

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Original Updated Corrected

2. Administrative Rule Chapter, Title and Number
SPS 220

3. Subject
Tanning Facilities

4. Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

5. Chapter 20, Stats. Appropriations Affected
20.165(1)(g)

6. Fiscal Effect of Implementing the Rule

No Fiscal Effect Increase Existing Revenues Increase Costs
 Indeterminate Decrease Existing Revenues Could Absorb Within Agency's Budget
 Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)

State's Economy Specific Businesses/Sectors
 Local Government Units Public Utility Rate Payers
 Small Businesses **(if checked, complete Attachment A)**

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes No

9. Policy Problem Addressed by the Rule

2015 Wisconsin Act 55 transferred responsibility for regulating tanning facilities from the Department of Health Services (DHS) to the Department of Safety and Professional Services (DPS), effective January 1, 2016. DHS 161 and 161 Appendix were renumbered SPS 220 and 220 Appendix at that time. This rule will align administrative provisions transferred from DHS with DPS's processes, and modernize the rule to reflect current practice for ensuring the safe and sanitary use of tanning devices.

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

The proposed rule was posted on the Department of Safety and Professional Services' website for 14 days in order to solicit comments from businesses, representative associations, local governmental units, and individuals that may be affected by the rule. No comments were received.

11. Identify the local governmental units that participated in the development of this EIA.

No local governmental units participated in the development of the EIA.

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

This proposed rule will not have a significant impact on specific businesses, business sectors, public utility rate payers, local governmental units, or the state's economy as a whole.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit of implementing the rule is to bring rules into alignment with current DPS administrative procedures, and to modernize the rule to ensure that it reflects current practices for the safe and sanitary use of tanning devices.

14. Long Range Implications of Implementing the Rule

The long range implication of implementing the rule is to provide consistency in administrative processes across DPS direct licensing, and the ensured safe and sanitary use of tanning devices in Wisconsin.

15. Compare With Approaches Being Used by Federal Government

Performance standards for sunlamp products--21 CFR 1040.20 establishes performance standards for sunlamp and

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sunlamp products and includes equipment requirements related to radiant power of sunlamps, timer systems, and protective eyewear. The regulation requires manufacturers to display a warning statement on sunlamp products similar to the statement Wisconsin state law requires tanning facility operators to post near each device. 21 CFR 1040.20 also requires users' instructions to include information for determining the correct exposure time and schedule for persons according to skin type.

Medical device classification--21 CFR 878.4635 regulates the manufacture of sunlamp products and ultraviolet lamps intended for use in sunlamp products. In 2014, the Food and Drug Administration (FDA) revised 21 CFR 878.4635 to reclassify sunlamp and ultraviolet (UV) lamps from low-risk (class I) to moderate-risk (class II) medical devices. As part of that reclassification, FDA placed additional controls on the manufacture of sunlamps and UV lamps to protect public health, such as performance testing, software validation, and demonstration that the device is biocompatible and safe to use.

21 CFR 878.4635 includes two warning label requirements. First, sunlamp or UV lamp manufacturers are required to include a warning in user instructions, catalogs, and other product-related documents stating that the products should not be used by people under the age of 18, who have skin lesions or open wounds, who have or have a history of skin cancer or who have been regularly evaluated for skin cancer. Second, FDA also requires sunlamp products to carry a "black-box warning" stating that the product should not be used by people under age 18. FDA requires "black-box warnings" on products the agency determines to present a significant risk. This is a labeling requirement and does not prohibit the use of sunlamp products by people under age 18.

FDA's "black-box warning" requirement for sunlamp products applies to both new products and units currently in use. Although manufacturers may provide labels to tanning facility operators for products currently in use, if a sunlamp product manufacturer is out of business, then the operator is responsible for acquiring or creating the "black-box warning" label for products used in their tanning facility.

Proposed federal regulations -- The FDA is proposing to restrict the use of sunlamp products to people age 18 years old and older, and require that they sign a risk acknowledgement certification before use, and then every 6 months, that states that they have been informed of the risks to health that may result from use of sunlamp products.

The FDA also solicited comments on a proposal to amend 21 CFR parts 1000 through 1010 and 21 CFR 1040.20 to update performance standards to reflect current science for sunlamp products and ultraviolet lamps and require more effective communication regarding the risks posed by these products.

Comparison with Wisconsin law --Wisconsin state law currently restricts use of sunlamp products to users age 16 or older, which is lower than the proposed federal restriction. Wisconsin requires users to sign a statement acknowledging receipt of certain information related to tanning risks. Wisconsin requires tanning equipment to be in compliance with 21 CFR 1040.20.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois: Illinois charges \$250 for an initial tanning facility license and a \$150 annual renewal fee. Illinois charges a nonrefundable \$250 fee for renewal of an expired permit. If an owner operates more than one tanning facility, the owner shall file a separate application and submit a separate fee for each facility owned and operated. Expired facilities that fail to pay a nonrefundable \$250 permit renewal fee within 90 days after the permit expiration are required to submit a new permit application and comply with requirements for new facilities in order to receive a tanning facility permit. Illinois inspects tanning facilities once a year.

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In Illinois, any tanning facility operating without a valid permit or operating on a revoked permit may be found guilty of committing a public nuisance. A person convicted of knowingly maintaining a public nuisance commits a Class A misdemeanor in Illinois. Each subsequent offense under the Act is a Class 4 felony. Penalties or fines may not exceed \$1,000 per day for each day the permit holder remains in violation. Illinois has established criteria to determine whether to assess a fine and to determine the amount of the fine.

Illinois also has established tanning facility requirements related to construction, operation, sanitation, recordkeeping, requirements specifically for stand-up booths, eyewear, and injury reporting. Illinois has adopted a table of examples of human skin types, similar to the table included in Wisconsin's SPS 220 Appendix, and a table with information to determine skin types.

Iowa: Iowa charges \$5 for a tanning facility permit and a \$33 inspection fee per tanning unit per year, up to a maximum of \$330 per facility. Owners are charged \$25 per month for each month a bill for inspection costs has not been received within 45 days of billing. The rules include a list of reasons to deny, revoke or terminate a permit, along with construction standards, operation of tanning devices, regulations for stand-up booths, protective eyewear and restrictions on claims that can be made in promotional materials. The rules include requirements related to electronically controlled tanning devices. Finally, the rule outlines procedures for inspections, violations, and injunctions. Operators are required to receive training and take a test every 5 years.

Michigan: Michigan does not register or inspect tanning salons or equipment and tanning facility operators are not licensed. Nonetheless, Michigan state law requires tanning facility operators to provide information warning customers about the dangers associated with tanning and to display a poster with a warning sign. Owners are prohibited from making certain advertising statements. Customers are required to sign an acknowledgement that they have received the warning statement each year.

Minnesota: Minnesota state law establishes standards for tanning equipment, stand-up booths, protective eyewear, and warning signs, and records requirements. State law restricts the use of tanning machines to people over the age of 18. Any person who operates a tanning facility in noncompliance with state law may be found guilty of a petty misdemeanor. Tanning facilities may be licensed under local ordinances and may establish more restrictive regulations of tanning facilities than in state law.

17. Contact Name

Jon Derenne, Administrative Rules Coordinator

18. Contact Phone Number

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This document can be made available in alternate formats to individuals with disabilities upon request.

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Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
 - Less Stringent Schedules or Deadlines for Compliance or Reporting
 - Consolidation or Simplification of Reporting Requirements
 - Establishment of performance standards in lieu of Design or Operational Standards
 - Exemption of Small Businesses from some or all requirements
 - Other, describe:
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4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
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