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REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS (RIS)

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Rule Set Information:
ARD assigned rule set number:
2022-8 LR
Title of proposed rule set:
Pharmacy-General Rules

Comparison of Rule(s) to Federal/State/Association Standard

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

The Drug Supply Chain Security Act (DSCSA) and corresponding federal regulations include requirements to develop and enhance drug supply chain security. They establish a federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and include product tracing requirements for entities in the drug supply chain, including, manufacturers, repackagers, wholesale drug distributors, and pharmacies. They also require the Food and Drug Administration (FDA) to establish federal standards for licensing of wholesale drug distributors and third-party logistics providers. States may not regulate tracing that is inconsistent with, more stringent than, or in addition to the federal requirements. States are also preempted from establishing licensure requirements that are inconsistent with or below the minimum standards established by federal law for wholesale distributors and third-party logistics providers. The DSCSA and federal regulations require a wholesale drug distributor and third-party logistics provider to maintain licensure in the state from which the drug is distributed and in most cases the state into which the drug is distributed if those states have a licensure process. State licensure information including significant discipline must be reported to the FDA on an annual basis. The DSCSA and federal regulations exclude a list of activities from the definition of wholesale distribution that have been adopted in the rules.

The rules include adoption of 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 rules.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act and corresponding Code of Federal Regulations, 42 CFR 423, require electronic prescribing under Medicare Part D for Schedule II to V controlled substances, which began in January of 2023. Section 17754a of the Public Health Code (Code), MCL 333.17754a, required the department to establish by rule the requirements for obtaining a waiver from electronically transmitting all prescriptions, including controlled substances. The rules provide for a waiver from electronic prescribing in certain circumstances. Most, but not all of the circumstances are consistent with the SUPPORT Act.

Under the Controlled Substances Act, (CSA), 21 USC 801 et seq., the federal government regulates 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 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.

Taking into consideration the federal laws and regulations referenced above, each state establishes its own requirements with respect to the licensing requirements of pharmacists, pharmacies, manufacturers of prescription drugs and devices (manufacturer), wholesale distributors of prescription drugs and devices (wholesale distributor), and wholesale distributor-brokers of prescription drugs and devices (wholesale distributor-broker).

A. Are these rules required by state law or federal mandate?

The proposed rules are required by sections 16287, 17722, 17731, 17737, 17742a, 17744f, 17748e, and 17754a of the Code, MCL 333.16287, MCL 333.17722, MCL 333.17731, MCL 333.17737, MCL 333.17742a, MCL 333.17744f, MCL 333.17748e, and MCL 333.17754a. The rules are not federally mandated.

MCL 333.16141 authorizes the department to promulgate rules to promote the effective and consistent administration of Article 15 of the Public Health Code. MCL 333.16145 authorizes a Board of Pharmacy (board) to promulgate rules necessary or appropriate to fulfill its functions as prescribed in Article 15. MCL 333.17742a authorizes the department, in consultation with the board, to establish requirements for licensure for remote pharmacies. MCL 333.17748a authorizes the department, in consultation with the board, to promulgate rules regarding conditions and facilities for the compounding of nonsterile and sterile pharmaceuticals. MCL 333.17748e authorizes the department, in consultation with the board, to establish requirements for licensure as a wholesale distributor-broker. MCL 333.17754a authorizes the department to establish by rule the requirements for obtaining a waiver from electronically transmitting a prescription, as well authorizing the department, in consultation with the board, to promulgate rules to implement MCL 333.17754a. MCL 333.17767 authorizes the board to promulgate rules necessary or appropriate to the licensing of pharmacists, drugs, dispensers, manufacturers, wholesale distributors, and wholesale distributor-brokers. MCL 333.17744f authorizes the board to promulgate rules necessary to effectuate PA 36 of 2021, regarding dispensing emergency supplies of insulin.

The applicable statutory authority for the proposed rules includes the following: Part 177 and sections 16141, 16145, 16148, 16174, 16175, 16178, 16182, 16186, 16204, 16205, 16215, and 16287 of the Code, MCL 333.17701 to MCL 333.17780, MCL 333.16141, MCL 333.16145, MCL 333.16148, MCL 333.16174, MCL 333.16175, MCL 333.16178, MCL 333.16182, MCL 333.16186, MCL 333.16204, MCL 333.16205, MCL 333.16215, and MCL 333.16287.

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

The proposed rules do not exceed a federal standard.

2. Compare the proposed rules 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, wholesale distributors, wholesale distributor-brokers and the practice of pharmacy.

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.

The proposed rules in Part 1 pertain to definitions and inspections. The proposed rules clarify the type of information that is not subject to an inspection. All states in the Great Lakes region provide for inspections.

The proposed rules in Part 2 pertain to licensure of pharmacists. 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. All states in the Great Lakes region require the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification for licensure by endorsement, as well as practical experience, and the multistate pharmacy jurisprudence examination (MPJE). The proposed rules allow for an applicant for licensure by endorsement to attest that the applicant has sufficient knowledge of the Code and rules to competently practice pharmacy in Michigan instead of passing the MPJE. The number of pharmacy practice experience hours required in an internship varies from state to state. Michigan's requirement of 1600 hours is average compared to the other states in the Great Lakes region.

The proposed rules in Part 3 pertain to pharmacy licenses. 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. Illinois, New York, and Wisconsin do not incorporate USP chapter 795 regarding nonsterile compounding in their rules. All states in the Great Lakes region except New York have adopted USP chapter 797 regarding sterile compounding. Only Ohio and Pennsylvania have adopted USP chapter 800 regarding hazardous drugs. No state in the Great Lakes region issues a separate license for a sterile compounding pharmacy. All states in the Great Lakes region, except Illinois, recognize the Verified Pharmacy Program (VPP) from the National Association of Board of Pharmacy (NABP). Only Ohio requires the VPP.

The proposed rules in Part 4 pertain to manufacturer licenses. Except for Indiana, all states in the Great Lakes region license manufacturers. Minnesota, New York, Ohio, Pennsylvania, and Wisconsin regulate manufacturers with a manufacturer license. Illinois regulates manufacturers as wholesale distributors. The proposed rules in Part 5 pertain to wholesale distributor and wholesale distributor-broker licenses. All states in the Great Lakes region license wholesale distributors. In Illinois, New York and Pennsylvania, wholesale distributors are not licensed by a board of pharmacy. Indiana, Minnesota, Ohio, and Pennsylvania regulate third-party logistics providers. Illinois licenses a virtual manufacturer as a wholesale drug distributor broker.

The proposed rules in Part 6 pertain to the practice of pharmacy. All states in the Great Lakes region regulate the practice of pharmacy. All states in the Great Lakes region except Illinois and Wisconsin have either enacted laws or have pending legislation regarding electronic transmission of prescriptions. All states in the Great Lakes region allow electronic prescribing of prescriptions. Records must be maintained for 2 years in Indiana, Minnesota, and Pennsylvania, 3 years in Ohio, and 5 years in Illinois, New York, and Wisconsin.

A. If the rules exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.

The standards pertaining to licensure, training, renewal, and duties differ from state to state. 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 rules.

The DSCSA and corresponding federal regulations include requirements to develop and enhance drug supply chain security. They establish a federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and include product tracing requirements for entities in the drug supply chain, including, manufacturers, repackagers, wholesale drug distributors, and pharmacies. They also require the FDA to establish federal standards for licensing of wholesale drug distributors and third-party logistics providers. States may not regulate tracing that is inconsistent with, more stringent than, or in addition to the federal requirements. States are also preempted from establishing licensure requirements that are inconsistent with or below the minimum standards established by federal law for wholesale distributors and third-party logistics providers. The proposed rules do not conflict with the DSCSA or federal regulations. The DSCSA and federal regulations exclude a list of activities from the definition of wholesale distribution. The rules have adopted the federal exclusions to the definition of wholesale distribution.

The rules adopt the pharmaceutical compounding standards of the 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.

The SUPPORT Act and corresponding Code of Federal Regulations, 42 CFR 423, require electronic prescribing under Medicare Part D for Schedule II to V controlled substances, and provide for exceptions to this requirement. The Code, MCL 333.17754a, required the department to establish by rule the requirements for obtaining a waiver from electronically transmitting all prescriptions, including controlled substances. The rules provide for a waiver from electronic prescribing in certain circumstances. Most, but not all of the circumstances are consistent with the SUPPORT Act.

Under the CSA, 21 USC 801 et seq., the federal government regulates 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 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.

Taking into consideration the federal laws and regulations referenced above, each state establishes its own requirements with respect to the licensing requirements of pharmacists, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers of prescription drugs and devices.

A. Explain how the rules have 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.

As a result of the Michigan Board of Pharmacy Rules Committee Work Group process with the public and research regarding federal laws and regulations, the resulting proposed rules are not in conflict with and are consistent in most respects with federal laws and regulations.

The DSCSA and federal regulations exclude a list of activities from the definition of wholesale distribution. The rules have adopted the federal exclusions to the definition of wholesale distribution. The 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 rules. The rules are consistent with the federal requirements and exceptions to electronic prescribing, except the rules allow a waiver from electronic prescribing for prescribers who issue prescriptions from a non-profit charitable medical clinic.

4. If MCL 24.232(8) applies and the proposed rules are more stringent than the applicable federally mandated standard, provide a statement of specific facts that establish the clear and convincing need to adopt the more stringent rules.

The federal government has not mandated that the state promulgate the proposed rules, consequently, MCL 24.232(8) is not applicable.

5. If MCL 24.232(9) applies and the proposed rules are more stringent than the applicable federal standard, provide either the Michigan statute that specifically authorizes the more stringent rules OR a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rules.

MCL 24.232(9) does not apply as this state establishes its own requirements with respect to the licensing requirements of pharmacists, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers. 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 rules are designed to alter.

The proposed rules are designed to alter the following behavior and frequency of behavior:

Limit the information that is subject to an inspection regarding matters relevant to an applicant or licensee's practice of pharmacy, manufacturing, and wholesale distribution of drugs and devices; limit applicants from submitting intern hours for licensure that are not acquired through an educational program, under the personal charge of a preceptor, through a preapproved unconventional internship, or through an educational program outside of the United States; limit graduates of programs outside of the United States from submitting internship hours from previous work outside of an educational program or under the personal charge of a preceptor; relieve preceptors from having to annually submit intern hours obtained in an educational program; relieve an applicant for endorsement from having to take the MPJE; limit a pharmacist in charge (PIC) or facility manager from being unable to fulfill their duties for 120 consecutive days without appointing a new PIC or facility manager; relieve an out-of-state pharmacy that will not compound sterile pharmaceutical products in this state from being limited to only one inspection entity; relieve an in-state pharmacy that will compound sterile pharmaceutical products from having difficulty proving USP compliance before being licensed; limit the existence of a pharmacy for not having the proper equipment; allow a manufacturer to use an inspection from the FDA; limit a pharmacy intern from providing final product verification without recording both the initials of the intern and supervising pharmacist; relieve the limitations on a pharmacy being able to locate an automated device as an extension of a pharmacy; relieve a pharmacy from being prohibited from locating a non-dispensing storage and pick up device on the premises of the pharmacy; and not allow a pharmacist to dispense an emergency supply of insulin.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rules.

The proposed rules are expected to alter the frequency of the targeted behavior as follows:

Inspections at the direction of the department will not involve purchasing data, other than shipment data and the current and historical selling price of the drug, or research data, other than research data that confirms the appropriate use of controlled substances for research purposes or research data for accountability for reconciliation of prescription drug inventories; applicants will only be able to submit intern hours that are acquired through an educational program, under the personal charge of a preceptor, through a preapproved unconventional internship, or through an educational program outside of the United States; graduates of programs outside of the United States will only be able to submit up to 1400 hours in an educational program experience towards an internship if the hours are not completed through an approved educational program or under the personal charge of a preceptor licensed in this state; preceptors in an educational program will not have to submit annual affidavits of hours; applicants for licensure by endorsement will no longer have to take the MPJE and instead will submit an affidavit; a PIC or facility manager who is unable to fulfill their duties for 120 consecutive days will appoint a new PIC or facility manager; an out-of-state pharmacy that will not compound sterile pharmaceutical products in this state may submit an inspection from NABP-VPP or a resident state board of pharmacy; an in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and within 6 months an inspection to assess USP compliance or accreditation; a pharmacy that dispenses drugs will have a sink with running water, a refrigerator for drugs, and a telephone; a manufacturer will have the option of submitting an inspection from the FDA, the manufacturer's resident state board of pharmacy, or NABP drug distributor accreditation; a pharmacy intern who provides final product verification will record both the initials of the intern and supervising pharmacist; a pharmacy may locate an automated device as an extension of a pharmacy in additional locations with limitations; a pharmacy may locate a non-dispensing storage and pick up device on the premises of the pharmacy; and a pharmacist may dispense an emergency supply of insulin.

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

The difference between current behavior and desired behavior is as follows:

Inspections at the direction of the department will not involve purchasing data or research data with some exceptions; applicants will only be able to submit intern hours that are acquired through an educational program, under the personal charge of a preceptor, through a preapproved unconventional internship, or through an educational program outside of the United States instead of submitting various work experience; graduates of programs outside of the United States will only be able to submit up to 1400 hours in an educational program experience towards an internship if the hours are not completed through an approved educational program or under the personal charge of a preceptor licensed in this state instead of submitting various work experience; preceptors will only have to submit the hours in the practice of pharmacy and only if the internship is outside of an educational program; applicants for licensure by endorsement will no longer have to take the MPJE and instead will submit an affidavit; a PIC or facility manager who is unable to fulfill their duties for 120 consecutive days will appoint a new PIC or facility manager instead of remaining in their role; an out-of-state pharmacy that will not compound sterile pharmaceutical products in this state may submit an inspection from NABP-VPP or a resident state board of pharmacy; an in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and within 6 months an inspection to assess USP compliance or accreditation instead of having to obtain proof that they meet USP compliance when they apply for licensure; a pharmacy that dispenses drugs will have a sink with running water, a refrigerator for drugs, and a telephone; a manufacturer will have the option of submitting an inspection from the FDA, the manufacturer's resident state board of pharmacy, or NABP drug distributor accreditation instead of being limited in the type of inspection allowed; a pharmacy intern who provides final product verification will record both the initials of the intern and supervising pharmacist; a pharmacy may locate an automated device as an extension of a pharmacy in additional locations with limitations; a pharmacy may locate a non-dispensing storage and pick up device on the premises of the pharmacy; and a pharmacist may dispense an emergency supply of insulin.

C. What is the desired outcome?

The desired outcome of the proposed rules is as follows:

Inspections at the direction of the department will be more useful to the department because applicants and licensees will have their company information protected; internship hours will primarily be obtained in an educational program, under the personal charge of a preceptor, or through a preapproved unconventional internship; graduates of programs outside of the United States will only be able to submit up to 1400 hours in an educational program experience towards an internship if the hours are not completed through an approved educational program or under the personal charge of a preceptor licensed in this state; more preceptors will volunteer if the requirements are not as cumbersome; applicants for licensure by endorsement will no longer have to take the MPJE as they are, in most cases, already familiar with pharmacy law; a PIC or facility manager who is unable to fulfill their duties for 120 consecutive days will appoint a new PIC or facility manager; an out-of-state pharmacy that will not compound sterile pharmaceutical products in this state may submit an inspection from NABP-VPP or a resident state board of pharmacy; an in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and within 6 months an inspection to assess USP compliance or accreditation, instead of attempting to show compliance with USP before being licensed; a pharmacy that dispenses drugs will have a sink with running water, a refrigerator for drugs, and a telephone; a manufacturer will have the option of submitting an inspection from the FDA, the manufacturer's resident state board of pharmacy, or NABP drug distributor accreditation; a pharmacy intern who provides final product verification will record both the initials of the intern and supervising pharmacist; more automated devices will be used to ensure easy access to prescriptions; a pharmacy may locate a non-dispensing storage and pick up device on the premises of the pharmacy to provide easy access to prescriptions; and a pharmacist may dispense an emergency supply of insulin.

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

The proposed rules are designed to alter the following harm:

Inspections at the direction of the department will be hindered by applicants or licensees because they protect company information; internships are obtained through experience that does not involve both practical and professional experience; less preceptors will volunteer if the requirements are cumbersome; less applicants for licensure by endorsement will apply if they are required to take an examination over information they have either already practiced or been tested on in another state; a PIC or facility manager staying in the position and being unable to fulfill their duties for 120 consecutive days; limiting options for inspections that result in more cumbersome licensing requirements; requiring an in-state pharmacy that will compound sterile pharmaceutical products to assess USP compliance or accreditation before being licensed; a pharmacy that dispenses drugs not having the proper equipment including a sink with running water, a refrigerator for drugs, and a telephone; not being able to determine who provided final product verification; limiting easy access for patients to pick up prescription drugs; and an individual not being able to find insulin in an emergency.

A. What is the rationale for changing the rules instead of leaving them as currently written?

The harm that will result from the behavior that the proposed rules are designed to alter will continue in the absence of the proposed rules. The proposed rules clarify concerns with the rules that have been raised by licensees, the department, or the public, that have resulted in previous harm to the public. Changes in the proposed rules may also have resulted from legislation.

8. Describe how the proposed rules 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.

The proposed rules protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome for alternatives for those required to comply, as the rules do the following: inspections at the direction of the department will be of greater use because applicants and licensees will have their company information protected; internship hours will primarily be obtained in an educational program, under the personal charge of a preceptor, or through a preapproved unconventional internship; graduates of programs outside of the United States will only be able to submit up to 1400 hours in an educational program experience towards an internship if the hours are not completed through an approved educational program or under the personal charge of a preceptor licensed in this state; more preceptors will volunteer if the requirements are not as involved; applicants for licensure by endorsement will no longer have to take the MPJE as they in most cases are already familiar with pharmacy law; a PIC or facility manager who is unable to fulfill their duties for 120 consecutive days will appoint a new PIC or facility manager; an out-of-state pharmacy that will not compound sterile pharmaceutical products in this state may submit an inspection from NABP-VPP or a resident state board of pharmacy; an in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and within 6 months an inspection to assess USP compliance, or accreditation, instead of attempting to show compliance with USP before being licensed; a pharmacy that dispenses drugs will have a sink with running water, a refrigerator for drugs, and a telephone; a manufacturer will have the option of submitting an inspection from the FDA, the manufacturer's resident state board of pharmacy, or NABP drug distributor accreditation; a pharmacy intern who provides final product verification will record both the initials of the intern and supervising pharmacist; more automated devices will be used to ensure easy access to prescriptions; a pharmacy may locate a non-dispensing storage and pick up device on the premises of the pharmacy to provide easy access to prescriptions; and a pharmacist may dispense an emergency supply of insulin.

Promulgation of rules related to licensure of pharmacists, interns, preceptors, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers is required by statute. These rules provide a regulatory framework for the practice of pharmacy. The proposed rules will clarify what is required for pharmacies who intend to compound and handle sterile pharmaceuticals or use an automated device. The proposed rules will also provide the requirements for the legislative mandate regarding dispensing emergency supplies of insulin. The proposed rules regulate 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.

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

There are no rules being rescinded in this proposed rule set.

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 reimbursements rates, etc. over and above what is currently expended for that function. It does not include more intangible costs for benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

10. Please provide the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings for the agency promulgating the rule).

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 rules.

The licensing and regulation of pharmacists, interns, preceptors, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers, 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 rules are necessary and suitable to accomplish their purpose, in relationship to the burden(s) the rules place on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

The rules are required to provide a mechanism for licensing and regulation of pharmacists, interns, preceptors, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers. The rules are not any more restrictive than is allowed by statute. Despite the cost-related burden, the rules and regulations are necessary. There is no expectation of additional burdens, fiscal, administrative, or duplicative acts, on individuals. There is a reduction of the burdens on applicants for licensure by endorsement who will no longer have to take the MPJE.

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

No additional burdens have been identified. The rules are required to provide a mechanism for licensing and regulation of pharmacists, interns, preceptors, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers. The rules are not any more restrictive than is allowed by statute.

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 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 revenues or 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 rules.

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 rules. 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 comply with the 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 rules.

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 rules have on rural areas?

The proposed rules are not expected to impact rural areas. The proposed rules apply to pharmacists, interns, preceptors, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers regardless of their location.

A. Describe the types of public or private interests in rural areas that will be affected by the rules.

The proposed rules are not expected to impact rural areas. The proposed rules apply to pharmacists, interns, preceptors, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers regardless of their location.

Environmental Impact

17. Do the proposed rules 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 rules.

The proposed rules impose requirements on individual licensees, pharmacies, manufacturers, wholesale distributors, wholesale distributor-brokers, and a prescriber's workplace. The proposed rules require a pharmacy that dispenses drugs to have a sink with running water, a refrigerator for drugs, and a telephone. The department did not consider exempting small businesses from the proposed rules as the proposed rules are necessary for the safety of the public no matter the size of the business and are the minimum regulations necessary to protect the public.

19. If small businesses are not exempt, describe (a) the manner in which the agency reduced the economic impact of the proposed rules 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 rules upon small businesses as described below (in accordance with MCL 24.240(1)(a-d)), or (b) the reasons such a reduction was not lawful or feasible.

The proposed rules will impose requirements on pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers any of which may qualify as a small business. The department did not consider exempting small businesses from the proposed rules as the proposed rules are required by statute and they 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 reduce the impact on all pharmacies and manufacturers as follows: an out-of-state pharmacy that will not compound sterile pharmaceutical products in this state will have a choice of inspections to submit to the department; an in-state pharmacy that will compound sterile pharmaceutical products will not have to provide proof of compliance with USP at licensure; and a manufacturer will have the option of submitting an inspection from the FDA, the manufacturer's resident state board of pharmacy, or NABP drug distributor accreditation.

A. Identify and estimate the number of small businesses affected by the proposed rules and the probable effect on small businesses.

There are approximately 3,540 pharmacies, 559 manufacturers, 1,827 wholesale distributors, 2 wholesale distributor-brokers, and 7 remote pharmacies in Michigan that may be considered small businesses depending on their size and annual sales.

The department does not collect or have access to information that would allow it to identify and estimate the number of pharmacies, manufacturers, wholesale distributors, wholesale distributor-brokers, and remote pharmacies in Michigan that are small businesses. No matter what type of business environment a licensee works in, he or she will have to take the necessary steps in order to comply with the proposed rules. The rules do not affect small businesses differently.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rules 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 for small businesses. However, the proposed rules have simplified the compliance requirements for all pharmacies as follows: an out-of-state pharmacy that will not compound sterile pharmaceutical products in this state may submit an inspection from NABP-VPP or a resident state board of pharmacy; an in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and within 6 months an inspection to assess USP compliance or accreditation instead of attempting to show compliance with USP before being licensed which has been difficult for pharmacies; and a manufacturer will have the option of submitting an inspection from the FDA, the manufacturer's resident state board of pharmacy, or NABP drug distributor accreditation.

Pharmacies and manufacturers already submit an inspection, so additional skills are not required to comply with the requirements.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rules.

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

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

The proposed rules impact an individual licensee as well as pharmacies, manufacturers, wholesale distributors, wholesale distributor-brokers, and remote pharmacies. There may be an impact on a small business in that all pharmacies, manufacturers, wholesale distributors, wholesale distributor-brokers, and remote pharmacies no matter the size, must comply with the rules. Exempting a small business is not in the best interest of the public.

There is no expected disproportionate effect 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 rules.

There is no separate cost for report preparation specific to small businesses.

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

The department does not determine which licensees qualify as a small business. In addition, the department does not determine the annual gross sales or number of full-time employees associated with each licensee 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. There is no separate cost for report preparation specific to small businesses.

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

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, wholesale distributors, wholesale distributor-brokers, and remote pharmacies 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 licensee 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 the regulation of pharmacies, manufacturers, wholesale distributors, wholesale distributor-brokers, and remote pharmacies to protect the public.

There are no expected costs to small businesses that will cause economic harm to a small business or the marketplace as a result of the proposed rules.

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 licensees that are small businesses 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 pharmacies, manufacturers, wholesale distributors, wholesale distributor-brokers, and remote pharmacies 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 to protect the public. Exempting or setting lesser standards of compliance for small businesses is not in the best interest of the public.

The proposed rules also impose requirements on individual licensees rather than small businesses. Even if a licensee's employer qualifies as a small business, the department could not exempt his or her employer because it would create disparity in the regulation of licensees. Therefore, 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 rules.

The department worked with multiple stakeholders at the Michigan Board of Pharmacy Rules Committee Work Group meetings, that included members from the Board of Pharmacy, educational institutions, businesses, and other members of the public in the development of the proposed rules. The board is composed of members of the profession and public members who work in businesses in Michigan.

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

Representatives from businesses were involved in the development of the rules. However, the department is not aware if they meet the definition of a "small business."

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 other than the costs for a pharmacy should it take advantage of the new rule that allows a pharmacy to place an automated device outside of a pharmacy or add a non-dispensing storage and pick up device on the premises of a pharmacy. Any pharmacy that dispenses drugs should already have a sink with running water, a refrigerator, and a telephone.

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

There are approximately 3,540 pharmacies, 559 manufacturers, 1,827 wholesale distributors, 2 wholesale distributor-brokers, and 7 remote pharmacies in Michigan that may be considered small businesses depending on their size and annual sales. The proposed rules will impact businesses or groups as follows: businesses that are required to be inspected under the rules will have their company information protected; a business that is required to maintain a PIC or facility manager must ensure that the PIC or facility manager is not absent and unable to fulfill their duties for 120 consecutive days; an out-of-state pharmacy that will not compound sterile pharmaceutical products in this state may submit an inspection from NABP-VPP or a resident state board of pharmacy which makes meeting the regulations easier; an in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and within 6 months an inspection to assess USP compliance or accreditation instead of attempting to show compliance with USP before being licensed which makes meeting the regulation easier on the pharmacy; a pharmacy that dispenses drugs will have a sink with running water, a refrigerator for drugs, and a telephone if it does not currently have these items; a manufacturer will have the option of submitting an inspection from the FDA, the manufacturer's resident state board of pharmacy, or NABP drug distributor accreditation which gives options to the manufacturer; a pharmacy, should it take advantage of the new rule that allows a pharmacy to place an automated device outside of a pharmacy or add a non-dispensing storage and pick up device on the premises of a pharmacy, will have additional costs and additional benefits.

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)? Please 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 other additional costs such as new equipment, supplies, labor, accounting, or recordkeeping on businesses or other groups unless a pharmacy takes advantage of the new rule that allows a pharmacy to place an automated device outside of a pharmacy, add a non-dispensing storage and pick up device on the premises of a pharmacy, or does not already have a sink with running water, refrigerator, and telephone.

29. Estimate the actual statewide compliance costs of the proposed rules 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.

The department does not expect the proposed rules to result in any additional educational costs, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or record keeping on regulated individuals or the public.

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

There are 17,266 pharmacists and 1,714 interns in Michigan. Pharmacists, interns, preceptors and the public will be affected by the rules, but the department does not expect any additional costs to these individuals.

B. What qualitative and quantitative impact do the proposed changes in rules have on these individuals?

The proposed rules could have the following impacts on individuals: applicants will only be able to submit intern hours that are acquired through an educational program, under the personal charge of a preceptor, through a preapproved unconventional internship, or through an educational program outside of the United States instead of submitting various work experience; graduates of programs outside of the United States will only be able to submit up to 1400 hours in an educational program experience towards an internship if the hours are not completed through an approved educational program or under the personal charge of a preceptor licensed in this state instead of submitting various work experience; preceptors will only have to submit the hours in the practice of pharmacy and only if the internship is outside of an educational program; applicants for licensure by endorsement will no longer have to take the MPJE and instead will submit an affidavit; a PIC or facility manager who is unable to fulfill their duties for 120 consecutive days will no longer be able to be the PIC or facility manager; and a pharmacy intern who provides final product verification will record both the initials of the intern and supervising pharmacist.

The public is impacted by every substantive change in the proposed rules as all changes have been proposed to protect the public.

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

Applicants for licensure by endorsement will no longer have to take the MPJE at a cost of $250.00. There may be additional fees associated with the examination.

31. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rules. Please provide both quantitative and qualitative information, as well as your assumptions.

The benefits of the proposed rules are as follows: businesses that are required to be inspected under the rules will have their company information protected; an out-of-state pharmacy that will not compound sterile pharmaceutical products in this state may submit an inspection from NABP-VPP or a resident state board of pharmacy which makes meeting the regulations easier; an in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and within 6 months an inspection to assess USP compliance or accreditation instead of attempting to show compliance with USP before being licensed which makes meeting the regulation easier on the pharmacy; a manufacturer will have the option of submitting an inspection from the FDA, the manufacturer's resident state board of pharmacy, or NABP drug distributor accreditation which gives options to the manufacturer; a pharmacy that places an automated device outside of a pharmacy or adds a non-dispensing storage and pick up device on the premises of a pharmacy has additional locations to deliver drugs; preceptors will only have to submit the hours in the practice of pharmacy and only if the internship is outside of an educational program; and applicants for licensure by endorsement will no longer have to take the MPJE and instead will submit an affidavit.

The public benefits by every substantive change in the proposed rules as all changes have been proposed to protect the public.

32. Explain how the proposed rules 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 the proposed rules and a cost-benefit analysis of the proposed rules.

Electronic Transmission/Waivers
https://www.cms.gov/Medicare/E-Health/Eprescribing

https://www.congress.gov/bill/115th-congress/house-bill/6/text Smart Act lists exceptions

Support Act
Overview of the SUPPORT Act Provisions Related to Imports | FDA

Food and Drug Administration
https://www.bing.com/search?q=FDA&form=ANNH01&refig=b8036c92a10a4270bd0281047a511690

National Alliance for Model State Drug Laws
https://namsdl.org/model-laws/

NABP
https://www.bing.com/search?q=nabp&cvid=431e38fbdbf44b9e963b989c0ff41463&aqs=edge.0.69i59j0l7j69i65j69i11004.1150j0j1&pglt=41&FORM=ANNAB1&PC=U531

Multistate Pharmacy Jurisprudence Examination (MPJE) | NABP

Verified Pharmacy Program Inspection Service | VPP (nabp.pharmacy)

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USP
USP General Chapter 795 | USP

https://www.usp.org/compounding/general-chapter-797

https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare

Human Drug Compounding | FDA

USP General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging | USP

Other
SAFEWO~2.PDF

Facts About the Current Good Manufacturing Practices (CGMPs) | FDA

Michigan Legislature - Act 368 of 1978

LARA
https://www.michigan.gov/lara/-/media/Project/Websites/lara/bpl/Shared-Files/BPL-Active-License-Counts.pdf?rev=7210aa39fba04c1895702b60c49a9f06

Wholesale Distributor

https://www.federalregister.gov/documents/2022/02/04/2022-01929/national-standards-for-the-licensure-of-wholesale-drug-distributors-and-third-party-logistics

FDA announces proposed rule: National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers | FDA

DSCSA

https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

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

No estimates or assumptions were made.

Alternative to Regulation

35. Identify any reasonable alternatives to the proposed rules that would achieve the same or similar goals.

There are no other reasonable alternatives to the proposed rules that would achieve the same or similar goals.

A. Please include any statutory amendments that may be necessary to achieve such alternatives.

There are no other reasonable alternatives to the proposed rules that would achieve the same or similar goals.

36. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rules that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

Since the rules are permitted and mandated by statute, private market-based systems cannot serve as an alternative. Each state is responsible for implementing its own laws and rules pertaining to pharmacists, interns, preceptors, pharmacies, manufacturers, wholesale distributors, wholesale distributor-brokers and remote pharmacies. Private market-based systems are not used for regulating the practice of pharmacy. These are state functions, so a regulatory program independent of state intervention cannot be established.

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

No alternatives were considered during rule development.

Additional Information

38. As required by MCL 24.245b(1)(c), please describe any instructions regarding the method of complying with the rules, if applicable.

Licensure by endorsement: The rules will explicitly inform applicants how to apply for a license.

Pharmacists, Pharmacies, Interns, Wholesale Distributors, Wholesale distributor-brokers, Remote pharmacies, and Manufacturers: The rules will explicitly inform applicants of any modifications to the licensure requirements.