

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-BENEFIT 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:

2020-29 LR

Title of proposed rule set:

Pharmacy Technicians

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.

Each state establishes its own requirements with respect to pharmacy technicians, so there are no federal rules or standards set by a national or state agency that the proposed rules can be compared to.

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

Yes, the Department of Licensing and Regulatory Affairs (Department) in consultation with the Board of Pharmacy (Board) is required to promulgate rules as follows: to include training standards for identifying victims of human trafficking, pursuant to MCL 333.16148; to complete continuing education (CE) hours in pain and symptom management for an applicant for licensure renewal, if continuing education is a condition for renewal, pursuant to MCL 333.16204; and to require applicants for license renewal to complete hours in pain and symptom management, pursuant to MCL 333.17731.

The following provisions authorize rule making: MCL 333.16145, MCL 333.16148, MCL 333.16174, MCL 333.16175, MCL 333.16178, MCL 333.16182, MCL 333.16186, MCL 333.16204, MCL 333.17731, MCL 333.17739, MCL 333.17739a, MCL 338.3501, MCL 445.2001, MCL 445.2011, and MCL 445.2030.

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.

The proposed rules are consistent with the standards required by the Public Health Code (Code) and are largely consistent with the requirements of other states in the Great Lakes region.

R 338.3651, R 338.3652, R 338.3653, and R 338.3657: The proposed rules pertain to the requirements for pharmacy technician licensure, temporary licensure, licensure by endorsement, and relicensure. The licensure requirements in the proposed rules are similar to the standards and requirements in other states in the Great Lakes Region. Illinois, Indiana, and Ohio require certification. Only New York and Pennsylvania do not license or register pharmacy technicians. Minnesota, Ohio, and Wisconsin register their pharmacy technicians.

R 338.3654: The proposed rule pertains to the examination requirements for licensure. Indiana, Minnesota, New York, Pennsylvania, and Wisconsin do not require an examination.

R 338.3655: The proposed rule pertains to Board-approved pharmacy technician educational programs and the process for approval. Although graduation from a pharmacy technician educational program is not a requirement for licensure, attendance in a program allows a student to participate in the activities of a pharmacy technician without a license while he or she is in the training programs included in this proposed rule. The proposed rule requires all Board-approved pharmacy technician programs to be accredited by an accrediting body recognized by the U.S. Department of Education or American Society of Health-System Pharmacists/Accreditation Council for Pharmacy Education Pharmacy Technician Accreditation Commission (ASHP/ACPE). Most states in the Great Lakes Region require training for pharmacy technicians.

R 338.3661, R 338.3662, and R 338.3663: The proposed rules pertain to the license renewal and continuing education (CE) requirements. Minnesota and Ohio require CE.

R 338.3665: The proposed rule pertains to the functions that may be performed by a pharmacy technician. Unlike Michigan, none of the other states in the Great Lakes Region have pharmacy technicians check the work of other pharmacy technicians.

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, examinations, educational training programs, relicensure, renewal, CE, 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.

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

Public Act 4 of 2020 authorized the Department to license a remote pharmacy that operates under a parent pharmacy through a telepharmacy system. Public Act 4 of 2020 established the term “qualified pharmacy technician.” A qualified pharmacy technician must meet all of the following requirements: hold a pharmacy technician license other than a temporary license or limited license; accumulate at least 1,000 hours of experience working in a pharmacy after being granted a temporary, limited, or full license; and hold a national certification as a pharmacy technician from an organization approved by the Board. Although, under the Public Health Code a pharmacy technician must be under the personal charge of a pharmacist, which means that the pharmacist is supervising the pharmacy technician in person under direct supervision. In a remote pharmacy, a qualified pharmacy technician may be overseen by a pharmacist in charge and staffed by a qualified pharmacy technician through a surveillance system and telepharmacy system.

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.

Except in a remote pharmacy, which has been excepted in the rules, as it is fully authorized in the Public Health Code, no coordination is needed because there are no other applicable laws that are inconsistent with the regulations in the proposed rules.

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.

There is no applicable federally mandated standard. 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 is no applicable federal standard.

Purpose and Objectives of the Rule(s)

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

The proposed rules are designed to alter the following behavior: reducing the confusion of applicants who desire to apply as a pharmacy technician but do not understand the process; eliminating the inconsistency in Board-approved pharmacy technician programs by requiring that they be accredited; allowing a pharmacy technician program student to perform pharmacy technician duties indefinitely without being fully licensed; allowing pharmacy technician employer programs and examinations to continue indefinitely without further review by the Board; relicensing an applicant after he or she has allowed a license to lapse without showing good moral character or submitting fingerprints; licensing an individual who has not taken the human trafficking required training; allowing continuing education to be met by taking a proficiency examination that the licensee may have taken in the past; reducing the confusion regarding the type of continuing education that is accepted by the Department; and limiting a pharmacy technician from assisting in the final product verification.

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 Department expects minimal requests from applicants regarding program and examination requirements; the proposed rules will eliminate the inconsistency in Board-approved pharmacy technician programs by requiring that they be accredited; a pharmacy technician will be limited to performing pharmacy technician duties for only two years from beginning a program without being fully licensed; pharmacy technician employer programs and examinations will be reviewed every 5 years; all applicants for relicensure will be required to show good moral character and submit their fingerprints; all applicants will take the human trafficking training; for all applicants renewing one year after the effective date of the rules, continuing education may no longer be met by taking a proficiency examination; and pharmacy technicians who meet the requirements in the rules will be authorized to assist in the final product verification.

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

The difference between current behavior and desired behavior is as follows: it is expected that there will be less confusion and questions from employer program applicants and licensure applicants regarding program and examination requirements. Requiring employer programs to be accredited will provide a more consistent education across all programs and benefit the applicants and public. Instead of allowing a pharmacy technician program student to perform pharmacy technician duties indefinitely without being fully licensed, a pharmacy technician student will be limited to performing pharmacy technician duties for only two years from beginning a program without being fully licensed. Instead of allowing pharmacy technician employer programs and examinations to continue indefinitely without further review by the Board, pharmacy technician employer programs and examinations will be reviewed every 5 years. Previously, applicants for licensure were not always required to show good moral character, submit their fingerprints, and take the human trafficking training. The proposed rules will require all applicants to comply with those requirements. The requirements for continuing education could be met by taking a proficiency examination, but the proposed rules no longer allow taking a proficiency examination and will require the licensee to meet other continuing education requirements. Lastly, pharmacy technicians who meet the requirements in the proposed rules will be authorized to assist in final product verification.

C. What is the desired outcome?

The desired outcome of the proposed rules is that the Department expects minimal requests from applicants regarding program and examination requirements; the proposed rules will eliminate the inconsistency in Board-approved pharmacy technician programs and result in a higher level of education for pharmacy technicians if programs are accredited; a pharmacy technician will be limited to performing pharmacy technician duties for only two years from the beginning of a program without being fully licensed which will reduce the time that a student may practice without being fully licensed; pharmacy technician employer programs and examinations will be reviewed every 5 years so that programs and examinations are up to date and those that are no longer offered can be taken off of the list kept by the Department; all applicants for relicensure will be required to show good moral character and submit their fingerprints which is in the best interest of the public that they serve; all applicants will take the human trafficking training so that they can spot a person being trafficked; continuing education may no longer be met by taking a proficiency examination; and pharmacy technicians that meet the requirements in the rules will be authorized to assist in the final product verification.

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: reduce the confusion of applicants who desire to apply as a pharmacy technician but do not understand the process; eliminate the inconsistency in Board-approved pharmacy technician programs by requiring that they be accredited; allowing a pharmacy technician program student to perform pharmacy technician duties indefinitely without being fully licensed; allowing pharmacy technician employer programs and examinations to continue indefinitely without further review by the Board; relicensing an applicant after he or she has allowed a license to lapse without showing good moral character or submitting fingerprints; licensing an individual who has not taken the human trafficking required training; allowing continuing education to be met by taking a proficiency examination that the licensee may have taken in the past; reduce the confusion regarding the type of continuing education that is accepted by the Department; and limiting a pharmacy technician from assisting in the final product verification.

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 mechanism for the practice pharmacy technicians. To protect the health and safety of Michigan's citizens, it is important that members of the profession adhere to minimal educational and professional standards.

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

There are no rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

Fiscal Impact on the Agency

Fiscal impact is an increase or decrease in expenditures from the current level of expenditures, i.e. hiring additional staff, higher contract costs, programming costs, changes in reimbursements rates, etc. over and above what is currently expended for that function. It does not include more intangible costs for benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

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

The proposed rules are not expected to have a fiscal impact on the agency.

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

No agency appropriation has been made nor has a funding source been provided for expenditures associated with implementing these rules.

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 submitting fingerprints for a background check by applicants is \$30.00. The estimated cost for human trafficking training is zero as the training may be found online. The background check and training will benefit Michigan citizens by requiring an applicant for licensure to demonstrate that he or she is of good moral character and knowledgeable about human trafficking.

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

The rules are required to provide a mechanism for licensing and regulation of the profession. The rules are not any more restrictive than is allowed by statute. Despite the cost-related burden of licensing, the rules and regulations are necessary in order to provide a framework of standards for educational, licensure, and CE requirements.

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 to state or local governmental 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, township, 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 anticipated actions that a governmental unit must take to comply with these 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 an individual licensed under the public health code as a pharmacy technician, regardless of his or her location.

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

No disparate impact of public or private interests is anticipated on rural areas because of the proposed rules.

Environmental Impact

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

The proposed rules do not have an environmental impact.

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 also require Board approved pharmacy technician programs to be accredited by July 1, 2022. The goal of the proposed rule requiring accreditation is to require consistency and a high level of education in the Board approved programs, exempting some programs would defeat the goal of the proposed rule.

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 also require Board approved pharmacy technician programs to be accredited by July 1, 2022. The goal of the proposed rule requiring accreditation is to require consistency and a high level of education in the programs, exempting some programs would defeat the goal of the proposed rule. Programs are offered at large and small pharmacies as well as proprietary schools licensed in Michigan.

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

There are approximately 15,231 pharmacy technicians and 1,346 limited pharmacy technicians in Michigan. There are 69 pharmacies that have been approved by the Board to offer a pharmacy technician employer-based training program and examination. In addition, employers such as Meijer, Walgreens, Walmart and Sam's Club, Kroger Company, Rite Aid, Costco, and CVS Drugs offer programs at multiple locations. There are seven proprietary schools offering a pharmacy technician program.

A licensee may work in a small business, but no matter what type of business environment the licensee works in, he or she will have to comply with the proposed rules. The rules do not impact small businesses differently than any other entity that desires to offer a pharmacy technician training program and examination.

The probable effect on entities that offer a training program and examination is that they must have the program accredited or they will no longer be able to offer the program after July 1, 2022.

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 proposed rules will apply to all licensed pharmacy technicians and entities that offer a pharmacy technician training program and examination. The rules were drafted to be the least burdensome on all affected licensees and programs.

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 in 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 entities that offer a pharmacy technician training program and examination. There may be an impact on a small business in that it must have the program accredited, however, allowing a small business to offer a program of lesser quality than another program is not in the best interests of the public.

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 affect individual licensure applications and renewals, which are already required of all licensees, regardless if they practice in a small business.

An entity that offers a pharmacy technician training program and examination must apply for and meet accreditation standards to be approved. In addition, it must apply every five years for re-approval, which will require proof of accreditation. Except for maintaining the program syllabus and activities performed in the program, the proposed rules do not require a program to submit or maintain any additional reports that are not already required in the rules.

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.

For all-Board approved pharmacy technician training programs, the cost of compliance will include the cost for accreditation. The cost of accreditation depends on the accreditor, the type of entity being accredited, as well as the number of sites being accredited. The cost is estimated at \$3,500.00 annually for an educational site to \$10,000.00 annually for a chain pharmacy.

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 costs for legal, consulting, or accounting services in addition to the accreditation process that a small business would incur in complying with the proposed rules.

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

There are no expected costs to a small business 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.

The proposed rules impose requirements on individual licensees. Even if a licensee's practice qualifies as a small business, the Department could not exempt his or her business because it would create disparity in the regulation of the profession.

If an entity that offers a Board approved pharmacy technician training program qualified as a small business, and the Department determined to set lesser standards for compliance, the cost to the Department would involve reviewing the applications and enforcing the standards. However, the real cost would be to the public who would be being served by pharmacy technicians who were trained at a lower level than pharmacy technicians educated in accredited programs.

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

The proposed rules impose requirements on individual licensees. Even if a licensee's work 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.

If an entity that offers a Board approved pharmacy technician training program qualified as a small business, and the Department determined to set lesser standards for compliance, the impact on the public interest would be being served by pharmacy technicians who were trained at a lower level than pharmacy technicians educated in accredited programs.

Therefore, exempting or setting lesser standards of compliance for a small business 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 work group sessions that included members from the Board of Pharmacy, educational institutions, large and small 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 small and large 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 estimated compliance cost would be the cost of entities to have their programs accredited.

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 15,231 pharmacy technicians and 1,346 limited pharmacy technicians in Michigan. There are 69 pharmacies that have been approved by the Board to offer a pharmacy technician employer-based training program and examination. In addition, employers such as Meijer, Walgreens, Walmart and Sam’s Club, Kroger Company, Rite Aid, Costco, and CVS Drugs offer programs at multiple locations. There are seven proprietary schools offering a pharmacy technician program.

A licensee may work in a small business, but no matter what type of business environment the licensee works in, he or she will have to comply with the proposed rules. The rules do not impact small businesses differently than any other entity that desires to offer a pharmacy technician training program and examination.

The probable effect on entities that offer a training program and examination is that they must have the program accredited or they will no longer be able to offer the program after July 1, 2022.

The public will be directly affected by the proposed rules. If an entity that offers a Board-approved pharmacy technician training program qualified as a small business, and the Department determined to set lesser standards for compliance, the impact on the public interest would be being served by pharmacy technicians who were trained at a lower level than pharmacy technicians educated in accredited programs.

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.

For all Board-approved pharmacy technician training programs, the cost of compliance will include the cost for accreditation. The cost of accreditation depends on the accreditor, the type of entity being accredited, as well as the number of sites being accredited. The cost is estimated at \$3,500.00 annually for an educational site to \$10,000.00 annually for a chain pharmacy.

No additional costs will be imposed on any businesses or groups.

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 submitting fingerprints for a background check by applicants is \$30.00. The estimated cost for human trafficking training is zero as the training may be found online. The background check and training will benefit Michigan citizens by requiring an applicant for licensure to demonstrate that he or she is of good moral character and knowledgeable about human trafficking.

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

The individuals affected are applicants for licensure, relicensure, and renewal.

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

The estimated cost for submitting fingerprints for a background check by applicants is \$30.00. The estimated cost for human trafficking training is zero as the training may be found online. The background check and training will benefit Michigan citizens by requiring an applicant for licensure to demonstrate that he or she is of good moral character and knowledgeable about human trafficking.

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

There are no cost reductions for businesses, individuals, groups of individuals, or governmental units as a result of the proposed rules.

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 direct benefits of the proposed rules include: reducing the confusion of applicants who desire to apply as a pharmacy technician but do not understand the process; eliminating calls to the Department regarding processes of licensure and pharmacy technician training programs; eliminating the inconsistency in Board-approved pharmacy technician programs by requiring that they be accredited; increasing the quality of pharmacy technician training programs; reducing the time that a technician training program student may perform pharmacy technician duties without being fully licensed; reviewing Board-approved pharmacy technician training programs and examinations more frequently; increasing the licensing requirements by requiring proof of good moral character; requiring applicants to take the human trafficking training; prohibiting applicants from taking the proficiency examination in lieu of continuing education courses and activities; reducing the confusion regarding the type of continuing education that is accepted by the Department; and allowing a pharmacy technician to assist in the final product verification.

The indirect benefits of the proposed rules include: maintaining a better list of active Board-approved pharmacy technician training programs; increasing the quality of licensees; and increasing the ability of a licensee to identify a human trafficking situation.

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 or job creation.

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.

Pharmacies will disproportionately be affected by the proposed rules. There are no other individuals or businesses expected to be a disproportionately affected 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.

<https://www.pharmacytimes.com/publications/issue/2006/2006-12/2006-12-6154>

<https://www.ashp.org/Professional-Development/Technician-Program-Accreditation/Applying-for-Accreditation>

<https://www.pharmacytimes.com/news/pharmacy-technician-license-requirements-by-state>

<https://nabp.pharmacy/news/news-releases/ptcb-reports-record-number-of-pharmacy-technician-certification-candidates/>

<https://nabp.pharmacy/news/news-releases/ashp-and-acpe-announce-new-commissioners-for-the-pharmacy-technician-accreditation-commission/>

https://nabp.pharmacy/wp-content/uploads/2016/07/08TF_Standard_Pharm_Tech_Educ_Training.pdf

National Association of Boards of Pharmacy 2020 - Survey of Pharmacy Law

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.

There were no estimates made because the rules impact an individual licensee as well as an applicant for licensure.

Alternative to Regulation

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

The rules are required by statute; there is no reasonable alternative to enacting the proposed rules.

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

There is no reasonable alternative to the proposed rules.

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

Since the rules are required by statute, private market-based systems cannot serve as an alternative. States regulate pharmacy technicians by statute, regulation, or both. Private market-based systems are not used for licensing and regulation. The licensing and regulation of pharmacy technicians are state functions, so a regulatory program independent of state intervention cannot be established. There are professional associations that establish criteria for membership as a pharmacy technician, but these professional organizations would provide the public with significantly less protection because membership in many of these organizations is voluntary. This means an individual who meets the membership requirements, but does not join one of the professional organizations, would be able to practice and there would be no way to ensure his or her competency or hold him or her accountable.

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.

Since the rules are specifically required by statute, there are no alternatives to the proposed rules that the agency could consider. They are necessary for the administration and enforcement of the licensing process.

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.

All instructions for licensure and the applications for pharmacy technician training programs are included in the applications and are also on the Department's website. The proposed rules inform an applicant of the relicensing requirements when his or her license has lapsed and the requirements for renewal and continuing education.