUDE, BUT IS NOT LIMITED TO INCLUDING, ALL OF
13 THE FOLLOWING INFORMATION IN THE RECORD REQUIRED UNDER THIS
14 SUBSECTION:

15 (A) THE NAME, STRENGTH, QUANTITY, AND DOSAGE FORM OF THE
16 COMPOUNDED PHARMACEUTICAL.

17 (B) THE FORMULA TO COMPOUND THAT INCLUDES MIXING INSTRUCTIONS,
18 ALL INGREDIENTS AND THEIR QUANTITIES, AND ANY ADDITIONAL
19 INFORMATION NEEDED TO PREPARE THE COMPOUNDED PHARMACEUTICAL.

20 (C) THE PRESCRIPTION NUMBER OR ASSIGNED INTERNAL
21 IDENTIFICATION NUMBER.

22 (D) THE DATE OF PREPARATION.

23 (E) THE MANUFACTURER AND LOT NUMBER OF EACH INGREDIENT.

24 (F) THE EXPIRATION OR BEYOND-USE DATE.

25 (G) THE NAME OF THE PERSON WHO PREPARED THE COMPOUNDED
26 PHARMACEUTICAL.

27 (H) THE NAME OF THE PHARMACIST WHO APPROVED THE COMPOUNDED

1 PHARMACEUTICAL.

2 (7) A PHARMACIST SHALL NOT OFFER EXCESS COMPOUNDED
3 PHARMACEUTICALS TO OTHER PHARMACIES FOR RESALE. A COMPOUNDING
4 PHARMACY SHALL NOT DISTRIBUTE SAMPLES OR COMPLIMENTARY STARTER
5 DOSES OF A COMPOUNDED PHARMACEUTICAL TO A HEALTH PROFESSIONAL.

6 (8) A COMPOUNDING PHARMACY MAY ADVERTISE OR OTHERWISE PROMOTE
7 THE FACT THAT THEY PROVIDE COMPOUNDING SERVICES.

8 (9) BASED ON THE EXISTENCE OF A HEALTH PROFESSIONAL/PATIENT
9 RELATIONSHIP AND THE PRESENTATION OF A VALID PRESCRIPTION, OR IN
10 ANTICIPATION OF THE RECEIPT OF A PRESCRIPTION BASED ON ROUTINE,
11 REGULARLY OBSERVED PRESCRIPTION PATTERNS, A PHARMACIST MAY COMPOUND
12 FOR A PATIENT A NONSTERILE OR STERILE PHARMACEUTICAL THAT IS NOT
13 COMMERCIALY AVAILABLE IN THE MARKETPLACE.

14 (10) NOTWITHSTANDING ANY PROVISION OF THIS ACT TO THE
15 CONTRARY, A PERSON SHALL NOT COMPOUND AND MANUFACTURE DRUG PRODUCTS
16 OR ALLOW THE COMPOUNDING AND MANUFACTURING OF DRUG PRODUCTS AT THE
17 SAME LOCATION.

18 (11) THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, MAY
19 PROMULGATE RULES REGARDING CONDITIONS AND FACILITIES FOR THE
20 COMPOUNDING OF NONSTERILE AND STERILE PHARMACEUTICALS.

21 SEC. 17748B. (1) EXCEPT AS OTHERWISE PROVIDED IN THIS
22 SUBSECTION, A PHARMACIST OR PHARMACY SHALL NOT COMPOUND NONSTERILE
23 OR STERILE PHARMACEUTICALS FOR A PRESCRIBER OR HEALTH FACILITY OR
24 AGENCY LICENSED UNDER ARTICLE 17 TO ADMINISTER TO THE PRESCRIBER'S,
25 FACILITY'S, OR AGENCY'S PATIENTS WITHOUT A PRESCRIPTION, UNLESS THE
26 PHARMACEUTICAL COMPOUNDED BY THE PHARMACIST OR PHARMACY COMPLIES
27 WITH THE MOST RECENT GUIDANCE ON PHARMACY COMPOUNDING OF HUMAN DRUG

1 PRODUCTS UNDER 21 USC 353A. UPON APPLICATION BY A PHARMACIST OR
2 COMPOUNDING PHARMACY, THE DEPARTMENT MAY AUTHORIZE THE PHARMACIST
3 OR COMPOUNDING PHARMACY TO COMPOUND NONSTERILE OR STERILE
4 PHARMACEUTICALS FOR A PRESCRIBER OR HEALTH FACILITY OR AGENCY
5 LICENSED UNDER ARTICLE 17 TO ADMINISTER TO THE PRESCRIBER'S,
6 FACILITY'S, OR AGENCY'S PATIENTS IN LIMITED QUANTITIES WITHOUT A
7 PRESCRIPTION. THIS SUBSECTION DOES NOT APPLY TO THE COMPOUNDING OF
8 TOPICAL NONSTERILE PHARMACEUTICALS. THE DEPARTMENT SHALL PRESCRIBE
9 THE FORM OF THE APPLICATION FOR USE UNDER THIS SUBSECTION, WHICH
10 APPLICATION MUST INCLUDE AT LEAST ALL OF THE FOLLOWING INFORMATION:

11 (A) THE NAME AND LICENSE NUMBER OF THE PHARMACIST OR PHARMACY
12 REQUESTING AUTHORIZATION TO COMPOUND UNDER THIS SUBSECTION.

13 (B) THE NAME OF THE SPECIFIC PRESCRIBER OR HEALTH FACILITY OR
14 AGENCY THAT IS REQUESTING COMPOUNDED PHARMACEUTICALS AND AN
15 AFFIDAVIT FROM THE PRESCRIBER OR DESIGNATED AGENT OF THE HEALTH
16 FACILITY OR AGENCY ATTESTING TO THE NEED AND THAT THE COMPOUNDED
17 PHARMACEUTICALS ARE ONLY FOR PATIENTS LOCATED IN THIS STATE OR IN
18 STATES IMMEDIATELY ADJACENT TO THIS STATE.

19 (C) THE PHARMACEUTICALS TO BE COMPOUNDED AND THE REASON FOR
20 THE NEED TO COMPOUND THE PHARMACEUTICALS.

21 (D) THE ANTICIPATED QUANTITIES OF PHARMACEUTICALS TO BE
22 COMPOUNDED EACH MONTH AND THE FREQUENCY OF THE NEED TO COMPOUND
23 BEFORE RECEIPT OF A PRESCRIPTION OR DOCUMENTATION SUPPORTING THE
24 ANTICIPATED QUANTITIES.

25 (E) THE CONDITIONS OF OPERATION INCLUDING PRACTICES CONSISTENT
26 WITH USP STANDARDS AND REQUIREMENTS FOR STERILITY TESTING.

27 (2) A PHARMACIST OR COMPOUNDING PHARMACY THAT IS AUTHORIZED TO

1 COMPOUND NONSTERILE OR STERILE PHARMACEUTICALS FOR A PRESCRIBER OR
2 HEALTH FACILITY OR AGENCY UNDER SUBSECTION (1) SHALL DO ALL OF THE
3 FOLLOWING:

4 (A) MAINTAIN COMPLETE AND ACCURATE RECORDS ON A MONTHLY BASIS
5 OF REQUESTS FROM AND PHARMACEUTICALS COMPOUNDED FOR EACH PRESCRIBER
6 OR HEALTH FACILITY OR AGENCY.

7 (B) PROVIDE THE INFORMATION DESCRIBED IN SUBDIVISION (A) TO
8 THE DEPARTMENT AS SPECIFIED IN RULES OR UPON REQUEST.

9 (3) THE AUTHORIZATION GRANTED UNDER SUBSECTION (1) IS FOR A 2-
10 YEAR PERIOD CONSISTENT WITH THE 2-YEAR LICENSE CYCLE OF THE
11 PHARMACY. THE DEPARTMENT MAY, WITHOUT PRIOR NOTICE TO THE
12 PHARMACIST OR PHARMACY, PHYSICALLY INSPECT THE FACILITY WHERE THE
13 COMPOUNDING OF NONSTERILE OR STERILE PHARMACEUTICALS OCCURS.

14 (4) THE DEPARTMENT SHALL NOT AUTHORIZE A PHARMACIST OR
15 COMPOUNDING PHARMACY TO COMPOUND NONSTERILE OR STERILE
16 PHARMACEUTICALS WITHOUT A PRESCRIPTION IF THE PHARMACIST OR
17 PHARMACY IS UNDER INVESTIGATION, IS IN THE PROCESS OF BEING
18 DISCIPLINED, OR IS IN A DISCIPLINARY STATUS.

19 (5) EXCEPT AS OTHERWISE PROVIDED IN THIS SUBSECTION, THE
20 DEPARTMENT MAY IMMEDIATELY REVOKE THE AUTHORIZATION GRANTED UNDER
21 SUBSECTION (1) IF THERE IS A CONFIRMED DEVIATION OR VIOLATION OF
22 THE COMPOUNDING PROCESS OR IF AN ADVERSE EVENT DIRECTLY RELATED TO
23 STERILITY OR INTEGRITY OF THE PRODUCT AND ASSOCIATED WITH A
24 COMPOUNDED NONSTERILE OR STERILE PHARMACEUTICAL IS DETECTED. IF THE
25 HEALTH, SAFETY, AND WELFARE OF THE PUBLIC ARE NOT IN IMMEDIATE
26 JEOPARDY, THE DEPARTMENT SHALL PROVIDE AT LEAST 30 DAYS' NOTICE OF
27 THE REVOCATION OF AUTHORIZATION UNDER THIS SUBSECTION.

1 (6) A PHARMACY OR PHARMACIST AUTHORIZED TO COMPOUND
2 PHARMACEUTICALS UNDER THIS SECTION THAT BECOMES AWARE OF AN ADVERSE
3 EVENT ATTRIBUTED TO THE INTEGRITY OF THE PRODUCT OF A COMPOUNDED
4 PHARMACEUTICAL SHALL REPORT THE ADVERSE EVENT TO THE DEPARTMENT NOT
5 LATER THAN 10 CALENDAR DAYS AFTER BECOMING AWARE OF THE ADVERSE
6 EVENT. FOR PURPOSES OF THIS SUBSECTION, AN ADVERSE EVENT DOES NOT
7 INCLUDE AN ISOLATED ALLERGIC REACTION TO A SUBSTANCE INCLUDED IN
8 THE COMPOUND IF THE ALLERGIC REACTION IS TREATED AND RELIEVED WITH
9 STANDARD PROTOCOL.

10 (7) THE DEPARTMENT SHALL POST AND MAINTAIN A LIST OF
11 PHARMACIES AND PHARMACISTS WHO ARE AUTHORIZED TO COMPOUND
12 PHARMACEUTICALS UNDER THIS SECTION ON ITS INTERNET WEBSITE. THE
13 DEPARTMENT SHALL UPDATE THE LIST REQUIRED UNDER THIS SUBSECTION AT
14 LEAST QUARTERLY.

15 (8) A PRESCRIBER OR HEALTH FACILITY OR AGENCY THAT OBTAINS
16 COMPOUNDED PHARMACEUTICALS UNDER THIS SECTION SHALL NOT REDISPENSE
17 OR SELL THE COMPOUNDED PHARMACEUTICAL TO A PATIENT, A PRESCRIBER,
18 OR HEALTH FACILITY OR AGENCY.

19 SEC. 17748C. EXCEPT FOR PHARMACEUTICALS ON THE MICHIGAN
20 PHARMACEUTICAL PRODUCT LIST MAINTAINED BY THE DEPARTMENT OF
21 COMMUNITY HEALTH, A PHARMACIST SHALL NOT COMPOUND A PHARMACEUTICAL
22 THAT IS COMMERCIALY AVAILABLE UNLESS 1 OF THE FOLLOWING
23 REQUIREMENTS IS MET:

24 (A) THE COMMERCIALY AVAILABLE PHARMACEUTICAL IS MODIFIED TO
25 PRODUCE A SIGNIFICANT DIFFERENCE, IN THE PROFESSIONAL JUDGMENT OF
26 THE PRESCRIBER, BETWEEN THE COMPOUNDED PHARMACEUTICAL FOR THE
27 PATIENT AND THE COMPARABLE COMMERCIALY AVAILABLE PHARMACEUTICAL.

1 (B) THE COMMERCIALY AVAILABLE PHARMACEUTICAL IS NOT AVAILABLE
2 FROM NORMAL DISTRIBUTION CHANNELS IN A TIMELY MANNER TO MEET THE
3 PATIENT'S NEEDS AND THE DISPENSING OF THE COMPOUNDED PHARMACEUTICAL
4 HAS BEEN APPROVED BY THE PRESCRIBER AND THE PATIENT. A PHARMACIST
5 WHO COMPOUNDS A COMMERCIALY AVAILABLE PHARMACEUTICAL AS PROVIDED
6 IN THIS SUBDIVISION SHALL MAINTAIN DOCUMENTATION OF THE REASON FOR
7 THE COMPOUNDING.

8 SEC. 17748D. (1) EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION,
9 A PERSON THAT VIOLATES SECTION 17748A OR 17748B IS GUILTY OF A
10 MISDEMEANOR.

11 (2) EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION, A PERSON
12 THAT KNOWINGLY OR WILLFULLY VIOLATES SECTION 17748A OR 17748B OR A
13 PERSON THAT FALSIFIES PRESCRIPTIONS IN ORDER TO COMPOUND A
14 PHARMACEUTICAL IN BULK IS GUILTY OF A FELONY PUNISHABLE BY
15 IMPRISONMENT FOR NOT MORE THAN 2 YEARS OR A FINE OF NOT MORE THAN
16 \$1,000.00, OR BOTH.

17 (3) EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION, A PERSON
18 THAT KNOWINGLY OR WILLFULLY VIOLATES SECTION 17748A OR 17748B OR A
19 PERSON THAT FALSIFIES PRESCRIPTIONS IN ORDER TO COMPOUND A
20 PHARMACEUTICAL IN BULK, WHICH ACTIVITY RESULTS IN PERSONAL INJURY,
21 IS GUILTY OF A FELONY PUNISHABLE BY IMPRISONMENT FOR NOT MORE THAN
22 4 YEARS OR A FINE OF NOT MORE THAN \$4,000.00, OR BOTH.

23 (4) A PERSON THAT KNOWINGLY OR WILLFULLY VIOLATES SECTION
24 17748A OR 17748B OR A PERSON THAT FALSIFIES PRESCRIPTIONS IN ORDER
25 TO COMPOUND A PHARMACEUTICAL IN BULK, WHICH ACTIVITY RESULTS IN
26 SERIOUS IMPAIRMENT OF A BODY FUNCTION, IS GUILTY OF A FELONY
27 PUNISHABLE BY IMPRISONMENT FOR NOT MORE THAN 5 YEARS OR A FINE OF

1 NOT MORE THAN \$5,000.00, OR BOTH. AS USED IN THIS SUBSECTION,
2 "SERIOUS IMPAIRMENT OF A BODY FUNCTION" MEANS THAT TERM AS DEFINED
3 IN SECTION 58C OF THE MICHIGAN VEHICLE CODE, 1949 PA 300, MCL
4 257.58C.

5 (5) A PERSON THAT KNOWINGLY OR WILLFULLY VIOLATES SECTION
6 17748A OR 17748B OR A PERSON THAT FALSIFIES PRESCRIPTIONS IN ORDER
7 TO COMPOUND A PHARMACEUTICAL IN BULK, WHICH ACTIVITY RESULTS IN
8 DEATH, IS GUILTY OF A FELONY PUNISHABLE BY IMPRISONMENT FOR NOT
9 MORE THAN 15 YEARS OR A FINE OF NOT MORE THAN \$20,000,00, OR BOTH.

10 (6) THE STATE ATTORNEY GENERAL OR COUNTY PROSECUTOR MAY BRING
11 AND PROSECUTE CRIMINAL CHARGES DESCRIBED IN THIS SECTION.

12 Enacting section 1. This amendatory act takes effect 90 days
13 after the date it is enacted into law.