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REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS (RIS)

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Rule Set Information:
ARD assigned rule set number:
2022-6 LR
Title of proposed rule set:
Pharmacy - Controlled Substances

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.

Under the Controlled Substances Act, (CSA), 21 USC 801 et seq., the federal government regulates the production, possession, and distribution of controlled substances. The CSA places drugs, chemicals, and plants into one of five schedules based on certain factors, including, but not limited to, the medical use of the substance and the potential abuse of the substance. In addition, the CSA requires individuals who manufacture, distribute, or dispense a controlled substance to be registered with the Drug Enforcement Administration in the U.S. Department of Justice. Registrants are required to keep a record of each controlled substance that was manufactured, received, sold, delivered, or disposed of, and maintain detailed inventories.

Each state establishes its own requirements with respect to the manufacture, distribution, and dispensing of controlled substances. In Michigan, Article 7, Controlled Substances, of the Michigan Public Health Code (Code) provides for the scheduling of controlled substances as well as establishes requirements for the licensure to manufacture, distribute, and dispense controlled substances. The CSA requires individuals who are registered under the CSA to keep certain records.

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

The following provisions of the Code mandate rules:

MCL 333.7203 requires the board to promulgate a rule to schedule a substance if it finds the substance has a potential for abuse.

MCL 333.7303 requires the board to designate by rule the controlled substances in Schedules 3 to 5 to be reported.

MCL 333.7333a requires the department to establish an electronic system for monitoring controlled substances.

MCL 333.17754a requires the department to establish by rule the requirements for obtaining a waiver from electronically transmitting all prescriptions, including controlled substances.

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.

There are various substances that are scheduled more stringently in the proposed rules than in the CSA. In the CSA, substances have been divided into 5 schedules as published in 21 CFR 1308.11 to 1308.15. The authority for the more stringent rule is MCL 333.7214, MCL 333.7201, and MCL 333.7220. It is necessary that these substances are listed in a higher schedule in this state than in the CSA as the legislature or Michigan Board of Pharmacy has applied the criteria for scheduling substances in MCL 333.7202, and have found that the substance has the potential for abuse in this state. The benefit of scheduling a substance more stringently is greater protection for the public from misuse of the substance. The costs of scheduling a substance more stringently are additional regulation of the misuse or diversion of the substance.

The remaining proposed rules do not exceed federal standards.

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

Although there are similar provisions to some of the proposed rules at the federal level and other states, the proposed rules do not exceed similar regulations, compliance requirements, or other standards adopted at the state, regional, or federal level.

Part 2 Schedules: The rules currently adopt the complete list of drugs and other substances that are considered controlled substances under the CSA, that have been divided into 5 schedules as published in 21 CFR 1308.11 to 1308.15. The adoption of the federal scheduling is subject to state laws that schedule, reschedule, or deschedule drugs, and MCL 333.7201. MCL 333.7201 allows the Michigan Board of Pharmacy to add substances, delete, or reschedule all substances that are enumerated in the schedules listed in state statutes. The proposed changes to R 338.3111 clarify that the federal schedule is adopted subject to drugs scheduled by the state after January 6, 2022, and the rules promulgated by the Michigan Board 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.

Brorphine was removed from the rule as an exception to the federal schedule because it is scheduled federally as a Schedule 1 drug. It is not scheduled in Illinois, Indiana, Minnesota, Ohio, and Pennsylvania. It is a Schedule 1 drug in Wisconsin and New York.

Gabapentin is not a scheduled federally or in Indiana, Ohio, Minnesota, New York, or Pennsylvania. However, Illinois and Wisconsin are monitoring this drug. The proposal is to remove Gabapentin from the rule as a Schedule 5 drug to align with the federal scheduling and the majority of the states in the Great Lakes Region. It will not be classified as a controlled substance upon removal.

Isomers are scheduled federally and are considered a Schedule 1 drug but are defined differently depending upon what section of the Code of Federal Regulations they are listed in. Isomers are Schedule 1 drugs in all of the Great Lakes Region states except for Indiana and Ohio. The proposed rules provide an exception to the federal scheduling so that the broader definition of this form of drug, defined in MCL 333.7212(3) would be adopted.

Pentazocine was removed from the rule as a Schedule 5 drug and will become a Schedule 4 drug to align with federal scheduling. This drug is scheduled similarly in all other Great Lakes Region states.

Salvia Divorum and Salvinorum A are not scheduled federally. However, they are Schedule 1 drugs in all of the Great Lakes Region states except for Minnesota and New York. The proposed rules provide an exception to the federal scheduling so these drugs would be included in the Michigan Board of Pharmacy schedule. These drugs were scheduled by the Michigan legislature before January 6, 2022, MCL 333.7212(1)(v) and (w), and are included in the board's schedule list for ease of public use.

Synthetic Cannabinoids are Schedule 1 drugs federally. They are Schedule 1 drugs in all of the Great Lakes Region states. The proposed rules provide an exception to the federal scheduling so that the broader definition of this form of drug, defined in MCL 333.7212(1)(e), would be adopted.

Synthetic Cathinones are Schedule 1 drugs federally. They are Schedule 1 drugs in Illinois, Indiana, Ohio, and Pennsylvania. They are not scheduled in Minnesota, New York, or Wisconsin. The proposed rules provide an exception to the federal scheduling so that the broader definition of this form of drug, defined in MCL 333.7212(1)(x), would be adopted.

Part 3 Licenses:
Clarifying language was provided to R 338.3132, which pertains to controlled substance licenses. The rules require a separate controlled substance license for each automated device located at an affiliated hospital location, or a hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility. The proposed changes state that if substances are stored at a health facility without an on-site pharmacy or an automated device stocked by a pharmacy, a designated prescriber must obtain a controlled substance license for the address where the drugs will be stored.

Additionally, a license exception was made for an emergency kit that contains controlled substances. All of the Great Lakes Region states have regulations about automated devices and emergency kits. None require a separate controlled substance license for the emergency kit. Further, the Drug Enforcement Agency does not require a separate registration for emergency kits in long term care facilities.

Part 5 Records:
R 338.3153, regarding invoices, acquisition, dispensing, administration, and distribution records, requires a licensee to maintain patient sales receipts and dispensing records in paper or electronic form for 90 days in the pharmacy for review. Additionally, a licensee must keep the original prescription record for 5 years after the last date of dispensing. The proposed rules permit a licensee to make an electronic duplicate of the original paper prescription, which will become the original prescription, 2 years from the last dispensing date. The proposed rule also requires a pharmacy that holds an additional license for an automated dispensing system that dispenses controlled substances to store inventories and schedule order forms at the licensed location of the automated device. This rule was changed to ensure consistency with the Pharmacy – General Rules. This rule was moved from another section and clarified the requirement that patient sales receipts and dispensing records need to be available for review by the department.

The proposed changes to R 338.3154, regarding medication records in medical institutions, clarify that if a controlled substance is dispensed from an automated device, then the documentation maintained on-site in the pharmacy must include the automated device's manufacturer name and model number and the name and address of the facility where the automated device is located.

All states in the Great Lakes Region have regulations regarding the maintenance of receipts and dispensing records for controlled substances.

Part 6 Dispensing and Administration of Controlled Substance Prescriptions:
The proposed changes to R 338.3161, pertaining to controlled substance prescriptions, clarify that a paper prescription complies with the rule if it contains preprinted numbers representing the quantity next to a box or line that the

prescriber can check. The prescription is not required to have preprinted numbers representing the quantity next to a box or line. The changes also add the requirement that the professional designation for the prescribing practitioner must be stored electronically so that the pharmacy can look up the credential of the prescriber instead of it being required to be written on the prescription. This will allow pharmacists to fill more prescriptions instead of declining to fill a prescription that is missing the information on the written document.

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. Pursuant to MCL 333.17754a, proposed R 338.6162a allows a prescriber to seek waiver of electronic prescription transmission requirements if the prescriber can attest that he or she intends, within 12 months, to not regularly practice their licensed profession for financial gain or as a means of livelihood. This broadens the exception to the electronic transmission requirements and permits licensees in this situation to seek a waiver so that they do not have to purchase the necessary equipment to comply with the requirements.

Lastly, the proposed changes to R 338.3165, pertaining to emergency dispensing of Schedule 2 substances, clarify that the prescriber must deliver to the dispensing pharmacist a written prescription postmarked within 7 days after the date the prescription was dispensed, or electronically transmit the prescription under R 338.3162a.

Part 7 Distributions: R 338.3185 pertains to discontinuances and transfers of business activities or practice. The proposed changes state that a licensee must provide written notification to the department 15 days before the controlled substances are transferred.

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

The rules do not exceed standards of 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.

Schedules: The proposed rules adopt the complete list of drugs and other substances that are considered controlled substances under the CSA except for those drugs or other substances treated differently by this state's laws and rules including: Isomers, Salvia Divorum, Salvinorum A, Synthetic Cannabinoids, and Synthetic Cathinones.

Licenses: There are no other laws or rules that duplicate, overlap, or conflict with the changes requiring that a designated prescriber obtain a controlled substance license for the address where drugs are stored at a health facility without an on-site pharmacy or an automated device stocked by a pharmacy. The same holds true for exempting an emergency kit from licensure.

Records: There are no other laws or rules that duplicate, overlap, or conflict with the changes requiring a licensee to maintain patient sales receipts and dispensing records for 90 days, allowing a licensee to make an electronic duplicate of a paper prescription 2 years from the last dispensing date, and requiring inventories and Schedule 2 order forms to be stored at the licensed location of the automated device that dispenses controlled substances.

Dispensing and Administration of Controlled Substance Prescriptions: 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. Pursuant to MCL 333.17754a, the proposed rules provide a waiver from electronic prescribing in certain circumstances where the licensee will not regularly practice their licensed profession for financial gain or as a means of livelihood within the next 12 months. Lastly, there are no other laws or rules that duplicate, overlap, or conflict with the changes that add the requirement that the professional designation for the prescribing practitioner be stored electronically or requiring a prescriber, who made an emergency prescription of a schedule 2 drug to deliver to the dispensing pharmacist the written prescription postmarked within 7 days of the date the prescription was dispensed, or to electronically transmit the prescription under R 338.3162a.

Distributions: With regard to the transfer of controlled substances, the licensee must obtain approval by the Drug Enforcement Agency pursuant to 21 CFR 1301.52.

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 proposed rules are not in conflict with and are consistent with federal laws and regulations.

The proposed rules adopt the complete list of drugs and other substances that are considered controlled substances under the CSA except for those drugs or other substances treated differently by this state's laws and rules including: Isomers, Salvia Divorum, Salvinorum A, Synthetic Cannabinoids, and Synthetic Cathinones.

The rules are consistent with federal and state laws applicable to controlled substance licensing, required records pertaining to controlled substances, dispensing and administration of prescriptions, distributions, and the federal requirements and exceptions to electronic prescribing.

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.

There are various drugs that are scheduled more stringently in the proposed rules than in the CSA. The authority for the more stringent rules is MCL 333.7214, MCL 333.7201, and MCL 333.7220.

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 do the following:

-Reduce confusion by the public and licensees regarding which substances are scheduled in this state.

-Clarify that if controlled substances are stored in an automated device at a facility without an on-site pharmacy, a designated prescriber must obtain a controlled substance license for the address where the drugs will be stored.

-Clarify that a controlled substance license is not required for an emergency kit that contains controlled substances.

-Clarify records requirements by stating that licensees must maintain, for department review, patient sales receipts and dispensing records for 90 days and that 2 years from the date of the last dispensing, an electronic duplicate of an original paper prescription may be made and utilized as the original prescription.

-Clarify that inventories and Schedule 2 order forms must be stored at the licensed location for the automated device that dispenses controlled substances.

-Clarify that a pharmacy in control of an automated device that dispenses controlled substances must document the manufacturer's name, and the name and address of the facility where the device is located.

-Clarify that a prescription is not required to have preprinted numbers representing the quantity next to a box or line.

-Clarify that the professional designation for the prescribing practitioner may be stored electronically instead of written on the prescription.

-Clarify that a prescriber may seek a waiver of the electronic transmission requirements if the prescriber can attest that he or she intends, within the next 12 months, to no longer regularly practice in the licensed profession for financial gain or as a means of livelihood.

-Clarify that a prescriber who prescribed a Schedule 2 substance in an emergency, must deliver to the dispensing pharmacist a written prescription postmarked within 7 days of the dispensing date, or electronically transmit the prescription under R 338.3162a.

-Require that a licensee provide written notification to the department 15 days before the controlled substances are transferred.

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:
-The public and licensees will know which substances are scheduled in this state.
-Licensees will know that if substances are stored at a health facility without an on-site pharmacy or an automated device stocked by a pharmacy, a designated prescriber must obtain a controlled substances license for the address where the drugs are stored.
-Licensees will understand that a separate controlled substance license is not needed for an emergency kit that contains controlled substances.
-Licensees will further understand the records requirements for controlled substances. Specifically, licensees will know that they must maintain, for department review, patient sales receipts and dispensing records for 90 days and that 2 years from the date of the last dispensing, an electronic duplicate of an original paper prescription may be made and utilized as the original prescription.
-Licensees will be aware that inventories and Schedule 2 order forms must be stored at the licensed location for the automated device that dispenses controlled substances and that a pharmacy in control of an automated device that dispenses controlled substances must document the manufacturer's name, and the name and address of the facility where the device is located.
-With regard to dispensing and administration of controlled substance prescriptions, licensees will understand that a prescription is not required to have preprinted numbers representing the quantity next to a box or line.
-Licensees will be aware that the professional designation for the prescribing practitioner may be stored electronically instead of written on the prescription.
-Licensees will be aware that a prescriber may seek a waiver of the electronic transmission requirements if the prescriber can attest that he or she intends, within the next 12 months, to no longer regularly practice in the licensed profession for financial gain or as a means of livelihood.
-The licensee will understand that a prescriber who prescribed a Schedule 2 substance in an emergency, must deliver to the dispensing pharmacist a written prescription postmarked within 7 days of the dispensing date, or electronically transmit the prescription under R 338.3162a.
-The licensee will know that written notification of a transfer of controlled substances must be given to the department 15 days before the transfer.

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

The proposed rules have been written to provide clarity for licensees. The difference between current behavior and desired behavior is as follows:
-Instead of frequently contacting the department, licensees and the public will understand that the federal schedule of controlled substances is adopted with exceptions that are provided for in statute and rule.
-Instead of contacting the department to ask if a license is needed, candidates will know when they must apply for a controlled substance license.
-Licensees will know the record requirements for controlled substances in that they must maintain, for department review, patient sales receipts and dispensing records for 90 days and that 2 years from the date of the last dispensing, an electronic duplicate of an original paper prescription may be made and utilized as the original prescription.
-Licensees will be aware that inventories and Schedule 2 order forms must be stored at the licensed location for the automated device that dispenses controlled substances and that a pharmacy in control of an automated device that dispenses controlled substances must document the manufacturer's name, and the name and address of the facility where the device is located.
- Licensees will clearly understand that a prescription is not required to have preprinted numbers representing the quantity next to a box or line and that the professional designation for the prescribing practitioner may be stored electronically instead of written on the prescription.
-Licensees will know when they can seek a waiver from the electronic transmission requirements.
-Licensees will know that that a prescriber must deliver a written prescription for a Schedule 2 substance, that was written in an emergency, to the dispensing pharmacist. It must be postmarked within 7 days of the dispensing date or transmitted under R 338.3162a.
-The licensee will know that written notification of a transfer of controlled substances must be given to the department 15 days before the transfer.

C. What is the desired outcome?

The desired outcome of the proposed rules is as follows:
-Licensees and the public will understand how to follow the federal, state, and board scheduling of controlled substances.
- Licensees will better understand what situations require a controlled substance license.
-Licensees will have clearer requirements for the records that must be kept for controlled substances and controlled substance prescriptions.
-Licensees will better understand when a waiver from the electronic prescription requirements can be granted and when the prescriber must send the written controlled substance prescription to the dispensing pharmacist in emergency situations.
-The department will know when transfers of controlled substances are taking place.

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:
-The use of a drug by the public without proper protections because it is not clear to the public and licensees that it is a controlled substance.
-Licensees dealing with controlled substances without a proper license.
-Licensees not keeping proper records pertaining to controlled substances.
-Licensees not being aware of when they can seek a waiver from the electronic prescribing requirements.
-Licensees not knowing when a prescription must be sent or received in situations when a controlled substance prescription was written and dispensed in an emergency situation.
-The department would not be aware that dangerous substances are being transferred therefore increasing the risk of drug diversion.

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.

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.

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 provide a regulatory system for controlled substances. To protect the health and safety of Michigan's citizens, it is important that health professionals that deal with controlled substances adhere to the rule requirements and professional standards of care. The rules are created with public safety in mind with scheduling designations, clear requirements for licensure, records, and dispensing and administration of controlled substance prescriptions.

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

R 338.3137 Eliminate drug-treatment program prescriber license requirement. This rule was rescinded because the drug treatment prescriber license was eliminated, and the rule was no longer needed.

R 338.3163 Individual with substance use disorder; prescribing, dispensing, and administering controlled substance. This rule was rescinded because Congress passed the Mainstreaming Addiction Treatment (MAT) Act that removed the federal "DATA 2000" or "DATA-Waiver Program. This change is intended to reduce barriers to obtaining medications for opioid use disorder (OUD) by eliminating burdens on providers who currently prescribe medications and new providers who wish to treat patients with OUD. Due to this movement at the federal level, the Michigan Board of Pharmacy recommends that this rule be rescinded, which regulates prescribing, dispensing and administering a controlled substance to an induvial with substance use disorder. The Bureau of Professional Licensing announced in July 2023 that it will not be enforcing this rule until the rule is either modified or rescinded. This rule limited the circumstances under which a practitioner could treat an individual with substance use disorder, as well as the number of individuals that could be treated. All other laws and rules, both federal and state, that deal with treating a substance use disorder must still be followed.

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 controlled substances, 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 proposed rules adopt the complete list of drugs and other substances that are considered controlled substances under the CSA except for those drugs or other substances treated differently by this state's laws and rules including: Isomers, Salvia Divorum, Salvinorum A, Synthetic Cannabinoids, and Synthetic Cathinones. These are necessary to provide public protection from misuse of the drugs and substances. The burdens caused by the rules are increased regulations that need to be followed.

The proposed changes regarding licenses clarify that if substances are stored at a facility without an on-site pharmacy or an automated device stocked by a pharmacy, a designated prescriber must obtain a controlled substance license for the address where the drugs will be stored. Additionally, the proposed rules clarify that a separate license for an emergency kit is not needed. These changes are necessary to provide clarity regarding licensure and alleviation from a license regulation for emergency kits.

The proposed changes regarding records clarify that: the licensee must maintain patient sales receipts and dispensing records for 90 days; a licensee may make an electronic duplicate of a paper prescription 2 years from the last dispensing date; and require inventories and Schedule 2 order forms to be stored at the licensed location of the automated device that dispenses controlled substances. Further, the clarification of what records must be maintained and in what form allows for the licensee to clearly understand the requirements to know how to comply with the rules. The changes did not create additional burden to the licensee.

The proposed changes to the rules regarding dispensing and administration of controlled substance prescriptions, provide for a waiver from electronic prescribing in situations where the licensee will not regularly practice their licensed profession for financial gain or as a means of livelihood within 12 months. This reduces a burden on licensees that fall into this category.

The proposed change that adds the requirement that the professional designation for the prescribing practitioner be stored electronically or requiring a prescriber, may be considered an additional burden but will result in fewer problems with a prescription that may cause it to go unfilled. Lastly, the change that requires that a prescriber who made an emergency prescription of a Schedule 2 drug, to deliver to the dispensing pharmacist a written prescription postmarked within 7 days of the date the prescription was dispensed, or to electronically transmit the prescription under R 338.3162a promotes compliance with the dispensing and administration regulations to allow for complete records of the incident to be given to the pharmacist.

The proposed change that adds the requirement that a licensee notify the department 15 days before controlled substances are transferred will help protect the health and safety of Michigan residents to decrease the chances of drug diversion and to ensure proper record keeping.

The rules are required to provide a mechanism for controlled substance licensing and regulation of controlled substances. 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.

The requirements in the proposed rules are needed and reasonable compared to the minimal burdens outlined above in order to protect the health, safety, and welfare of Michigan residents. The changes to the rules will protect Michigan residents by scheduling dangerous drugs/substances, reducing the number of prescriptions that go unfilled due to incomplete information on the prescription, and clarifying license, record, and distribution requirements to reduce the frequency of abuse and diversion. The rules are required to provide a mechanism for controlled substance licensing and regulation of controlled substances. The rules are not any more restrictive than is allowed by statute. Despite the minimal 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 actions that governmental units must take to comply with the 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 licensees 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 public or private interests in rural areas. The proposed rules apply to licensees 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. Even if a licensee's workplace qualifies as a small business, the department could not exempt his or her business because it would create a disparity in the regulation of the profession.

The proposed rules impose requirements on pharmacies and a prescriber's workplace, both 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.

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 impose requirements on pharmacies and a prescriber's workplace, both which may qualify as a small business. The rules are required by statute and 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.

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

There are approximately 3,517 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 and dispensers of controlled substances 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. The anticipated effects on licensees are minimal because the proposed rules clarify what is already required of licensees and not of the business in which they may work.

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. 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. The rules require a pharmacist and a controlled substance licensee to comply with statutorily mandated record keeping for controlled substances. However, there is no report that needs to be generated. Record keeping requirements apply to all licensees who hold a controlled substance license and pharmacists who fill and dispense controlled substance prescriptions.

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 3,517 pharmacies in the state. The department does not determine which licensed pharmacies 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 pharmacy license to allow for determining the number of small businesses. However, the impact on licensees who qualify as a small business is minimized in the proposed rules because they are written to provide the minimum amount of regulation necessary to protect the public. 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 that dispense controlled substances in Michigan are subject to the same requirements and costs as a result of the administrative rules. There are no expected costs that should adversely affect competition in the marketplace.

The costs to a pharmacy are outweighed by the benefit of ensuring that the public is protected. Despite the minimal burdens resulting from the proposed rules, the rules and regulations are necessary in order to provide a framework of standards for the regulation of controlled substances 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 pharmacies is not in the best interest of the public and would increase the cost of protecting the public.

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 exempt his or her business because it would create disparity in the regulation of controlled substance licenses. Therefore, exempting or setting lesser standards of compliance for small businesses is not in the best interest of the public.

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

The costs to a pharmacy are outweighed by the benefit of ensuring that the public is protected. Despite the minimal burdens contained in 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 controlled substance licenses. 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 in addition to the impact on prescribers' and dispensers' employers and pharmacies.

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 3,517 pharmacies in Michigan. The proposed rules will impact pharmacies, prescribers, and dispensers.

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.

The licensees and the public will directly benefit from the proposed changes to the rules.

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 department does not expect the proposed rules to result in additional costs for education or 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 and dispensers of controlled substances will be affected by the proposed rules. There are 82,848 controlled substance licensees.

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

There are no other qualitative or quantitative impacts as it relates to the actual statewide compliance costs of the proposed rules because the proposed rules create no expected increased or decreased costs for education, training, experience, application fees, examination fees, or licensure fees.

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

There may be reductions in costs associated with reductions in diversion and abuse of opioids, however, those costs cannot be estimated at this time.

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 proposed rules use clear, concise language, and implement the statutory requirements for scheduling, licensing, records and dispensing and administration, and distribution of controlled substance prescriptions. The clear, concise language allows the public and licensees to better understand the requirements.

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.

American Society of Consultant Pharmacists

https://www.ascp.com/page/issuedea

Electronic Transmission/Waivers

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

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

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

https://casetext.com/regulation/illinois-administrative-code

https://regulations.justia.com/states/illinois/title-68/part-1330/

http://ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1941&ChapAct=720%26nbsp%3BILCS%26nbsp%3B570%2F&ChapterID=53&ChapterName=CRIMINAL+OFFENSES&ActName=Illinois+Controlled+Substances+Act%2E

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

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

https://iga.in.gov/laws/2023/ic/titles/25#25-26-13.5

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

https://law.justia.com/codes/indiana/2019/title-25/article-26/chapter-13-5/section-25-26-13-5-15/

https://casetext.com/regulation/indiana-administrative-code/title-856-indiana-board-of-pharmacy/article-1-pharmacies-and-pharmacists/rule-856-iac-1-281-institutional-pharmacies-and-pharmacy-services

Minnesota:

https://www.revisor.mn.gov/statutes/cite/151

https://www.revisor.mn.gov/statutes/cite/151.58

https://www.revisor.mn.gov/statutes/cite/152

https://www.revisor.mn.gov/rules/6800.6700/

New York
https://www.nysenate.gov/legislation/laws/PBH/3306

https://regs.health.ny.gov/content/section-41518-pharmacy-services

Ohio
http://codes.ohio.gov/orc/3719

https://www.pharmacy.ohio.gov/LawsRules/General

https://codes.ohio.gov/ohio-administrative-code/rule-4729:5-3-17

https://codes.ohio.gov/ohio-administrative-code/rule-4729:9-1-01

https://codes.ohio.gov/ohio-administrative-code/rule-4729:5-9-03.1

Pennsylvania
www.pacode.com

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

https://www.pacodeandbulletin.gov/Display/pacode?file=/secure/pacode/data/028/028toc.html&d=reduce

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

https://www.health.pa.gov/topics/Documents/Laws%20and%20Regulations/DDC_Act.pdf

Wisconsin
Wisconsin Legislature: 450.11(5)

https://docs.legis.wisconsin.gov/statutes/statutes/961.pdf

https://docs.legis.wisconsin.gov/code/register/2017/740B/insert/phar7

https://dsps.wi.gov/Pages/Professions/ControlledSubstancesSUA/Default.aspx

https://dsps.wi.gov/Pages/RulesStatutes/ControlledSubstances.aspx

https://docs.legis.wisconsin.gov/code/admin_code/phar/7/iii/43#:~:text=December%202020%20No.-,780.,and%20compliance%20with%20this%20section.

https://docs.legis.wisconsin.gov/code/admin_code/phar/7.pdf

https://docs.legis.wisconsin.gov/code/admin_code/phar/8

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.

Section 7301 of the Code, MCL 333.7301, permits the Board of Pharmacy (administrator) to promulgate rules relating to the manufacture, distribution, and prescribing of Schedule 2 controlled substances and the dispensing of controlled substances in this state. MCL 333.7203 requires the board to promulgate a rule to schedule a substance if it finds the substance has a potential for abuse. MCL 333.17754a requires the department to establish by rule the requirements for obtaining a waiver from electronically transmitting all prescriptions, including controlled substances. 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 scheduling controlled substances, licenses, records and dispensing and administration of controlled substance prescriptions. Private market-based systems are not used for regulating controlled substances. 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 waivers: The rules will explicitly inform prescribers how to apply for a waiver and when the department will grant a waiver.

The rest of the rules include instructions for compliance.