Michigan Office of Administrative Hearings and Rules Administrative Rules Division (ARD)

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REGULATORY IMPACT STATEMENT and COST-BENEFT ANALYSIS (RIS)

Agency Information:

Department name:

Licensing and Regulatory Affairs

Bureau name:

Bureau of Professional Licensing

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Rule Set Information:

ARD assigned rule set number:

2022-2 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.

There are no parallel federal rules or standards set by a state or national licensing agency or accreditation association.

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) are 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 CE is a condition for renewal, pursuant to MCL 333.16204 and MCL 333.17731; and to implement sections 16284 and 18285 of the Public Health Code (Code), regarding telehealth, pursuant to MCL 333.16287.

The following provisions authorize rule making: MCL 333.16145, MCL 333.16148, MCL 333.16184, MCL 333.16186, MCL 333.16201, MCL 333.16204, MCL 333.16205, MCL 333.16215, MCL 333.16287, MCL 333.17731, MCL 333.17739, MCL 333.17739a, MCL 333.17739b, MCL 333.17739c, 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 proposed rules do not exceed any federal standards.

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

The proposed rules are consistent with the standards required by the Code and are largely consistent with the requirements of other states in the Great Lakes Region.

R 338.3651: The proposed rule contains definitions.

R 338.3651a, R 338.3652, R 338.3653, R 338.3657, and R 338.3659: The proposed rules pertain to the requirements for pharmacy technician licensure, temporary licensure, licensure by endorsement, relicensure, and the human trafficking training. 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. Minnesota, Ohio, and Wisconsin register their pharmacy technicians. Pennsylvania does not license pharmacy technicians.

R 338.3654: The proposed rule pertains to the examination requirements for licensure and requires a board-approved proficiency examination to have a minimum passing score. Indiana, Minnesota, 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 they are in the training programs included in this proposed rule. The proposed rule allows a community college to apply for a comprehensive curriculum-based pharmacy technician education and training program. All states in the Great Lakes Region, except Pennsylvania and Wisconsin, require training for pharmacy technicians.

R 338.3661, R 338.3662, and R 338.3663: The proposed rules pertain to the license renewal and CE requirements. In the Great Lakes Region, Illinois, Minnesota, and Ohio require CE. Illinois requires 20 hours every 24 months. Minnesota requires 20 hours every 2 years. Ohio requires 10 hours every 2 years.

R 338.3665: The proposed rule pertains to the functions that may be performed by a pharmacy technician. In Illinois, a pharmacy technician may check the work of another pharmacy technician. In Illinois and Ohio, a pharmacy technician may accept a called in prescription from a physician's office. All states in the Great Lakes Region allow a pharmacy technician to enter prescriptions into a pharmacy computer. Illinois and Ohio allow a pharmacy technician to transfer a prescription order.

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.

There are no other laws, rules or other legal requirements that duplicate, overlap, or conflict with the proposed rules. Each state establishes its own requirements with respect to pharmacy technicians. There are no federal rules or standards set by a national or state agency that the proposed rules exceed.

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.

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 Code a pharmacy technician must be under the personal charge of a pharmacist while participating in pharmacy services, 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.

The proposed rules allow a pharmacy technician to function remotely, under supervision that is less than personal charge of a pharmacist, while performing functions listed in the rule. Those tasks include: verification of a patient's medication history; data entry regarding processing prescription data and patient data; claims adjudication; handling phone calls regarding processing prescription data and patient data; processing refill requests; technology-assisted final product verification; and transferring prescriptions for non-controlled substances. The proposed rules do not allow a pharmacy technician to handle all of the same tasks outside of the personal charge of a pharmacist that are allowed in a remote pharmacy.

There are no other laws, rules or other legal requirements that conflict with the proposed rules. There are no federal rules or standards set by a national or state agency that the proposed rules exceed.

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.

MCL 24.232(8) does not apply.

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: using a pharmacy technician examination or program in this state that has not been Board reviewed in the last year under the modified rules; using a pharmacy technician examination in this state that has less than a 70% passing score; not allowing a comprehensive curriculum-based pharmacy technician education and training program conducted by a community college in this state; not allowing a pharmacy technician student who is less than 18 years of age to participate in practical training in a pharmacy; having a deficient pharmacy technician program in this state; requiring licensees to take a human trafficking training, implicit bias training, as well as 20 CE hours; filing a late request for waiver of CE; not accepting CE earned during the 60-day grace period prior to renewal; allowing more than 2 CE hours for the presentation of a CE program that is not a part of the licensee's regular job description; reviewing the pharmacy technician CE courses and programs under a different standard than the standard used for reviewing pharmacist CE; limiting the qualifications for a pharmacy technician to perform final product verification; and requiring all pharmacy technician functions to take place in a pharmacy under the personal charge of a pharmacist.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rules.

It is expected that the rules will alter the frequency of the targeted behavior as follows: all existing Board approved pharmacy technician examinations and programs in this state will be reviewed by the Board before December 31, 2023; all Board approved pharmacy technician examinations in this state will have a 70% passing score; the Board will review comprehensive curriculum-based pharmacy technician education and training programs conducted by a community college; a student in a pharmacy technician program who is less than 18 years of age may participate in practical training in a pharmacy; a deficient pharmacy technician program will not accept students until the deficiency is fixed; licensees may meet the pharmacy ethics and jurisprudence CE requirement by taking more than 1 course or program; licensees may use the human trafficking training and implicit bias training toward the required 20 CE hours: a licensee will apply for a waiver of CE pursuant to the required time requirements: a licensee will be able to use CE earned up to the date of the filing of the renewal of their license toward the CE requirement even if earned during the 60-day grace period; the 5 hours of CE in live, synchronous, courses or programs may be earned in-person or virtual; a licensee may only earn 2 CE hours for the presentation of a CE program that is not a part of the licensee's regular job description; the review of pharmacy technician CE courses and programs and pharmacist CE courses and programs will be the same; a pharmacy technician may qualify to perform final product verification by either work experience or training; and a pharmacy technician will be allowed to work remotely in a limited capacity outside of the personal charge of a pharmacist.

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

The difference between the current behavior/practice and desired behavior/practice is: instead of approving programs and examinations indefinitely, all programs and examinations will require a review by December 31, 2023, and again every 5 years; instead of not requiring a minimum passing score, all Board approved pharmacy technician examinations in this state will have a minimum 70% passing score; under the proposed rules the Board will review comprehensive curriculum-based pharmacy technician education and training programs conducted by a community college; under the proposed rules a student in a pharmacy technician program who is less than 18 years of age may participate in practical training in a pharmacy; under the proposed rules a deficient pharmacy technician program will lose its approval by the Board; under the new rules licensees may meet the pharmacy ethics and jurisprudence CE requirement by taking more than 1 course or program; instead of taking the human trafficking training, implicit bias courses and 20 CE hours, a licensee may use the human trafficking training and implicit bias training toward the required 20 CE hours; a licensee will apply for a waiver of CE pursuant to the required time requirements instead of having their request reviewed after their renewal date; a licensee will be able to use CE earned up to the date of the filing of the renewal of their license toward the CE requirement even if earned during the 60-day grace period; under the proposed rules the 5 hours of CE in live, synchronous, courses or programs may be earned in-person or virtual; instead of earning up to 10 hours a licensee may only earn 2 CE hours for the presentation of a CE program that is not a part of the licensee's regular job description; under the proposed rules the review of pharmacy technician CE courses and programs and pharmacist CE courses and programs will be the same; under the proposed rules a pharmacy technician may qualify to perform final product verification by either work experience or training; and under the proposed rules a pharmacy technician will be allowed to work remotely in a limited capacity outside of the personal charge of a pharmacist.

C. What is the desired outcome?

The desired outcome of the proposed rules is that the Department expects the following: all programs and examinations will be reviewed by December 31, 2023, and again every 5 years; all Board approved pharmacy technician examinations in this state will have a minimum 70% passing score; the Board will review comprehensive curriculum-based pharmacy technician education and training programs conducted by a community college; a student in a pharmacy technician program who is less than 18 years of age may participate in practical training in a pharmacy; a deficient pharmacy technician program will lose its approval by the Board; licensees may meet the pharmacy ethics and jurisprudence CE requirement by taking more than 1 course or program; a licensee may use the human trafficking training and implicit bias training toward the required 20 CE hours; a licensee will apply for a waiver of their CE according to the rules that will be reviewed prior to their license expiration date; a licensee will be able to use CE earned up to the date of the filing of the renewal of their license toward the CE requirement; the required 5 hours of CE in live, synchronous, courses or programs may be earned in-person or virtually; a licensee may only earn 2 CE hours for the presentation of a CE program that is not a part of the licensee's regular job description; the review of pharmacy technician CE courses and programs and pharmacist CE courses and programs will be the same; a pharmacy technician may qualify to perform final product verification by either work experience or training; and a pharmacy technician will be allowed to work remotely in a limited capacity outside of the personal charge of a pharmacist.

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: allowing pharmacy technician training programs to continue indefinitely without any follow up review; Board approved pharmacy technician examinations will continue to have various minimum passing scores; a community college is unable to apply to the Board for approval of a training program; a student younger than 18 who is in a pharmacy technician program may not participate in practical training in a pharmacy; a pharmacy technician program with deficiencies continues to instruct students; licensees struggle to find one course or program that meets both the pharmacy ethics and jurisprudence CE requirement; licensees must take a human trafficking training, implicit bias course, and an additional 20 CE hours; a licensee will apply for a waiver of CE without enough time for the Board to address their request before their license expires; a licensee is unable to use the CE earned up to the date of filing of their license renewal toward their CE requirements; a licensee is unable to use a virtual course with interaction with the instructor toward the 5 hours of live CE; a licensee teaches the same presentation 10 times and earns 10 CE hours; the review of pharmacy technician CE courses is not the same as the review of pharmacist CE courses; a pharmacy technician may only qualify to perform final product verification by having work experience; and a pharmacy technician is not authorized to work remotely.

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 rationale for changing the rules is that the Department and Board desire the following behavior: all programs and examinations will be reviewed by December 31, 2023, and again every 5 years; all Board approved pharmacy technician examinations in this state will have a minimum 70% passing score; the Board will review comprehensive curriculum-based pharmacy technician education and training programs conducted by a community college; a student in a pharmacy technician program who is less than 18 years of age may participate in practical training in a pharmacy; a deficient pharmacy technician program will lose its approval by the Board; licensees may meet the pharmacy ethics and jurisprudence CE requirement by taking more than 1 course or program; a licensee may use the human trafficking training and implicit bias training toward the required 20 CE hours; a licensee will apply for a waiver of their CE according to the rules that will be reviewed prior to their license expiration date; a licensee will be able to use CE earned up to the date of the filing of the renewal of their license toward the CE requirement; the required 5 hours of CE in live, synchronous, courses or programs may be earned in-person or virtually; a licensee may only earn 2 CE hours for the presentation of a CE program that is not a part of the licensee's regular job description; the review of pharmacy technician CE courses and programs and pharmacist CE courses and programs will be the same; a pharmacy technician may qualify to perform final product verification by either work experience or training; and a pharmacy technician will be allowed to work remotely in a limited capacity outside of the personal charge of a pharmacist.

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 of pharmacy technicians. To protect the health and safety of Michigan's citizens, it is important that members of the profession, as well as training programs, adhere to minimal educational, training, and professional standards.

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

No rules are 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 the proposed 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.

There are no additional burdens placed on individuals as a result of the proposed rules. The proposed rules will reduce burdens on individuals as follows: additional training opportunities may exist with the addition of community colleges offering training programs; licensees will be able to use their training in human trafficking and implicit bias towards their CE requirements; licensees will be able to use virtual courses in addition to live courses to meet their requirement of 5 live CE hours; licensees will have the option of training or experience to qualify to perform final product verification; and licensees will be able to work remotely on limited tasks.

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 other state or local governmental units, or cost increases or reductions to other state or local government units, as a result of the proposed rules.

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

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

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

There are no actions that governmental units must take to comply with 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 licensees and pharmacy technician training programs regardless of their location.

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

The proposed rules are not expected to impact rural areas. The proposed rules apply to licensees and pharmacy technician training programs regardless of their location.

Environmental Impact

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

No, 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 rather than small businesses. Even if a licensee's practice 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 training programs to be reviewed under the modified rules by the end of 2023. The goal of having all programs reviewed under the modified rules is to bring all programs up to current standards as well as put all programs on a 5-year renewal cycle. Exempting some programs that are offered by small businesses 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 training programs to be reviewed under the modified rules by the end of 2023. The goal of having all programs reviewed under the modified rules is to bring all programs up to current standards as well as put all programs on a 5-year renewal cycle. Exempting some programs that are offered by small businesses would defeat the goal of the proposed rule. Programs are offered at large and small pharmacies, proprietary schools, and under the proposed rules, in community colleges.

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

As of December 6, 2022, there are approximately 25,415 pharmacy technicians and 1,133 limited pharmacy technicians in Michigan. There are approximately 240 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 8 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 and examination reviewed under the modified rules by the end of 2023 and again in 5 years.

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 who offer a pharmacy technician training program and examination. The rules were drafted to be the least burdensome on all affected licensees and entities that offer a program.

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 the 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 who offer a pharmacy technician training program and examination. There may be an impact on a small business in that it must have the program and examination reviewed under the modified rules by the end of 2023 and again in 5 years. Allowing a small business to offer a program or examination of lesser quality than another program or examination 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 of if they practice in a small business. There is no separate cost to small businesses.

An entity that offers a pharmacy technician training program and examination must apply for and meet the standards in the rules and Code. In addition, they must apply every five years for re-approval. There are no new requirements for reports in the proposed rules. The existing rules require a program to maintain a record of a student's training and education and the program syllabus and activities performed in the program.

22. Analyze the costs of compliance for all small businesses affected by the proposed rules, including costs of equipment, supplies, labor, and increased administrative costs.

There are no expected increased costs for small businesses concerning the costs of equipment, supplies, labor, or administrative costs.

23. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rules.

There are no expected increased costs for small businesses concerning legal, consulting, or accounting services.

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

There are no expected costs to small businesses that will cause economic harm to a small business or the marketplace as a result of the proposed rules.

25. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

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

If the Department set lesser standards of compliance for programs offered by small businesses, the cost to the Department would still involve reviewing the applications and enforcing the standards. However, there would be a negative effect to the public served by pharmacy technicians who were trained under a lesser standard of education.

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 set lesser standards for compliance, there would be a negative impact on the public interest. The public would be served by pharmacy technicians who were trained at a lower level than pharmacy technicians educated in other 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 the Michigan Board of Pharmacy Rules Committee Work Group meetings, which included members from the Board of Pharmacy, educational institutions, businesses, and other members of the public in the development of the proposed rules. The Board is composed of members of the profession and members of the public who may work in businesses of different sizes in Michigan.

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

Representatives from businesses were involved in the development of the rules. However, the Department is not aware if they meet the definition of a "small business."

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

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

The Department does not expect any statewide compliance costs of the proposed rules on businesses or groups.

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

As of December 6, 2022, there are approximately 25,415 pharmacy technicians and 1,133 limited pharmacy technicians in Michigan. There are approximately 240 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 8 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 and examination reviewed under the modified rules by the end of 2023 and again in 5 years.

B. What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Please identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

The Department does not expect the proposed rules to result in any additional costs such as new equipment, supplies, labor, accounting, or recordkeeping on businesses or other groups.

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.

There are no additional compliance costs placed on individuals as a result of the proposed rules.

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

The individuals affected are applicants for licensure, relicensure, and renewal, and the public using a pharmacy.

As of December 6, 2022, there are approximately 25,415 pharmacy technicians and 1,133 limited pharmacy technicians in Michigan.

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

The proposed rules will impact individuals as follows: additional training opportunities may exist with the addition of community colleges offering training programs; the public will be positively affected by requiring all Board approved proficiency examinations to require a 70% passing score; the public will be served by allowing the Department to withdraw its approval of programs if deficiencies are not resolved; licensees will be impacted in that they may use their training in human trafficking and implicit bias towards their CE requirements; licensees will be impacted in that they may use virtual courses in addition to live courses to meet their requirement of 5 live CE hours; licensees will be impacted in that they may only earn 2 hours of CE for presenting a CE program that is not a part of their regular job description; both the public and licensees benefit with an option of training in addition to experience to qualify to perform final product verification; and both the public and licensees will benefit by allowing pharmacy technicians to perform limited functions remotely.

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

There will be a reduction in costs to individuals as follows: licensees will be able to use human trafficking training, and implicit bias training towards their CE requirements; licensees will be able to use virtual courses towards the 5 hours of live courses requirement; the savings to licensees due to these rule modifications cannot be quantified as the cost of a CE course varies, however, it is expected that there will be a reduction in costs.

There will be a reduction in costs to entities that apply for CE approval as they will be asked to submit less supporting documentation with their application with the modification of the review process.

There may be a reduction in costs for pharmacies as a result of allowing pharmacy technicians to perform limited functions remotely.

There is no expected reduction in costs to 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: eliminating the inconsistency in Board approved pharmacy technician programs by requiring that they all meet the modified rules and be reviewed every 5 years; increasing the type of pharmacy technician training programs; increasing the quality of programs by requiring a 70% passing score on examinations; reducing the confusion regarding the type of CE that is accepted by the Department; reducing the cost to entities that apply for CE approval as there is less to submit with an application; allowing a pharmacy technician to assist in the final product verification with either training or experience; reducing the cost for licensees to meet CE requirements; and reducing the cost for pharmacies by allowing pharmacy technicians to perform limited functions remotely.

The indirect benefits of the proposed rules include maintaining a better list of active Board approved pharmacy technician training programs and increasing the quality of licensees.

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

The rules are not expected to have an impact on business growth, job creation, or job elimination.

33. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

Pharmacy technician licensees, pharmacy technician students, entities that have a pharmacy technician training program, and pharmacies that employ pharmacy technicians will be affected by the proposed rules. There are no other individuals or businesses expected to be 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.

Survey of Pharmacy Law, National Association of Boards of Pharmacy 2022

NABP | National Association of Boards of Pharmacy

https://mn.gov/boards/pharmacy/education/techniciancontinuingeducation.jsp

https://www.howtobecomeapharmacytech.org/pharmacy-technician-requirements-pennsylvania/

https://www.dos.pa.gov/ProfessionalLicensing/BoardsCommissions/Pharmacy/Pages/Applications-and-Forms.aspx A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., that demonstrate a need for the proposed rules.

No estimates or assumptions were made.

Alternative to Regulation

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

Since the rules are required by statute, there is no other reasonable alternative to the proposed rules that would achieve the same or similar goal.

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

There is no other reasonable alternative to the proposed rules that would achieve the same or similar goal.

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 their competency or hold them 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 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 CE.