Michigan Office of Administrative Hearings and Rules Administrative Rules Division (ARD) MOAHR-Rules@michigan.gov REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS (RIS)

Agency Information: Department name:

Health and Human Services

Bureau name:

Public Health Administration

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Rule Set Information:

ARD assigned rule set number: 2023-59 HS

Title of proposed rule set: Body Art Facilities

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 federal rules or standards. Michigan's were based and created on standards set introduced in 1998 and are currently known as the National Environmental Health Association (N.E.H.A.)'s Body Art: A Comprehensive Guidebook and Model Code. National industry organizations such as the Association of Professional Piercers also follow and promote this N.E.H.A. code to ensure safety to the public receiving body art procedures.

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

The rules are being promulgated under the authority of the Public Health Code and are needed for owners, operators, and health officials alike in defining the narrow parameters of the state statute. There are no state or federal laws that mandate rule promulgation for body art facilities.

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

There are no federal standards for this rule set.

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

The rules are similar to other states. Initial recommendations entitled the National Environmental Health Association's Comprehensive Guidebook and Model Code of 1999 were adopted and applied by states nationwide. The rules do not exceed these standards. Body art in Ohio is regulated under the authority of Chapter 3730.01 of the Ohio Revised Code (ORC) and Chapter 3701-9 of the Ohio Administrative Code (OAC). Indiana Code 16-19-3-4.1 requires the Indiana State Department of Health (ISDH) to adopt rules to regulate the sanitary operation of tattoo parlors. The rule, 410 IAC 1-5, became law on June 12, 1998, and was readopted July 15, 2010.

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

The rules do not exceed standards in other states.

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

No known duplication, overlap, or conflicts exist. The rules cross-reference several areas in state law that may apply to body art procedures. The rules provide the specific citation to an existing law and have been incorporated by reference.

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 agency has worked to ensure seamless coordination with the state, the local county health departments, and the owners and operators of the body art facilities. There is no duplication of the rules; citations to coordinating agencies; MIOSHA, LEO, were properly cited as adopted by reference.

Purpose and Objectives of the Rule(s)

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

As public health is of paramount concern, the rules will provide the necessary minimum requirements to hold accountable those owners, operators, and technicians who wish to perform body art. Facilities will be required to pass an inspection report annually by the local health department that has jurisdiction. The local health departments work on a daily basis to address complaints and perform spot inspections to ensure facilities are complying with the rules.

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

The local health departments and facilities have been following direction from the agency pending rule promulgation via the document, "Requirements of Body Art Facilities" based on current statutory authority. These requirements are the basis of the administrative rules pending for promulgation. There is no anticipated change to the frequency of the targeted behavior anticipated as the requirements have been followed statewide.

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

Differences between the current practice and desired practices is expected, for the most part, to be minimal. The biggest difference is the legal authority to enforce the rules in the event of a violation in order to protect the public health and safety of those citizens desiring body art procedures.

C. What is the desired outcome?

The desired outcomes are to ensure consistent guidelines for the facilities regarding the expectations for body art practices, and to ensure local health departments are consistent in their application of enforcing the guidelines for the health and safety of customers desiring body art procedures.

5. Identify the harm resulting from the behavior that the proposed rules are designed to alter and the likelihood that the harm will occur in the absence of the rule.

There are no current body art administrative rules. In absence of these rules, the spread of disease by improper or illegal procedures performed by body art owners, operators, and technicians is likely. At-home "scratchers" do not follow proper infection control and most at-home procedures are at times linked to substance abuse situations that also hamper proper infection control and leads to the spread of infectious diseases. The rules promote quality control and prevent the spread of infections and diseases, e.g. Hepatitis C, from occurring in this state. The rules also serve as enforcement to the major threat to the public by illegal body artists offering at-home services in unsanitary conditions. These illegal artists advertise on the internet through social media sites such as Craigslist, Facebook, and Instagram.

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

This is a new rule set.

6. Describe how the proposed rules protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

The intent of the rules is to protect the health, safety, and welfare of Michigan citizens. The rules are the least burdensome to the environment as there is no longer inconsistency and subjective interpretation of what is required to protect the health, safety, and welfare of Michigan citizens.

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

Fiscal Impact on the Agency

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

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

There is no cost change anticipated to the agency. Any agency staff currently employed to oversee the state's actions on body art compliance have been in place for years with the enactment of the statute in 2010. There are no potential savings anticipated by this rule set.

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

There are no agency appropriations the state receives for this program area. Funding for the program is from yearly license fees and 14-day temporary license fees.

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

The rules are necessary and suitable for both the local health inspectors and facilities, including local units of government enforcement of the law. The rules are the least burdensome to individuals as they are meant to protect the health, safety, and welfare of citizens, e.g. preventing the outbreak of infections and diseases, and requiring minimum requirements of sanitation, disposal of hazard waste, and facility requirements.

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

As indicated in the previous answer, the rules are the least burdensome to individuals and are needed to protect the health, safety, and welfare of individuals. The rules provide minimum standards to be followed by the facilities and consistent enforcement by the local health departments.

Impact on Other State or Local Governmental Units

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

When the statute was enacted in 2010, local health departments hired staff and have been inspecting and following state requirements and have been reimbursed by the agency for the work they perform. That is not expected to increase or decrease revenues or increase or decrease costs to the local government as a result of these rules. All counties currently have body art regulation and licensure in place.

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

Local agencies currently inspect and approve facilities for state licensure. This is the only reporting service, duty, or responsibility requirement required by law. Enforcing the public act is authorized to the local health departments that have jurisdiction.

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.

Local health departments will be required to promote the rules for consistency in the establishment and enforcement of body art facilities. There is no anticipated increase or changes to operational practices as the local health departments are currently involved in inspections of facilities by statute. The problem is the consistency from one local health department to the next. There are no further government agencies expected to be impacted by these rules.

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

There are no appropriations made to state or local governmental units or an identified funding source as there are no additional expenditures anticipated with the proposed rules.

Rural Impact

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

The rules will be consistently applied statewide, in urban and rural areas. No impact will occur to rural areas.

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

Private interests involve both the facilities and the patrons who engage in body art procedures. Public interests are also involved as the rules promote safety to the health of patrons and the body art staff to prevent the spread of blood borne pathogens.

Environmental Impact

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

There is a positive impact to environment with these proposed rules. By reference, the rules enforce the medical waste requirements and administrative rules of the Michigan Department of Environment, Great Lakes, and Energy ensuring proper disposal of otherwise harmful medical waste in the state.

Small Business Impact Statement

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

No exemptions were considered. The rules are intended to prevent the spread of communicable disease for all defined body art businesses, small or large, though, the majority of the body art facilities are small businesses with approximately 1 to 9 staff only.

17. If small businesses are not exempt, describe (a) the manner in which the agency reduced the economic impact of the proposed rules on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rules upon small businesses as described below (in accordance with MCL 24.240(1)(a-d)), or (b) the reasons such a reduction was not lawful or feasible.

The proposed rules involve nationwide minimum standards for compliance. The agency based these minimum requirements on the risk of infection and disease for the health, welfare, and safety of Michigan citizens. The agency did not expand upon the body art processes outside these minimum standards imposed. The fees are statutorily set, and the agency must follow the mandate of the fees.

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

The majority of the body art businesses are considered "small businesses". Businesses vary only in number of artists at each location. Current yearly licensure shows there are 1,094 body art facilities. The effect on the facilities should be similar in compliance with the rules.

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.

There is no differing compliance defined in the law or in the standards for small businesses. The rules are consistent for all body art facilities. For those facilities who do not have the proper equipment as set forth by the minimum standards preventing the spread of disease, the agency proposes a six-month moratorium on these requirements to allow the facilities to purchase the required equipment.

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.

Businesses are not required to report anything to the state program but are required to apply each year to renew their licensure and allow one inspection a year by local agencies to ensure compliance with the minimum standards.

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

The rules will set performance standards intended to curtail public outbreak of disease and will replace what is currently being used by counties as an operations manual that defines or interprets the current statutory language.

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

The rules have no impact based on size or geographic location. The majority of the body art facilities are considered "small businesses". Rules were standardized on communicable disease prevention for all body art businesses statewide regardless of the number of customers they service.

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

The proposed rules require facilities to maintain documentation, including the procedure done on each client, health questionnaire, consent by the client, vaccination status or declination, and post exposure follow up. These documents must be available for inspection by the local health department.

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

A minimum number of facilities may not have the proper equipment as set forth by the minimum standards in the proposed rules for preventing the spread of disease. Proper equipment includes the purchase of an autoclave which can run anywhere from \$1,000 to \$8,000 for body art facilities, yet many facilities have moved to using disposable supplies, which do not require an autoclave. Supplies and labor should remain constant and will not be impacted by the rules. If there are increased administrative costs, they would involve documents needed for inspection for those facilities that do not electronically keep their files.

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

There are no additional costs in the rules for body art businesses.

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

The cost of an autoclave may be the only cost issue with body art facilities for those that do not use single-use applications. That cost is estimated between \$1,000 to \$8,000. This still allows the body art facility to change their method to single-use, as stated.

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

There are no exemptions to the rule set. The rules are consistent across all body art facilities. It would likely cost the agency more to devote staff time to determining which licensees work for small businesses and then enforce different requirements for those individuals."

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

Exempting or setting lesser standards will promote harm and morbidity to the public. Health and safety requirements are expected from any state body art facility that performs services to the public. Allowing small, at-home businesses on social media to avoid state taxes and proper infection control standards adds to the disease burden of local county morbidity statistics.

25. Describe whether and how the agency has involved small businesses in the development of the proposed rules. The agency established a workgroup comprised of several body art facility owners and operators, in addition to local health departments and agency staff. Body art facility owners and operators contributed their ideas and the impact of the proposed rules in reaching the final rule drafts.

A. If small businesses were involved in the development of the rules, please identify the business(es). Gamma Piercing, Ann Arbor; My Little Needle, Plymouth; Ironclad, Troy; Dark Sky Tattoo, Ferndale.

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

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

The only additional costs anticipated involves the purchase of an autoclave for any facility that needs to upgrade in order to comply with the new rules. Licensing, certificates, and other costs were not affected by this rule change as they were costs already imposed by statute. Actual statewide compliance costs for the facility to purchase an autoclave is \$1,000 to \$8,000.

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

The public consumer will be directly affected and benefit from the proposed rules. The public benefits from the safety aspect of the rules by ensuring they will not be affected by outbreaks of disease and assurances of a clean business environment when seeking body art. Second, the approximately 1,200 licensed body art facilities will benefit and are directly affected by the rules as there will be consistent requirements for each facility and will keep the owners, operators, and staff free from disease as well. The owners and operators will also directly benefit and be affected by the consistent application of the rules, so they no longer need to guess whether they are in compliance. Third, the local health departments are directly affected by and benefit as the rules will provide the guidelines for inspections and consistent application of the rules for violations and enforcement procedures. None of these groups should bear the cost of anything other than the purchase of an autoclave, if the purchase is necessary.

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.

There are no additional costs anticipate other than the purchase of an autoclave, if needed, by some of the body art facilities. That cost is approximated at \$1,000 to \$8,000.

27. Estimate the actual statewide compliance costs of the proposed rules on individuals (regulated individuals or the public). Include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping.

All the costs regarding the licensing and operation of a body art facility are statutory and not in these proposed rules. There are no other actual statewide compliance costs other than the purchase of an autoclave, if necessary, by some of the body art facilities. That cost is estimated from \$1,000 to \$8,000.

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

Approximately 1,200 licensed body art facilities will be affected by these rules, in addition to those applying for temporary licenses which total approximately 300-500 per year. The public consumer, number unknown but increasing yearly, will be affected by the rules; perhaps in the hundreds of thousands. All the state's local health departments will be affected by the proposed rules, in addition to the state agency, DHHS.

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

The public consumer can anticipate having body art performed in all of the approximately 1,200 facilities in a clean environment under the minimum standards imposed by the rules. As the body art business continues to flourish, the public will seek out reputable body art facilities which should increase the number of customers at the facility and may increase employment opportunities for individuals to perform their art and for those who are hired to assist with the day-to-day functioning of the facilities. The local health department will have consistent rules for inspection and enforcement. DHHS will continue licensing facilities and may see an increase in license revenues and will continue its ongoing efforts to improve the standards of body art statewide.

28. 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 anticipated to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rules.

29. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rules. Please provide both quantitative and qualitative information, as well as your assumptions.

Primary and direct benefits would be protecting the safety and health of the people of the state of Michigan, consistency with application and enforcement by local health departments of the proposed rules to ensure the safety and health of the state's citizens, and body art facilities can expect more consistency with the rules regarding inspections and enforcement. Secondary and indirect benefits include reduction in outbreaks of infections and medical costs due to unsafe facilities.

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

The proposed rules with their emphasis on enforcement against illegal and unsafe and unlicensed body artists will have consumers seeking services in safe and sanitary body art establishments, which may impact job growth and job creation. The rules should have no bearing on job elimination for the facilities.

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

Typical market forces are in play. The businesses that can expand through multiple locations have the advantage for better marketing. However, it is quality of work that brings in repeat business and referrals. Geographic location may play a part in available customer base. The owners who may be required to purchase an autoclave may be disproportionately affected, however, it is anticipated that is less than 5% of the total licensed body art facilities in the State.

32. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of the proposed rules and a costbenefit analysis of the proposed rules.

The agency had determined that the only cost to the facilities would be the purchase of an autoclave, averaging \$1000 to \$8,000, yet the majority of the facilities have benefited from the single-use application that is safer for the consumer, and would decrease costs in the event of a recall, contamination, and outbreak.

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.

Costs of tattoo equipment and supplies compiled by DHHS and various body art facilities. DHHS has the records of those licensed facilities in the state. The facility license, EGLE, and blood borne pathogens certificates are determined by the various departments that provide these licenses and certificates.

Alternative to Regulation

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

There are no known alternatives to the proposed rules. While local health departments attempt to ensure that current body art facilities conform to ordinary standards for the health, safety, and welfare of Michigan citizens, an allencompassing rule set will provide consistency and expectations of how the body art facility and industry is anticipated to perform their procedures with the least amount of disruption and cost.

A. Please include any statutory amendments that may be necessary to achieve such alternatives. Statutory amendments under the Body Art Facilities statutes, MCL 333.13101 through 333.13112, would result in a large, cumbersome statute. The rules, which have the full force and effect of law, provide the detail required to compliment the statute that defines the legal expectations, assists in removing confusion, and interprets issues of what is required in the day-to-day operations of a body art facility.

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

It is unclear how a similar regulatory program would operate through a private market-based mechanism. The requirement of oversight for protection of the public health should not be delegated. Further, there are no known private market-base mechanisms in place in other states. The private market-based approach would be operating under a stringent for-profit motivation which could raise costs or fees to the body art facilities in order to satisfy regulatory reporting. The agency is unaware of any state that uses private, market-based systems for its body art program.

35. Discuss all significant alternatives the agency considered during rule development and why they were not incorporated into the rules. This section should include ideas considered both during internal discussions and discussions with stakeholders, affected parties, or advisory groups.

No other alternatives would be acceptable to promote disease prevention.

Additional Information

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

The agency's body art program will notify all body art facility owners and health departments of the promulgation of the final rules as the first basis of compliance. The agency has a public website which will be constantly updated regarding changes and compliance requirements for the rules, including forms and other materials, in addition to each local health inspector ensuring each body art facility and its owners acknowledge the rules, and to answer any questions on compliance and refer the facility to the state agency for information outside the compliance requirements.