

Michigan Office of Administrative Hearings and Rules

Administrative Rules Division (ARD)

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**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:

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Rule Set Information:

ARD assigned rule set number:

2020-27 LR

Title of proposed rule set:

Dentistry - 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.

Each state establishes its own requirements with respect to dentists, dental therapists, hygienists, and dental assistants, so there are no federal rules or standards set by a national or state agency that most of the proposed rules can be compared to. However, the Amalgam Separator Act, 2008 PA 503, (2008), requires dental offices to install dental amalgam systems to reduce mercury from being discharged into sewers. Section 16631 of the Public Health Code (Code), MCL 333.16631, requires the Department in consultation with the Department of Environmental Quality (DEQ), renamed the Michigan Department of Environment, Great Lakes and Energy (EGLE), to promulgate rules regarding best management practices for dental amalgam collection, disposal, and recycling and the retention and inspection of dental office records. The amalgam rules were effective in 2012. In addition, the United States Environmental Protection Agency (EPA) enacted requirements on the handling of mercury in 40 CFR Part 441 (2016). The date for compliance with the EPA's amalgam requirements for existing dental offices is July 14, 2020, and for newly purchased or built dental offices within 90 days of taking ownership.

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

Yes, the Department in consultation with the 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; to promulgate rules regarding the best management practices for dental amalgam collection, disposal, and recycling and the retention and inspection of dental office records regarding dental amalgam, pursuant to MCL 333.16631; and to prescribe the form and content of a record of dental treatment on a patient to be used for identification purposes, pursuant to MCL 333.16644. Public Act 463 of 2018, which regulates dental therapists, mandates that the Department, in consultation with the Board, promulgate rules the Department considers necessary to implement sections 16651 to 16658 of the Public Health Code (Code), MCL 333.16651 to 333.16658.

The following provisions allow for rule making: MCL 333.16145, 333.16174, 333.16178, 333.16182, 333.16186, 333.16201, 333.16205, 333.16215, 333.16608, 333.16611, 333.16625, 333.16626, 333.16644, MCL 338.3501, 445.2001, 445.2011, and 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 Code and are largely consistent with the requirements of other states in the Great Lakes region.

Part 1 of the proposed rules are similar to the standards and requirements in the other states in the Great Lakes region regarding requiring dental records and maintaining records regarding controlled substances. Other states do not have a requirement in the rules that a dental professional identify themselves and provide a written consent for treatment to the patient.

Part 2: The licensure requirements and use of titles are similar to the standards and requirements in the other states in the Great Lakes region.

Similar to Michigan, Illinois, Indiana, Minnesota, Ohio, and Pennsylvania all require the following for licensure: graduate from a Commission on Dental Accreditation (CODA) accredited program; pass the national board exam and clinical exam; and show good moral character. Similar to Michigan, Minnesota licenses dental therapists. Michigan, Indiana, Minnesota, Ohio, and Wisconsin require passing a jurisprudence examination for a dental professional license. Wisconsin does not require proof of good moral character for a dental professional license. Michigan, Minnesota, Ohio, and Pennsylvania all license dental assistants. Each of the four states that license dental assistants have different educational and testing requirements. Indiana, Minnesota, Ohio, and Wisconsin limit the number of times a dental professional applicant may take the clinical examination. The proposed rules in Michigan have no limits on retaking an examination for any dentistry profession unless the testing authority limits the number of retakes. Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin license dentist applicants who graduated from a nonaccredited dental institution if thereafter they graduate from a 2-year accredited program and pass the national and clinical examination.

Part 3: The educational program standards proposed in Michigan for dentists and hygienists are similar to the standards and requirements in the other states in the Great Lakes region. All states in the Great Lakes region require graduation from a CODA accredited program for licensure as a dentist or hygienist. The educational requirements for dental assistants vary for the four states that license dental assistants.

Part 4a: Michigan, Minnesota, Ohio, and Pennsylvania license dental assistants and allow dental assistants to participate in specific duties under various levels of supervision. Indiana and Illinois limit dental assistant functions but do not require a license. Wisconsin has very minimal requirements but does require a dental assistant to be supervised by a dentist and be appropriately trained. All states in the Great Lakes region have regulations on the functions of a hygienist.

Part 4B: Michigan is on the forefront of licensing dental therapists. Other states that regulate dental therapy include Alaska, Arizona, Connecticut, Maine, Nevada, New Mexico, and Vermont. Similar to the proposed rules, Minnesota requires a dental therapist to practice under the supervision of a dentist who is licensed in that state, and supervision does not require the supervising dentist to be on site.

Part 5: Illinois and Minnesota have systems for specialty licensure similar to Michigan. Each state either issues a certification or license to applicants who have passed a specialty board examination. The specialties recognized include those recognized by the American Dental Association (ADA). All of the states in the Great Lakes region, except Pennsylvania, allow licensure for an applicant who is currently licensed in another state and has experience.

Part 6: Michigan requires a dentist to obtain training and use appropriate facilities but does not require the dentist to apply for a permit. All of the states in the Great Lakes region regulate and require a permit to use general anesthesia. Only Illinois, Minnesota, and Pennsylvania regulate the use of nitrous oxide inhalation analgesia. Only Minnesota, Ohio, and Pennsylvania require an office inspection to use general anesthesia and conscious sedation. The proposed rules regulate a hygienist's administration of anesthesia through training, examination, and certification. In Michigan the monitoring and assisting in the administration of nitrous oxide by a registered dental assistant is regulated through education. In Pennsylvania a hygienist is not permitted to administer nitrous oxide. In Illinois, Minnesota, and Ohio, although the use is regulated, the hygienist does not need a permit.

Part 7: The amount of CE hours required for dentists per year varies from 10 to 25. The amount of CE hours required for hygienists per year varies from 6 to 13.

Part 8: In other states that have amalgam regulations, the regulations are not handled through dentistry regulations.

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

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

Although other states do not have a requirement that a dental professional identify themselves and provide a written consent for treatment to the patient, the proposed rules include this requirement because of the potential expected confusion in dental offices when dental therapists are licensed in this state. Very few states license dental therapists.

Michigan is one of the few states that licenses dental therapists. The proposed dental therapy rules are required by the Code to implement licensure of dental therapists.

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

The Amalgam Separator Act, 2008 PA 503, (2008), requires dental offices that discharge dental amalgam into a wastewater system, to install a dental amalgam system to remove the dental amalgam and mercury before the waste is discharged. Section 16631 of the Code, MCL 333.16631, requires the Department, in consultation with the DEQ, renamed the EGLE, to promulgate rules regarding best management practices for dental amalgam collection, disposal, and recycling, and the retention and inspection of dental office records. The rules were effective in 2012, and require dentists, who discharge dental amalgam in a dental office, to remove the amalgam with an amalgam separator. The rules also require all dentists, who use, remove, or discharge dental amalgam, except those exempted from the rule, to comply with R 338.11815, which regulates the collection, disposal and recycling of dental amalgam. The EPA enacted requirements on the handling of mercury in 40 CFR Part 441 (2016), for a dental discharger, which is defined as "a facility where the practice of dentistry is performed, including, but not limited to, institutions, permanent or temporary offices, clinics, home offices, and facilities owned and operated by federal, state or local governments, that discharges wastewater to a publicly owned treatment works." The date for compliance with the EPA's amalgam requirements for existing dental offices is July 14, 2020, and for new dental offices, within 90 days of taking ownership. The federal rules and the proposed rules are consistent with each other except the federal rules exempt dentists that are prosthodontists, while 2008 PA 503 does not include this exemption.

There are no other laws, rules, or other legal requirements that may duplicate, overlap, or conflict with these proposed 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.

The proposed amalgam rules are mandated by 2008 PA 503. The department worked with EGLE to coordinate the proposed rules with the federal requirements. The proposed rules clarify the existing rules by updating legal citations, changing “school” to “educational program”, and moving the definition of recycle and recycling to the definition section.

No other coordination is needed because there are no other applicable laws that regulate the areas addressed in the proposed rules.

4. If MCL 24.232(8) applies and the proposed rules are more stringent than the applicable federally mandated standard, a statement of specific facts that establish the clear and convincing need to adopt the more stringent rules and an explanation of the exceptional circumstances that necessitate the more stringent standards is required.

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, either the 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 and an explanation of the exceptional circumstances that necessitate the more stringent standards is required.

R 338.11811(2) does not exempt a prosthodontist from the amalgam requirements, and, therefore, the proposed rules are more stringent than the federal rules that regulate the discharge of amalgam from a dental office.

Even if the proposed rules are more stringent than the applicable federal regulations, this is a result of 2008 PA 503, which lists the following as the only exemptions to the amalgam regulations: oral and maxillofacial surgeons, oral and maxillofacial radiologists, oral pathologists, orthodontists, periodontists, dentists while providing services in a dental school, in a hospital, or through a local health department, and dentists who install and use a holding tank and do not discharge amalgam waste.

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

Part 1. The proposed rules require a dentist, dental therapist, dental hygienist, and dental assistant to identify themselves to the patient at the inception of care and provide a written consent for treatment. This proposed rule is designed to reduce confusion for the patient and allegations that the patient is unaware that he or she is being treated by someone other than the dentist.

Part 2. The proposed rules are designed to ensure that licensees are appropriately educated and trained, have passed a thorough examination, and have no disciplinary issues in other jurisdictions, so that citizens receiving care are protected.

Part 3. The education requirements are designed to ensure that licensees are appropriately educated and trained, so that citizens receiving care are protected.

Part 4A. The proposed rules are designed to alter the wide-spread confusion amongst dental professionals regarding the procedures that they may perform and the training that is required.

Part 4B. The proposed rules are designed to eliminate confusion amongst dental professionals regarding the scope of practice of a dental therapist.

Part 5. The proposed rules are designed to clarify the requirements for licensure in a specialty practice to ensure specialists are safe to practice, and to limit confusing advertising.

Part 6. The training and facility requirements are designed to ensure that licensees are appropriately trained and are working in safe facilities, so that citizens receiving care are protected.

Part 7. The proposed rules are designed to ensure that dental professionals have appropriate training with a hands-on component in life support, in dental ethics and jurisprudence, human trafficking, and opioids and controlled substances and infection control when applicable to protect the citizens they serve. The changes in the continuing education review procedure is to make sure that all programs are reviewed but given a term of approval, so they do not return for review for multiple years unless there is a change in the program.

Part 8. The proposed rules are designed to provide clarity to licensees to reduce confusion.

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

Part 1. General Provisions

This proposed rule is designed to reduce confusion for the patient and the frequency of allegations that the patient was unaware that he or she was being treated by someone other than the dentist.

Part 2. Licensure

The proposed rules are designed to ensure that before each applicant is licensed he or she is appropriately educated and trained, have passed a thorough examination, and have no disciplinary issues in other jurisdictions, so that citizens receiving care are protected.

Part 3. Education

The education requirements are designed to ensure that every licensee is appropriately educated and trained, so that citizens receiving care are protected.

Part 4A. Delegation, Supervision, Assignment of Dental Assistants, Registered Dental Assistants, and Registered Dental Hygienists

The proposed rules are designed to alter the wide-spread confusion amongst dental professionals regarding the procedures that they may perform and the training that may be required.

Part 4B. Supervision of Dental Therapists

The proposed rules are designed to eliminate confusion amongst dental professionals regarding the scope of practice of a dental therapist.

Part 5. Specialties

The proposed rules are designed to clarify the requirements for licensure in a specialty practice to ensure specialists are safe to practice and to eliminate false advertising.

Part 6. General Anesthesia and Intravenous Conscious Sedation and Enteral Sedation

The training and facility requirements are designed to ensure that licensees are appropriately trained and are working in safe facilities, so that citizens receiving care are protected.

Part 7. Continuing Education

The proposed rules are designed to ensure that dental professionals have appropriate training with a hands-on component in life support, in dental ethics and jurisprudence, human trafficking, opioids and controlled substances, and infection control, to protect the citizens they serve. The changes in the continuing education review procedure is to ensure that all programs are reviewed with a term of approval, so they do not return for review for multiple years or unless there is a change in the program.

Part 8. Dental Amalgam

The proposed rules are designed to provide clarity to licensees to reduce confusion.

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

Part 1. General Provisions

This proposed rule is designed to reduce confusion for the patient and the frequency of allegations that the patient was unaware that he or she was being treated by someone other than the dentist.

Part 2. Licensure

The proposed rules are designed to ensure that before each applicant is licensed he or she is appropriately educated and trained, have passed a thorough examination, and have no disciplinary issues in other jurisdictions, so that citizens receiving care are protected.

Part 3. Education

The education requirements are designed to ensure that every licensee is appropriately educated and trained, so that citizens receiving care are protected.

Part 4A. Delegation, Supervision, Assignment of Dental Assistants, Registered Dental Assistants, and Registered Dental Hygienists

The proposed rules are designed to alter the wide-spread confusion amongst dental professionals regarding the procedures that they may perform and the training that may be required.

Part 4B. Supervision of Dental Therapists

The proposed rules are designed to eliminate confusion amongst dental professionals regarding the scope of practice of a dental therapist.

Part 5. Specialties

The proposed rules are designed to clarify the requirements for licensure in a specialty practice to ensure specialists are safe to practice and to eliminate false advertising.

Part 6. General Anesthesia and Intravenous Conscious Sedation and Enteral Sedation

The training and facility requirements are designed to ensure that licensees are appropriately trained and are working in safe facilities, so that citizens receiving care are protected.

Part 7. Continuing Education

The proposed rules are designed to ensure that dental professionals have appropriate training with a hands-on component in life support, in dental ethics and jurisprudence, human trafficking, opioids and controlled substances, and infection control, to protect the citizens they serve. The changes in the continuing education review procedure is to ensure that all programs are reviewed with a term of approval, so they do not return for review for multiple years or unless there is a change in the program.

Part 8. Dental Amalgam

The proposed rules are designed to provide clarity to licensees to reduce confusion.

C. What is the desired outcome?

Those individuals who wish to practice in the dental professions will be better regulated. By making improvements and clarifications to the rules, applicants and licensees should find compliance easier. This should result in fewer questions, fewer regulatory problems, and greater safety and protection of the public.

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.

Part 1. General Provisions

This proposed rule is designed to reduce confusion for the patient and the frequency of allegations that the patient was unaware that he or she was being treated by someone other than the dentist. It is unlikely that this will occur if the proposed rule is adopted.

Part 2. Licensure

The proposed rules are designed to ensure that this state does not grant licensure to an applicant who is not appropriately educated and trained, has not passed a thorough examination, and has disciplinary issues in other jurisdictions. It is unlikely that these harms will occur if the proposed rules are adopted.

Part 3. Education

The proposed rules are designed to ensure that this state does not grant licensure to an applicant who is not appropriately educated and trained. It is unlikely that this will occur if the proposed rules are adopted.

Part 4A. Delegation, Supervision, Assignment of Dental Assistants, Registered Dental Assistants, and Registered Dental Hygienists

The proposed rules are designed to alter the wide-spread confusion amongst dental professionals regarding the procedures that they may perform and the training that may be required. It is unlikely that this will occur if the proposed rules are adopted.

Part 4B. Supervision of Dental Therapists

The proposed rules are designed to eliminate confusion amongst dental professionals regarding the scope of practice of a dental therapist. It is unlikely that this will occur if the proposed rules are adopted.

Part 5. Specialties

The proposed rules are designed to ensure that this state does not grant a specialty license to a dentist who is not appropriately educated and trained in that specialty and to eliminate confusing advertising of dental specialists. It is unlikely that this will occur if the proposed rules are adopted.

Part 6. General Anesthesia and Intravenous Conscious Sedation and Enteral Sedation

The training and facility requirements are designed to ensure that licensees are not physically in danger while dentists use general anesthesia, intravenous conscious sedation, and enteral sedation on patients during procedures. It is unlikely that this will occur if the proposed rules are adopted.

Part 7. Continuing Education

The proposed rules are designed to ensure that dental professionals: do not participate in life support training that is not appropriate for health professionals and does not have a hands-on component; are not lacking in an understanding of the ethics and Michigan laws related to dentistry; are unable to recognize human trafficking; and are not aware and educated on the topics of opioid crisis and infection control. It is unlikely that these harms will occur if the proposed rules are adopted.

Part 8. Dental Amalgam

The proposed rules are designed to reduce confusion. The proposed rules provide clarity.

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

Part 1. General Provisions

This proposed rule is designed to reduce confusion for the patient and the frequency of allegations that the patient was unaware that he or she was being treated by someone other than the dentist. It is unlikely that this will occur if the proposed rule is adopted.

Part 2. Licensure

The proposed rules are designed to ensure that this state does not grant licensure to an applicant who is not appropriately educated and trained, has not passed a thorough examination, and has disciplinary issues in other jurisdictions. It is unlikely that these harms will occur if the proposed rules are adopted.

Part 3. Education

The proposed rules are designed to ensure that this state does not grant licensure to an applicant who is not appropriately educated and trained. It is unlikely that this will occur if the proposed rules are adopted.

Part 4A. Delegation, Supervision, Assignment of Dental Assistants, Registered Dental Assistants, and Registered Dental Hygienists

The proposed rules are designed to alter the wide-spread confusion amongst dental professionals regarding the procedures that they may perform and the training that may be required. It is unlikely that this will occur if the proposed rules are adopted.

Part 4B. Supervision of Dental Therapists

The proposed rules are designed to eliminate confusion amongst dental professionals regarding the scope of practice of a dental therapist. It is unlikely that this will occur if the proposed rules are adopted.

Part 5. Specialties

The proposed rules are designed to ensure that this state does not grant a specialty license to a dentist who is not appropriately educated and trained in that specialty and to eliminate confusing advertising of dental specialists. It is unlikely that this will occur if the proposed rules are adopted.

Part 6. General Anesthesia and Intravenous Conscious Sedation and Enteral Sedation

The training and facility requirements are designed to ensure that licensees are not physically in danger while dentists use general anesthesia, intravenous conscious sedation, and enteral sedation on patients during procedures. It is unlikely that this will occur if the proposed rules are adopted.

Part 7. Continuing Education

The proposed rules are designed to ensure that dental professionals: do not participate in life support training that is not appropriate for health professionals and does not have a hands-on component; are not lacking in an understanding of the ethics and Michigan laws related to dentistry; are unable to recognize human trafficking; are not aware and educated on the topics of opioid crisis and infection control. It is unlikely that these harms will occur if the proposed rules are adopted.

Part 8. Dental Amalgam

The proposed rules are designed to reduce confusion. The proposed rules provide clarity.

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 dentistry. To protect the health and safety of Michigan's citizens, it is important that members of the dentistry profession adhere to minimal education, training, licensure requirements, supervision, and professional standards.

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

R 338.11107, R 338.11117, R 338.11123, R 338.11222, R 338.11241, R 338.11245, R 338.11402, R 338.11403, R 338.11404, R 338.11404a, R 338.11405, R 338.11405a, R 338.11405b, R 338.11405c, R 338.11406, R 338.11408, R 338.11409, R 338.11410, R 338.11505, R 338.11604, R 338.11704b, and R 338.11704c will be rescinded.

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 may have a fiscal impact on the agency with the licensing of dental therapists, that is a new profession.

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

The licensing and regulation of the profession, including the promulgation and implementation of rules, is funded by the collection of licensing fees. As a result, there was no reason to make an agency appropriation or provide a funding source.

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 fingerprints for relicensure is approximately \$25.00. However, the cost is outweighed by the benefit of ensuring that the applicant is of good moral character for licensure.

The estimated cost for certification in basic or advanced cardiac life support for health care providers with a hands-on component is \$100.00. However, the cost is outweighed by the benefit of ensuring that the applicant is trained in life support as a health care provider, with a hands-on component.

The estimated cost for 1 hour of training in infection control is \$35.00. However, the cost is outweighed by the benefit of ensuring that the applicant is knowledgeable in infection control in a dental office.

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 by statute to provide a mechanism for licensing and regulation of the dental profession and are required to protect the public. 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 continuing education requirements.

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.

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 individuals licensed under the Code, 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.

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

No. Although the proposed rules include modifications to the existing rules that regulate the discharge of dental amalgam, none of the modifications are substantive. The modifications include: adding proper citations to laws and standards; moving the definition of recycling to the definition section; clarify that the term “dentist” means to engage in the practice of dentistry; and clarify that the dentist shall retain the records and submit the records when requested, which are required pursuant to the amalgam rules.

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 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.

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 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. However, the impact on a licensee who works as part of a small business is minimized in the proposed rules, as the rules are written broadly. A licensee, whether he or she works in small business or not, should not be significantly impacted by the changes.

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

As of June 1, 2020, there are approximately 7,823 dentists, 108 clinical academic limited dentists, 61 educational limited dentists, 4 nonclinical academic limited dentists, 0 dental therapists, 10,403 hygienists, 1 clinical academic limited hygienist, and 1,844 dental assistants licensed in Michigan.

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 because the impact is to the individual licensee only.

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 dentists, dental therapists, dental hygienists, and dental assistants. The rules were drafted to be the least burdensome on all affected licensees.

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

The agency did not consolidate or simplify compliance and reporting requirements with the proposed rules.

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

The agency did not establish performance standards to replace design or operation standards required by these rules.

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

The proposed rules do not impact small business; rather, they impact an individual licensee. Therefore, there is no disproportionate impact on a small business because of its size or geographic location.

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

The proposed rules affect individual licensure applications and renewals, which are already required of all licensees, regardless if they practice in a small business. There is no separate cost to small businesses.

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 will be no increased costs of compliance for a small business 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 costs for legal, consulting, or accounting services 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 rather than a small business. 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. Therefore, there is no cost to the agency for administering or enforcing the rules because exempting or setting lesser standards of compliance for a small business is not in the best interest of the public.

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

The proposed rules impose requirements on individual licensees rather than a small business. 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. 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 the Board of Dentistry 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. Concerns were also received and discussed with various associations, educational institutions, and individual citizens.

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

The department worked with the Board of Dentistry 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. Concerns were also received and discussed with various associations, educational institutions, and individual citizens.

28. 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.

No businesses or groups will be directly affected or benefitted by the proposed rules. No additional costs will be imposed on any businesses or groups.

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.

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.

All initial licensees and possibly applicants applying for relicensure, depending on the number of years their license has lapsed, will incur the cost for fingerprints, which is estimated at \$25.00.

All initial licensees, applicants for relicensure, and licensees applying for renewal will incur the cost for certification in basic or advanced cardiac life support for health care providers with a hands-on component, which is estimated to be \$100.00.

Dental therapists, dental hygienists, and dental assistants renewing their license are required to provide proof of taking 1 hour of continuing education in infection control, which is estimated to be \$35.00.

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

As of June 1, 2020, there are approximately 7,823 dentists, 108 clinical academic limited dentists, 61 educational limited dentists, 4 nonclinical academic limited dentists, 0 dental therapists, 10,403 hygienists, 1 clinical academic limited hygienist, and 1,844 dental assistants licensed in Michigan.

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

All initial licensees and possibly applicants applying for relicensure, depending on the number of years their license has lapsed, will incur the cost for fingerprints, which is estimated at \$25.00.

All initial licensees, applicants for relicensure, and licensees applying for renewal will incur the cost for certification in basic or advanced cardiac life support for health care providers with a hands-on component, which is estimated to be \$100.00.

Dental therapists, dental hygienists, and dental assistants renewing their license are required to provide proof of taking 1 hour of continuing education in infection control, which is estimated to be \$35.00.

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.

Part 1. General Provisions

This proposed rule will reduce confusion for a patient and the frequency of complaints that a patient was being treated by someone other than the dentist.

Part 2. Licensure

The proposed rules will ensure that before each applicant is licensed, he or she is appropriately educated and trained, has passed a thorough examination, and has no disciplinary issues in other jurisdictions, so that citizens receiving care are protected.

Part 3. Education

The education requirements will ensure that every licensee is appropriately educated and trained, so that citizens receiving care are protected.

Part 4A. Delegation, Supervision, Assignment of Dental Assistants, Registered Dental Assistants, and Registered Dental Hygienists

The proposed rules will alter the wide-spread confusion amongst dental professionals regarding the procedures that they may perform and the training that is required.

Part 4B. Supervision of Dental Therapists

The proposed rules will eliminate confusion amongst dental professionals regarding the scope of practice of a dental therapist.

Part 5. Specialties

The proposed rules will clarify the requirements for licensure in a specialty practice to ensure specialists are safe to practice and eliminate confusing advertising regarding dental specialists that are licensed in this state.

Part 6. General Anesthesia and Intravenous Conscious Sedation and Enteral Sedation

The proposed rules will ensure that licensees are appropriately trained and are working in safe facilities when using general anesthesia, intravenous conscious sedation, and enteral sedation, so that citizens receiving care are protected.

Part 7. Continuing Education

The proposed rules will ensure that dental professionals have appropriate training in life support, dental ethics and jurisprudence, human trafficking, opioids and controlled substances, and infection control to protect the citizens they serve. The changes in the continuing education review procedure will ensure that all programs are reviewed but given a term of approval, so they do not return for review for multiple years unless there is a change in the program.

Part 8. Dental Amalgam

The proposed rules will clean up the rules and provide clarity to licensees, which will reduce confusion.

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. There may be additional jobs in the field of dental therapy, however, it is not clear how many currently licensed dental assistants and dental hygienists will be trained to take on dental therapy responsibilities.

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

There is not expected to be a disproportionate affect 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.

Indiana

Board of Dentistry: <https://www.in.gov/pla/dental.htm>

CE: <https://www.in.gov/pla/2393.htm>

Statutes and rules: <https://www.in.gov/pla/2404.htm>

Illinois

Illinois Board of Dentistry: <https://www.boardofdentistry.net/state-licensure-dentist>

Illinois State Dental Society: <https://www.isds.org/advocacy/il-dental-practice-act-rules>

Minnesota

Dental Therapy Association: <http://www.mndta.org/>

Minnesota Department of Health: <https://www.health.state.mn.us/data/workforce/oral/docs/2018dtb.pdf>

Minnesota Board of Dentistry: <https://mn.gov/boards/dentistry/>

Ohio

Amalgam: <https://www.epa.ohio.gov/portals/41/sb/publications/dentaloffice.pdf>

<https://www.epa.ohio.gov/Portals/35/pretreatment/AmalgamFactSheet.pdf>

<https://www.epa.ohio.gov/Portals/35/pretreatment/AmalgamFlowChart.pdf>

Pennsylvania

Amalgam:

<https://www.padental.org/images/onlinedocs/resourcesprograms/publications/wastemanagementguidelines07.pdf>

Wisconsin

State Legislature: https://docs.legis.wisconsin.gov/code/admin_code/de

Laws and Regulations: [https://www.ada.org/~media/ADA/Education%20and%](https://www.ada.org/~media/ADA/Education%20and%20Careers/Files/Wisconsin_Licensure.pdf?la=en)

[20Careers/Files/Wisconsin_Licensure.pdf?la=en](https://www.ada.org/~media/ADA/Education%20and%20Careers/Files/Wisconsin_Licensure.pdf?la=en)

Amalgam: <https://www.wda.org/regulatory/amalgam-dental-waste/#overview>

General

State Licensure by State: <https://www.ada.org/en/education-careers/licensure/licensure-information-by-state>

American Association of Dental Boards: <https://dentalboards.org/>

Pathways to Licensure: <https://www.ada.org/en/education-careers/licensure/licensure-dental-students/licensure-pathways>

Amalgam: <https://www.ada.org/en/advocacy/current-policies/dental-amalgam>

<https://www.epa.gov/eg/dental-effluent-guidelines>

<https://www.ada.org/en/advocacy/current-policies/dental-amalgam>

Dental Assistants: <https://www.dalefoundation.org/Resources-And-State-Requirements/State-Dental-Assistant-Requirements/Michigan>

Dental Therapy

National Partnership for Dental Therapy: <https://www.dentaltherapy.org/>

MI Dental Access: <http://www.midentalaccess.org/>

PEW: <https://www.pewtrusts.org/en/research-and-analysis/articles/2016/09/28/states-expand-the-use-of-dental-therapy>

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., which 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. No estimate could consider the setting where an individual may use his or her license.

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

Some of the rules are required by statute. There is no other reasonable alternative to the proposed rules that would achieve the same or similar goals.

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

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

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

Since the rules are required by statute, private market-based systems cannot serve as an alternative. States regulate dentists, dental therapists, dental hygienists, and dental assistants by statute, regulation, or both. Private market-based systems are not used for licensing and regulation. The licensing and regulation of dental professions, including dentists, dental therapists, dental hygienists, and dental assistants, are state functions, so a regulatory program independent of state intervention cannot be established. There are professional associations that establish criteria for membership, 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.

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 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. However, the Board of Dentistry rules committee, stakeholders, and affected parties discussed how dental therapists should acquire the 500 hours of clinical experience required by Public Act 463 of 2018, which mandates that the Department, in consultation with the Board, promulgate rules the Department considers necessary to implement sections 16651 to 16658 of the Code, MCL 333.16651 to 333.16658, which regulates dental therapists. The proposed rule requires the clinical experience to take place in an accredited institution prior to licensure. There were discussions regarding the dental therapy student obtaining a limited or temporary license from the state to acquire the clinical experience, post education, through noneducational institutions, with a supervisory dentist. It was the consensus of the Board, as well as the general preference of the stakeholders at the work group sessions, that the 500 hours of clinical experience should take place in an accredited institution as part of the dental therapist's education.

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

Licensing: The proposed rules explicitly inform licensees of the license requirements.

Relicensure/Continuing Education: The proposed rules explicitly inform applicants of the relicensure requirements and licensees of the continuing education requirements.

Delegation, Supervision, Assignment of Dental Assistants, Registered Dental Assistants, and Registered Dental Hygienists and Supervision of Dental Therapists: The proposed rules explicitly inform licensees of the procedures that dental assistants, registered dental assistants, registered dental hygienists, and dental therapists may perform, and the training that is required.

General Anesthesia and Intravenous Conscious Sedation and Enteral Sedation: The proposed rules explicitly inform licensees of the required training and facilities necessary to use general anesthesia, intravenous conscious sedation, and enteral sedation, so that citizens receiving care are protected.