

Administrative Rules Committee**December 12, 2007****License Fees, Food Code, Smoke Detectors, Tattoo/Body Art, and Tanning Facilities****North Dakota Department of Health**

Good morning, Mr. Chairman and members of the Rules Committee. My name is Kenan Bullinger, and I am the director of the Division of Food and Lodging for the North Dakota Department of Health. In the interest of time, I will be presenting some information on five sets of regulations our division has recently proposed or changed.

1. The license fee increases, tattoo/body art and tanning facility regulations are a result of statutory changes or new statutes passed in the last legislative session.
2. These rules are not related to any federal statute or regulation. However, the changes to our state's food code regulations are modeled after the 2005 Food and Drug Administration's Food Code. We periodically make changes to our state's food code as the federal model code is updated, which is every four years.
3. A Notice of Intent to Amend Administrative Rules was sent to Legislative Council on June 20, 2007. Public notices on the administrative rules hearing were printed in the state's major newspapers in late June or early July of 2007. A public hearing was held on August 1 and a 13-day written comment period after the hearing date was established.
4. A summary of the comments received and the department's consideration of those comments is attached for your information.
5. The approximate cost of providing public notice and holding the hearing on the rules for all divisions was approximately \$1,450.
6. As mentioned earlier, the Division of Food and Lodging was involved with five sets of rules as follows:
 - License Fee Increases: Annual license fees were increased for all food and lodging facilities to generate the special funds necessary to hire an additional FTE. This new position was granted by the legislature to assist in handling the increased workload the division will encounter enforcing the new tattoo/body art and tanning facility laws and regulations.

- Food Code: The department updated its state food code regulations, which are periodically amended to maintain uniformity with the federal model food code. These regulations are updated every four to five years.
 - Smoke Detectors: With the department assuming regulatory responsibility in assisted living facilities a few years back, some minor but important amendments were needed to establish some smoke alarm and detector placement and testing frequencies within these facilities.
 - Tattoo/Body Art: The 2007 Legislature passed new legislation dealing with tattoo and body art facilities. Administrative rules were adopted to implement this new legislation.
 - Tanning Facilities: The 2007 Legislature passed new legislation dealing with tanning facilities. Administrative rules were adopted to implement this new legislation.
7. Attached for your information are the regulatory analyses for each set of regulations.
 8. Also attached for your information are the economic impact statements on small entities.
 9. A constitutional takings assessment was not prepared as these rules will not limit the use of private real property.
 10. These rules were not adopted as emergency rules under NDCC 28-32-03.

I am happy to answer any questions you may have.

Changes to NDAC Articles 33-31, 33-33 and 33-39

Various License Fees for Food and Lodging Establishments

Regulatory Analysis:

1. Describe the classes of people likely to be affected by the proposed rule, including classes bearing the cost of the proposed rule and classes benefiting from the proposed rule: The owners of various food and lodging facilities licensed and inspected by the Department will be affected by the proposed rules.
2. Describe the probable impact, including the economic impact, of the proposed rule: The impact of these proposed rules is economic. Increased annual license fees are proposed to offset the increased costs to the department to carry out new regulatory work and also generate the revenue needed to hire an additional employee. New licensure and inspection responsibilities were assigned to the department dealing with body art and tanning facilities.
3. Describe the probable costs to the agency of implementation and enforcement of the proposed rule and any anticipated effect on state revenues: The only costs to the department in the implementation and enforcement of these rules is the time needed to change the licensing database with the proposed increases and to add two new license categories for body art and tanning. Total costs to make these database changes should be around \$300.
4. Describe any alternative methods of achieving the purpose of the proposed rule that were considered: There are no alternative methods to generate the revenue needed to address the increased costs.

Small Entity Regulatory Analysis:

1. Was establishment of less stringent compliance or reporting requirements for small entities considered? Less stringent requirements were not considered. The proposed rules deal strictly with license fee increases.
2. Was establishment of less stringent schedules or deadlines for compliance or reporting requirements considered for small entities? Less stringent schedules or deadlines are not applicable with these proposed rules. However, most of our license fees are based on size of the establishment. Lower fees are established for smaller entities.
3. Was consolidation or simplification of compliance or reporting considered? Consolidation or simplification of compliance or reporting was not applicable with these proposed rules.
4. Were performance standards established for small entities for replacement design or operational standards required in the proposed rules? No changes in performance or operational standards were part of these proposed rules.
5. Was exemption for small entities from all or part of these requirements in the proposed rules considered? No exemption for small entities from any part of these rules was considered.

Small Entity Economic Impact Statement:

1. Which small entities will be subject to these proposed rules? All food and lodging facilities, large and small, are subject to these proposed rules.
2. What are the administrative and other costs required for compliance with the proposed rules? The costs required for compliance with these rules are simply the increased license fees for existing establishments and newly created licenses fees for body art and tanning facilities.
3. What is the probable cost and benefit to the private persons and consumers who may be affected by these proposed rules? There should be no consumers affected by these rules unless the licensed establishments pass those increased license fees onto the consuming public.
4. What is the probable affect on state revenues? These proposed rules should generate approximately \$150,000 in additional revenue.
5. Are there less intrusive or less costly methods of achieving the purpose of the proposed rules? Less intrusive or less costly methods were not pursued because lesser increases would not have allowed the department to generate the revenue needed to adequately fund and enforce the new legislation relating to body art and tanning.

ND Requirements for Food and Beverage Establishments

Regulatory Analysis:

1. Describe the classes of people likely to be affected by the proposed rule, including classes bearing the cost of the proposed rule and classes benefiting from the proposed rule: The owners of various retail food, foodservice and beverage establishments will be better protected with the adoption of these rules. These Food Code rules are science based and are modeled after the Food and Drug Administration's 2005 Model Food Code. This model code is used extensively across the country by state and local health jurisdictions with input from the industry. This code will bring North Dakota in uniformity with other jurisdictions and protect the public and owners of various establishments with sound and enforceable regulations.
2. Describe the probable impact, including the economic impact, of the proposed rule: These rules will have little economic impact on the regulated community but will improve the conditions for which food is prepared and sold in our state and offer sound public health protection to the consuming public.
3. Describe the probable costs to the agency of implementation and enforcement of the proposed rule and any anticipated effect on state revenues: The only additional costs to the department will be the cost of updating and printing new hard copies of the state food code so it can be distributed to the licensed food and beverage establishments, which is estimated at \$3,500. There will be no additional enforcement costs or effect on state revenues with these rule changes.
4. Describe any alternative methods of achieving the purpose of the proposed rule that were considered: The department has always used the federal model food code as it's basis for food establishment regulations. This provides uniformity and this code is based on sound science with input from the food industry. The industry prefers we adopt a uniform code and not create our own regulations.

Small Entity Regulatory Analysis:

1. Was establishment of less stringent compliance or reporting requirements for small entities considered? Less stringent requirements were not considered. Food safety regulations are extremely important and should not be lessened for smaller entities or foodborne outbreaks could result.
2. Was establishment of less stringent schedules or deadlines for compliance or reporting requirements considered for small entities? These were also not considered as the rule changes will not have significant impact on small entities for compliance and no effect on reporting.
3. Was consolidation or simplification of compliance or reporting considered? These new rules will not be difficult to comply with and simplification of food safety regulations could jeopardize public health.

4. Were performance standards established for small entities for replacement design or operational standards required in the proposed rules? No changes in performance or operational standards were part of these rules.
5. Was exemption for small entities from all or part of these requirements in the proposed rules considered? Food safety regulations are vitally important for all segments of the food industry, whether large or small. Compromising food safety is not an option.

Small Entity Economic Impact Statement:

1. Which small entities will be subject to these proposed rules? All food and beverage establishments large and small are subject to these proposed rules.
2. What are the administrative and other costs required for compliance with the proposed rules? There should be no additional costs for any establishment for compliance with these rules.
3. What is the probable cost and benefit to the private persons and consumers who may be affected by these proposed rules? These rules will result in better public health protection for all citizens who frequent licensed establishments.
4. What is the probable affect on state revenues? These proposed rules will have no affect on state revenues.
5. Are there less intrusive or less costly methods of achieving the purpose of the proposed rules? Less intrusive rules would result in lesser public health protection and protection for the licensed facilities. These rules have no bearing on costs.

Changes to NDAC Chapter 33-33-05

Smoke Detectors and Alarm Systems

Regulatory Analysis:

1. Describe the classes of people likely to be affected by the proposed rule, including classes bearing the cost of the proposed rule and classes benefiting from the proposed rule: The owners of various lodging and assisted living facilities licensed and inspected by the Department will be affected by the proposed rules.
2. Describe the probable impact, including the economic impact, of the proposed rule: There should be little impact on the facilities affected by these proposed regulations. Some of these changes were simply housekeeping in nature in the changing of terminology of "motels, hotels and lodgings" to "lodging facilities". In addition, life/safety provisions were added for assisted living facilities but most are already in compliance with these proposed rules.
3. Describe the probable costs to the agency of implementation and enforcement of the proposed rule and any anticipated effect on state revenues: The only costs to the department in the implementation and enforcement of these rules is a small change to the printing of inspection forms for these establishments which should be less than \$300.
4. Describe any alternative methods of achieving the purpose of the proposed rule that were considered: There are no alternative methods of achieving the purpose of these proposed rules. Less stringent requirements would result in lesser protection to the tenants and consumers who frequent or live in these facilities.

Small Entity Regulatory Analysis:

1. Was establishment of less stringent compliance or reporting requirements for small entities considered? Less stringent requirements were not considered. Life/safety provision for any type of lodging or assisted living facility are vitally important no matter how large or small.
2. Was establishment of less stringent schedules or deadlines for compliance or reporting requirements considered for small entities? Less stringent schedules or deadlines are not applicable with these proposed rules. Most facilities are already in compliance with these proposed rules.
3. Was consolidation or simplification of compliance or reporting considered? Consolidation or simplification or compliance or reporting was not applicable with these proposed rules.
4. Were performance standards established for small entities for replacement design or operational standards required in the proposed rules? No changes in performance or operational standards were part of these proposed rules.
5. Was exemption for small entities from all or part of these requirements in the proposed rules considered? No exemption for small entities from any part of these rules was considered. Life/safety is important for all entities.

Small Entity Economic Impact Statement:

1. Which small entities will be subject to these proposed rules? All lodging and assisted living facilities, large and small, are subject to these proposed rules.
2. What are the administrative and other costs required for compliance with the proposed rules? Most facilities are already in compliance. These rules simply clarify how many rooms need to be checked and the frequency for that testing.
3. What is the probable cost and benefit to the private persons and consumers who may be affected by these proposed rules? Private persons and consumers who stay at lodging or assisted living facilities will be better protected from a life/safety standpoint.
4. What is the probable affect on state revenues? These proposed rules will have no affect on state revenues.
5. Are there less intrusive or less costly methods of achieving the purpose of the proposed rules? Less intrusive or less costly methods were not pursued as that would not afford the protection needed to insure the safety of the consuming public of these services.

New Article 33-41

Tattoo and Body Art Facilities

Regulatory Analysis:

1. Describe the classes of people likely to be affected by the proposed rule, including classes bearing the cost of the proposed rule and classes benefiting from the proposed rule: The owners of all tattoo and body art establishments will be affected by the proposed rules. The consumers who utilize the services provided by these facilities will benefit from these newly regulated firms.
2. Describe the probable impact, including the economic impact, of the proposed rule: These proposed rules establish some new requirements for persons operating these types of establishments. With those not being regulated before, there will be some economic impact in getting into compliance but because the department has no previous experience with these facilities, it is hard to estimate how much economic impact these rules will have. We know there are many facilities that run good operations and are already in compliance and these rules should have no impact.
3. Describe the probable costs to the agency of implementation and enforcement of the proposed rule and any anticipated effect on state revenues: A number of the body art establishments currently operating in the state are already regulated by local health units who have in place ordinances very similar to these proposed rules. The department will now regulate those current facilities outside of local jurisdiction, which is not expected to be more than 10-15 facilities. The costs associated with this new licensing and inspection activity is expected to be around \$9,500 for each biennium.
4. Describe any alternative methods of achieving the purpose of the proposed rule that were considered: There are no alternative methods of achieving the purpose of these proposed rules. Less stringent requirements would result in lesser protection to the consumers who frequent these facilities.

Small Entity Regulatory Analysis:

1. Was establishment of less stringent compliance or reporting requirements for small entities considered? Less stringent requirements for small entities were not considered as these rules are important at establish the necessary safeguards for all facilities, large or small.
2. Was establishment of less stringent schedules or deadlines for compliance or reporting requirements considered for small entities? Less stringent schedules or deadlines are not applicable with these proposed rules.
3. Was consolidation or simplification of compliance or reporting considered? Consolidation or simplification for compliance or reporting was not considered for smaller entities with these proposed rules. All provisions are important.

4. Were performance standards established for small entities for replacement design or operational standards required in the proposed rules? No changes in performance or operational standards were part of these proposed rules.
5. Was exemption for small entities from all or part of these requirements in the proposed rules considered? No exemption for small entities from any part of these rules was considered. These public health provisions are important for all entities.

Small Entity Economic Impact Statement:

1. Which small entities will be subject to these proposed rules? All body art facilities, large and small, are subject to these proposed rules.
2. What are the administrative and other costs required for compliance with the proposed rules? These proposed rules establish some basic public health provisions to ensure protection to the clients and operators. Most operators already employ good public health perimeters but there may be some additional recordkeeping required but will have little cost associated with them.
3. What is the probable cost and benefit to the private persons and consumers who may be affected by these proposed rules? Private persons and consumers who utilize the body art services will be better protected from communicable diseases.
4. What is the probable affect on state revenues? These proposed rules will generate license revenue of about \$1500 per year.
5. Are there less intrusive or less costly methods of achieving the purpose of the proposed rules? Less intrusive or less costly methods were not pursued as that would not afford the protection needed to insure the safety of the consuming public of these services.

New Article 33-42

Tanning Facilities

Regulatory Analysis:

1. Describe the classes of people likely to be affected by the proposed rule, including classes bearing the cost of the proposed rule and classes benefiting from the proposed rule: The owners of all tanning establishments will be affected by the proposed rules. The consumers who utilize the services provided by these facilities will benefit from these newly regulated firms.
2. Describe the probable impact, including the economic impact, of the proposed rule: These proposed rules establish some new requirements for persons operating these types of establishments. With those not being regulated before, there will be some economic impact in getting into compliance but because the department has no previous experience with these facilities, it is hard to estimate how much economic impact these rules will have. We know there are many facilities that run good operations and are already in compliance and these rules should have no impact.
3. Describe the probable costs to the agency of implementation and enforcement of the proposed rule and any anticipated effect on state revenues: The costs associated with this new licensing and inspection activity is expected to be around \$75,000 for each biennium.
4. Describe any alternative methods of achieving the purpose of the proposed rule that were considered: There are no alternative methods of achieving the purpose of these proposed rules. Less stringent requirements would result in lesser protection to the consumers who frequent these facilities.

Small Entity Regulatory Analysis:

1. Was establishment of less stringent compliance or reporting requirements for small entities considered? Less stringent requirements for small entities were not considered as these rules are important at establish the necessary safeguards for all facilities, large or small.
2. Was establishment of less stringent schedules or deadlines for compliance or reporting requirements considered for small entities? Less stringent schedules or deadlines are not applicable with these proposed rules.
3. Was consolidation or simplification of compliance or reporting considered? Consolidation or simplification for compliance or reporting was not considered for smaller entities with these proposed rules. All proposed provisions are important.
4. Were performance standards established for small entities for replacement design or operational standards required in the proposed rules? No changes in performance or operational standards were part of these proposed rules.
5. Was exemption for small entities from all or part of these requirements in the proposed rules considered? No exemption for small entities from any part of these rules was considered. These public health provisions are important for all entities.

Small Entity Economic Impact Statement:

1. Which small entities will be subject to these proposed rules? All tanning facilities, large and small, are subject to these proposed rules.
2. What are the administrative and other costs required for compliance with the proposed rules? These proposed rules establish some basic public health provisions to ensure protection to the clients and operators. Most operators already employ good public health perimeters but there may be some additional recordkeeping or manpower costs associated. Consent forms will also need to be developed by the operators.
3. What is the probable cost and benefit to the private persons and consumers who may be affected by these proposed rules? Private persons and consumers who utilize the tanning services will be better protected from overexposure and communicable diseases.
4. What is the probable affect on state revenues? These proposed rules will generate license revenue of about \$25,000 per year.
5. Are there less intrusive or less costly methods of achieving the purpose of the proposed rules? Less intrusive or less costly methods were not pursued as that would not afford the protection needed to insure the safety of the consuming public of these services. However, the department has established a lesser license fee of \$90 per year for smaller entities with fewer than ten tanning beds versus \$110 for entities with more than ten tanning beds.

SUMMARY OF ORAL AND WRITTEN COMMENTS RECEIVED

FOOD AND LODGING DIVISION

Changes to NDAC 33-33-04, Requirements for Food and Beverage Establishments: No oral comments received. Written letter of support from Fargo/Cass Public Health received and copy attached.

Changes to NDAC 33-31, 33-33 and 33-39 relating to various license fee increases: No written or oral comments received.

Changes NDAC 33-33-05 relating to smoke detectors and alarm systems: Written comments received from the ND Long Term Care Association (copy attached):

First comment was on allowing the owner, manager or their designee be allowed to test the alarm systems in lodging or assisted living facilities. The department agrees with that comment and made that change in subsection 2 of section 33-33-05.

The second comment dealt with clarifying the "spot testing" requirement of alarm systems in lodging and assisted living facilities. It was suggested that 10% of the lodging or assisted living units be tested. The department agrees with that comment and clarified that requirement in subsection 2 of section 33-33-05.

The third comment was in relation to the testing frequency of alarm systems. These written comments suggested more frequent checks for battery operated detectors (weekly) versus hard wired systems (monthly). The department agreed with this comment and made that change in subsection 2 of 33-33-05.

New Article 33-41 relating to tattoo and body art regulations: Written comments from Mr. Dave Peske, ND Medical Association (copy attached):

First comment dealt with removing the definition for "physician" in the rules as that term was not used in the text of the rules. The term "physician" is used in subsection 1 of section 33-41-01-04 and the department feels this definition should be retained in the rules.

The second comment dealt with removing the redundant requirement for confidentiality of the client's health assessment. The department agreed as all clients records are mandated to be confidential as stated in subsection 3 of section 33-41-01-05.

The third comment stated that licensed body art operators are not trained and licensed medical professionals who can be expected to be knowledgeable about medical conditions of their clients. So evaluating their client's medical conditions is not appropriate. Agreeing with his suggestion of simply assessing the health status of the client is more appropriate in this situation.

A proposed set of the body art regulations was sent to the owners of Michael Jay's Tattoo and Piercing Clinic operating in Bismarck. That facility had followed the legislation in the recent session and agreed to review the department's proposed regulations. Several comments/suggestions were received from this facility:

In subsection 11 of section 33-41-01-01, they suggested removal of "outer perimeter" of the ear as being allowed for piercing and to never allow cartilage piercing. The department feels the outer perimeter of the ear is non-cartilaginous and should be allowed for piercing. The outer perimeter of the ear is also allowed for piercing in the National Environmental Health Association's Model Body Art Code from which these regulations were drafted.

In subsection 7 of section 33-41-01-02, they suggested clarity in the requirement for having "one toilet in a body art establishment" and not allowing use in an adjoining mall or business. The department felt that the mandate was clear in its' intent of requiring a minimum of "one toilet in a body art establishment".

Michael Jay's suggested that language be added to subsection 9 of section 33-41-01-03 that states married minors are emancipated or free of parental control or consent. This issue is addressed in subsection 2 of section 14-09-20 of the North Dakota Century Code so there is no need to clarify this exemption through these regulations.

In subsection 2 of section 33-41-01-04, Michael Jay's had some concerns that the written instructions for aftercare of a body art procedure should advise the client to consult a physician at first signs of infection or swelling. The department acknowledges that swelling is common after most body art procedures. However, the first signs of infection needs to be addressed with a physician and should remain in the rules. The department will insure that aftercare procedures include information on infection and what a client should look for as signs of an infection.

Michael Jay's suggested that the "time" of the body art procedure also be required in the records retention requirements in section 33-41-01-06, which the department has agreed to.

Michael Jay's suggested that dry-heat sterilizers not be allowed as a method to sterilize non-disposable instruments. Dry heat sterilizers are effective in sterilizing and will be allowed by the department. Verifying their effectiveness will be accomplished with the monthly spore destruction tests as required in subsection 4 of section 33-41-01-08.

Michael Jay's suggested the addition of a new subsection to section 33-41-01-10 which prohibit the licensing and operation of body art procedures in a private residence. The department does allow other businesses to operate within the home as long as that business is conducted in a room or rooms used only for that business. In addition, the home based operation must meet all the requirements as stated in these regulations and cannot violate any local zoning ordinances.

New Article 33-42 relating to tanning facilities: Written letter of support provided by Fargo/Cass Public Health received and attached.

Written comment from Mr. Dave Peske, ND Medical Association (copy attached) stated that the American Medical Association does not function in the role of determining or endorsing the health benefits of tanning beds as proposed in section 33-42-01-03. The department accepted the revision suggested by the ND Medical Association which now states that only those health benefits recognized by a credible scientific or medical source are acceptable in any written or verbal advertising.

Oral comments were received at the administrative rules hearing held on August 1. Speaking in support of the proposed tanning regulations were Mel Fischer, City of Bismarck and Lisa Clute, administrator with the First District Health Unit in Minot. Greg Weimer, owner of a tanning facility in Bismarck, spoke in opposition to only allowing health benefits as approved by the American Medical Association. His concern was similar to that expressed by the ND Medical Association and has been changed as stated above.