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REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS (RIS)

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Rule Set Information:
ARD assigned rule set number:
2025-28 LR
Title of proposed rule set:
Pharmacy - General Rules

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

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

Inspection Requirements for Compounding Pharmacies – R 338.532a, R 338.533, R 338.534, R 338.534a.

Section 503B of the Food Drug and Cosmetic Act (FDCA), 21 USC 353b, provides for a risk-based schedule for the Food and Drug Administration (FDA) to inspect registered outsourcing facilities. Because the risk-based schedule may not align with the rules' requirement that facilities compounding under section 503B submit an inspection within the previous 18 months, R 338.532a provides a process for the board to approve a third party to inspect these pharmacies in accordance with current and as amended good manufacturing practice for finished pharmaceuticals found in 21 CFR, part 211. The proposed rules also clarify that an inspection is required for the renewal of a pharmacy license for a nonresident pharmacy that compounds drugs under section 503B, whether or not the facility is registered as an outsourcer with the FDA.

Independent Ordering and Administration of Immunizations – R 338.581

Under Section 319F-3 of the Public Readiness and Emergency Preparedness Act (PREP Act), 42 USC 247d-6d, the Secretary of Health and Human Services is authorized to issue a declaration to provide liability immunity to certain individuals and entities against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures, except for claims involving willful misconduct. Under the 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 Fed. Reg. 99875 (Dec. 11, 2024) (Declaration), effective until December 31, 2029, a state-licensed pharmacist who orders and administers vaccines that the Centers for Disease Control and Prevention (CDC)/Advisory Committee on Immunization Practices (ACIP) recommend to persons ages 3 through 18 according to the CDC/ACIP's standard immunization schedule, a seasonal influenza vaccine administered by a qualified pharmacy technician or intern that the CDC/ACIP recommends to person aged 19 and older according

to CDC/ACIP's standard immunization schedule, or FDA-authorized or FDA-licensed COVID-19 vaccines to persons age 3 years or older, is immune from liability.

The Declaration preempts any state law to the extent that it would otherwise prohibit a qualified person from prescribing, dispensing, or administering COVID-19 vaccines, seasonal influenza vaccines or COVID-19 tests. The Declaration also authorizes a pharmacy intern or qualified pharmacy technician to administer the foregoing vaccines. Under the Declaration, a licensed pharmacist must have completed the immunization training that the licensing state requires for pharmacists to order and administer vaccines. If the state does not specify training requirements, the pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. The training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. The pharmacist must also have a current certificate in basic cardiopulmonary resuscitation and complete a minimum of 2 hours of ACPE-approved, immunization-related continuing pharmacy education during each state license renewal period.

Section 17724 of the Public Health Code, MCL 333.17724, permits a pharmacist, without acting under the direction of a physician, to order and administer a qualified immunizing agent to an individual who is 3 years of age or older. Qualified immunizing agent means a vaccine that is recommended by the ACIP of the CDC and that is approved or authorized by the FDA or has been authorized for emergency use by the FDA. A pharmacist must successfully complete a training program established by rule before ordering or administering a qualified vaccine without acting under the direction of a physician.

R 338.581 would require a pharmacist to successfully complete a training course on the administration of vaccines that is provided by an entity accredited by the ACPE.

Pharmacist Testing and Treatment – R 338.581a

The Declaration also provides liability immunity to pharmacists, pharmacy interns, and qualified pharmacy technicians to administer COVID-19 tests, and to a state-licensed pharmacist who orders and administers, and a pharmacy intern or qualified pharmacy technician supervised by a pharmacist who administers, FDA-authorized, approved, or licensed COVID-19 therapeutics.

If the COVID-19 therapeutic is administered through intramuscular or subcutaneous injections, the pharmacist, pharmacy intern, or qualified pharmacy technician must complete a practical training program that is approved by the ACPE and includes hands-on injection technique, clinical evaluation of indications and contraindications of COVID-19 therapeutics, and any additional training required in the FDA approval, authorization, or licensing. The pharmacist, pharmacy intern, or qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation.

The Clinical Laboratory Improvement Amendments (CLIA) to the PHSA, 42 USC 263a, apply to facilities that test human specimens for health assessment or to diagnose, prevent, or treat diseases. Under CLIA, the FDA categorizes laboratory tests based on their complexity. FDA-waived tests are simple tests with a low risk for incorrect results, which can be performed in various settings without extensive training.

Section 17724a of the Public Health Code, MCL 333.17724a, authorizes a pharmacist to order a qualified laboratory test to an individual. Under Section 17724a, a qualified laboratory test is a test that is classified as waived by the FDA, requires only the use of a specimen collected by a nasal or throat swab or a finger prick, and is used to detect or screen for COVID-10, influenza, or a respiratory infection. Section 17724a of the Public Health Code also provides that a pharmacist who orders qualified laboratory tests for purpose of detecting or screening for COVID-19 or influenza may, without a prescription, dispense a drug to the individual if the pharmacist determines the drug is needed to treat the individual for COVID-19 or influenza based on the test result, the drug is an antiviral drug and is available at the pharmacy, the drug is provided pursuant to protocols established by the CDC or public health guidelines established by the department of health and human services, and the pharmacist advises the individual of

the test result and refers the individual to a physician, or another health professional, designated by the individual.

R 338.581a requires a pharmacist, before ordering and administering a qualified laboratory test or dispensing a drug without a prescription based on the test result under Section 17724a, to complete a training program requiring the pharmacist to demonstrate sufficient knowledge of how to administer and interpret each laboratory test that the pharmacist may order, and demonstrate sufficient knowledge of each illness, condition, or disease for which the pharmacist provides treatment based on the test result. R 338.581a provides that an employer-based training, training completed as part of a professional degree from an ACPE-accredited school of pharmacy, and a certificate program are acceptable to meet the requirements of the rule.

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

The rules are not federally mandated. The following state laws require rules:

MCL 333.16148 requires training standards for identifying victims of human trafficking.

MCL 333.16204 states that if a board requires completion of continuing education as a condition for renewal, it shall require an appropriate number of hours or courses in pain and symptom management.

MCL 333.16287 requires rules to implement telehealth services.

MCL 333.17724 requires rules to implement the ordering and administration of a qualified immunizing agent by a pharmacist. The rules must require a training program to include a course on the administration of vaccines that is provided by an entity accredited by the Accreditation Council for Pharmacy Education.

MCL 333.17724a requires rules to implement the ordering and administration of qualified laboratory tests by a pharmacist, who may, without a prescription, dispense an antiviral drug to treat COVID-19 or influenza based on the test result. The rules must require a training program to require a pharmacist to demonstrate sufficient knowledge of how to administer and interpret each laboratory test that the pharmacist may order and demonstrate sufficient knowledge of each illness, condition, or disease, being COVID-19, influenza, or a respiratory infection, for which the pharmacist provides treatments based on the results of a qualified laboratory test.

MCL 333.17731 mandates rules requiring each applicant for license renewal to complete as part of the continuing education or proficiency examination requirement an appropriate number of hours or courses in pain and symptom management.

MCL 333.17737 requires rules to establish standards for an internship program and participation therein by interns and preceptors.

MCL 333.17744f requires rules concerning a pharmacist dispensing an emergency supply of insulin.

MCL 333.17744g requires rules concerning a pharmacist prescribing and dispensing a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive, and requires by rule, the development of a self-screening risk assessment tool.

MCL 333.17748e mandates rules requiring an applicant for a wholesale distributor-broker license to demonstrate to the satisfaction of the board that, at the time of the application for initial licensure, the applicant facilitates deliveries or trades for at least 50 qualified pharmacies that are each licensed in good standing in their state of licensure.

MCL 333.17754a requires rules concerning the electronic transmission of a prescription, which must include requirements for obtaining a waiver.

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

The rules do not exceed a federal standard.

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

Telehealth

R 338.507 pertains to telehealth services and requires a health professional to obtain patient consent for treatment before providing a telehealth service and keep it as part of the medical record. R 338.507 provides that a pharmacist who is a prescriber acting within the scope of their practice may prescribe a drug if they refer the patient to a geographically accessible provider, if medically necessary, and make the pharmacist available to provide follow-up care. R 338.507 further requires a health professional to act within the scope of their practice and exercise the same standard of care applicable to an in-person healthcare service.

Indiana requires informed consent for telehealth services and that the provider create and maintain a medical record. Illinois, Indiana and Pennsylvania require telehealth services to meet the same standard of care as in-person services. Ohio provides that once informed consent is obtained, a health care professional is not liable for a claim made on the basis that the services do not meet the same standard of care as in-person services.

Adoption of United States Pharmacopeia (USP) Standards

R 338.533 updates the USP standards to include the 2024 revision of Ch. 797, the 2020 revision of Ch. 800, and the 2024 revision of Ch. 825, with the exception of flavoring.

Illinois has adopted the 2024 edition of the USP, with the exception of Ch. 800. Indiana requires adherence to all current USP standards related to sterile compounding, personnel cleansing and gowning. Minnesota has adopted USP Chapters 795 and 797. New York has not formally adopted USP standards but considers them standards of practice, according to the 2025 NABP Survey. Ohio has adopted the 2020 editions of USP Chapters 795, 797, and 800. Pennsylvania requires the compounding of sterile and nonsterile preparations to be done in accordance with current USP chapters governing compounding. Wisconsin's rules include a statement that the intent of the chapter is to create a regulatory standard that aligns with compounding standards found in the USP general chapters lower than the number 1000.

Inspection Requirements for Compounding Facilities

R 338.532a provides a process for the board to approve entities to inspect facilities that compound drugs under Section 503B of the FDCA in accordance with current and as amended good manufacturing practice for finished pharmaceuticals, 21 CFR part 211. R 338.534 clarifies that an inspection is required for the renewal of a pharmacy license for a nonresident facility that compounds drugs under Section 503B of the FDCA whether or not the facility is registered as an outsourcer with the FDA.

Illinois requires outsourcers to register with the FDA and be licensed as wholesalers, which requires an inspection by Illinois' regulatory agency. Indiana licenses both compounding pharmacies and outsourcers as pharmacies and requires an inspection for resident pharmacies prior to licensure. Minnesota requires both compounding pharmacies and outsourcers to pass an inspection prior to initial licensure and license renewal. Minnesota requires an in-state outsourcer to pass a current good manufacturing practices inspection conducted by an authorized representative of the board prior to initial licensure or license renewal. An out-of-state outsourcer may be required to pay for the inspection unless the applicant furnishes an inspection report issued by the appropriate regulatory agency of the state where the facility is located or the FDA. New York requires resident and nonresident outsourcers, upon initial registration and at least annually thereafter, to submit the results on an inspection by either the FDA, the department, or a third party acceptable to the department. Ohio requires outsourcers to register with the FDA. Ohio's board is authorized to make agreements with other entities to exchange information concerning licensing and inspection of outsourcers. Pennsylvania requires resident outsourcers to register as manufacturers and to register with the FDA. Nonresident outsourcers are not required to register unless sales staff are present in Pennsylvania.

Independent Ordering and Administration of Immunizations

R 338.581 requires a pharmacist to successfully complete training on the administration of vaccines that is provided

by an ACPE-accredited entity before ordering or administering a qualified immunizing agent, in accordance with MCL 333.17724.

The other Great Lakes states have various requirements for a pharmacist to provide immunizations. Illinois requires training accredited by the ACPE, a similar health authority, or a professional body approved by the division of professional regulation. Indiana requires a training in immunization provided by an ACPE-provider. Minnesota requires a training approved by the ACPE or the board if the pharmacist delegates their authority to administer a COVID-19 or influenza vaccine to a pharmacy technician. Ohio requires 5 hours of ACPE accredited training, while Wisconsin requires 12. Wisconsin further requires liability insurance.

New York and Pennsylvania each require a separate credential for a pharmacist to administer vaccines.

Independent Testing and Treatment
R 338.581a requires a pharmacist, before ordering or administering a qualified laboratory test or dispensing a drug without a prescription under Section 17724a, to complete a training program requiring the pharmacist to demonstrate sufficient knowledge of how to administer and interpret each lab test that the pharmacist may order, and demonstrate sufficient knowledge of each illness, condition, or disease for which the pharmacist dispenses a drug without a prescription. R 338.581a also provides that an employer-based training, training completed as part of a professional degree from an ACPE-accredited school of pharmacy, and a certificate program are all acceptable.

Illinois permits ordering and administering point of care tests, screening, and treatments for influenza, COVID-19, Group A Strep, RSV, head louse, and health conditions identified by a statewide public health emergency. A pharmacist may order and administer COVID-19 therapeutics authorized, approved, or licensed by the FDA with notice to the patient's physician and appropriate record retention. There is no training requirement.

Ohio requires a pharmacist who conducts a CLIA-waived test in a CLIA-certified facility that has obtained a certificate of waiver to receive appropriate training to conduct testing in a safe and effective manner.

Independent Prescription and Dispensation of Contraceptives
R 338.581b, R 338.581c, R 338.581d, and R 338.592 implement the prescription and dispensing of a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive by a pharmacist. R 338.581b requires a pharmacist to complete a training on prescribing and dispensing contraceptives that is provided by an entity accredited by the ACPE before prescribing contraceptives. R 338.581c requires a pharmacist who issues a contraceptive prescription to comply with the standard procedure described in R 338.581c, which requires the pharmacist to review the patient's completed self-screening risk assessment tool (SSRA) described in R 338.581d and R 338.592 before prescribing a contraceptive. Upon issuing a contraceptive prescription, R 338.581c requires the pharmacist to refer the patient to the patient's primary care physician (PCP), or, if the patient does not have a PCP, to another licensed health professional the pharmacist considers appropriate. If the patient has not had a physical exam in the previous 12 months, the pharmacist shall refer the patient to the patent's PCP. If the pharmacist does not prescribe a contraceptive, the pharmacist shall refer the patient to a PCP or another licensed health professional. R 338.581c requires the pharmacist to provide the patient with a written record of the prescribed contraceptive and advise the patient to consult with a physician or other licensed health professional. R 338.581c also requires the pharmacist to dispense the prescribed contraceptive as soon as practicable and transfer the prescription to a pharmacy of the patient's choice, if requested. R 338.592 sets forth the questions to be included on the SSRA and R 338.581d provides that the questions may be reordered or reformatted, and the patient may complete the SSRA electronically.

Illinois, Indiana, and New York have statewide standing orders in place authorizing pharmacists to dispense contraceptives. Minnesota's board of pharmacy has adopted protocols for a pharmacist to dispense a contraceptive. Wisconsin, Ohio, and Pennsylvania do not permit pharmacists to prescribe contraceptives.

The Great Lakes states that authorize pharmacists to dispense contraceptives require a pharmacist to first complete training. Illinois and New York require a training program covering specified topics. Illinois requires the training to be

provided by an ACPE-accredited provider. Minnesota requires training on prescribing contraceptives that is offered by a college of pharmacy or by a provider accredited by the ACPE, or a program approved by the board as well as continuing education as specified by the board.

Illinois, Indiana, Minnesota, and New York require the patient to complete a SSRA for the pharmacist to review prior to dispensing a contraceptive. Indiana, Minnesota and New York require the pharmacist to measure the patient's blood pressure. Illinois, Indiana, New York, and Minnesota have adopted procedures based on the United States Medical Eligibility Criteria for Contraceptive Use published by the CDC. If the patient is not eligible under the state's protocol or procedure to receive the contraceptive from a pharmacist, the pharmacist refers the patient to the patient's PCP or another healthcare provider.

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

The standards pertaining to licensure, training, renewal, and duties differ from state to state. There are some differences between states, however, the regulatory framework is similar. Overall, the standards in the proposed rules do not exceed those of the other states in the Great Lakes region.

Further, the proposed rules pertaining to telehealth, immunizations ordered and administered by pharmacists, qualified laboratory tests ordered and administered by pharmacists, drugs dispensed by pharmacists without a prescription based on the qualified laboratory test results, and hormonal contraceptives prescribed by pharmacists, are mandated by the Public Health Code.

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

The Declaration under the PREP Act overlaps with the new rules concerning pharmacists ordering and administering qualified immunizations and ordering and administering qualified laboratory tests and dispensing, without a prescription, a drug based on the test result. However, the Declaration preempts state laws and rules to the extent that they conflict with the Declaration.

R 338.3135 of the Pharmacy – Controlled Substances rules requires applicants for renewal of a controlled substance license to complete a training in opioids and other controlled substances awareness with each renewal cycle. To avoid confusion, the proposed rules remove "1-time" in reference to the training required under the Pharmacy - Controlled Substances rules.

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.

Because the rules concerning pharmacists ordering and administering immunizations, ordering and administering qualified laboratory tests, and dispensing drugs without a prescription based on the test results are mandated by statute, it is not practicable to coordinate them with the Declaration concerning those activities. However, the training required under the Declaration for a pharmacist to order and administer immunizations also meets the training required to administer qualified immunizations under proposed R 338.581.

The changes to R 338.521, R 338.523, and R 338.525 include removing "1-time" in reference to the training in opioid and controlled substances awareness because that training is currently required for every controlled substance license renewal cycle under the Pharmacy – Controlled Substances rules.

Purpose and Objectives of the Rule(s)

4. Identify the behavior and frequency of behavior that the proposed rules are designed to alter.

The proposed rules include changes to conform with current drafting standards, supply clarity, and improve ease of reading throughout the set.

R 338.501. This rule contains definitions. The revision adds two new definitions to improve ease of reading.

R 338.507. This new rule pertains to telehealth services and is required by MCL 333.16287.

R 338.525. This rule pertains to the requirements for relicensure of a pharmacist license. The proposed changes include a clarification that the rule pertains to pharmacists whose license has lapsed and who are not currently licensed in good standing in another state or province of Canada and the removal of "1-time" in reference to the training in opioid and controlled substance awareness training because the training is currently required for every renewal under R 338.3135 of the Pharmacy – Controlled Substances rules.

R 338.531a. This rule pertains to the requirements for a waiver of the remote pharmacy requirement that the remote pharmacy be located at least 10 miles from the nearest pharmacy. The proposed change would remove the requirement that the request be submitted on a form provided by the department.

R 338.532a. This new rule provides a process for the board to approve inspection entities to inspect facilities that compound pharmaceuticals under current and as amended good manufacturing practice.

R 338.533. This rule pertains to compounding standards and requirements. The proposed changes would update the compounding standards adopted by reference, clarify how the standards may be obtained, clarify that a pharmacy that provides compounding services under Section 503A of the FDCA shall comply with the compounding standards adopted by reference and that a pharmacy that provides compounding under Section 503B of the FDCA shall comply with current good manufacturing practice.

R 338.534. This rule pertains to out-of-state pharmacy licensure inspection, in-state pharmacy licensure renewal inspection, and outsourcing facility licensure renewal inspection. The proposed changes would clarify that pharmacies that will provide sterile compounded pharmaceuticals and are not registered as outsourcing facilities shall have an inspection within 18 months before the date of license renewal or, for an out-of-state pharmacy, for initial licensure and renewal, unless the pharmacy is accredited by a national accrediting organization, and that a pharmacy that compounds under Section 503B is required to be inspected in accordance with current and as amended good manufacturing practice by either the FDA or an inspection organization approved by the board.

R 338.534a. This rule pertains to in-state initial pharmacy inspections. The proposed change clarifies that the references to sterile compounding pertain to compounding under section 503A of the FDCA.

R 338.555. This rule pertains to the adoption by reference of federal good manufacturing practice for finished pharmaceuticals. The changes clarify the adoption of current good manufacturing practice for finished pharmaceuticals set forth in the federal regulations and update the cost for copies of the regulations obtained through the department to 25 cents per page.

R 338.581. This new rule pertains to the training required for a pharmacist to order and administer a qualified immunizing agent and is required by MCL 333.17724.

R 338.581a. This new rule pertains to the training required for a pharmacist to order and administer a qualified laboratory test and dispense a drug without a prescription based on the test result. This rule is required by MCL 333.17724a.

R 338.581b. This new rule pertains to the training required for a pharmacist to prescribe and dispense a contraceptive. This rule is required by MCL 333.17744g.

R 338.581c. This new rule pertains to the standard procedure for a pharmacist to prescribe and dispense a contraceptive. This rule is required by MCL 333.17744g

R 338.581d. This new rule pertains to the self-screening risk assessment tool required for a pharmacist to prescribe a contraceptive. This rule is required by MCL 333.17744g

R 338.592. This new rule contains the self-screening risk assessment tool questions in Appendix A. This rule is required by MCL 333.17744g.

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:

Inspection agencies may apply for board approval to inspect in accordance with good manufacturing practice for finished pharmaceuticals; compounding pharmacies will be required to comply with the most current USP Chapters 795, 797, 800, and 825, with the exception of flavoring; licensees will be authorized to provide telehealth services; pharmacists with appropriate training will be authorized to order and administer qualified immunizations, order and administer qualified laboratory tests and dispense, without a prescription, an antiviral drug to treat COVID-19 or influenza based on the test result, and prescribe hormonal contraceptives.

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

Currently, there is no process for the board to approve an inspection agency to perform inspections in accordance with good manufacturing practice for finished pharmaceuticals. The USP compounding standards include Chapters 795 and 797 as revised in 2023, with the exception of flavoring. There is no rule pertaining to telehealth services. Pharmacists are not able to order and administer qualified immunizations, order and administer qualified laboratory tests and dispense, with a prescription, and antiviral drug to treat COVID-19 or influenza based on the test result, or prescribe hormonal contraceptives because the rules necessary to implement these new functions under Sections 17724, 17724a, and 17744g of the Public Health Code have not yet been promulgated.

The desired practice is to approve inspection agencies to perform inspections in accordance with good manufacturing practice for finished pharmaceuticals using a process that parallels the existing approval process for agencies that perform inspections in accordance with USP standards and to update the adopted USP standards. It is further desired to promulgate rules mandated under Sections 16287, 17724, 17724a, and 17744g to implement telehealth services; pharmacist ordering and administration of qualified immunizations; pharmacist ordering and administration of qualified laboratory tests and dispensing, without a prescription, and antiviral drug to treat COVID-19 or influenza based on the test result; and pharmacist prescription of hormonal contraceptives.

C. What is the desired outcome?

The desired outcome is to clarify the existing rules and promulgate the new rules required under the Public Health Code to regulate telehealth; update compounding standards; establish a process for the board to approve inspection entities to inspect facilities that compound under good manufacturing practice; implement pharmacist ordering and administration of qualified immunizations, pharmacist ordering and administration of qualified laboratory tests and dispensing a drug without a prescription based on the test result, pharmacist prescription of hormonal contraceptives; and to improve and clarify the rules, so licensees find compliance easier. This should result in fewer questions, fewer regulatory problems, and greater safety and protection of the public.

5. 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.

Outdated rules create conflict and confusion for licensees. The proposed changes include the following:

R 338.501 contains definitions. The revisions are designed to reduce confusion.

R 338.525 pertains to the requirements for relicensure of a pharmacist license. The changes will clarify that a pharmacist whose license has lapsed in Michigan and who holds a license in another state that is not in good standing must comply with the rule. Also, removing "1-time" in reference to the opioid and controlled substance awareness training require under R 338.3125 of the Pharmacy – Controlled Substances rules will eliminate conflict between the two rules, since the Pharmacy – Controlled Substances rules have been updated to require the training with each controlled substance license renewal.

R 338.531a. This rule pertains to the requirements for a waiver of the remote pharmacy requirement that the remote pharmacy be located at least 10 miles from the nearest pharmacy. The proposed change would eliminate the requirement that the request be submitted on a form by the department, making it easier for applicants to submit waiver requests.

R 338.532a. This new rule provides a process for the board to approve inspection entities to inspect facilities that compound pharmaceuticals under current and as amended good manufacturing practice for finished pharmaceuticals. Currently, some nonresident outsourcers have difficulty renewing their licenses due to the FDA's risk-based timeline for inspections. It is especially difficult for outsourcers located in a state where the local board of pharmacy does not require inspections. This new rule is intended to provide another option so the affected pharmacies may submit an inspection by a board-approved entity and timely renew their Michigan licenses.

R 338.533 pertains to compounding standards and requirements. The updated standards ensure that compounding pharmacies are following the most current standards to protect the public.

R 338.534 clarifies the inspection requirements for compounding pharmacies. This rule is intended to prevent confusion among compounding pharmacies as to whether, when, and by which entity an inspection is required initial licensure and license renewal.

R 338.534a. This rule pertains to in-state initial pharmacy inspections. The proposed change clarifies that the references to sterile compounding pertain to compounding under section 503A of the FDCA.

R 338.555. This rule pertains to the adoption by reference of federal good manufacturing practice for finished pharmaceuticals. The changes clarify the adoption of current good manufacturing practice for finished pharmaceuticals set forth in the federal regulations and update the cost for copies of the regulations obtained through the department to 25 center per page.

R 338.507 pertaining to telehealth, R 338.581 pertaining to the training required for a pharmacist to order and administer a qualifying immunizing agent, R 338.581a pertaining to the training required for a pharmacist to order and administer a qualified laboratory test and dispense a drug without a prescription based on the test result, and R 338.581b, R 338.581c, R 338.581d, and R 338.592 pertaining to pharmacists prescribing contraceptives, are all mandated by statute and must be promulgated regardless of an analysis of the harm that would result if they were not. However, the harm that would result if these rules were not promulgated would include confusion about how to conduct telehealth services and the inability for pharmacists to exercise their new authority to order and administer qualified immunizing agents, order and administer qualified laboratory tests and dispense drugs based on the test results, and prescribe contraceptives.

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

The proposed rule set provides clarity to the rules on the licensure and practice of pharmacy. Further, R 338.507 pertaining to telehealth, R 338.581 pertaining to the training required for a pharmacist to order and administer a qualifying immunizing agent, R 338.581a pertaining to the training required for a pharmacist to order and administer a qualified laboratory test and dispense a drug without a prescription based on the test result, and R 338.581b, R 338.581c, R 338.581d, and R 338.592 pertaining to pharmacists prescribing contraceptives, are all mandated by statute.

6. 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 supply a regulatory mechanism for the practice of pharmacy. To protect the health, safety, and welfare of Michigan's citizens, it is important that licensees adhere to practice standards. The proposed rules will ensure that compounding pharmacies are practicing to the most current standards and are properly inspected and that pharmacists who independently order and administer qualified immunization, order and administer qualified laboratory tests and dispense drugs based on the test results, and prescribe contraceptives are properly trained and patients receiving pharmacist-prescribed contraceptives are appropriately screened and referred to other health care practitioners when necessary.

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

No recission of any rule is necessary.

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.

8. 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.

9. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rules.

There has been no agency appropriation for the proposed rules because there are no expected agency expenditures associated with the proposed rules.

10. Describe how the proposed rules are necessary and suitable to accomplish their purpose, in relationship to the burden(s) the rules place on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

The rules are required to provide a mechanism for licensing and regulation of pharmacists, interns, preceptors, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers. The rules are not any more restrictive than is allowed by statute. Despite the cost-related burden, the rules and regulations are necessary. There are some expectations of additional burdens, fiscal, administrative, or duplicative acts, on pharmacists.

Pharmacists who order and administer qualified immunizations must complete a training course on the administration of immunizations. For example, both the Michigan Pharmacists Association (MPA) and Wayne State University (WSU) offer 20-hour ACPE-accredited certificate programs in Pharmacy-Based Immunization Delivery ranging in cost from $135 for a WSU student to $510 MPA non-members. These programs appear to be designed to meet the training requirements of the federal PREP Act. Pharmacists who have already completed training to satisfy the PREP Act may apply the same training to satisfy R 338.581. The training required by R 338.581 is less stringent than these certificate programs, with no minimum number of hours. It is possible that less expensive training programs may eventually be offered to satisfy the less stringent requirements of R 338.581.

Additionally, if the pharmacist chooses to order qualified laboratory tests and dispense drugs without a prescription based on the test result, they must complete a training program requiring the pharmacist to demonstrate sufficient knowledge of how to administer and interpret each laboratory test that the pharmacist may order or administer and demonstrate sufficient knowledge of each illness, condition, or disease for which the pharmacist dispenses a drug based on the results of the laboratory test. For example, the MPA and the National Community Pharmacists Association (NCPA) both offer a 20-hour Pharmacy-Based Point-of-Care Test and Treat National Certificate. The cost ranges from $295 for an MPA student member to $495 for an NCPA.

Lastly, before issuing a prescription for a contraceptive, a pharmacist shall successfully complete a training course on prescribing and dispensing contraceptives that is provided by an entity accredited by the ACPE. For example, the American Pharmacists Association offers a 4-hour, ACPE-accredited program that costs $169 for members and $295 members for nonmembers.

It is expected that pharmacists and their employers will factor in the training costs associated with expanded practice functions into the price of the pharmacist's services.

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

Due to the implementation of Sections 17724, 17724a, and 17744g of the Public Health Code, MCL 333.17724, MCL 333.17724a, and MCL 333.17744g, concerning pharmacists ordering and administering qualified immunizing agents, ordering qualified laboratory tests, and dispensing medications based on the results, and prescribing hormonal contraceptives, it is necessary to protect public health and safety. In order to do so, the rules require the pharmacist to complete training related to these new practice privileges prior to exercising them.

Impact on Other State or Local Governmental Units

11. 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.

12. 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 the governmental units must take to comply with the proposed rules.

13. 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

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

The proposed rules impose requirements on licensees regardless of where they are located. Even if an individual licensee or pharmacy is located in a rural area, the department could not vary the requirements based on the licensee's location because that would create a disparity in the regulation of pharmacy.

It is expected that R 338.507 concerning telehealth, R 338.581 concerning immunizations, R 338.581a concerning laboratory tests and dispensing antiviral drugs without a prescription, and R 338.581b, R 338.581c, R 338.581d, and R 338.592 concerning pharmacists prescribing hormonal contraceptives, may improve access to healthcare in rural areas. A Senate Fiscal Agency (SFA) analysis of P.A. 97 of 2023, which authorized pharmacists to order and administer qualified immunizations and qualified laboratory tests, and to dispense, without a prescription, antiviral drugs based on the test results, noted that pharmacists are often the only healthcare professionals that are easily accessible to patients in rural areas. An SFA analysis of HB 5435 and HB 5436, which were later enacted as P.A. 242 of 2024 authorizing pharmacists to prescribe hormonal contraceptives, noted that 1/3 of Michigan counties lacks an obstetrician/gynecologist, resulting in a lack of medical professional who can prescribe hormonal contraceptives.

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

Residents in need of telehealth services, immunizations, laboratory tests, antiviral drugs, or hormonal contraceptives may receive increased access to those services from R 338.507, R 338.581, R 338.581a, R 338.581b, R 338.581c, R 338.581d, and R 338.592.

Environmental Impact

15. Do the proposed rules have any impact on the environment? If yes, please explain.

No, the proposed rules will have no impact on the environment.

Small Business Impact Statement

16. Describe whether and how the agency considered exempting small businesses from the proposed rules.

The agency did not consider exempting small businesses because doing so would create a disparity in the regulation of pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers.

17. 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 agency did not attempt to reduce the economic impact on small businesses because doing so would create a disparity in the regulation of pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers.

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

There are approximately 1,100 independent pharmacies in Michigan, according to a February 17, 2025 Capital News Service article published in the Clare County Cleaver. Independent pharmacies are used to estimate the number of pharmacies that are small businesses because they are not affiliated with large chains or hospitals.

The proposed rule changes affect pharmacies that compound pharmaceuticals under Sections 503A and 503B of the FDCA. According to the website NPI Profile, there are 241 pharmacies in Michigan with primary or secondary health provider taxonomy codes indicating compounding. It is unclear how many of these 241 pharmacies are small businesses.

There are currently 552 manufacturers licensed in Michigan. It is unknown how many of these licensees are small businesses. The proposed rule changes will increase copy costs for the department to provide printed good manufacturing practice standards to these licensees from 10 cents per page to 25 cents per page. The probable effect of this cost increase is small because the standards are available from the FDA's website at no cost.

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

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

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

The agency did not consolidate or simplify compliance and reporting requirements with the proposed rules for small businesses. Doing so would create a disparity in the regulation of pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers.

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

The agency did not set up performance standards to replace design or operation standards.

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

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

19. 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 do not require any new reports. Although R 338.534 clarifies that out-of-state pharmacies that compound drugs under Section 503B of the FDCA must submit an inspection report from the FDA or an entity approved under R 338.532a, as sterile compounders, out-of-state pharmacies are already required to submit an inspection report under R 338.534. The change to R 338.532a is intended to expand the number of approved entities who may conduct the inspection in accordance with good manufacturing practice for finished pharmaceuticals, similar to how third parties that inspect in accordance with USP standards may be approved under the current R 338.532.

20. 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 is no expectation of an effect on small businesses because of the proposed rules, nor are there any added costs.

21. 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.

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

There is no expected cause of economic harm or for the rules to adversely affect competition in the marketplace.

23. 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.

If a rule exempts or sets lesser standards for compliance by a small business, there would be no cost to the agency for administering that rule.

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

The rules are intended to protect the public in the least restrictive way. Exempting or setting lesser standards for licensees that are small businesses would compromise patient safety. For example, if pharmacies that are small businesses were held to less stringent standards for compounding, patients may receive ineffective or unsafe medications.

25. 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 board rules committee work group meetings, which included members from the board and members of the public in the development of the proposed rules. The board is composed of members of the profession, some of whom may work in small businesses. However, no one who took part in the development of the rules identified themselves as representatives of small businesses.

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

No one who took part in the development of the rules identified themselves as representatives of small businesses.

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

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

There are no estimated compliance costs with these rule amendments on businesses or groups.

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

The proposed rules directly affect licensees. Licensees bear the cost of and directly benefit from the proposed rules. As of July 23, 2025, there were 3,345 pharmacies, 15 remote pharmacies, 552 manufacturers, 1,963 wholesale distributors, and 6 wholesale distributor-brokers licensed in Michigan.

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.

Manufacturers who wish to obtain a printed copy of the good manufacturing practice for finished pharmaceuticals regulations from the department will pay an additional 15 cents per page. As of July 23, 2025, there were 552 licensed manufacturers in Michigan. However, the good manufacturing practice regulations are available at no cost on the FDA’s website.

27. 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 proposed rules are not expected to increase costs for individuals. Pharmacists who wish to order and administer qualified immunization, order and administer qualified laboratory tests and dispense drugs based on the test results, and prescribe contraceptives will need to obtain the training required under the rules.

Pharmacists who order and administer qualified immunizations must complete a training course on the administration of immunizations. For example, both the MPA and WSU offer 20-hour ACPE-accredited certificate programs in Pharmacy-Based Immunization Delivery ranging in cost from $135 for a WSU student to $510 for MPA non-members. These programs appear to be designed to meet the training requirements of the federal PREP Act. Pharmacists who have already completed training to satisfy the PREP Act may apply the same training to satisfy R 338.581. The training required by R 338.581 is less stringent than these certificate programs, with no minimum number of hours. It is possible that less expensive training programs may eventually be offered to satisfy the less stringent requirements of R 338.581.

Additionally, if the pharmacist chooses to order qualified laboratory tests and dispense drugs without a prescription based on the test result, they must complete a training program requiring the pharmacist to demonstrate sufficient knowledge of how to administer and interpret each laboratory test that the pharmacist may order or administer and demonstrate sufficient knowledge of each illness, condition, or disease for which the pharmacist dispenses a drug based on the results of the laboratory test. For example, the MPA and the NCPA both offer a 20-hour Pharmacy-Based Point-of-Care Test and Treat National Certificate. The cost ranges from $295 for an MPA student member to $495 for an NCPA.

Lastly, before issuing a prescription for a contraceptive, a pharmacist shall successfully complete a training course on prescribing and dispensing contraceptives that is provided by an entity accredited by the ACPE. For example, the American Pharmacists Association offers a 4-hour, ACPE-accredited program that costs $169 for members and $295 members for nonmembers.

However, pharmacists are not required to obtain additional training unless they wish to engage in these newly-authorized functions. Further, the training may be used toward the continuing education requirements for license renewal if it complies with R 338.3662.

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

The proposed rules directly affect licensees. Licenses bear the cost of and directly benefit from the proposed rules. As of July 29, 2025, there were 18,283 pharmacists, 6 special volunteer pharmacists, and 1,313 pharmacy interns, 31,138 pharmacy technicians, 1 special volunteer pharmacy technician, 1 temporary military spouse pharmacy technician, and 662 limited licensed pharmacy technicians in Michigan.

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

The qualitative impact of the proposed rules on the citizens of Michigan will be that they will know a licensee meets the minimum requirements for licensure, and they will be able to receive qualified immunizations, qualified laboratory tests, antiviral drugs to treat COVID-19 and influenza infections, and contraceptive prescriptions from pharmacists. The proposed rule amendments help to ensure the health, safety, and welfare of Michigan citizens without more costs.

The qualitative impact on licensees and applicants by the proposed rules will be the knowledge that they and their peers have achieved the minimum requirements for licensure and can appropriately support the needs of the citizens of Michigan, including the ability to meet the citizens' needs for immunizations, laboratory tests, antiviral drugs to treat COVID-19 and influenza, and contraceptives. The quantitative impact on licenses and applicants by the proposed rules is that they will have credentials that will meet the minimum requirements of licensure. These credentials will allow them to have access to job opportunities and compensation in line with their education and work experience.

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

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

29. 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 licensing. The clear, concise language allows the public, licensees, and schools to better understand the requirements for licensure and the practice of pharmacy.

30. Explain how the proposed rules will impact business growth and job creation (or elimination) in Michigan.

There is no expected significant impact on business growth, job growth, or job elimination because of the rules.

31. 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.

The department does not expect any disproportionate effect on any individuals or businesses by their industrial sector, segment of the public, business size, or geographical location.

32. 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.

Federal Sources

Federal Food, Drug, and Cosmetic Act, 21 USC Ch. 9.
https://uscode.house.gov/view.xhtml;jsessionid=BB41F0E97DC0FF12CF4F3B7ACAD2FA41?req=granuleid%3AUSC-prelim-title21-chapter9&saved=%7CZ3JhbnVsZWlkOlVTQy1wcmVsaW0tdGl0bGUyMS1zZWN0aW9uMzUzYg%3D%3D%7C%7C%7C0%7Cfalse%7Cprelim&edition=prelim

Current Good Manufacturing Practice for Finished Pharmaceuticals, 21 CFR 211.
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211

Public Readiness and Emergency Preparedness Act, 42 USC 247d-6d – 247d-6e.
https://uscode.house.gov/view.xhtml?req=granuleid:USC-2010-title42-section247d-6d&num=0&edition=2010

12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 Fed. Reg. 99875 (Dec. 11, 2024).
https://www.federalregister.gov/documents/2024/12/11/2024-29108/12th-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical

CLIA
https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter6A/subchapter2/partF/subpart2&edition=prelim

Certificate of waiver tests, 42 CFR 493.15(c)
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#p-493.15(c)

Illinois

https://idfpr.illinois.gov/profs/pharm.html

https://www.ilga.gov/Legislation/ILCS/Articles?ActID=3807&ChapterID=24&Chapter=PROFESSIONS,%20OCCUPATIONS,%20AND%20BUSINESS%20OPERATIONS&MajorTopic=REGULATION

https://ilga.gov/Legislation/ILCS/Articles?ActID=1318&ChapAct=225 ILCS 85/&ChapterID=24&ChapterName=PROFESSIONS%20AND%20OCCUPATIONS&ActName=Pharmacy%20Practice%20Act.

https://www.ilga.gov/agencies/JCAR/Sections?PartID=06801330&TitleDescription=TITLE%2068:%20%20PROFESSIONS%20AND%20OCCUPATIONS

https://idfpr.illinois.gov/content/dam/soi/en/web/idfpr/forms/dpr/Standing%20Order%205%2010%202023.pdf

https://idfpr.illinois.gov/content/dam/soi/en/web/idfpr/forms/dpr/Hormonal%20Contraception%20Standing%20Order%20FAQs.pdf

https://idfpr.illinois.gov/content/dam/soi/en/web/idfpr/forms/dpr/Final%20Visit%20SummaryTemplate.pdf

https://idfpr.illinois.gov/content/dam/soi/en/web/idfpr/forms/dpr/Self-Screening%20Risk%20Assessment%20Tool%20w%20Eligibility%20Criteria.pdf

Indiana

https://www.in.gov/pla/professions/pharmacy-home/

https://iga.in.gov/laws/2025/ic/titles/25#25-1-9.5

https://iga.in.gov/laws/2025/ic/titles/25/#25-26

https://iar.iga.in.gov/code/2026/856

https://irp.cdn-website.com/43f0df5e/files/uploaded/Indiana_Standing_Order_Materials.pdf

Minnesota

https://mn.gov/boards/pharmacy/

https://www.revisor.mn.gov/statutes/cite/62A.673#stat.62A.673.2

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

https://www.revisor.mn.gov/rules/6800/

https://mn.gov/boards/assets/Minnesota%20Board%20of%20Pharmacy%20Protocol%20for%20Pharmacist%20Contraceptive%20Prescribing%20Approved_tcm21-464043.pdf

https://mn.gov/boards/assets/Minnesota%20Board%20of%20Pharmacy%20Standard%20Procedures%20Algorithm%20for%20RPh%20Prescribing%20of%20Contraceptives%20Approved_tcm21-463710.pdf

https://mn.gov/boards/assets/MECCorrespondingToMNQuestionnaire_tcm21-463705.pdf

https://mn.gov/boards/assets/Minnesota%20Board%20of%20Pharmacy%20Contraceptive%20Prescribing%20Protocol%20Visit%20Summary%20Template%20Approved_tcm21-463706.pdf

New York

https://www.op.nysed.gov/professions-index/pharmacy

https://www.op.nysed.gov/professions/pharmacist/laws-rules-regulations/part-63

https://www.op.nysed.gov/professions/pharmacist/laws-rules-regulations/article-137?page=1

https://www.op.nysed.gov/professions/pharmacist/frequently-asked-questions/administration-of-immunizations

https://www.health.ny.gov/community/reproductive_health/docs/hormonal_contraceptives_so.pdf

https://www.health.ny.gov/community/reproductive_health/

https://www.op.nysed.gov/professions/pharmacist/frequently-asked-questions/Dispensing-of-Hormonal-Contraception

Ohio

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

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

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

Pennsylvania

https://www.pa.gov/agencies/dos/department-and-offices/bpoa/boards-commissions/pharmacy

https://www.pa.gov/content/dam/copapwp-pagov/en/dos/department-and-offices/bpoa/pharmacy/Law%20-%20Act%20699%20of%201961.pdf

https://www.pacodeandbulletin.gov/Display/pacode?file=/secure/pacode/data/049/chapter27/chap27toc.html&d=reduce

https://www.palegis.us/statutes/consolidated/view-statute?txtType=HTM&ttl=40&div=0&chapter=48

https://www.pa.gov/agencies/dos/resources/professional-licensing-resources/telemedicine-faqs

https://www.pa.gov/content/dam/copapwp-pagov/en/dos/department-and-offices/bpoa/pharmacy/PharmM%20-%20Compounding%20Regulations%20Finalized.pdf
https://apps.health.pa.gov/PDF/DDC/Blank%20Application-DDC-2025.pdf

Wisconsin

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

https://www.forwardhealth.wi.gov/WIPortal/cms/public/html/pharmacy_prov_type

https://docs.legis.wisconsin.gov/document/statutes/440.01(1)(hm)

https://docs.legis.wisconsin.gov/statutes/statutes/440/i/17#

https://docs.legis.wisconsin.gov/statutes/statutes/450

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

Other Sources

https://www.usp.org/products/usp-compounding-compendium

2025 Survey of Pharmacy Law, National Association of Boards of Pharmacy, available at

https://nabp.pharmacy/news-resources/resources/publications/survey-of-pharmacy-law/

https://www.clarecountycleaver.net/stories/independent-pharmacies-face-challenges-in-michigan,108562

https://www.michigan.gov/lara/bureau-list/bpl/license-lists-and-reports

https://npiprofile.com/taxonomy/code/3336C0004X/state/mi?page=2

https://cphs.wayne.edu/practice/immunization-certificate.php

https://www.michiganpharmacists.org/education-pharamacy-immunization-training

https://www.michiganpharmacists.org/education-poct-certificate

https://ncpa.org/pharmacy-based-point-care-testing-certificate-program

https://www.pharmacist.com/Education/Advanced-Training-Self-Paced/Hormonal-Contraceptive-Products

https://www.legislature.mi.gov/documents/2023-2024/billanalysis/Senate/pdf/2023-SFA-0219-N.pdf

https://legislature.mi.gov/documents/2023-2024/billanalysis/Senate/pdf/2023-SFA-5435-F.pdf

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.

The number of independent pharmacies was used to estimate the number of pharmacies that are small businesses because independent pharmacies are not affiliated with large chains or hospitals.

Alternative to Regulation

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

Since statute mandates the rules, there are no reasonable alternatives to the proposed rules.

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

Since statute mandates the rules, there are no reasonable alternatives to the proposed rules.

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

Since statute mandates the rules, private market-based systems cannot serve as an alternative. The licensing and regulation of pharmacy are state functions, so a regulatory program independent of state intervention cannot be set up. One could consider pharmacy-related professional associations as regulatory mechanisms that are independent of state intervention; however, these professional organizations would provide the public with significantly less protection because membership in these organizations is voluntary. This means an individual or business who meets the membership requirements, but does not join, would still be able to practice and there would be no way to ensure competency or accountability for harm done to clients.

No other states in the Great Lakes region use a private, market-based system to regulate pharmacy.

35. 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.

Since statute mandates the rules, there are no reasonable alternatives to the proposed rules. There were no alternatives that the department considered to achieve the intended changes. They are necessary for the administration and enforcement of the licensing process.

Additional Information

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

The rules include the instructions for compliance.