Michigan Office of Administrative Hearings and Rules
Administrative Rules Division (ARD)
611 W. Ottawa Street
Lansing, MI 48909
Phone: 517-335-8658 Fax: 517-335-9512

REGULATORY IMPACT STATEMENT and COST-BENEFT ANALYSIS (RIS)

Agency Information:

Department name:
Licensing and Regulatory Affairs

Bureau name:
Bureau of Professional Licensing

Name of person filling out RIS:
Andria Ditschman

Phone number of person filling out RIS:
517-290-3361

E-mail of person filling out RIS:
DitschmanA@michigan.gov

Rule Set Information:

ARD assigned rule set number:
2020-82 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. The CSA does not require registrants to take training on opioids and controlled substances. Registrants, however, are required to keep a record of each controlled substance that was manufactured, received, sold, delivered, or disposed of, and maintain detailed inventories.

The CSA provides for an exemption from a separate registration for practitioners who dispense or prescribe scheduled drugs for use in maintenance or detoxification treatment.

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.

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 establishing requirements for the licensure to manufacture, distribute, and dispense controlled substances.

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

The following provisions of the Code mandate rules: MCL 333.7333a requires the department to establish an electronic system for monitoring controlled substances. 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 333.17754a 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 of 1970, 21 USC 801. 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 sections 7214(f), 7201, and 7220 of the Code, 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 section 7202 of the Code, 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 of 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.

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.

Kentucky, New York, Pennsylvania, and Wisconsin require an education course for practitioners and pharmacists in pain treatment. Kentucky, New York, and Pennsylvania require their education course to include treatment of addiction. Ohio encourages all practitioners who encounter patients with chronic pain in the usual course of their practice to take a course in chronic pain and addiction. Ohio also requires that each person who holds a license to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine or surgery to be offered a continued education in diagnosing and treating chronic pain. Pennsylvania requires all dispensers and prescribers to be trained in the practices of prescribing or dispensing opioids. Illinois requires a course on safe opioid prescribing practices. Indiana requires a course on opioid prescribing and opioid abuse. Minnesota requires education in prescribing opioids and controlled substances.

All states in the Great Lakes Region have a prescription drug monitoring program for schedule 2 to 5 controlled substances.

In the Great Lakes Region, Tennessee, Kentucky, Ohio, Minnesota, and Illinois have all scheduled or are monitoring gabapentin. Michigan and Alabama are the only states that have scheduled tianeptine sodium.

All states in the Great Lakes Region except Wisconsin have either enacted laws or have pending legislation regarding electronic transmission of prescriptions.

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. Overall, the standards in the proposed rules do not exceed those of the other states in the Great Lakes Region.

Michigan is one of the few states that has added gabapentin and tianeptine sodium to its lists of scheduled substances. It is necessary that these substances are listed in a higher schedule in this state than in other states as the legislature or Michigan Board of Pharmacy has applied the criteria for scheduling substances in section 7202 of the Code, 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 of misuse of the substance. The costs of scheduling a substance more stringently are additional regulation of the misuse or diversion of the substance.

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

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: marijuana, tianeptine sodium, gabapentin, and ephedrine.

The CSA provides for an exemption from a separate registration for practitioners who dispense or prescribe scheduled drugs for use in maintenance or detoxification treatment. The proposed rules are consistent with the requirements of the CSA.

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. Pursuant to the Code, 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.

R 338.3162b(1)(a) requires a pharmacist, dispensing prescriber, and veterinarian who dispenses a schedule 2 to 5 controlled substance drug or a pharmacy that dispenses one of these drugs to an address in the state to report to the electronic monitoring system the "patient identifier" as defined in R 338.3102(1)(f). R 338.3102(1)(f) specifies the information that is considered to be a patient identifier, including a patient's full name; address, including zip code, date of birth, and photo identification issued by this state. Rule 338.3162b is being amended to require the information included in the definition of "patient identifier" for both a patient and a client (owner) of an animal. The type of information being added to R 338.3162b(1) clarifies the information that is included in the definition of "patient identifier."

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.

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 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: marijuana, tianeptine sodium, gabapentin, and ephedrine.

The CSA provides for an exemption from a separate registration for practitioners who dispense or prescribe scheduled drugs for use in maintenance or detoxification treatment. The proposed rules are consistent with the requirements of the CSA.

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.

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 sections 7214(f), 7201, and 7220 of the Code, 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: reduce confusion by the public and licensees regarding which substances are scheduled in this state; reduce confusion for candidates applying for a controlled substance license; reduce confusion as to when the opioid and other controlled substance training must be taken by a physician assistant and others who are delegated to, allowed by a practice agreement, or allowed by an order, to prescribe or dispense a controlled substance; waive the controlled substance license for prescribers who provide maintenance or detoxification treatment in the course of their professional practice or who are registered with the Department of Drug Enforcement Administration (DEA) to provide such treatment; clarify for licensees when they may prescribe, dispense, and administer a controlled substance to a drug dependent individual; provide licensees with criteria to determine if a significant loss of a controlled substance has occurred; provide clarification as to when an inventory is required; require licensees to keep records for two years and original prescriptions for 5 years; require electronic transmission of controlled substance prescriptions unless the prescriber's circumstances fall within one of the exceptions in the Code, or they receive a waiver pursuant to the proposed rule, 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; and clarify the term "dispense" to assist a licensee to determine when to report to the electronic system for monitoring.

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; candidates will know when they must apply for a license regarding controlled substances; licensees will take the opioid and other controlled substance training when required by the rules; prescribers who provide maintenance or detoxification treatment in the course of their professional practice or who are registered with the DEA to provide such treatment will not require a controlled substance license; a licensee will only prescribe, dispense, and administer a controlled substance to a drug dependent individual when allowed under the rules; licensees will submit a report of a significant loss only when the criteria of "significant" in the rule is met; inventories of controlled substances will be submitted when required by the rules; licensees will keep records for two years and original prescriptions for 5 years; prescribers will electronically transmit prescriptions unless an exception applies or they are granted a waiver from the department, 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; licensees will report to the electronic system for monitoring as required by the rules.

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

The difference between current behavior and desired behavior is as follows: instead of frequently contacting the department, licensees and the public will be able to use the federal schedule of controlled substances; 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 be educated in various substantive areas related to opioids and other controlled substances which will make them better providers; prescribers who provide maintenance or detoxification treatment in the course of their professional practice or who are registered with the DEA to provide such treatment will no longer need a controlled substance license; a licensee will only prescribe, dispense, and administer a controlled substance to a drug dependent individual when allowed under the rules; licensees will submit a report of a significant loss only when the criteria of "significant" in the rule is met; licensees will know when they must submit an inventory of controlled substances; licensees will keep records for two years and original prescriptions for 5 years and be able to replace the written prescription with an electronic version after 2 years: 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; licensees will know when they must report to the electronic system for monitoring instead of attempting to report both when the prescription is placed on the shelf and when it is picked up.

C. What is the desired outcome?

The desired outcome of the proposed rules is as follows: licensees and the public will be able to use the federal schedule of controlled substances in Michigan; providers will know when they must apply for a controlled substance license; licensees will be educated in opioids and other controlled substances which will make them better providers; prescribers who provide maintenance or detoxification treatment in the course of their professional practice or who are registered with the DEA to provide such treatment will no longer need a controlled substance license; a licensee will only prescribe, dispense, and administer a controlled substance to a drug dependent individual in limited circumstances; licensees will submit a report of a significant loss only when the criteria of "significant" in the rule is met; controlled substance inventories will be timely submitted; licensees will keep records for two years and original prescriptions for 5 years and be able to replace the written prescription with an electronic version after 2 years: 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; licensees will timely report to the electronic system for monitoring.

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; health providers lacking education in opioids and other controlled substances; continuing to require a prescriber to have a license only because they provide maintenance or detoxification treatment; licensees prescribing, dispensing, and administering a controlled substance to a drug dependent individual; licensees not reporting a significant loss of a controlled substance; licensees not taking an inventory of controlled substances; licensees not keeping records; prescribers refusing to electronically transmit prescriptions when it would benefit the patient and prescribers not having an option to waive the requirement when electronic transmission is not appropriate; and licensees failing to property report to the electronic system for monitoring.

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 minimal training and professional standards.

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

R 338.3109 and R 338.3182 are being rescinded as they are obsolete. R 338.3112, R 338.3113, R 338.3113a, R 338.3114, R 338.3114a, R 338.3116, R 338.3117, R 338.3118, R 338.3119, R 338.3119a, R 338.3119b, R 338.3120, R 338.3121, R 338.3121a, R 338.3122, R 338.3123, R 338.3125, R 338.3126, R 338.3127 and R 338.3129 regulate scheduling of substances. They are being rescinded as the proposed rules will adopt the complete list of drugs and other substances that are controlled substances under the CSA. R 338.3136 and R 338.3152 are being rescinded as the regulations are found elsewhere in the rules. R 338.3162e is being rescinded pursuant to MCL 333.7333a.

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 estimated cost for licensees or a licensees' employer 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 estimated cost for licensees to take the one-time training in opioids and controlled substances is approximately free to $100.00. There are various trainings. A participant may also decide to attend more than 1 program in order to meet the training requirements. The training may be offered by a nationally recognized or state recognized health related organization, a state or federal agency, a continuing education program or activity, or an educational program for initial licensure or registration by a college or university that is accepted by a licensing board established under article 15 of the Michigan Public Health Code. The training may be by teleconference, webinar, online presentation, live presentation, or printed or electronic media. Despite the cost-related burden the need to educate licensees is necessary.

The estimated cost for a licensee to report to the electronic system for monitoring is unknown. The proposed rule requires additional information to be submitted to the database which may require more time from a licensee to collect the information. However, use of the information to reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk is necessary in relationship to the burden on the licensee.

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.

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 need to educate licensees on opioids and controlled substances is necessary; and the collection of information and use of that information to reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk is necessary. 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.

Impact on Other State or Local Governmental Units

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

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

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

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

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

There are no actions that governmental units must take to comply with the proposed rules.

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

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

Rural Impact

16. In general, what impact will the rules have on rural areas?

The proposed rules are not expected to impact rural areas. The proposed rules apply to 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 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 will 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 will 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 3,505 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 may be an impact on a small business in that all pharmacies, no matter the size, are required to report dispensing of controlled substances to the electronic system of monitoring and will be required to accept electronic transmissions of prescriptions. However, allowing a small business to reduce its reporting of dispensed controlled substances or refuse to accept electronic transmissions is not in the best interest of the public.

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

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

The proposed rules require a pharmacist, dispensing prescriber, and veterinarian who dispense a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state to report the following additional specific information to the Prescription Drug Monitoring Program: patient's or client's (the animal's owner) full name, address, phone number, gender, and date of birth; the species code as specified by the American Society for Automation in Pharmacy (ASAP); number of refills authorized; refill number of the prescription fill; prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription; prescription payment type; electronic prescription reference number, if applicable; and patient's or client's location code when receiving pharmacy services, as specified by ASAP.

As the program is mandatory there is no cost to sign up and access the program. In addition, there is a process to request a waiver from reporting if the dispenser does not have the ability to report as required in this rule. There is no separate cost for report preparation specific to small businesses as this is an additional reporting requirement for all licensees who dispense controlled substances.

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 3,505 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 as this is an additional reporting requirement for all licensees who dispense controlled substances.

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 proposed rules so 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 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 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 cost-related burdens of the proposed rules, the rules and regulations are necessary to protect the public. Exempting or setting lesser standards of compliance for small businesses is not in the best interest of the public.

The proposed rules also impose requirements on individual licensees rather than small businesses. Even if a licensee's employer qualifies as a small business, the department could not exempt his or her employer because it would create disparity in the regulation of 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 3,505 pharmacies in Michigan. The proposed rules will impact pharmacies and prescribers' and dispensers' workplaces. Pharmacies and dispensers' workplaces will be required to report additional information on dispensing of controlled substances to the electronic system of monitoring. Prescribers' workplaces will be required to electronically transmit controlled substance prescriptions and pharmacies will be required to accept electronic transmissions.

Pharmacies will bear the cost of accepting electronic transmissions and reporting information to the electronic system of monitoring. 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 public will directly benefit by electronic transmission of controlled substance prescriptions.

There may be businesses that help with electronic transmission of prescriptions that may directly benefit from the proposed 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 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 estimated cost for licensees to take the one-time training in opioids and controlled substances is approximately free to $100.00. There are various trainings. A participant may also decide to attend more than 1 program in order to meet the training requirements. The training may be offered by a nationally recognized or state recognized health related organization, a state or federal agency, a continuing education program or activity, or an educational program for initial licensure or registration by a college or university that is accepted by a licensing board established under article 15 of the Michigan Public Health Code. The training may be by teleconference, webinar, online presentation, live presentation, or printed or electronic media. Despite the cost-related burden the need to educate licensees is necessary.

The estimated cost for a licensee to report to the electronic system for monitoring is unknown. The proposed rule requires additional information to be submitted to the database which may require more time from a licensee to collect the information. However, use of the information to reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk is necessary in relationship to the burden on the licensee.

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 and dispensers of controlled substances will be affected by the proposed rules to electronically transmit prescriptions and to report to the electronic system for monitoring. There are 80,553 controlled substance licensees.

Individuals who apply for a controlled substance license or are licensed to prescribe or dispense controlled substances, and anyone that is delegated to, allowed by a practice agreement, or ordered to prescribe or dispense by a prescriber or dispenser, will be required to attend an opioid and controlled substances awareness training. There are 80,553 controlled substance licensees. The number of individuals who will act in the future pursuant to delegation, an order, or a practice agreement are unknown and, therefore, the number of individuals that will be affected cannot be stated.

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

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.

The estimated cost for licensees to take the one-time training in opioids and controlled substances is approximately free to $100.00. There are various trainings. A participant may also decide to attend more than 1 program in order to meet the training requirements. The training may be offered by a nationally recognized or state recognized health related organization, a state or federal agency, a continuing education program or activity, or an educational program for initial licensure or registration by a college or university that is accepted by a licensing board established under article 15 of the Michigan Public Health Code. The training may be by teleconference, webinar, online presentation, live presentation, or printed or electronic media.

The estimated cost for a licensee to report to the electronic system for monitoring is unknown. The proposed rule requires additional information to be submitted to the database which may require more time from a licensee to collect the information.

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 benefits of the proposed rules are as follows: licensees and the public will be able to use the federal schedule of controlled substances in Michigan; providers will know when they must apply for a controlled substance license; licensees will be educated in opioids and other controlled substances which will make them better providers; prescribers who provide maintenance or detoxification treatment in the course of their professional practice or who are registered with the DEA to provide such treatment will no longer need a controlled substance license; a licensee will only prescribe, dispense, and administer a controlled substance to a drug dependent individual in limited circumstances; licensees will submit a report of a significant loss only when the criteria of "significant" in the rule is met; controlled substance inventories will be timely submitted; licensees will keep records for two years and original prescriptions for 5 years and be able to replace the written prescription with an electronic version after 2 years: 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; licensees will timely report to the electronic system for monitoring.

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 CMS

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

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

Centers for Disease Control and Prevention
https://www.cdc.gov/drugoverdose/policy/index.html

CDC Guideline for Prescribing Opioids for Chronic Pain
https://www.cdc.gov/drugoverdose/prescribing/guideline.html

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

National Association of State Controlled Substances Authorities
http://www.nascsa.org/rxMonitoring.htm

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

Substance Abuse and Mental Health Services Administration
https://www.samhsa.gov/medication-assisted-treatment/training-resources/opioid-courses

U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division

https://www.deadiversion.usdoj.gov/faq/rx_monitor.htm

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

Illinois
https://www.idfpr.com/profs/ContSub.asp

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

Illinois Statute
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://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/

Ohio Controlled Substances Statute
http://codes.ohio.gov/orc/3719

Ohio Controlled Substances Rules
http://www.pharmacy.ohio.gov/rules/index.htm

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/

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

Wisconsin Statutes and Rules
https://dsps.wi.gov/Pages/RulesStatutes/ControlledSubstances.aspx

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

Virginia

https://www.dhp.virginia.gov/forms/OpioidWaiverRequest/default.asp#:~:text=Waiver%20For%20Electronic%20Transmission%20Of%20Opioid%20Prescriptions.%20Virginia,control%20of%20the%20prescriber%2C%20or%20other%20exceptional%20

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)

Scheduling
https://www.pharmacytimes.com/contributor/jennifer-gershman-pharmd-cph/2017/07/4-controlled-substance-laws-and-regulations-you-should-know-

https://www.dea.gov/drug-scheduling

https://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_11.htm

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1308&showFR=1

https://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_14.htm

Controlled Substances - Alphabetical Order (usdoj.gov)

gabapentin - Bing

Diversion
https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm

https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

Prescription monitoring program - Wikipedia

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/

Guidance Documents
https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf

Record Keeping
https://gvma.net/dea-record-keeping-requirements/

https://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_04.htm

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. Establishing an electronic system for monitoring schedule 2 to 5 drugs dispensed in this state by veterinarians, pharmacists, and dispensing prescribers is mandated by section 7333a of the Michigan Public Health Code, MCL 333.7333a. 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 training for controlled substances licenses and submittal of information to a prescription drug monitoring program used in each state. Private market-based systems are not used for regulating controlled substances training or collection of information by the state for drug monitoring. 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.

Opioid and controlled substance training: The rules will explicitly inform licensees of the training requirements.

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.

Electronic system for monitoring schedules 2, 3, 4, and 5 controlled substances: The rules will explicitly inform licensees of the specific type of information that must be submitted. In addition, instructions on how to use the electronic data transmittal process are on the Bureau of Professional Licensing website.