Office of Regulatory Reinvention
111 S. Capitol Avenue; 8th Floor, Romney Building
Lansing, MI 48933
Phone: (517) 335-8658 FAX: (517) 335-9512

REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS (RISCBA)

PART 1: INTRODUCTION

Under the Administrative Procedures Act (APA), 1969 PA 306, the agency that has the statutory authority to promulgate the rules must complete and submit this form electronically to the Office of Regulatory Reinvention (ORR) at **orr@michigan.gov** no less than 28 days before the public hearing.

1. Agency Information

Agency name:	Department of Licensing and Regulatory Affairs
Division/Bureau/Office:	Bureau of Professional Licensing
Name, title, phone number, and e-mail of person completing this form:	Andria M. Ditschman 517-241-9255 DitschmanA@michigan.gov
Name of Departmental Regulatory Affairs Officer reviewing this form:	Liz Arasim Department of Licensing and Regulatory Affairs

2. Rule Set Information

ORR assigned rule set number:	2018-039 LR
Title of proposed rule set:	Board of Pharmacy – General Rules

PART 2: KEY SECTIONS OF THE APA

MCL 24.207a "Small business" defined.

Sec. 7a. "Small business" means a business concern incorporated or doing business in this state, including the affiliates of the business concern, which is independently owned and operated, and which employs fewer than 250 full-time employees or which has gross annual sales of less than $6,000,000.00.

MCL 24.232 (8) Except for an emergency rule promulgated under section 48, and subject to subsection (10), if the federal government has mandated that this state promulgate rules, an agency shall not adopt or promulgate a rule more stringent than the applicable federally mandated standard unless the director of the agency determines that there is a clear and convincing need to exceed the applicable federal standard.

(9) Except for an emergency rule promulgated under section 48, and subject to subsection (10), if the federal government has not mandated that this state promulgate rules, an agency shall not adopt or promulgate a rule more stringent than an applicable federal standard unless specifically authorized by a statute of this state or unless the director of the agency determines that there is a clear and convincing need to exceed the applicable federal standard.

(10) Subsections (8) and (9) do not apply to the amendment of the special education programs and services rules, R 340.1701 to R 340.1862 of the Michigan Administrative Code. However, subsections (8) and (9) do apply to the promulgation of new rules relating to special education with the rescission of R 340.1701 to R 340.1862 of the Michigan Administrative Code.

MCL 24.240 Reducing disproportionate economic impact of rule on small business; applicability of section and MCL 24.245(3).

Sec. 40. (1) When an agency proposes to adopt a rule that will apply to a small business and the rule will have a disproportionate impact on small businesses because of the size of those businesses, the agency shall

consider exempting small businesses and, if not exempted, the agency proposing to adopt the rule shall reduce the economic impact of the rule on small businesses by doing all of the following when it is lawful and feasible in meeting the objectives of the act authorizing the promulgation of the rule:

(a) Identify and estimate the number of small businesses affected by the proposed rule and its probable effect on small businesses.

(b) Establish differing compliance or reporting requirements or timetables for small businesses under the rule after projecting the required reporting, record-keeping, and other administrative costs.

(c) Consolidate, simplify, or eliminate the compliance and reporting requirements for small businesses under the rule and identify the skills necessary to comply with the reporting requirements.

(d) Establish performance standards to replace design or operational standards required in the proposed rule.

(2) The factors described in subsection (1)(a) to (d) shall be specifically addressed in the small business impact statement required under section 45.

(3) In reducing the disproportionate economic impact on small business of a rule as provided in subsection (1), an agency shall use the following classifications of small business:

(a) 0-9 full-time employees.

(b) 10-49 full-time employees.

(c) 50-249 full-time employees.

(4) For purposes of subsection (3), an agency may include a small business with a greater number of full-time employees in a classification that applies to a business with fewer full-time employees.

(5) This section and section 45(3) do not apply to a rule that is required by federal law and that an agency promulgates without imposing standards more stringent than those required by the federal law.

MCL 24.245 (3) Except for a rule promulgated under sections 33, 44, and 48, the agency shall prepare and include with the notice of transmittal a **regulatory impact statement** which shall contain specific information (information requested on the following pages).

PART 3: AGENCY RESPONSE

Please provide the required information using complete sentences. **Do not answer any question with "N/A" or "none."**

Comparison of Rule(s) to Federal/State/Association Standards:

1. Compare the proposed rule(s) to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist.

Each state establishes its own requirements with respect to the licensing requirements of pharmacists, pharmacies, manufacturers of prescription drugs and devices (manufacturer), and wholesale distributors of prescription drugs and devices (wholesale distributor). In addition to state laws and rules, federal laws regulate the practice of pharmacy with respect to controlled substances and chemicals used in the manufacture of controlled substances and requires pharmacies to register or self-certify with the Drug Enforcement Administration (DEA). Registration with the DEA is required to prevent diversion and abuse of controlled substances and chemicals used in the manufacture of controlled substances, and to ensure an adequate and uninterrupted supply of controlled substances for the United States. A pharmacy must maintain a state license in order to get a DEA license.

The proposed rules require that pharmacies comply with all federal requirements regarding controlled substances when discontinuing operations, and with security standards for the protection of protected health information set forth in the Health Insurance Portability and Accountability Act. The rules adopt the pharmaceutical compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, and the regulations regarding good manufacturing practices for finished pharmaceuticals set forth in 21 CFR. sections 211.1 to 211.208 (1978). Some aspects of the practice of pharmacy, such as the labeling of prescription drugs, are regulated by the Federal Food,

Drug, and Cosmetic Act of 2016, 21 USC sections 351 to 399f and have been adopted by the proposed rules.

There are no federal rules or standards set by a national or state agency that the proposed rules exceed.

A. Are these rule(s) required by state law or federal mandate?

The proposed rules are required by sections 17722, 17731, and 17737 of the Public Health Code (Code), MCL 333.17722, MCL 333.17731, and MCL 333.17737. The rules are not federally mandated.

The proposed rules are authorized by state law. Part 177 and sections 16145, 16148, 16174, 16175, 16178, 16182, and 16186 of the Public Health Code (Code), MCL 333.17701 to MCL 333.17780, MCL 333.16145, MCL 333.16148, MCL 333.16174, MCL 333.16175, MCL 333.16178, MCL 333.16182, and MCL 333.16186, authorize the Board of Pharmacy to promulgate rules that are necessary or appropriate to fulfill its function to regulate pharmacists, pharmacies, manufacturers, and wholesale distributors. These provisions of the Code authorize the Board to do the following: establish specific requirements for licenses, renewals, and relicensure of pharmacists, pharmacies, manufacturers, and wholesale distributors; require examinations and minimum passing scores for pharmacist applicants; establish standards for the education and training of applicants; regulate, control, and inspect the practice of pharmacy and of drugs and devices manufactured, distributed, prescribed, dispensed, administered, or issued in this state; regulate the safety, processes, records, and activities of pharmacies, manufacturers, and wholesale distributors; and regulate sterile compounding.

MCL 333.16145, MCL 333.16148, MCL 333.16174, MCL 333.16175, MCL 333.16178, MCL 333.16182, and MCL 333.16186, MCL 333.17722, MCL 333.17731, MCL 333.17737, MCL 333.17746, MCL 333.17748, MCL 333.17748a, MCL 333.17748b, MCL 333.17751, MCL 333.17753, MCL 333.17757, MCL 333.17760, MCL 333.17767, MCL 338.3501, MCL 445.2001, MCL 445.2011, and MCL 445.2030.

B. If these rule(s) exceed a federal standard, identify the federal standard or citation, describe why it is necessary that the proposed rule(s) exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.

The proposed rules do not exceed any federal standards.

2. Compare the proposed rule(s) to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities.

Each state establishes its own requirements with respect to the licensing requirements of pharmacists, pharmacies, manufacturers, and wholesale distributors.

The proposed rules are consistent with the standards required by the Code and are largely consistent with the requirements of other states in the Great Lakes region.

Part 1 of the proposed pharmacy rules pertains to pharmacy services in medical institutions, definitions, resale of drugs and devices, and inspections of applicants and licensees. The requirements for pharmacy services in medical institutions vary from state to state. All states in the Great Lakes Region require inspections. The requirements regarding the resale of drugs and devices are similar to the standards and requirements in the other states in the Great Lakes Region. Only Illinois does not have a drug repository donation program and does not allow return and reuse of medications.

Part 2 of the proposed pharmacy rules pertains to licensure of pharmacists. This part includes the rules pertaining to training for identifying victims of human trafficking, limited licenses, internship

requirements, preceptor licenses, examinations, pharmacist licensure by examination and endorsement, and relicensure requirements. All states in the Great Lakes region license pharmacists, require internships or on the job training, and regulate examination, endorsement, and relicensure. The licensure requirements for pharmacists in the proposed rules are similar to the standards and requirements in the other states in the Great Lakes Region.

Part 3 of the proposed pharmacy rules pertains to pharmacy licenses. This part includes the application requirements for pharmacies, sterile compounding services and the adoption by reference of standards that apply to these services, inspections, discontinuance and resumption of sterile compounding services, housing of a pharmacy, professional and technical equipment and supplies, closure of a pharmacy, and relicensure. All states in the Great Lakes region regulate pharmacies. The licensure requirements for pharmacies in the proposed rules are similar to the standards and requirements in the other states in the Great Lakes Region. All states in the Great Lakes Region require nonresident pharmacies that perform business in their state to be licensed or registered by their state, however, Illinois, Indiana, Ohio, and Pennsylvania do not require nonresident pharmacists to be licensed by their state and these state's requirements vary. None of the states in the Great Lakes region require a separate license for sterile compounding pharmacies, but most states require compliance with the USP chapters regarding compounding and sterile compounding. Fees regarding licensure, registration, and renewal are not consistent from state to state and range from $75.00 in Wisconsin to $320.00 in Ohio. Renewal schedules range from one to three years in the Great Lakes region.

Part 4 of the proposed pharmacy rules pertains to manufacturer licenses. This part includes licensure requirements for manufacturers, persons to whom drugs or devices may be sold, adoption by reference of the federal regulation on good manufacturing practices for finished pharmaceuticals, closure of a manufacturer, and relicensure. All states in the Great Lakes region except Indiana license manufacturers. Minnesota, New York, Ohio, Pennsylvania, and Wisconsin regulate manufacturers with a manufacturer license. Illinois regulates manufacturers as wholesale distributors.

Part 5 of the proposed pharmacy rules pertains to wholesale distributor licenses. This part includes the determination of a pharmacy as a wholesale distributor, the licensure requirements for wholesale distributors, persons to whom drugs or devices may be sold, wholesale distributor practices, recordkeeping and policy requirements for wholesale distributors, facility requirements, examination of drugs and devices, closure of a wholesale distributor, and relicensure. All states in the Great Lakes region license wholesale distributors. Indiana, Ohio, and Pennsylvania regulate third party logistics providers. The only states in the Great Lakes region that regulate wholesale distributors of nonprescription drugs are Minnesota and Pennsylvania. Like Michigan, New York, Ohio, Pennsylvania, and Wisconsin also regulate prescription devices. Only Wisconsin does not license outsourcing facilities.

Part 6 of the proposed pharmacy rules pertains to the practice of pharmacy. This part includes prescription drug labeling and dispensing, prescription drug receipts, noncontrolled prescriptions, customized patient medication packages, prescription records, prescription refill records, automated devices, professional responsibility of a pharmacist, and hospice emergency drug boxes. All states in the Great Lakes region regulate the practice of pharmacy. Substitution of drugs is addressed by each state, however, the specific regulations are different. Michigan, Indiana, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin all require either "Dispense as Written," "May Not Substitute," or "Brand Medically Necessary" if the prescriber does not approve substitution of a drug. Pennsylvania is the only state in the Great Lakes region that prohibits substitution of some drugs. In all states in the Great Lakes region except New York, a prescription for a noncontrolled drug is good for 1 year. Michigan, Illinois, and Wisconsin require that prescription records are kept for 5 years. Ohio licensees must keep records for 3 years, and Indiana, Minnesota, and Pennsylvania licensees must keep records for 2 years. All states

in the Great Lakes region allow electronic prescribing of prescriptions. Most states in the Great Lakes region allow centralized prescription filling.

A. If the rule(s) exceed standards in those states, explain why and specify the costs and benefits arising out of the deviation.

Most states in the Great Lakes region regulate the standards pertaining to resale of drugs and devices, inspections of pharmacies, licensure of pharmacists, pharmacies, manufacturers, and wholesale distributors, and the practice of pharmacy. There are some differences between states, however, the regulatory framework is very similar. Overall, the standards in the proposed rules do not exceed those of the other states in the Great Lakes region.

3. Identify any laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rule(s).

There are no other laws, rules or other legal requirements that conflict with the proposed rules. Each state establishes its own requirements with respect to the licensing requirements of pharmacists, pharmacies, manufacturers, and wholesale distributors. In addition to state laws and rules, federal laws regulate the practice of pharmacy with respect to controlled substances and chemicals used in the manufacture of controlled substances and requires pharmacies to register or self-certify with DEA. Registration is required to prevent diversion and abuse of controlled substances and chemicals used in the manufacture of controlled substances, and to ensure an adequate and uninterrupted supply of controlled substances for the United States. A pharmacy must maintain a state license in order to get a DEA license.

The proposed rules require that pharmacies comply with all federal requirements regarding controlled substances when discontinuing operations and security standards for the protection of protected health information set forth in the Health Insurance Portability and Accountability Act. The rules adopt the pharmaceutical compounding standards of the USP and the good manufacturing practice regulations for finished pharmaceuticals. Some aspects of the practice of pharmacy, such as the labeling of prescription drugs, are regulated by the Federal Food, Drug, and Cosmetic Act of 2016, 21 USC sections 351 to 399f which have been adopted by the proposed rules. There are no federal rules or standards set by a national or state agency that the proposed rules exceed.

A. Explain how the rule has been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

There are no other laws, rules or other legal requirements that conflict with the proposed rules. The proposed rules require that pharmacies comply with all federal requirements regarding controlled substances when discontinuing operations and security standards for the protection of protected health information set forth in the Health Insurance Portability and Accountability Act. The rules adopt the pharmaceutical compounding standards of the USP and the good manufacturing practice regulations for finished pharmaceuticals. Some aspects of the practice of pharmacy, such as the labeling of prescription drugs, are regulated by the Federal Food, Drug, and Cosmetic Act of 2016, 21 USC sections 351 to 399f which have been adopted by the proposed rules. There are no federal rules or standards set by a national or state agency that the proposed rules exceed.

4. If MCL 24.232(8) applies and the proposed rule(s) is more stringent than the applicable federally mandated standard, **a statement of specific facts that establish the clear and convincing need to adopt the more stringent rule(s) and an explanation of the exceptional circumstances that necessitate the more stringent standard** is required below:

MCL 24.232(8) does not apply.

5. If MCL 24.232(9) applies and the proposed rule(s) is more stringent than the applicable federal standard, **either the statute that specifically authorizes the more stringent rule(s) or a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rule(s) and an explanation of the exceptional circumstances that necessitate the more stringent standard** is required below:

MCL 24.232(9) does not apply as this state establishes its own requirements with respect to the licensing requirements of pharmacists, interns, preceptors, pharmacies, manufacturers, and wholesale distributors. The proposed rules require that pharmacies comply with all federal requirements regarding controlled substances when discontinuing operations and security standards for the protection of protected health information set forth in the Health Insurance Portability and Accountability Act. The rules adopt the pharmaceutical compounding standards of the USP and the good manufacturing practice regulations for finished pharmaceuticals. Some aspects of the practice of pharmacy, such as the labeling of prescription drugs, are regulated by the Federal Food, Drug, and Cosmetic Act of 2016, 21 USC sections 351 to 399f, which have been adopted by the proposed rules. There are no federal rules or standards set by a national or state agency that the proposed rules exceed.

Purpose and Objectives of the Rule(s):

6. Identify the behavior and frequency of behavior that the proposed rule(s) are designed to alter.

The current Pharmacy – General Rules are incomplete, disorganized, and difficult to use. The draft rules have been reorganized and substantially rewritten to provide for rules that encompass all the necessary requirements for licensing and regulating the practice for pharmacists, interns, preceptors, pharmacies, manufacturers, and wholesale distributors. The draft rules include parts for general provisions, pharmacist licenses, pharmacy licenses, manufacturer licenses, wholesale distributor licenses, and the practice of pharmacy.

Part 1 of the proposed pharmacy rules pertains to pharmacy services in medical institutions, definitions, resale of drugs and devices, and inspections of applicants and licensees.

Part 2 of the proposed pharmacy rules pertains to licensure of pharmacists. This part includes the rules pertaining to training for identifying victims of human trafficking, educational limited licenses, internship requirements, preceptor licenses, examinations, pharmacist licensure by examination and endorsement, and relicensure.

Part 3 of the proposed pharmacy rules pertains to pharmacy licenses. This part includes the application requirements for pharmacies, sterile compounding services and the adoption by reference of standards that apply to these services, inspections, discontinuance and resumption of sterile compounding services, housing of a pharmacy, professional and technical equipment and supplies, closure of a pharmacy, and relicensure.

Part 4 of the proposed pharmacy rules pertains to manufacturer licenses. This part includes licensure requirements for manufacturers, persons to whom drugs or devices may be sold, adoption by reference of a federal regulation on good manufacturing practices for finished pharmaceuticals, closure of a manufacturer, and relicensure.

Part 5 of the proposed pharmacy rules pertains to wholesale distributor licenses. This part includes the determination of a pharmacy as a wholesale distributor, the licensure requirements for wholesale distributors, persons to whom drugs or devices may be sold, wholesale distributor practices, recordkeeping and policy requirements for wholesale distributors, facility requirements, examination of drugs and devices, closure of a wholesale distributor, and relicensure.

Part 6 of the proposed pharmacy rules pertains to the practice of pharmacy. This part includes prescription drug labeling and dispensing, prescription drug receipts, noncontrolled prescriptions, a customized patient medication package, prescription records, prescription refill records, automated devices, professional responsibility of a pharmacist, and hospice emergency drug boxes.

The purpose of the proposed rules is set forth below:

Part 1. General Provisions

R 338.486: This proposed rule pertains to pharmacy services in a medical institution, including personnel, dispensing medications, stocking of medications, inspecting areas where medications are stored, security, educational programs on medications, access to medications during the absence of the pharmacist, required written policies on safe medication practices, and destruction or stocking of unused portions of prescription medication.

R 338.501: The definitions were previously included in R 338.471a, which is being rescinded. This proposed rule pertains to the definitions used throughout the rules. The definitions that are new include approved education program, compounding, practical experience, and virtual manufacturer.

R 338.503: The subject matter of this proposed rule was previously included in R 338.472, which is being rescinded. This proposed rule will prohibit prescription drugs and devices that have been dispensed from being returned or exchanged for resale.

R 338.505: The provisions of this proposed rule were previously included in R 338.493f, which is being rescinded. This proposed rule has been moved to a location that makes the rule applicable to all licensees in the Pharmacy-General rules. The rule pertains to inspection of applicants and licensees and the matters that are relevant to inspections.

Part 2. Pharmacist Licenses

R 338.511: The subject matter of this proposed rule was previously included in R 338.471b, which is being rescinded. This proposed rule, which requires training in identifying victims of human trafficking, has been moved to part 2 that regulates pharmacist licensing and has been revised to make it applicable to applicants who have been licensed in the past or who will be licensed in the future.

R 338.513: The subject matter of this proposed rule was previously included in various rules in the previous rule set, which are being rescinded. This proposed rule pertains to the application and renewal process for an educational limited license.

R 338.515: The subject matter of this proposed rule was previously included in R 338.473 and R 338.473a, which are being rescinded. The language in the rules that is being rescinded has been rewritten to simplify the proposed rule. This proposed rule pertains to internship requirements, defines an unconventional internship, and clarifies that an applicant must obtain an educational limited license before starting an internship that includes the practice of pharmacy in Michigan.

R 338.517: The subject matter about preceptor licensure and responsibilities in this rule was previously included in R 338.473c, which is being rescinded. This proposed rule rewrites the language from R 338.473c to simplify the rule.

R 338.519: The subject matter of this proposed rule was previously included in R 338.473b, R 338.474a, and R 338.475, which are being rescinded. This proposed rule pertains to the examinations that are adopted by reference, acceptable scores, and retaking the examinations. An applicant for

licensure who fails to pass either the North American Pharmacist Licensure Examination or the Michigan Multistate Pharmacy Jurisprudence Examination shall provide the Board certification from an approved education program that he or she satisfactorily completed courses that provide a thorough review of the area or areas that he or she failed before being allowed to retest.
R 338.521: The subject matter of this proposed rule was previously included in R 338.474, which is being rescinded. This proposed rule pertains to pharmacist licensure by examination and rewrites the language from R 338.474.

R 338.523: The subject matter of this proposed rule was previously included in R 338.475, which is being rescinded. This proposed rule revises language from R 338.475 on the application and requirements for a pharmacist license by endorsement.

R 338.525: The subject matter of this proposed rule was previously included in R 338.477b, R 338.477c, and R 338.477d, which are being rescinded. The provisions of the previous rules have been consolidated and placed into a table and apply only to lapsed pharmacist licenses. This proposed rule will require applicants to establish good moral character and submit fingerprints as required by applicants pursuant to MCL 333.16174(3).

Part 3. Pharmacy Licenses

R 338.531: The subject matter of this proposed rule was previously included in R 338.477 and R 338.477a, which are being rescinded. The proposed rule establishes requirements for obtaining a pharmacy license. This proposed rule clarifies what type of inspection information is required if a pharmacy intends to compound sterile pharmaceutical products and adopts and requires a licensee to comply with the compounding standards of the USP that are adopted by reference in the proposed rule.

R 338.532: This is a new rule. This proposed rule pertains to sterile compounding services and accrediting organizations and inspection entities. Section 17748a of the Public Health Code, MCL 333.17748a, requires the Board to identify approved accrediting organizations or inspection entities for pharmacies that compound sterile pharmaceuticals. The rule requires that the list be posted on the Department's webpage. This proposed rule includes the process for an organization to petition the Board for approval as an accrediting organization or inspection entity. The rule provides that the Board approval is good for 3 years and that the approval may be rescinded upon just cause.

R 338.533: This is a new rule that pertains to sterile compounding standards. This proposed rule adopts the sterile compounding standards of the USP, published by the USP Convention. The rule requires outsourcing facilities located in Michigan or that distribute sterile compounded pharmaceuticals into the state to be inspected and registered as an outsourcing facility by the United States Food and Drug Administration (FDA) prior to applying for a Michigan license. This rule also requires an outsourcing facility to undergo an inspection by the Board or a third party recognized by the Board if it is registered with the FDA but has not undergone an FDA inspection. This rule also establishes requirements for outsourcing facilities.

R 338.534: This is a new rule that pertains to inspections of pharmacies applying for licensure. This proposed rule requires an inspection for all of the following types of pharmacies applying for licensure: a pharmacy located outside of Michigan that will not ship compounded sterile pharmaceutical products into Michigan; a pharmacy located outside of Michigan that intends to ship sterile compounded pharmaceutical products into Michigan; and any new pharmacy located in Michigan. A pharmacy in Michigan that intends to provide sterile compounded pharmaceuticals in Michigan must be inspected by the Department or another entity listed in the proposed rule.

R 338.535: This proposed rule requires a pharmacy that discontinues sterile compounding services to notify the Department and to reapply to the Department to resume such services.

R 338.536: The subject matter of this proposed rule was previously included in R 338.482, which is being rescinded. This rule pertains to the housing of a pharmacy and includes most of the language from R 338.482 with minor changes. The proposed rule requires a lighted and ventilated room and a prescription Department devoted to the practice of pharmacy. This proposed rule also includes the size requirements for a pharmacy.

R 338.537: The subject matter of this proposed rule was previously included in R 338.481, which is being rescinded. This proposed rule pertains to the pharmacy professional and technical equipment and supplies, and it deletes the current requirement that a pharmacy must "have the necessary equipment to dispense prescription drugs" as the provision is redundant. The language in the proposed rule has been simplified to clarify the rule.

R 338.538: This is a new rule that requires a pharmacy that is closing to return the license, the controlled substance license, and provide to the Department, within 15 days of the date of closing, written notification about the disposition of controlled substances, non-controlled substances, records and prescription files.

R 338.539: This is a new rule. This rule requires an applicant for relicensure of a pharmacy to satisfy the same requirements as a new pharmacy.

Part 4. Manufacturer Licenses

R 338.551: The subject matter on licensure of a manufacturer of prescription drugs or devices in this proposed rule was previously included in R 339.493d, which is being rescinded, along with the licensing of wholesale distributors. This proposed rule pertains only to manufacturers of drugs or devices and has been rewritten and moved to this new part. The proposed rule establishes the application requirements, including requiring a separate license for each location where prescription drugs or devices are manufactured.

R 338.553: The subject matter of this proposed rule was previously included in R 338.493g, which is being rescinded. This proposed rule will clarify that a manufacturer of prescription drugs or devices may provide drugs or devices to those persons licensed by the Board to distribute, prescribe, or dispense in or outside of this state.

R 338.555: This is a new rule that requires a manufacturer of prescription drugs or devices to comply with the federal regulations on good manufacturing practices for finished pharmaceuticals.
The subject matter of this proposed rule was previously included in R 338.493b.

R 338.557: This is a new rule. This proposed rule requires a manufacturer of prescription drugs or devices that is closing the business to return to the Department the manufacturer license and the controlled substance license, and within 15 days of the date of closing provide to the Department written notification that includes the disposition of controlled substances, noncontrolled substances, records, and prescription files.

R 338.559: This is a new rule that requires an applicant for relicensure as a manufacturer to satisfy the same requirements as a new manufacturer.

Part 5. Wholesale Distributor Licenses

R 338.561: The subject matter of this proposed rule was previously included in R 338.493a, which is being rescinded. This proposed rule will revise the language in the current rule to clarify that a pharmacy that transfers prescription drugs or devices in certain scenarios must obtain a license as a wholesale distributor.

R 338.563: A portion of the subject matter on licensure as a wholesale distributor in this proposed rule was previously included along with the licensing of manufacturers of drugs and devices in R 338.493d, which is being rescinded. This proposed rule pertains only to wholesale distributors and the provisions from R 338.493d have been rewritten and moved to this new part. The proposed rule establishes application requirements, including educational, training and experiential requirements for a facility manager.

R 338.565: The subject matter of this proposed rule was previously included in R 338.493g, which is being rescinded. This proposed rule modifies language of the current rule to clarify that a wholesale distributor may provide prescription drugs or devices to persons who are licensed by the Board to distribute, prescribe, or dispense prescription drugs or services in or outside of this state.

R 338.567: This is a new rule that requires a wholesale distributor that does not physically touch prescription drugs or devices to file an affidavit attesting to this fact with the Department. A wholesale distributor that has filed an affidavit is unable to touch prescription drugs or devices as part of its wholesale operation until it has notified the Department that it is taking custody of prescription drugs or devices and the premises of the operation has been inspected by the Department.

R 338.569: The subject matter on wholesale distributor recordkeeping and policy requirements in this proposed rule was previously included along with the facility requirements and examination of materials in R 338.493c, which is being rescinded. This proposed rule rewrites the previous language, so it now pertains only to recordkeeping and policy requirements. This proposed rule requires wholesale distributors to maintain the following: inventories and records of transactions on prescription drugs or devices; a list of persons who are in charge of the distribution, storage and handling of prescription drugs or devices; and, the records described in the rule for 2 years after disposition of the prescription drugs or devices.

R 338.571: The subject matter of this proposed rule was previously included along with the recordkeeping and policy requirements and examination of materials in R 338.493c, which is being rescinded. This proposed rule has been rewritten and now pertains only to facility requirements. The proposed rule requires wholesale distributors that have physical custody or control of prescription drugs or devices to meet the facility requirements in the rule.

R 338.573: The subject matter of this proposed rule was previously included along with the recordkeeping and policy requirements, and facility requirements in R 338.493c, which is being rescinded. This proposed rule now pertains only to examination of materials and returned and damaged or outdated prescription drugs and devices. The proposed rule requires wholesale distributors that inspect shipping containers to be sure incoming and outgoing containers have not been damaged or are being held under conditions that are not suitable. This proposed rule also provides requirements for returned, damaged, deteriorated, misbranded, or adulterated prescription drugs or devices.

R 338.575: This is a new rule. This proposed rule requires a wholesale distributor that is closing to return to the Department the wholesale distributor license and the controlled substance license, and within 15 days of the date of closing to provide a written notification to the Department that includes the disposition of controlled substances, noncontrolled substances, records, and prescription files.

R 338.577: This is a new rule that requires an applicant for relicensure as a wholesale distributor to satisfy the same requirements as a new wholesale distributor.

Part 6. Practice of Pharmacy

R 338.582: The subject matter of the proposed rule was previously included in R 338.479, which is being rescinded. This rule pertains to the requirements regarding prescription drug labeling and dispensing.

R 338.583: The subject matter of the proposed rule was previously in R 338.479a, which is being rescinded. This proposed rule pertains to the requirements regarding prescription drug receipts.

R 338.584: The subject matter of this proposed rule was previously in R 338.479b, which is being rescinded. This proposed rule establishes requirements regarding noncontrolled prescriptions.

R 338.585: The subject matter of this proposed rule was previously in R 338.479c, which is being rescinded. This proposed rule establishes requirements regarding a customized patient medication package.

R 338.586: The subject matter of this proposed rule was previously in R 338.480, which is being rescinded. This proposed rule establishes requirements regarding prescription records.

R 338.587: The subject matter of this proposed rule was previously in R 338.480a, which is being rescinded. This proposed rule establishes requirements regarding prescription refill records, manual systems, profile systems, automated systems, confidentiality, and access.

R 338.588: The subject matter of this proposed rule was previously in R 338.489, which is being rescinded. This proposed rule establishes requirements regarding automated devices. A definition of automated device was added to the rule as well as a requirement that if a pharmacist delegates the stocking of the device, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing bar-coding or another Board-approved error prevention technology. The proposed rule requires an automated device that is operated at a location affiliated with a hospital but not at the same location as the pharmacy owned by the hospital to comply with provisions in the Public Health Code on this type of automated device.

R 338.589: The subject matter in this proposed rule was previously in R 338.490, which is being rescinded. This proposed rule establishes requirements regarding professional responsibility of a pharmacist.

R 338.590: The subject matter of this proposed rule was previously in R 338.500, which is being rescinded. This proposed rule establishes requirements regarding hospice emergency drug boxes.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rule(s).

Part 1 of the proposed rules includes the provisions that regulate a pharmacy in a medical institution, including requiring technologies to ensure that the correct drugs are stocked at the institution.

Promulgation of rules related to licensure of pharmacists, interns, preceptors, pharmacies, manufacturers, and wholesale distributors, in parts 2 through 5 of the proposed rules, are required by statute. The proposed rules provide a regulatory framework for the licensure of pharmacists, pharmacies, manufacturers, and wholesale distributors. The proposed rules will clarify the requirements for initial licensure and relicensure, which will protect the public.

Part 3 of the proposed rules will require a pharmacy that intends to compound sterile pharmaceuticals to meet specific inspection requirements to ensure that the pharmacy is meeting the compounding standards of the USP.

The practice of pharmacy in part 6 of the proposed rules will clarify how drugs are labeled, what receipts are required for purchasers, the regulations pertaining to noncontrolled prescriptions, how to process a customized patient medication package, maintaining prescription records, how and where automated devices are allowed, the professional responsibilities of a pharmacist, and the regulations relating to a hospice emergency drug box.

B. Describe the difference between current behavior/practice and desired behavior/practice.

The practice of pharmacy is regulated by law, which mandates licensure. Updating standards for licensure, organizing the rule set into a more user-friendly format, updating outdated information, and providing regulations related to compounding sterile pharmaceuticals, virtual manufacturers, inspections, and the practice of a pharmacy helps add clarity and certainty to the rules and will make compliance easier for applicants and licensees.

C. What is the desired outcome?

Those individuals who wish to practice as a pharmacist, pharmacy intern, preceptor, or in a pharmacy, manufacturer, or wholesale distributor will be regulated. By making improvements and clarifications to the rules, applicants and licensees should find compliance easier. This should result in fewer questions, fewer regulatory problems, and greater safety and protection of the public.

7. Identify the harm resulting from the behavior that the proposed rule(s) are designed to alter and the likelihood that the harm will occur in the absence of the rule.

Without the proposed rules pharmacists, pharmacy interns, preceptors, pharmacies, manufacturers, and wholesale distributors would lack the clarity the proposed rules provide in the regulatory framework for the licensure and practice of pharmacy. The proposed rules will provide greater clarity to licensees and aid in compliance with requirements under the rules. Part 1 of the proposed rules will require pharmacies in a medical institution to use technologies to ensure that the correct drugs are dispensed to the public. Part 2 through 5 of the proposed rules will clarify the licensing requirements for pharmacists, pharmacies, manufacturers, and wholesale distributors and the minimum requirements that licensees must meet in order to handle, dispense, store, and transfer drugs to the public. Part 3 of the proposed rules will clarify what is required for pharmacies who intend to compound and handle sterile pharmaceuticals. This part adopts the sterile compounding standards of the USP to attempt to avoid mistakes in sterile compounding that could harm the public. The practice of pharmacy in part 6 of the proposed rules will clarify how drugs are labeled, what receipts are required for purchasers, the regulations pertaining to noncontrolled prescriptions, how to process a customized patient medication package, maintaining prescription records, how and where automated devices are allowed, the professional responsibilities of a pharmacist, and the regulations relating to a hospice emergency drug box, which further regulates the practice of pharmacy to protect the public.

A. What is the rationale for changing the rule(s) instead of leaving them as currently written?

The proposed rules update the previously adopted rules, organize the rules in a format that is more user friendly for licensees, places rules together that address the same subject matter, clarifies the rules, and adds further protections for the public. The proposed rules also clarify areas in licensing that have been raised by licensees or are a result of previous harm to the public, such as mistakes made in compounding sterile pharmaceuticals which can be a health threat to the public.

8. Describe how the proposed rule(s) protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

Part 1 of the proposed rules includes the provisions that regulate a pharmacy in a medical institution, including requiring technologies to ensure that the correct drugs are stocked. Promulgation of rules related to licensure of pharmacists, interns, preceptors, pharmacies, manufacturers, and wholesale distributors, in parts 2 through 5 of the proposed rules, are required by statute. These rules provide a regulatory framework for the practice of pharmacy for pharmacists, pharmacies, manufacturers, and wholesale distributors. The proposed rules will also clarify what is required for pharmacies who intend to compound and handle sterile pharmaceuticals. The proposed rules adopt the sterile compounding standards of the USP to attempt to avoid mistakes in sterile compounding that have harmed the public in the past. The practice of pharmacy in part 6 of the proposed rules will clarify how drugs are labeled, what receipts are required for purchasers, the regulations pertaining to noncontrolled prescriptions, how to process a customized patient medication package, maintaining prescription records, how and where automated devices are allowed, the professional responsibilities of a pharmacist, and the regulations relating to a hospice emergency drug box, which further regulates the practice of pharmacy to protect the public. The proposed rules will protect the welfare of Michigan citizens by providing greater clarity to licensees, which will aid in compliance with requirements under the rules. The system of licensure of pharmacies will prohibit unsafe conditions surrounding the compounding of sterile pharmaceuticals and provide for inspections.

9. Describe any rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

The current Pharmacy – General Rules are incomplete, disorganized, and difficult to use. The draft rules have been reorganized and substantially rewritten to provide for rules that encompass all the necessary requirements for licensing and regulating the practice for pharmacists, interns, preceptors, pharmacies, manufacturers, and wholesale distributors. Therefore, all rules in this rule set except for R 338.486, which is referenced in the Public Health Code, are being rescinded.

Fiscal Impact on the Agency:

Fiscal impact is an increase or decrease in expenditures from the current level of expenditures, i.e. hiring additional staff, higher contract costs, programming costs, changes in reimbursement rates, etc. over and above what is currently expended for that function. It does not include more intangible costs or benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

10. Describe the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings).

The Department does not expect the implementation of the proposed rules to result in additional costs or savings for the Department.

11. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rule(s).

The licensing and regulation of the profession, including the promulgation and implementation of rules, is funded by the collection of licensing fees. As a result, there was no reason to make an agency appropriation or provide a funding source. Also, the Department does not expect the proposed rules to increase expenditures.

12. Describe how the proposed rule(s) is necessary and suitable to accomplish its purpose, in relationship to the burden(s) it places on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

Licensing: The proposed rules will require a pharmacist applicant to pay for the following: the North American Pharmacist Licensure Examination (NAPLEX) at a cost of approximately $575; the Michigan Multistate Pharmacy Jurisprudence Examination (MPJE) at a cost of approximately $200; a training on

identifying victims of human trafficking with a cost depending on the class; cost to take the TOEFL-IBT of $195.00; a licensing fee of $60.60; a background check of approximately $25.00; and a controlled substance fee of $146.45.

The proposed rules are necessary, suitable, and the least burdensome requirements on licensees to ensure that licensees are educated, can communicate effectively with clients, and are safe to practice.

Relicensure of a Pharmacist: The proposed rules will require pharmacists who have let their license lapse to meet specific requirements depending on the length of time they have been unlicensed. The requirements include payment of an application fee, a background check, fees for attendance of 30 hours of continuing education, and a fee to attend a training on identifying victims of human trafficking if they have not yet attended the training.

All of the relicensure requirements are the minimum necessary to ensure that licensees are educated and safe to practice.

Licensure of Pharmacy, Manufacturer, and Wholesale Distributor: The proposed rules require a pharmacy, manufacturer, and wholesale distributor applicant to pay a licensing fee, a background check of approximately $25, and an inspection fee when applicable. The pharmacy license fee is $181.80. The manufacturer and wholesale distributor license fee is $85.85. The estimated cost for an inspection is between $1,995 and $3,000 depending on the type of pharmacy.

The costs associated with licensure of a pharmacy, manufacturer, and wholesale distributor are outweighed by the benefit of ensuring that the public is protected from the distribution of tainted pharmaceuticals.

A. Despite the identified burden(s), identify how the requirements in the rule(s) are still needed and reasonable compared to the burdens.

The rules are required by statute to provide a mechanism for licensing and regulation of the profession. The rules are not any more restrictive than is allowed by statute. Despite the cost-related burden of licensing, the rules and regulations are necessary in order to provide a framework of standards for licensure and practice requirements.

Impact on Other State or Local Governmental Units:

13. Estimate any increase or decrease in revenues to other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Estimate the cost increases or reductions for such other state or local governmental units as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

There are no anticipated increases or decreases in revenues to other state or local government units as a result of the proposed rules.

A. Estimate the cost increases or reductions for other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

There are no anticipated increases or decreases in costs to other state or local government units as a result of the proposed rules.

14. Discuss any program, service, duty or responsibility imposed upon any city, county, town, village, or school district by the rule(s).

There are no anticipated or intended programs, services, duties, or responsibilities imposed on any city, county, town, village, or school district as a result of these proposed rules.

A. Describe any actions that governmental units must take to be in compliance with the rule(s). This section should include items such as record keeping and reporting requirements or changing operational practices.

There are no actions that governmental units must take to be in compliance with these proposed rules.

15. Describe whether or not an appropriation to state or local governmental units has been made or a funding source provided for any additional expenditures associated with the proposed rule(s).

No appropriations have been made to any governmental units as a result of these rules. No additional expenditures are anticipated or intended with the proposed rules.

Rural Impact:

16. In general, what impact will the rule(s) have on rural areas?

The proposed rules are not expected to impact rural areas. The proposed rules apply to pharmacist, pharmacy, manufacturer, and wholesale distributor licenses, regardless of their location.

A. Describe the types of public or private interests in rural areas that will be affected by the rule(s).

The proposed rules are not expected to impact rural areas. The proposed rules apply to pharmacist, pharmacy, manufacturer, and wholesale distributor licenses, regardless of their location.

Environmental Impact:

17. Do the proposed rule(s) have any impact on the environment? If yes, please explain.

No, the rules will not have an impact on the environment.

Small Business Impact Statement:

18. Describe whether and how the agency considered exempting small businesses from the proposed rule(s).

The proposed rules impose requirements on individual licensees and pharmacies, manufacturers, and wholesale distributors. A pharmacy, manufacturer, and wholesale distributor may be considered a small business. The agency did not consider exempting small businesses from the proposed rules as the rules regarding compounding are required by statute, and all other rules that apply to pharmacies, manufacturers, and wholesale distributors provide a mechanism for licensing and regulation that are necessary for the safety of the public no matter the size of the business. Despite the cost-related burden of licensing and regulation, the rules and regulations are necessary in order to provide a framework of standards for licensure and practice requirements.

19. If small businesses are not exempt, describe (a) how the agency reduced the economic impact of the proposed rule(s) on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rule(s) upon small businesses as described below, per MCL 24.240(1)(a)-(d), or (b) the reasons such a reduction was not lawful or feasible.

The proposed rules impose requirements on individual licensees and pharmacies, manufacturers, and wholesale distributors. A pharmacy, manufacturer, and wholesale distributor may be considered a small business. The compounding rules are required by statute and all other rules that apply to pharmacies, manufacturers, and wholesale distributors provide a mechanism for licensing and regulation that are necessary for the safety of the public no matter the size of the business. Therefore, reducing any disproportionate impact upon small businesses is not lawful nor feasible.

The proposed rules will require a pharmacy, manufacturer, and wholesale distributor applicant to pay

for a background check and an inspection when applicable. The proposed rules require a pharmacy, manufacturer, and wholesale distributor applicants to pay a licensing fee, the cost of a background check of approximately $25, and an inspection fee when applicable. The pharmacy license fee is $181.80. The manufacturer and wholesale distributor license fee is $85.85. The estimated costs for an inspection are between $1,995 and $3,000 depending on the type of pharmacy.

The costs associated with licensure of a pharmacy, manufacturer, and wholesale distributor are outweighed by the benefit of ensuring that the public is protected from the distribution of tainted pharmaceuticals. Despite the cost-related burden of licensing, the rules and regulations are necessary in order to provide a framework of standards for licensure and practice requirements.

A. Identify and estimate the number of small businesses affected by the proposed rule(s) and the probable effect on small business.

There are approximately 3,443 pharmacies, and 2,050 manufacturers and wholesale distributors in Michigan, may be considered small businesses depending on their size and annual sales.

The proposed rules will require a pharmacy, manufacturer, and wholesale distributor applicant to pay for a background check and an inspection when applicable. The proposed rules require a pharmacy, manufacturer, and wholesale distributor applicant to pay a licensing fee, the cost of a background check of approximately $25, and an inspection fee when applicable. The pharmacy license fee is $181.80. The manufacturer and wholesale distributor license fee is $85.85. The estimated costs for an inspection are between $1995 and $3,000 depending on the type of pharmacy. A pharmacy, manufacturer, and wholesale distributor will apply to renew their license every 2 years.

The costs associated with licensure of a pharmacy, manufacturer, and wholesale distributor are outweighed by the benefit of ensuring that the public is protected from the distribution of tainted pharmaceuticals. Despite the cost-related burden of licensing, the rules and regulations are necessary in order to provide a framework of standards for licensure and practice requirements.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rule after projecting the required reporting, record-keeping, and other administrative costs.

The agency did not establish separate compliance or reporting requirements for small businesses. The rules were drafted to be the least burdensome on all affected licensees.

C. Describe how the agency consolidated or simplified the compliance and reporting requirements for small businesses and identify the skills necessary to comply with the reporting requirements.

The agency did not consolidate or simplify compliance and reporting requirements with the proposed rules.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rule(s).

The agency did not establish performance standards to replace design or operation standards required by these rules.

20. Identify any disproportionate impact the proposed rule(s) may have on small businesses because of their size or geographic location.

There is no expected disproportionate impact on small businesses because of their size or geographic location.

21. Identify the nature of any report and the estimated cost of its preparation by small businesses required to

comply with the proposed rule(s).

The proposed rules do not require pharmacies, manufacturers, or wholesale distributors to prepare a report. There is no separate cost for report preparation to small businesses.

22. Analyze the costs of compliance for all small businesses affected by the proposed rule(s), including costs of equipment, supplies, labor, and increased administrative costs.

As of April 1, 2019, there are approximately 3,443 pharmacies, and 2,050 manufacturers and wholesale distributors in the state. The department does not determine which licensed pharmacies, manufacturers, or wholesale distributors qualify as small businesses. In addition, the department does not determine the annual gross sales or number of full-time employees associated with each pharmacy, manufacturer, or wholesale distributor license to allow for determining the number of small businesses. However, the impact on licensees who qualify as a small business is minimized in the proposed rules because they are written to provide the minimum amount of regulation necessary to protect the public. Although the proposed rules amend current requirements pertaining to pharmacies, manufacturers, and wholesale distributors, overall the requirements are substantially similar to the current rules. The proposed changes provide greater clarification that is anticipated to make it easier for licensees to comply with the rules, which should result in fewer violations of the rules and reduce the overall costs of compliance.

23. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rule(s).

There are no expected increased costs for small businesses concerning legal, consulting, or accounting services.

24. Estimate the ability of small businesses to absorb the costs without suffering economic harm and without adversely affecting competition in the marketplace.

All pharmacies, manufacturers, and wholesale distributors doing business in Michigan are subject to the same requirements and costs as a result of the proposed rules so there are no expected costs that should adversely affect competition in the marketplace.

The costs to a pharmacy, manufacturer, and wholesale distributor are outweighed by the benefit of ensuring that the public is protected. Despite the cost-related burdens of the proposed rules, the rules and regulations are necessary in order to provide a framework of standards for licensure and practice requirements to protect the public.

25. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

Exempting or setting lesser standards of compliance for pharmacies, manufacturers, and wholesale distributors is not in the best interest of the public and would increase the cost of protecting the public.

26. Identify the impact on the public interest of exempting or setting lesser standards of compliance for small businesses.

The costs to a pharmacy, manufacturer, and wholesale distributor are outweighed by the benefit of ensuring that the public is protected. Despite the cost-related burdens of the proposed rules, the rules and regulations are necessary in order to provide a framework of standards for licensure and practice requirements to protect the public. Exempting or setting lesser standards of compliance for small businesses is not in the best interest of the public.

27. Describe whether and how the agency has involved small businesses in the development of the proposed rule(s).

The Department worked with the Board of Pharmacy as well as associations that represent pharmacies in the development of the proposed rules. The Board is composed of members of health professions, individuals, both small and large business entities in Michigan, as well as public members.

A. If small businesses were involved in the development of the rule(s), please identify the business(es).

The Department worked with the Board of Pharmacy as well as associations that represent pharmacies in the development of the proposed rules. The Board is composed of members of health professions, individuals, both small and large business entities in Michigan, as well as public members.

Cost-Benefit Analysis of Rules (independent of statutory impact):

28. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups.

The Department does not expect any statewide compliance costs of the proposed rules on businesses or groups in addition to the impact on pharmacies, manufacturers, and wholesale distributors aforementioned.

A. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rule(s).

The Department does not expect any businesses or groups to be directly affected by, bear the cost of, or directly benefit from the proposed rules in addition to the impact on pharmacies, manufacturers, and wholesale distributors aforementioned.

B. What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

The Department does not expect the proposed rules to result in any additional costs such as new equipment, supplies, labor, accounting, or recordkeeping on businesses or other groups in addition to the impact on pharmacies, manufacturers, and wholesale distributors aforementioned.

29. Estimate the actual statewide compliance costs of the proposed rule(s) on individuals (regulated individuals or the public). Include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping.

Licensing: The proposed rules will require a pharmacist applicant to pay for the following: the North American Pharmacist Licensure Examination (NAPLEX) at a cost of approximately $575; the Michigan Multistate Pharmacy Jurisprudence Examination (MPJE) at a cost of approximately $200; a training on identifying victims of human trafficking with a cost depending on the class; cost to take the TOEFL-IBT of $195.00; a licensing fee of $60.60; a background check of approximately $25.00; and a controlled substance fee of $146.45.

Relicensure of a Pharmacist: The proposed rules will require applicants who have let their license lapse to meet specific requirements depending on the length of time they have been unlicensed. The requirements include: payment of an application and license fee at a cost of approximately $84.00 to $112.00; the NAPLEX at a cost of approximately $575; the MPJE at a cost of approximately $200.00; a background check at a cost of approximately $25.00; fees for attendance of 30 hours of continuing education at an estimated cost of $25.00 to 300.00; and a fee to attend a training on identifying victims of human trafficking with a cost depending on the class.

A. How many and what category of individuals will be affected by the rules?

There are approximately 15,915 licensed pharmacists in Michigan.

B. What qualitative and quantitative impact does the proposed change in rule(s) have on these individuals?

Licensing: The proposed rules will require a pharmacist applicant to pay for the following: the NAPLEX at a cost of approximately $575; the MPJE at a cost of approximately $200; a training on identifying victims of human trafficking with a cost depending on the class; cost to take the TOEFL-IBT of $195.00; a licensing fee of $60.60; a background check of approximately $25.00; and a controlled substance fee of $146.45.

Relicensure of a Pharmacist: The proposed rules will require applicants who have let their license lapse to meet specific requirements depending on the length of time they have been unlicensed. The requirements include: payment of an application and license fee at a cost of approximately $84.00 to $112.00; the NAPLEX at a cost of approximately $575; the MPJE at a cost of approximately $200.00; a background check at a cost of approximately $25.00; fees for attendance of 30 hours of continuing education at an estimated cost of $25.00 to 300.00; and a fee to attend a training on identifying victims of human trafficking with a cost depending on the class.

30. Quantify any cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rule(s).

There are no expected reductions in costs to businesses, individuals, groups of individuals or governmental units as a result of the proposed rules.

31. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rule(s). Provide both quantitative and qualitative information, as well as your assumptions.

The proposed rules will regulate a pharmacy in a medical institution and require technologies to ensure that the correct drugs are stocked. The proposed rules in parts 2 through 5 provide a regulatory framework for the practice of pharmacy for pharmacists, pharmacies, manufacturers, and wholesale distributors. The proposed rules will clarify what is required for pharmacies who intend to compound and handle sterile pharmaceuticals. The proposed rules adopt the sterile compounding standards of the USP to attempt to avoid mistakes in sterile compounding that have harmed the public in the past. The practice of pharmacy in part 6 of the proposed rules will clarify how drugs are labeled, what receipts are required for purchasers, the regulations pertaining to noncontrolled prescriptions, how to process a customized patient medication package, maintaining prescription records, how and where automated devices are allowed, the professional responsibilities of a pharmacist, and the regulations relating to a hospice emergency drug box, which further regulates the practice of pharmacy to protect the public.

The proposed rules will protect the welfare of Michigan citizens by providing greater clarity to licensees, which will aid in compliance with requirements under the rules. The system of licensure of pharmacies will prohibit unsafe conditions surrounding the compounding of sterile pharmaceuticals and provide for inspections.

32. Explain how the proposed rule(s) will impact business growth and job creation (or elimination) in Michigan.

The rules are not expected to have an impact on business growth, job creation, or job elimination.

33. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

There is not expected to be a disproportionate effect due to industrial sector, segment of the public, business size, or geographic location.

34. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of a proposed rule(s) and a cost-benefit analysis of the proposed rule(s).

Federal Pharmacy Law
https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/

http://www.rx-wiki.org/index.php?title=Federal_pharmacy_law

Compounding
https://www.jointcommission.org/assets/1/6/Feb_2017_State_Compounding_Regulations.pdf

https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155666.htm

Pharmacy
https://nabp.pharmacy/

NABP 2019 Survey of Pharmacy Law

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., which demonstrate a need for the proposed rule(s).

There were no estimates or assumptions made. All information used in the preparation of the proposed rules are included above.

Alternatives to Regulation:

35. Identify any reasonable alternatives to the proposed rule(s) that would achieve the same or similar goals. Include any statutory amendments that may be necessary to achieve such alternatives.

The rules are required by statute; there is no reasonable alternative to the proposed rules.

A. In enumerating your alternatives, include any statutory amendments that may be necessary to achieve such alternatives.

There is no reasonable alternative to the proposed rules.

36. Discuss the feasibility of establishing a regulatory program similar to that in the proposed rule(s) that would operate through private market-based mechanisms. Include a discussion of private market-based systems utilized by other states.

Since the rules are required by statute, private market-based systems cannot serve as an alternative. States regulate pharmacists, pharmacies, manufacturers of prescription drugs and devices, and wholesale distributors of prescription drugs and devices by statute, regulation, or both. Private market-based systems are not used for licensing and regulation. The licensing and regulation of pharmacists, pharmacies, manufacturers of prescription drugs and devices, and wholesale distributors of prescription drugs and devices are state functions, so a regulatory program independent of state intervention cannot be established. There are professional associations that establish criteria for membership, but these professional organizations would provide the public with significantly less protection because membership in many of these organizations is voluntary. This means an individual who meets the membership requirements, but does not join one of the professional organizations, would be able to practice and there would be no way to ensure their competency or hold them accountable.

37. Discuss all significant alternatives the agency considered during rule development and why they were not incorporated into the rule(s). This section should include ideas considered both during internal discussions and discussions with stakeholders, affected parties, or advisory groups.

Since the rules are specifically required by statute, there are no alternatives to the proposed rules that the agency could consider. They are necessary for the administration and enforcement of the licensing process.

Additional Information:

38. As required by MCL 24.245b(1)(c), describe any instructions on complying with the rule(s), if applicable.

Licensure: The rules will explicitly inform licensees of the requirement for licensure, including: the number of times the applicant may take an examination; which examinations are required; how an internship is acquired; what is necessary to become a preceptor; and what requirements must be met to be relicensed if a license has lapsed. All requirements for licensure will be included on licensure applications.

Inspections: The proposed rules will explicitly inform licensees of how to apply to provide inspections for the Board of Pharmacy; when an inspection is required; and what type of inspection is required.

↓ **To be completed by the ORR** ↓

PART 4: REVIEW BY THE ORR

Date RISCBA received:	3-29-2019/4-23-19

Date RISCBA approved:	**4/24/19**

Date of disapproval:	
Explanation:	