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REGULATORY IMPACT STATEMENT and COST-BENEFT ANALYSIS (RIS)

Agency Information:

Department name:

Licensing and Regulatory Affairs

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Rule Set Information:

ARD assigned rule set number:

2020-128 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 are being adopted in the rules.

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.

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 beginning in 2021 and provide for exceptions to this requirement. Section 17754a of the Public Health Code (Code), MCL 333.17754a, requires the Department to establish by rule the requirements for obtaining a waiver from electronically transmitting all prescriptions, including controlled substances. The proposed rules will 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 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 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 17722, 17731, 17737, 17742a, 17748e, and 17754a of the Public Health Code (Code), MCL 333.17722, MCL 333.17731, MCL 333.17737, MCL 333.17742a, MCL 333.17748e, and MCL 333.17754a. 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, wholesale distributors, and wholesale distributor-brokers. These provisions of the Code authorize the Board to do the following: establish specific requirements for licenses, renewals, and relicensure of pharmacists, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers; 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, wholesale distributors, and wholesale distributor-brokers; regulate compounding; license a remote pharmacy; provide a process for a waiver from the 10-mile limitation for a remote pharmacy; and provide a waiver from the legislative mandate to electronically transmit a prescription.

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 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. The proposed rule allowing licensure by endorsement from Canada is authorized by section 16186(3) of the Code, MCL 333.16186. 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 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. Most states require compliance with the USP chapters regarding sterile compounding as well as requiring inspections, however, no state issues a separate license for a sterile compounding pharmacy. Most states are not yet requiring compliance with USP 800. All states in the Great Lakes region, except Illinois, recognize the Verified Pharmacy Program (VPP) from the National Association of Board of Pharmacy. Only Ohio requires the VPP. Most states in the Great Lakes region allow for telepharmacy or remote pharmacies.

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. The Code requires a wholesale distributor-broker to hold a license to do business in this state and to receive a license it must meet all the requirements that are established by rule. All states in the Great Lakes region license wholesale distributors. 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 Wisconsin have either enacted laws or have pending legislation regarding electronic transmission of prescriptions. Michigan, Illinois, and Wisconsin require that prescription records are kept for 5 years. Michigan allows a prescription to be duplicated in an electronic form after 2 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. All states in the Great Lakes region except Wisconsin have either enacted laws or have pending legislation regarding electronic transmission of prescriptions. Indiana, New York, and Pennsylvania require electronic transmission of prescriptions with some exceptions.

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 proposed rules adopt 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 beginning in 2021 and provide for exceptions to this requirement. The Code, MCL 333.17754a, requires the Department to establish by rule the requirements for obtaining a waiver from electronically transmitting all prescriptions, including controlled substances. The proposed rules will 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 proposed rules adopt the federal exclusions to the definition of wholesale distribution. 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. Together, the Code and proposed rules are consistent with the federal requirements and exceptions to electronic prescribing, except the proposed 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: make preceptor affidavits less subjective by requiring actual internship hours instead of comments on the ability to practice; allow an applicant who has failed the North American Pharmacist Licensure Examination (NAPLEX) or the MPJE to review the material in a preparation course or with an instructor instead of completing courses in an education program; clarify that an applicant who has completed the FPGEC certification has met the English proficiency requirement; allow an applicant for licensure by endorsement to obtain a license in this state if he or she either holds a license in another state or holds a license in Canada and meets additional requirements; require an applicant for relicensure to submit to the Department any discipline that occurs between the time he or she applies and the time he or she is licensed; establish the requirements for a remote pharmacy license; provide a process to receive a waiver from the 10-mile requirement between a remote pharmacy and another pharmacy; require an in-state and out-of-state pharmacy that will provide sterile compounding in this state to submit an onsite physical inspection and report completed no more than 18 months before the application; clarify that a pharmacy that starts or resumes sterile compounding must apply to the Department and submit the required inspection report; require a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker that is closing to maintain records for the same amount of time that records would have been maintained if the pharmacy remained open; clarify the process for renewal versus relicensure for a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker; add the requirements for a facility manager if a manufacturer chooses to use a facility manager instead of a pharmacist in charge; adopt the federal exclusions to the definition of wholesale distribution to ensure that the rules do not require a pharmacy to obtain a license as a wholesale distributor if the same activities would not be considered wholesale distribution under the federal law; add the licensure and record keeping requirements for a wholesale distributor-broker; reduce the time from 3 years to 2 years before a prescription may be electronically duplicated; provide the requirements for electronic transmission of prescriptions; provide the process for a waiver from the mandate to electronically transmit a prescription after a specific date; and clarify that if final product verification is delegated, then both the pharmacist and technician must record their initials.

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: preceptors will be required to submit actual internship hours instead of comments on the ability to practice; an applicant who has failed the NAPLEX or the MPJE will review the material in a preparation course or with an instructor; an applicant who has completed the FPGEC certification will not have to otherwise meet the English proficiency requirement; an applicant may obtain a license by endorsement if he or she either holds a pharmacist license in another state or holds a pharmacist license in Canada and meets additional requirements; an applicant for relicensure who has incurred discipline on another license between application and licensure in this state will report it to the Department; the remote pharmacy requirements will be in rule; a remote pharmacy applicant that is located within 10 miles from another pharmacy can apply for a waiver; an in-state or out-of-state pharmacy that will provide sterile compounding in this state will submit an onsite physical inspection and report completed no more than 18 months before the application; a pharmacy that starts or resumes sterile compounding will apply to the Department and submit the required inspection report; a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker that closes will maintain records for the same amount of time that records would have been maintained if the pharmacy remained open; a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker will follow the requirements for renewal and relicensure; if a manufacturer chooses to use a facility manager instead of a pharmacist in charge it will follow the facility manager requirements; this state will not require a pharmacy to obtain a license as a wholesale distributor if the same activities would be exempt under federal law; a wholesale distributor-broker will maintain records and follow the licensure requirements; prescriptions may be electronically duplicated after 2 years; prescriptions will be electronically transmitted; prescribers may apply for a waiver from the mandate to electronically transmit a prescription; and if final product verification is delegated, then both the pharmacist and technician will record their initials.

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

The difference between current behavior and desired behavior is as follows: preceptors will be required to submit actual internship hours instead of comments on the ability to practice; an applicant who has failed the NAPLEX or the MPJE will review the material in a preparation course or with an instructor instead of taking courses in an education program; an applicant who has completed the FPGEC certification will not have to otherwise meet the English proficiency requirement; an applicant may obtain a license by endorsement if he or she either holds a pharmacist license in another state or holds a pharmacist license in Canada and meets additional requirements; an applicant for relicensure who has incurred discipline on another license between application and licensure in this state will report it to the Department and be subject to discipline in this state; an applicant for a remote pharmacy license will be able to review the requirements in the rules; a remote pharmacy applicant that is located within 10 miles from another pharmacy can apply for a waiver instead of not being able to apply for a remote pharmacy license; an in-state or out-of-state pharmacy that will provide sterile compounding in this state will submit an onsite physical inspection and report completed no more than 18 months before the application instead of being able to use an inspection that is older; a pharmacy that starts or resumes sterile compounding will apply to the Department and submit the required inspection report; a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker that closes will maintain records for the same amount of time that records would have been maintained if the pharmacy remained open; a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker will follow the requirements for renewal and relicensure that have been added to the rules; if a manufacturer chooses to use a facility manager instead of a pharmacist in charge it will follow the facility manager requirements; instead of adopting only a few exemptions, all of the activities exempted under federal law from the definition of wholesale distribution will be adopted in this state; a wholesale distributor-broker will maintain records and follow the licensure requirements; prescriptions may be electronically duplicated after 2 years instead of 3 years; prescriptions will be electronically transmitted unless they fall under 1 of the exemptions or a waiver is granted; prescribers may apply for a waiver from the mandate to electronically transmit a prescription; and if final product verification is delegated, then both the pharmacist and technician will record their initials.

C. What is the desired outcome?

The desired outcome of the proposed rules is as follows: preceptors will be required to submit actual internship hours instead of comments on the ability to practice; an applicant who has failed the NAPLEX or the MPJE will review the material in a preparation course or with an instructor; an applicant who has completed the FPGEC certification will not have to otherwise meet the English proficiency requirement; an applicant may obtain a license by endorsement if he or she either holds a pharmacist license in another state or holds a pharmacist license in Canada and meets additional requirements; an applicant for relicensure who has incurred discipline on another license between application and licensure in this state will report it to the Department; the remote pharmacy requirements will be in rule; a remote pharmacy applicant that is located within 10 miles from another pharmacy can apply for a waiver; an in-state or out-of-state pharmacy that will provide sterile compounding in this state will submit an onsite physical inspection and report completed no more than 18 months before the application; a pharmacy that starts or resumes sterile compounding will apply to the Department and submit the required inspection report; a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker that closes will maintain records for the same amount of time that records would have been maintained if the pharmacy remained open; a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker will follow the requirements for renewal and relicensure; if a manufacturer chooses to use a facility manager instead of a pharmacist in charge it will follow the facility manager requirements; this state will not require a pharmacy to obtain a license as a wholesale distributor if the same activities would be exempt under federal law; a wholesale distributor-broker will maintain records and follow the licensure requirements; prescriptions may be electronically duplicated after 2 years; prescriptions will be electronically transmitted; prescribers may apply for a waiver from the mandate to electronically transmit a prescription; and if final product verification is delegated, then both the pharmacist and technician will record their initials.

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: preceptors currently comment on the ability to practice which is subjective; an applicant who has failed the NAPLEX or the MPJE is limited to courses in an education program which is limited and inflexible; an applicant must meet the English proficiency requirement and it is not clear whether the FPGEC meets that requirement; requiring a licensee in another state or 1 who is licensed in Canada, has taken a Canadian examination, and graduated from an accredited program from being licensed in this state; an applicant for relicensure being able to be relicensed with sanctions on his or her license; pharmacies acting as remote pharmacies without going through a licensure process or waiver review; an in-state or out-of-state pharmacy that will provide sterile compounding in this state from having an up-to-date physical inspection and report; a pharmacy starting or resuming sterile compounding without the appropriate protections for the public; a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker that closes and destroys all of the pharmacy records; a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker having to meet too many requirements for renewal of a license or too few requirements for relicensure of a license; a manufacturer choosing to use a facility manager instead of a pharmacist in charge with no requirements regarding the facility manager; only adopting a few of the federal exemptions to the definition of wholesale distribution which would require a rule inconsistent with the DSCSA; a wholesale distributor-broker that does not maintain records and follow the licensure requirements; limiting prescriptions from being electronically duplicated for a longer period of time; fewer prescriptions being electronically transmitted and no waiver process from the mandate; and less verification of who handled the final verification if both the pharmacist and technician do not record their initials.

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 areas in licensing that have been raised by licensees, are a result of previous harm to the public, or 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 alternative for those required to comply, as the rules do the following: make preceptor affidavits less subjective by requiring actual internship hours instead of comments on the ability to practice; allow an applicant who has failed the NAPLEX or the MPJE to review the material in an preparation course or with an instructor instead of completing courses in an education program; clarify that an applicant who has completed the FPGEC certification has met the English proficiency requirement; allow an applicant for licensure by endorsement to obtain a license in this state if he or she either holds a license in another state or holds a license in Canada and meets additional requirements; require an applicant for relicensure to submit discipline that occurs between the time he or she applies and licensure to the department; establish the requirements for a remote pharmacy license; provide a process to receive a waiver from the 10-mile requirement between a remote pharmacy and another pharmacy; require an in-state and out-of-state pharmacy that will provide sterile compounding in this state to submit an onsite physical inspection and report completed no more than 18 months before the application; clarify that a pharmacy that starts or resumes sterile compounding must apply to the department and submit the required inspection report; require a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker that is closing to maintain records for the same amount of time that records would have been maintained if the pharmacy remained open; clarify the process for renewal versus relicensure for a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker; add the requirements for a facility manager if a manufacturer chooses to use a facility manager instead of a pharmacist in charge; adopt the federal exclusions to the definition of wholesale distribution to ensure that the rules do not require a pharmacy to obtain a license as a wholesale distributor if the same activities would not be considered wholesale distribution under the federal law; add the licensure and record keeping requirements for a wholesale distributor-broker; reduce the time from 3 years to 2 years before a prescription may be electronically duplicated; provide the requirements for electronic transmission of prescriptions; provide the process for a waiver from the mandate to electronically transmit a prescription after a specific date; and clarify that if final product verification is delegated, then both the pharmacist and technician must record their initials.

Promulgation of rules related to licensure of pharmacists, interns, preceptors, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers are required by statute. These rules provide a regulatory framework for the practice of pharmacy. The proposed rules will clarify what is required for pharmacies that intend to compound and handle sterile pharmaceuticals or practice in a remote pharmacy. 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 proposed rules will also provide the requirements for the legislative mandate for the electronic transmission of prescriptions and the waiver process in limited circumstances. 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 proposed rules will provide a licensure process for remote pharmacies and wholesale distributor-brokers, a waiver process for remote pharmacies, and a waiver process for electronic transmission of prescriptions. The department expects the proposed rules may result in additional administrative costs, however, there will also be licensure fees associated with the licensure process. The department does not expect the implementation of the proposed rules to result in additional 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 estimated cost for licensees or licensees' employers to set up a system to allow for electronic transmission of prescriptions varies depending on the services needed. There are free e-prescribing systems, however, they may have limitations on the type of services they provide. There are many companies that will assist with electronic transmission of data. Estimates of cost range from $35.00 to $150.00 per provider per month. Despite the cost-related burden, electronic transmission of prescriptions will allow for the electronic exchange of prescription data between physician practices and pharmacies, potentially improve the efficiency of the prescribing process, and reduce medication errors.

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.

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

Despite the cost-related burden, the proposed rules will allow for the electronic exchange of prescription data between physician practices and pharmacies, potentially improve the efficiency of the prescribing process, and reduce medication errors. 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.

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 rule that allows for a waiver to the limitation that a remote pharmacy may not be located within 10 miles of another pharmacy may allow for greater use of the remote pharmacy waiver in rural areas.

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

The proposed rule that allows for a waiver to the limitation that a remote pharmacy may not be located within 10 miles of another pharmacy may allow for greater use of the remote pharmacy waiver in rural areas. Therefore, a pharmacy in a rural area may have a greater chance of receiving a waiver.

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 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. However, the proposed waiver rule from electronic transmission of prescriptions does allow a waiver for the following: the prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber; the prescriber demonstrates exceptional circumstances; or the prescriber issues prescriptions from a non-profit charitable medical clinic.

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 licensing rules regulate individual licensees. While a licensee may work independently or as part of a small business, the law does not allow the rules to exempt these individuals from the requirements of the rules.

The proposed rules will impose requirements on pharmacies, manufacturers, wholesale distributors, wholesale distributor-brokers, and a prescriber's workplace, 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. However, the proposed waiver rule from electronic transmission of prescriptions does allow a waiver for the following: the prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber; the prescriber demonstrates exceptional circumstances; or the prescriber issues prescriptions from a non-profit charitable medical clinic.

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

There are approximately 3,504 pharmacies, 584 manufacturers, 1,730 wholesale distributors, and 3 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 small businesses involving prescribers who are required to electronically transmit prescriptions that may be affected. 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. However, the proposed waiver rule from electronic transmission of prescriptions does allow a waiver for the following: the prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber; the prescriber demonstrates exceptional circumstances; or the prescriber issues prescriptions from a non-profit charitable medical clinic.

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.

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 a prescriber's workplace. There may be an impact on a small business in that all pharmacies, no matter the size, are required to accept electronic transmissions of prescriptions and a prescriber's workplace may have to transmit prescriptions electronically. Allowing a small business to refuse to send or accept electronic transmissions is not in the best interest of the public. However, the proposed waiver rule from electronic transmission of prescriptions does allow a waiver for the following: the prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber; the prescriber demonstrates exceptional circumstances; or the prescriber issues prescriptions from a non-profit charitable medical clinic.

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.

The proposed rules require a wholesale distributor-broker to maintain a list of officers, directors, managers, and other persons who are in charge of wholesale drug delivery and trade including a description of their duties and a summary of their qualifications as well as maintain for at least 7 years the transaction history, transaction statements, and transaction information required by section 17748e of the code, MCL 333.17748e. There is no separate cost for report preparation specific to small businesses as this is an additional reporting requirement for all wholesale distributor-broker licensees.

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.

There are approximately 3,504 pharmacies, 584 manufacturers, 1,730 wholesale distributors, and 3 remote pharmacies in this state. 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, and wholesale distributor-brokers 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. A prescriber's workplace that must comply with electronic transmission of prescriptions may apply for a waiver and the proposed waiver rule from electronic transmission of prescriptions does allow a waiver for the following reasons: the prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber; the prescriber demonstrates exceptional circumstances; or the prescriber issues prescriptions from a non-profit charitable medical clinic.

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, and wholesale distributor-brokers 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. However, the proposed waiver rule from electronic transmission of prescriptions does allow a waiver for the following: the prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber; the prescriber demonstrates exceptional circumstances; or the prescriber issues prescriptions from a non-profit charitable medical clinic.

The proposed rules also impose requirements on individual licensees rather than on small businesses. Even if a licensee's employer qualifies as a small business, the Department could not without an applicable exception or waiver, exempt his or her business 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.d

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, and wholesale distributor-brokers 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. However, the proposed waiver rule from electronic transmission of prescriptions does allow a waiver for the following: the prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber; the prescriber demonstrates exceptional circumstances; or the prescriber issues prescriptions from a non-profit charitable medical clinic.

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 prescribers' employers, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers.

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 3,504 pharmacies and 3 remote pharmacies in this state. The proposed rules will impact pharmacies and prescribers' workplaces. Prescribers' workplaces will be required to electronically transmit prescriptions and pharmacies will be required to accept electronic transmissions. Pharmacies will bear the cost of accepting electronic transmissions. A licensee may work in a business, but no matter what type of business environment the licensee works in, he or she will have to comply with the proposed rules. It is not clear if the licensee or employer will bear the cost of establishing a system to electronically transfer prescriptions. The proposed waiver rule from electronic transmission of prescriptions does allow a waiver for the following: the prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber; the prescriber demonstrates exceptional circumstances; or the prescriber issues prescriptions from a non-profit charitable medical clinic.

The public will directly benefit by electronic transmission of prescriptions. There may be businesses that help with electronic transmission of prescriptions that may directly benefit from the proposed rules.

The public will directly benefit from the addition of remote pharmacies. Pharmacies will bear the cost of applying for a license and establishing a remote pharmacy. Pharmacies in rural areas may benefit from the remote pharmacy waiver.

Canadian licensees will directly benefit from the proposed licensure by endorsement rule that allows an applicant with a Canadian license to apply for and obtain a license in this state.

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 in addition to the impact on pharmacies and employers.

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 estimated cost for licensees to set up a system to allow them to electronically transmit prescriptions varies depending on the services needed. There are free e-prescribing systems, however, they may have limitations on the type of services they provide. There are many companies that will assist with electronic transmission of data. Estimates of cost range from $35.00 to $150.00 per provider per month. Despite the cost-related burden, electronic transmission of prescriptions will allow for the electronic exchange of prescription data between physician practices and pharmacies, potentially improve the efficiency of the prescribing process, and reduce medication errors.

The department does not expect the proposed rule 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?

Prescribers of both controlled substances and non-controlled substances will be affected by the proposed rules as they are required to electronically transmit prescriptions. There are 1,839 interns who will be affected by the proposed rules as their preceptors will be required to submit the hours worked by an intern. There are 17,052 pharmacists who will be affected by the proposed practice of pharmacy rules.

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

The estimated cost for licensees and pharmacies to set up a system to allow them to electronically transmit and receive prescriptions varies depending on the services needed. There are free e-prescribing systems, however, they may have limitations on the type of services they provide. There are many companies that will assist with electronic transmission of data. Estimates of cost range from $35.00 to $150.00 per provider per month.

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

Although they cannot be quantified at this time, there may be reductions in costs as follows: for pharmacies who maintain duplicate electronic copies of prescriptions instead of hard copies; for prescribers and employers who invest in electronically transmitting prescriptions; for pharmacies that use a remote pharmacy; and for prescribers who qualify for an electronic transmission waiver.

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: preceptor affidavits will be less subjective; an applicant who has failed the NAPLEX or the MPJE will be able to review the material in an preparation course or with an instructor; an applicant who has completed the FPGEC certification will meet the English proficiency requirement; an applicant for licensure by endorsement will more easily be licensed in this state; an applicant for relicensure must submit sanctions on their license which protects the public; a pharmacy may qualify for a remote pharmacy application even if they are within 10 miles of another pharmacy if they qualify for a waiver; sterile compounders will be required to always have an inspection that is recent; a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker that is closing must maintain their records; allow a manufacturer to use a facility manager; adopt the federal exclusions to the definition of wholesale distribution to ensure that the rules do not require a pharmacy to obtain a license as a wholesale distributor if the same activities would not be considered wholesale distribution under the federal law; add the licensure and record keeping requirements for a wholesale distributor-broker; reduce the time from 3 years to 2 years before a prescription may be electronically duplicated; require initials of both the pharmacist and technician if final verification is delegated; and unless there is an exception or waiver all prescribers will electronically transmit prescriptions which will allow for the electronic exchange of prescription data between physician practices and pharmacies, potentially improve the efficiency of the prescribing process, and reduce medication errors.

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

Federal Register – Medicare Program - https://www.federalregister.gov/documents/2020/08/04/2020-16897/medicare-program-electronic-prescribing-of-controlled-substances-request-for-information-rfi

https://www.bestnotes.com/medicare-announces-new-federal-epcs-mandate-deadline/

https://insights.id.me/article/healthcare/a-guide-to-state-and-federal-epcs-requirements-and-deadlines/

https://www.cms.gov/files/document/12120-pfs-final-rule.pdf - CMS proposed rule for enforcement of 1/1/22

https://www.acep.org/globalassets/new-pdfs/advocacy/acep-response-to-electronic-prescribing-for-controlled-substances-rfi.pdf

https://www.cms.gov/Medicare/E-Health/Eprescribing/Adopted-Standard-and-Transactions

https://www.govinfo.gov/content/pkg/FR-2020-08-17/pdf/2020-17127.pdf CFR Rule Modification

https://www.healthit.gov/sites/default/files/appa-1.1.pdf

https://home.svmic.com/resources/newsletters/252/mandatory-electronic-prescribing-for-controlled-substances-epcs-effective-january-1-2021

https://www.law.cornell.edu/cfr/text/42/423.160 Federal rule

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

Privacy and Security Solutions for Interoperable Health Information Exchange Report on State Prescribing Laws: Implications for e-Prescribing, Table A-1 (healthit.gov)

E-Prescribing State Laws (mdtoolbox.com)

42 CFR Subpart D - Cost Control and Quality Improvement Requirements | CFR | US Law | LII / Legal Information Institute (cornell.edu)

https://apps.leg.wa.gov/RCW/default.aspx?cite=69.50.312

https://www.bestnotes.com/medicare-announces-new-federal-epcs-mandate-deadline/#:~:text=On%20December%201%2C%202020%2C%20the%20Centers%20for%20Medicare,date%20has%20been%20set%20for%20January%201%2C%202022.

Food and Drug Administration
https://www.fda.gov/Drugs/default.htm

U.D. Department of Health and Human Services
https://www.hhs.gov/opioids/prevention/index.html

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

Illinois Rules
http://www.ilga.gov/commission/jcar/admincode/077/07703100sections.html

Indiana
https://secure.in.gov/pla/3026.htm

Indiana Rules
https://www.in.gov/pla/3878.htm

Indiana Statute
http://iga.in.gov/

Ohio Board of Pharmacy
http://www.pharmacy.ohio.gov/

Pennsylvania
https://apps.health.pa.gov/ddc/DDCFaqs.asp

Pennsylvania Rules

www.health.state.pa.us/ddc or www.pacode.com

Pennsylvania Statutes
https://apps.health.pa.gov/ddc/

Table of State Regs
https://www.healthit.gov/sites/default/files/appa-1.1.pdf
https://www.usa.gov/federal-agencies/centers-for-medicare-and-medicaid-services

Indiana
https://www.in.gov/isdh/27380.htm

http://iga.in.gov/legislative/laws/2019/ic/titles/035/#35-48

New York
Mandatory Prescriber Education (ny.gov)

Wisconsin
Wisconsin Legislature: 450.11(5)

Telehealth
https://www.brookings.edu/research/removing-regulatory-barriers-to-telehealth-before-and-after-covid-19/

https://www.cms.gov/files/document/covid-rural-health-clinics.pdf

https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet

https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/federal-disaster-resources/102236

https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf

https://www.sheehan.com/news/recent-changes-to-federal-telehealth-laws-in-response-to-the-covid-19-outbreak/

https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0930_2.htm

https://www.pharmhealthlaw.com/single-post/2020/03/31/dea-covid-waiver-practitioners-may-prescribe-controlled-substances-without-an-in-person-evaluation/

LARA
https://www.michigan.gov/documents/lara/lara_purchaselicenselist_attachmenta_health_active_license_types_415303_7.pdf

Wholesale Distributor
https://www.fda.gov/drugs/drug-supply-chain-integrity/verify-wholesale-drug-distributor-licenses

https://www.lawinsider.com/dictionary/virtual-manufacturer

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

https://www.fda.gov/media/106961/download

https://www.federalregister.gov/documents/2021/08/03/2021-16522/enhanced-drug-distribution-security-at-the-

package-level-under-the-drug-supply-chain-security-act

https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-resources-state-officials

https://www.fda.gov/media/93779/download

Canada

https://napra.ca/pages/Licensing_Registration/Authorities.aspx?id=1971

https://www.pharmacists.ca/pharmacy-in-canada/becoming-a-pharmacist-in-canada/

https://www.slideshare.net/dennis2841981/international-pharmacy-graduates-licensing-procedure-in-quebec#:~:text=International%20pharmacy%20graduates%20licensing%20procedure%20in%20quebec%201.,file%20be%20studied.%202.%20Procedures%20and%20processes%201

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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, and wholesale distributor-brokers. 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.

Electronic transmission of prescriptions and waiver: The rules will explicitly inform prescribers how to apply for a waiver and when the department will grant a waiver.

Remote pharmacy application and waiver: The rules will explicitly inform applicants how to apply for a license and waiver and when the Department will grant a waiver.

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

Wholesale distributor-broker license: The rules will explicitly inform applicants how to apply for a license.