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:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Investigations and complaints closed or dismissed.

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

(d) Recommendations by boards and task forces.

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

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

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

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

FOLLOWING CIRCUMSTANCES:

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

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

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

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

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

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

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

(C) THE COMPOUNDING OF A NONSTERILE PHARMACEUTICAL USING FDA-APPROVED INGREDIENTS PURSUANT TO A PRESCRIPTION OR MEDICAL OR DENTAL ORDER.

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

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

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

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

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

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

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

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

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

THE REVISION. WITHIN 30 DAYS AFTER TAKING NOTICE OF THE REVISION, THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, SHALL DECIDE WHETHER THE REVISION CONTINUES TO PROTECT THE PUBLIC HEALTH AS IT RELATES TO THE MANNER THAT THE OFFICIAL COMPENDIUM IS USED IN THIS ACT. IF THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, DECIDES THAT THE REVISION CONTINUES TO PROTECT THE PUBLIC HEALTH, THE DEPARTMENT MAY ISSUE AN ORDER TO INCORPORATE THE REVISION BY REFERENCE. IF THE DEPARTMENT ISSUES AN ORDER UNDER THIS SUBSECTION TO INCORPORATE THE REVISION BY REFERENCE, THE DEPARTMENT SHALL NOT MAKE ANY CHANGES TO THE REVISION.

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

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

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

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

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

(5) ~~(4)~~ "Pharmacy" means a building or part of a building in which the practice of pharmacy is conducted. **FOR THE PURPOSE OF A DUTY PLACED ON A PHARMACY UNDER THIS PART, "PHARMACY" MEANS THE**

PERSON TO WHICH THE PHARMACY LICENSE IS ISSUED, UNLESS OTHERWISE SPECIFICALLY PROVIDED.

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

(a) The interpretation and evaluation of the prescription.

(b) Drug product selection.

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

(d) The maintenance of legally required records.

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

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

(2) "STERILE PHARMACEUTICAL" MEANS A DOSAGE FORM OF A DRUG THAT IS FREE FROM LIVING MICROBES AND FREE FROM CHEMICAL OR PHYSICAL CONTAMINATION. AS USED IN THIS SUBSECTION, "DOSAGE FORM" INCLUDES, BUT IS NOT LIMITED TO, PARENTERAL, INJECTABLE, AND OPHTHALMIC DOSAGE FORMS.

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

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

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

Sec. 17742. (1) 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) BY 1 YEAR AFTER THE EFFECTIVE DATE OF THIS SECTION, A PHARMACY THAT IS LICENSED ON THE EFFECTIVE DATE OF THIS SECTION AND THAT PROVIDES COMPOUNDING SERVICES FOR STERILE PHARMACEUTICALS SHALL BE ACCREDITED BY A NATIONAL ACCREDITING ORGANIZATION APPROVED BY THE BOARD OR BE IN COMPLIANCE WITH USP STANDARDS IN A MANNER DETERMINED BY THE BOARD.

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

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

(5) A PHARMACY SHALL NOTIFY THE DEPARTMENT OF A COMPLAINT REGARDING COMPOUNDING ACTIVITIES FILED BY ANOTHER STATE IN WHICH

THE PHARMACY IS LICENSED FOR VIOLATIONS OF THAT STATE'S PHARMACY LAWS, AN INVESTIGATION BY FEDERAL AUTHORITIES REGARDING VIOLATIONS OF FEDERAL LAW, OR AN INVESTIGATION BY ANY AGENCY INTO VIOLATIONS OF ACCREDITATION STANDARDS WITHIN 30 DAYS OF KNOWLEDGE OF THE COMPLAINT OR INVESTIGATION.

(6) A PHARMACIST SHALL MAINTAIN A RECORD OF A COMPOUNDED STERILE PHARMACEUTICAL IN THE SAME MANNER AND FOR THE SAME RETENTION PERIOD AS PRESCRIBED IN RULES FOR OTHER PRESCRIPTION RECORDS. THE PHARMACIST SHALL INCLUDE, BUT IS NOT LIMITED TO INCLUDING, ALL OF THE FOLLOWING INFORMATION IN THE RECORD REQUIRED UNDER THIS SUBSECTION:

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

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

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

(D) THE DATE OF PREPARATION.

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

(F) THE EXPIRATION OR BEYOND-USE DATE.

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

(H) THE NAME OF THE PHARMACIST WHO APPROVED THE COMPOUNDED PHARMACEUTICAL.

(7) A PHARMACIST SHALL NOT OFFER EXCESS COMPOUNDED PHARMACEUTICALS TO OTHER PHARMACIES FOR RESALE. A COMPOUNDING

PHARMACY SHALL NOT DISTRIBUTE SAMPLES OR COMPLIMENTARY STARTER DOSES OF A COMPOUNDED PHARMACEUTICAL TO A HEALTH PROFESSIONAL.

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

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

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

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

SEC. 17748B. (1) EXCEPT AS OTHERWISE PROVIDED IN THIS SUBSECTION, A PHARMACIST OR PHARMACY SHALL NOT COMPOUND NONSTERILE OR STERILE PHARMACEUTICALS FOR A PRESCRIBER OR HEALTH FACILITY OR AGENCY LICENSED UNDER ARTICLE 17 TO ADMINISTER TO THE PRESCRIBER'S, FACILITY'S, OR AGENCY'S PATIENTS WITHOUT A PRESCRIPTION, UNLESS THE PHARMACEUTICAL COMPOUNDED BY THE PHARMACIST OR PHARMACY COMPLIES WITH THE MOST RECENT GUIDANCE ON PHARMACY COMPOUNDING OF HUMAN DRUG PRODUCTS UNDER 21 USC 353A. UPON APPLICATION BY A PHARMACIST OR COMPOUNDING PHARMACY, THE DEPARTMENT MAY AUTHORIZE THE PHARMACIST OR COMPOUNDING PHARMACY TO COMPOUND NONSTERILE OR STERILE

PHARMACEUTICALS FOR A PRESCRIBER OR HEALTH FACILITY OR AGENCY LICENSED UNDER ARTICLE 17 TO ADMINISTER TO THE PRESCRIBER'S, FACILITY'S, OR AGENCY'S PATIENTS IN LIMITED QUANTITIES WITHOUT A PRESCRIPTION. THIS SUBSECTION DOES NOT APPLY TO THE COMPOUNDING OF TOPICAL NONSTERILE PHARMACEUTICALS. THE DEPARTMENT SHALL PRESCRIBE THE FORM OF THE APPLICATION FOR USE UNDER THIS SUBSECTION, WHICH APPLICATION MUST INCLUDE AT LEAST ALL OF THE FOLLOWING INFORMATION:

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

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

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

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

(E) THE CONDITIONS OF OPERATION INCLUDING PRACTICES CONSISTENT WITH USP STANDARDS AND REQUIREMENTS FOR THIRD-PARTY TESTING.

(2) A PHARMACIST OR COMPOUNDING PHARMACY THAT IS AUTHORIZED TO COMPOUND NONSTERILE OR STERILE PHARMACEUTICALS FOR A PRESCRIBER OR HEALTH FACILITY OR AGENCY UNDER SUBSECTION (1) SHALL DO ALL OF THE FOLLOWING:

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

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

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

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

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

(6) A PHARMACY OR PHARMACIST AUTHORIZED TO COMPOUND PHARMACEUTICALS UNDER THIS SECTION THAT BECOMES AWARE OF AN ADVERSE EVENT ATTRIBUTED TO THE INTEGRITY OF THE PRODUCT OF A COMPOUNDED PHARMACEUTICAL SHALL REPORT THE ADVERSE EVENT TO THE DEPARTMENT NOT

LATER THAN 10 CALENDAR DAYS AFTER BECOMING AWARE OF THE ADVERSE EVENT.

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

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

SEC. 17748C. A PHARMACIST SHALL NOT COMPOUND A PHARMACEUTICAL THAT IS COMMERCIALLY AVAILABLE UNLESS ALL OF THE FOLLOWING REQUIREMENTS ARE MET:

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

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

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

MISDEMEANOR.

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

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

(4) A PERSON THAT KNOWINGLY OR WILLFULLY VIOLATES SECTION 17748A OR 17748B OR A PERSON THAT FALSIFIES PRESCRIPTIONS IN ORDER TO COMPOUND A PHARMACEUTICAL IN BULK, WHICH ACTIVITY RESULTS IN SERIOUS IMPAIRMENT OF A BODY FUNCTION, IS GUILTY OF A FELONY PUNISHABLE BY IMPRISONMENT FOR NOT MORE THAN 5 YEARS OR A FINE OF NOT MORE THAN $5,000.00, OR BOTH. AS USED IN THIS SUBSECTION, "SERIOUS IMPAIRMENT OF A BODY FUNCTION" MEANS THAT TERM AS DEFINED IN SECTION 58C OF THE MICHIGAN VEHICLE CODE, 1949 PA 300, MCL 257.58C.

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

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