

[See PDF for proper formatting]

STATE OF WISCONSIN
DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

IN THE MATTER OF RULEMAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : DEPARTMENT OF SAFETY
DEPARTMENT OF SAFETY AND : AND PROFESSIONAL SERVICES
PROFESSIONAL SERVICES : ADOPTING RULES
: (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Department of Safety and Professional Services to repeal SPS 220.12 (1) (title), (2) and (3), and 220.13; to amend SPS 220.03 (8), and 220.11 (2); to repeal and recreate SPS 220.04 and SPS 220 Appendix A; and to create SPS 220.04 (note), 220.045 and 220.11 (note), relating to tanning facilities.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 463.25, Stats.

Statutory authority: s. 463.25 (12), Stats.

Explanation of agency authority:

Section 463.25 (12) states that the department “may promulgate rules necessary to administer this section.”

Related statutes or rules: Chapter 440, Department of Safety and Professional Services, and chs. SPS 1 to 9 outline the Department of Safety and Professional Services’ uniform administrative procedures for issuing licenses and disciplinary actions against licensees.

Plain language analysis: 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.

Section 1 amends SPS 220.03 (8) to revise the definition for “Tanning device” to refer to the definition given in s. 463.25 (1) (b), Stats.

Section 2 repeals and recreates SPS 220.04 to remove outdated references to fees and to clarify that fees for tanning facility permits will be established by the department under its authority in ss. 440.03(9)(a) and 440.05(1), Stats., to remove a provision relating to the process for approving or denying applications for tanning facility permits as duplicative of the department's existing procedures found in SPS 4, and to create requirements to receive or maintain a tanning facility permit license, including that tanning facility permit applicants and permit holders must not have been convicted of a felony while engaged in the practice of operating a tanning facility, and must comply with department orders to correct, or take substantial steps approved by the department to correct, violations of any sanitary or other rule of the department within the time limit stated by the department in a notification of violation. These rules are necessary to make the chapter consistent with department administrative processes and to ensure the public health and safety in tanning facilities.

Section 3 creates a note in SPS 220.04 with contact information for obtaining a tanning facility license application.

Section 4 creates SPS 220.045 providing for the tanning facility permit expiration date.

Section 5 amends SPS 220.11 (2) to provide that the department may inspect a facility upon receipt of an injury report received under SPS 220.11 if the department determines an establishment presents a hazard to public health and safety.

Section 6 creates a note with contact information for filing an injury report required under SPS 220.11.

Section 7 repeals SPS 220.12 (1) (title).

Section 8 repeals SPS 220.12 (2) and (3), aligning the rule with the department's uniform procedures for denying, suspending, or revoking credentials found in chs. SPS 1 to 9, and ch. 440, Stats.

Section 9 repeals SPS 220.13 as the penalty is already provided for in statute.

Section 10 repeals and recreates SPS 220 Appendix A to modernize the table and clarify that the information in the appendix is based on the Fitzpatrick Skin Type Scale, which is a recognized public health tool for classifying skin types to determine a person's potential reaction to solar radiation.

Summary of, and comparison with, existing or proposed federal regulation:

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

Comparison with rules in adjacent states:

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.

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.

Summary of factual data and analytical methodologies:

The proposed rule project amends ch. SPS 220 and SPS 220 Appendix, as transferred from ch. DHS 161 and DHS 161 Appendix, to align the rule with Department of Safety and Professional Services uniform administrative procedures, and to modernize the rule to ensure it reflects current practices for the safe and sanitary use of tanning devices.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis document is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department’s Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Jon Derenne, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8935, Madison, Wisconsin 53705; (608) 266-0955; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Jon Derenne, Rule Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8935, Madison, WI 53705, by phone to (608) 266-0955, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the hearing scheduled for 11:00 AM on July 17, 2019 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. SPS 220.03 (8) is amended to read:

SPS 220.03 (8) ~~“Tanning device” means any equipment that emits electromagnetic radiation having wavelengths in air 200 to 400 nanometers and that is used for tanning of human skin and any equipment used with that equipment, including but not limited to protective eyewear, timers and handrails, except that “tanning device” does not include a phototherapy device used by a physician~~ has the meaning given in s. 463.25 (1) (b), Stats.

SECTION 2. SPS 220.04 is repealed and recreated to read:

SPS 220.04 Permit requirements.

No person may operate a tanning facility without a permit issued by the department. Applicants for a permit and permit holders shall comply with all of the following conditions:

- (1) Application for a permit shall be submitted annually on a form provided by the department, which shall include all of the following information:
 - (a) The name and complete mailing address of the tanning facility.
 - (b) The name of the facility operator.
 - (c) The phone number of the facility.
 - (d) The brand and model number of each tanning device.
 - (e) The primary type of business in which the facility is located.
 - (f) A statement as to whether the applicant has ever been convicted of a felony committed while engaged in the practice of operating a tanning facility.
- (2) The application in sub. (1) shall be accompanied by the permit fee established by the department under ss. 440.03 (9) (a) and 440.05 (1), Stats.
- (3) Subject to ss. 111.321, 111.322, and 111.335, Stats., applicants for a permit and permit holders may not have been convicted of a felony committed while engaged in the practice of operating a tanning facility.
- (4) A permit holder shall notify the department in writing of any change in information that appears on the permit, such as facility ownership, business status, or address. That notification shall be sent to the department within 30 days after the change is made.
- (5) Permit holders and permit applicants shall correct, or take substantial steps approved by the department to correct, a violation of any sanitary or other rule of the department within the time limit stated by the department in a notification of violation.
- (6) No permit issued by the department may be transferred from one person to another or from one facility to another.

SECTION 3. SPS 220.04 (note) is created to read:

Note: Applications are available from the Department of Safety and Professional Services, P.O. Box 8935, Madison, Wisconsin 53708, or from the department's website at dpsps.wi.gov.

SECTION 4. SPS 220.045 is created to read:

SPS 220.045 Permit expiration.

Permits issued by the department shall expire annually on June 30.

SECTION 5. SPS 220.11 (2) is amended to read:

SPS 220.11 (2) The department shall may inspect a facility upon receipt of a notice of injury.

SECTION 6. SPS 220.11 (Note) is created to read:

SPS 220.11 Note: Contact the Department of Safety and Professional Services at (608) 266-2112 or (877) 617-1565 to report an injury from a tanning device. Report forms are available from the Department of Safety and Professional Services, P.O. Box 8935, Madison, Wisconsin 53708, or from the department's website at dps.wi.gov.

SECTION 7. SPS 220.12 (1) (title) is repealed.

SECTION 8. SPS 220.12 (2) and (3) are repealed.

SECTION 9. SPS 220.13 is repealed.

SECTION 10. SPS 220 Appendix A is repealed and recreated to read:

SUN-REACTIVE SKIN TYPES USED IN CLINICAL PRACTICES

Skin Type	Skin Reactions to Solar Radiation*
I	Always burns easily and severely (pain); tans little or none and peels
II	Usually burns easily and severely (painful burn); tans minimally or lightly, also peels
III	Burns moderately and tans about average
IV	Burns minimally, tans easily and above average with each exposure; exhibits IPD (immediate pigment darkening**) reaction
V	Rarely burns, tans easily and substantially; always exhibits IPD reaction
VI	Never burns and tans profusely; exhibits IPD reaction

Note: Categories are based on the Fitzpatrick Skin Type Scale.

*Based on the first 45-60 minutes (equals 2-3 minimum erythema dose) exposure of the summer sun (early June) at sea level.

**Immediate pigment darkening refers to the skin's response to sun exposure that occurs within the first few minutes to a few hours after exposure to sunlight.

SECTION 11. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

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 (DSPS), 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 DSPS'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 DSPS 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 DSPS 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

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

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.

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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

(608) 266-0955

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

ADMINISTRATIVE RULES
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:

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
-