

STATEMENT OF SCOPE

Department of Health Services

Rule No.: Chapters DHS 161 and 161 Appendix A (Renumbered chs. SPS 220 and 220 Appendix A July 1, 2016)

Relating to: Tanning Facilities

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only):

N/A

2. Detailed description of the objective of the proposed 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. The department proposes modifying ch. DHS 161 (ch. SPS 220), Tanning Facilities, and its appendix, DHS 161 Appendix A (ch. SPS 220 Appendix A), to align these administrative rules with DSPS's licensing and other administrative processes and modernize the rule, as needed, to reflect current practice for ensuring the safe and sanitary use of tanning devices.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

DHS 161 and 161 Appendix A (ch. SPS 220 and 220 Appendix A) implement statutory requirements found in s. 255.08, Stats. DHS 161 (ch. SPS 220) includes requirements for issuing, denying, suspending and revoking tanning facility permits; requirements that tanning facilities display and provide certain health information to customers; and requirements prohibiting the use of a tanning device by a person under 16 years old, as required by law. The rule also outlines procedures for the safe and sanitary use of tanning devices and injury reporting procedures. DHS 161 Appendix A (ch. SPS 220 Appendix A) includes a table describing sun-reaction for various skin types to be used to determine appropriate exposure times as recommended by the tanning device manufacturer. The department's tanning regulations have not been updated since they were first adopted in 1993. The department issues permits for approximately 1,000 tanning facilities.

2015 Wisconsin Act 55 transfers responsibility for the tanning facility program from DHS to DSPS effective January 1, 2016. Approval of this scope statement will allow DHS and DSPS, working in consultation with industry and public health representatives, to begin to review and revise DHS 161 and 161 Appendix A (ch. SPS 220 and 220 Appendix A) prior to the program's transfer.

If the rules are not updated, they will contain references that are inconsistent with DSPS administrative processes after the program is transferred, potentially causing confusion for Wisconsin's tanning facility owners and operators and tanning facility users. Without revision, the rules also may not reflect current practice for protecting public health and safety in tanning facilities.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language): The department has authority for promulgating rules related to tanning under ss. 255.08 (12), and 254.34 (1) (a), Stats., as follows:

255.08(12) - Tanning facilities.

255.08(12) RULES. The department may promulgate rules necessary to administer this section.

254.34(1)(a) – Powers and duties.

254.34(1) The department is the state radiation control agency and shall do all of the following:

(a) Promulgate and enforce rules, including registration and licensing of sources of ionizing radiation, as may be necessary to prohibit and prevent unnecessary radiation exposure.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule :

160 hours.

6. List with description of all entities that may be affected by the proposed rule :

The proposed rule revision will benefit tanning facility owners and operators by ensuring the rule reflects appropriate licensing and administrative procedures. It will benefit consumers by ensuring the rule reflects current information regarding the safe use of tanning devices.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule :

21 CFR 1040.20 establishes performance standards for sunlamp and sunlamp products and includes equipment requirements related to radiant power of sunlamps, requirements for timer systems, and requirements for protective eyewear. Along with other labeling requirements, the regulation includes a requirement for sunlamps to display a warning statement similar to the statement required by s. 255.08 (4) and DHS 161.07. It also requires users' instructions to include, among other items, instructions for determining the correct exposure time and schedule for persons according to skin type, similar to the information provided in DHS 161 Appendix A.

21 CFR 878.463 regulates sunlamp products and ultraviolet lamps intended for use in sunlamp products. In 2014, the Food and Drug Administration (FDA) revised this rule to reclassify sunlamp and ultraviolet (UV) lamps from low-risk (class I) to moderate-risk (class II) devices. This reclassification placed additional controls on 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. The rule requires that sunlamp products carry a visible black-box warning stating the product should not be used on people under age 18. Finally, it requires that user instructions, consumer-directed catalogs, specification sheets, descriptive brochures, and web-pages in which sunlamps or UV lamps are offered for sale include warnings that the product should not be used by people under the age of 18, people who have skin lesions or open wounds, people who have or have a history of skin cancer or by people who have been regularly evaluated for skin cancer.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

This rule is not anticipated to result in revisions that will have a negative economic impact on business. It will not have a significant economic impact on small businesses.

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