

Summary of Express Terms

The proposed Subpart amendment contains the following provisions:

The proposed amendment revises the term “tanning facility” to include the regulation of establishments whether or not a fee is charged to be consistent with the Public Health Law. The minimum age that individuals are allowed to use a regulated ultraviolet (UV) indoor tanning devices is raised to eighteen years old, and the amount of the registration fee and inspection fee have also been revised to conform with the Public Health Law. A definition of “disinfect” is added and clarifications are made to existing equipment cleaning and disinfection procedures.

The proposed regulation also clarifies existing language to improve understanding and consistent implementation.

Pursuant to the authority vested in the Commissioner of Health by Sections 3551 and 3554 of the Public Health Law, Subpart 72-1 of Title 10 (Health) of the official compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivisions (c) – (k) of section 72-1.1 are re-lettered (d) – (l) and a new subdivision (c) is added, to read as follows:

(c) Disinfect means adequate antimicrobial treatment by a disinfectant capable of destroying pathogenic non-spore forming bacteria, viruses, fungi, parasites and protozoa on treated surfaces.

Re-lettered subdivisions (j) and (k) of Section 72-1.1 are amended to read as follows:

(j) Sanitize means adequate antimicrobial treatment by a disinfectant [determined to be] capable of [destroying] reducing the number of pathogenic [organisms] non-spore forming bacteria on treated surfaces. Exposure to the ultraviolet radiation produced by the ultraviolet radiation device itself is not considered an adequate sanitizing agent.

(k) Tanning facility means any establishment where one or more ultraviolet radiation devices are used, offered, or made available for use by any human being, [for which] whether or not a fee is charged, directly or indirectly, excluding a facility where such device is used by a qualified health care professional for treatment of medical conditions.

Paragraphs (1), (4) and (7) of subdivision (c) of section 72-1.2(c) are amended, and a new paragraph (8) is added, to read as follows:

(1) the conspicuous posting of the tanning facility's [license] permit and appropriate warning

signs;

(4) the requirement that each tanning facility provide [safety goggles] adequate protective eyewear [and any other safety-related devices] to customers without additional charge therefor;

(7) requiring patrons to provide identification and sign a statement of acknowledgment prior to undergoing ultraviolet radiation exposure at a tanning facility[.];

(8) requiring tanning facilities to prohibit the use of ultraviolet radiation devices by persons under eighteen (18) years of age.

Paragraphs (4) and (7) of subdivision (b) of section 72-1.3 are amended to read as follows:

(4) Failure to [assure and] maintain the accuracy of ultraviolet radiation device timers;

(7) Inadequate sanitizing of tanning beds, tanning booths, pillows, or headrests; inadequate disinfection of [or] reusable protective eyewear;

Subdivisions (a), (c) and (f) of Section 72-1.4 are amended to read as follows:

(a) The PIO shall issue a permit to a person who meets the requirements of these rules and submits an application on a form prescribed by the State Commissioner of Health along with payment of a \$[30] 120 registration fee per biennial registration period and an inspection fee as specified in section 72-1.5(b) of this Subpart;

(c) Permits may be issued for a period of less than two years, with appropriate proration of the registration fee at the rate of \$[1.25] 5.00 per month or each portion of a month thereof.;

(f) [Operators of facilities doing business on the effective date of these rules shall apply for a permit within 60 days of the effective date of these rules.] Operators of tanning facilities [that will begin operation after the effective date of these rules] shall obtain a permit before beginning operation.

Subdivisions (a) and (b) of section 72-1.5 are amended to read as follows:

(a) A person operating a tanning facility shall allow the Department and PIO representatives access to conduct inspections and access to all equipment and records as may be necessary to determine compliance with these rules[, provided such inspections are conducted during normal business hours] at any time the facility is in operation.

(b) An inspection fee not to exceed \$[50] 200 per ultraviolet radiation device will be charged once per biennial licensing period.

The title of section 72-1.8, paragraph (2) of subdivision (a), subdivision (b), and paragraph (1) of subdivision (c), are amended and subdivision (d) is repealed, to read as follows:

72-1.8 Patron identification[,] and acknowledgement[s and consent] requirements.

(2) No person under [seventeen] eighteen ([17]18) years of age shall be permitted to use an

ultraviolet radiation device. [Persons seventeen (17) years of age to eighteen (18) years of age must provide a consent form as described in Section 72-1.8 (d) of the Subpart.]

(b) The operator shall provide to all patrons the Department's Tanning Hazards [i]Information [s]Sheet which advises of health risks and conditions under which the use of ultraviolet radiation is contraindicated, such as the use of photosensitizing drugs. Prior to initial exposure, each patron shall also be provided the opportunity to read a copy of the warning sign specified in Section 72-1.9(a)(2) of these rules.

(1) During the initial visit to the tanning facility, the operator shall require that each patron [eighteen (18) years of age and older] sign a statement that the warning sign and [informational pamphlet] Tanning Hazard Information Sheet has been read and understood prior to using any ultraviolet radiation device, and that the patron agrees to wear adequate protective eyewear.

Section 72-1.9 is amended to read as follows:

72-1. 9 Physical facilities and equipment.

Each tanning facility shall be constructed, operated and maintained [to] in good repair and shall meet the following minimum requirements:

(a) Required warning sign[s].

(1) The [W]warning sign[s] shall be readily legible, clearly visible, and not obstructed by any barrier, equipment, or other item present so that the patron can easily view the warning sign before energizing the ultraviolet radiation device. This sign is in addition to manufacturer's signs affixed to the device.

(2) Each warning sign shall be at least [8.5] 11 inches by [11] 17 inches, and use upper and lower case letters which are at least 10 mm (0.39 inches) and 5 mm (0.20 inches) in height, respectively. Lettering shall be bolded as in the text below. Signs shall have the following wording:

WARNING ULTRAVIOLET RADIATION

FOLLOW INSTRUCTIONS.

AVOID OVEREXPOSURE.

The manufacturer's maximum exposure time for this device is (specify) minutes.

As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer.

WEAR PROTECTIVE EYEWEAR. FAILURE TO USE PROTECTIVE EYEWEAR

MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYE.

MEDICATIONS OR COSMETICS MAY INCREASE YOUR SENSITIVITY TO

ULTRAVIOLET RADIATION. Consult a physician before using tanning equipment if

you are using medications or have a history of skin problems or believe yourself to be

especially sensitive to sunlight. IF YOU DO NOT TAN IN THE SUN, YOU ARE

UNLIKELY TO TAN FROM THE USE OF THIS PRODUCT.

(b) Posting of required warning[s]. A warning sign shall be posted in the immediate proximity

(within three feet) of each ultraviolet radiation device. The operator shall enter the

manufacturer's maximum exposure time on the sign for the device it is posted near.

(c) Equipment.

(1) Only [adequately labeled] ultraviolet radiation devices adequately labeled in accordance with 21 CFR 1040.20 or any successor regulation shall be used in tanning facilities.

(2) Each ultraviolet radiation device shall incorporate a timer system with multiple timer settings as specified on the manufacturer's label. The maximum timer interval(s) shall not exceed the manufacturer's maximum recommended exposure time.

(i) No timer interval shall have an error greater than +/- 10% of the maximum timer interval for the product.

(ii) The operator shall perform annual testing on all timers to ensure that this standard is met.

(iii) The timer must not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when emission from the ultraviolet lamp has been interrupted.

(3) Each ultraviolet radiation device shall allow the patron using the ultraviolet radiation device to terminate ultraviolet radiation emission manually at any time without disconnecting the electrical plug, removing the ultraviolet lamp or leaving the immediate environs of the ultraviolet radiation device.

(4) Timers shall be set by the operator or by a designated employee; patrons shall not have the ability to reset timers.

(5) [No later than two years after the effective date of this Subpart, existing ultraviolet radiation devices not equipped with a remote timer control system are required to have remote timer controls or a lock out device installed, such that patrons can not reset the timer.

(6) New facilities (including existing facilities with change of ownership) shall install remote timer controls or a lock out device prior to the operation of ultraviolet radiation devices.

(7)]All ultraviolet radiation devices, and electrical components of such devices, shall be maintained in good repair [free of electrical hazards].

[(8)] (6) All ultraviolet lamps must be shielded with an acrylic cover to protect patrons from injury caused by touching or breaking lamps.

[(9)] (7) Additional requirements for stand-up booths:

- (i) There shall be physical barriers or other means such as handrails or floor markings to indicate the recommended exposure distance between ultraviolet lamps and the patron's skin.
- (ii) Doors shall open outwardly. Handrails and non-slip floors shall be provided.

[(10)] (8) Defective or burned out ultraviolet lamps or filters shall be replaced with a type compatible for use in that device as specified on the product label on the ultraviolet radiation device, or as recommended by the manufacturer.

[(11)] (9) Equipment maintenance records must be maintained for a minimum of two (2) years.

The operator must be able to produce such records upon inspection of the facility by the Department or the PIO's representative.

(d) Sanitation.

(1) Ultraviolet radiation devices [and protective eyewear] shall be cleaned and then sanitized with an adequate disinfectant after each use; protective eyewear shall be cleaned and then disinfected with an adequate disinfectant after each use.

(2) The ultraviolet light produced by the ultraviolet radiation device shall not be considered an adequate sanitizing agent.

(3) When the operator dilutes a concentrated disinfectant in lieu of using a commercially prepared, full strength disinfectant, a test kit or other device that accurately measures the concentration of the disinfectant in parts per million (ppm) shall be used to measure the strength of the solution. The diluted disinfectant shall be tested when initially prepared and at least weekly thereafter to ensure sufficient strength of the disinfectant.

(4) The ultraviolet radiation device shall be cleaned and then sanitized according to the following minimum provisions:

(i) A clean paper or cloth towel shall be used each time the tanning device is cleaned [and sanitized];

(ii) The disinfectant shall be one specifically manufactured for sanitizing ultraviolet light-emitting equipment and shall be prepared and used according to manufacturer's [specifications] instructions found on the product label;

(5) Protective eyewear shall be cleaned and then disinfected according to the following minimum provisions: [The disinfectant used to clean and sanitize protective eyewear shall be one specifically manufactured for sanitizing ultraviolet radiation protective eyewear and shall be prepared and used according to the manufacturer's specifications.]

(i) A clean paper or cloth towel shall be used each time the protective eyewear is cleaned;

(ii) The disinfectant shall be one specifically manufactured for disinfecting protective eyewear and shall be prepared and used according to manufacturer's instructions found on the product label;

(6) Each container of disinfectant shall be adequately labeled as to its contents. Written procedures maintained at the facility shall include proper mixing and handling instructions for each disinfectant used to ensure proper concentration and safe use of the disinfectant.

(7) Pillows and headrests shall be covered in an easily cleanable material and shall be cleaned and then sanitized with an adequate disinfectant after each use.

(8) If towels or other linens are provided for patron use, they shall be washed with a detergent in hot water, rinsed and thoroughly dried after each use.

Subdivisions (a) and (d) of section 72-1.10 are amended to read as follows:

(a) The operator shall [assure] ensure that each patron using an ultraviolet radiation device possesses adequate protective eyewear; such protective eyewear shall be in accordance with all applicable federal regulations.

(d) The protective eyewear provided by the operator other than single-use disposable eyewear shall be cleaned and then disinfected after each use according to provisions detailed in section 72-1.9(d)(5) of this Subpart.

Section 72-1.11 is amended to read as follows:

72-1.11 Additional [O]operator responsibilities.

(a) The operator shall maintain a record of each patron's tanning visits, recording the date, duration of tanning exposure, and ultraviolet radiation device used. Each record shall be maintained for a minimum of two (2) years[.] and shall be available for review by the Permit Issuing Official or representative.

(b) The operator [must] shall report certain injuries and illnesses to the PIO, and [to] keep a record of reportable injuries and illnesses on a form prescribed by the Department, as detailed in section 72-1.7 of this Subpart. Each record shall be maintained for a minimum of two (2) years[.] and shall be available for review by the Permit Issuing Official or representative.

(c) The operator [must] shall [keep and] maintain an equipment maintenance log as detailed in section 72-1.9 (c)(11) of this Subpart. Each record shall be maintained for a minimum of two (2) years and shall be available for review by the Permit Issuing Official or representative.

(d) The operator [must] shall maintain records showing the results of annual timer tests as detailed in section 72-1.9 (c)(2)(ii) of this Subpart. Each record shall be maintained for a minimum of two (2) years[.] and shall be available for review by the Permit Issuing Official or representative.

(e) The operator shall maintain each Tanning Facilities Statement of Acknowledgement form, detailed in section 72-1.8(c) of this Subpart, and shall be available for review by the Permit Issuing Official or representative.

Regulatory Impact Statement

Statutory Authority:

Article 35-A of the Public Health Law (PHL) defines requirements for the regulation of ultraviolet radiation (tanning) devices and authorizes the Commissioner to promulgate rules and regulations necessary to effectuate the provisions of the Article, including the regulation of non-medical ultraviolet radiation devices.

Legislative Objectives

In enacting PHL Article 35-A on July 10, 1990, the Legislature established requirements for the regulation of non-medical ultraviolet radiation (tanning) devices to standardize protections for people using these devices in New York State. By enacting Chapter 194 of the Laws of 2018, the legislature furthered this objective for children by increasing the minimum age of people allowed to use tanning devices and eliminating the ability of a child to obtain parental consent to use the device. The proposed amendment furthers the legislative objective of protecting people using tanning devices by incorporating the legislation into regulation, improving warning messages about health risks associated with use of ultraviolet radiation devices and clarifying the health and safety standards for disease prevention already contained in the regulation.

Needs and Benefits:

Chapter 194 of the Laws of 2018 amended PHL Article 35-A prohibiting children under 18 years old from using tanning facilities and changing the definition of Tanning Facility to include all facilities, whether or not a fee is charged, directly or indirectly. The regulatory amendments pertaining to the minimum age of patrons and applicability of the regulation conform with PHL Article 35-A. Additionally, the amendments require a larger warning sign to accommodate the required notification and enhance the consistency and clarity of the regulations. Compliance with Subpart 72-1 of the SSC is essential to protect the public from risks related to indoor tanning facilities.

The revised rule modifies the minimum age that individuals are allowed to use commercial ultraviolet (UV) indoor tanning devices and modifies the amount of the registration fee and inspection fee in accordance with legislation. Public Health Law Article 35-A now prohibits the use of indoor tanning facilities by individuals less than 18 years of age and establishes a biennial registration fee of one hundred and twenty dollars and a biennial inspection fee of two hundred dollars. The laws previously prohibited children less than 17 years of age from using UV tanning devices, required those between 17 - 18 to obtain written parental consent, and had a biennial registration fee of thirty dollars and a biennial inspection fee of fifty dollars. The revised rulemaking to Subpart 72-1 also clarifies existing language to improve understanding and consistent implementation.

Costs to Regulated Parties:

The proposed amendments increase the biennial registration fee from thirty dollars to one hundred and twenty dollars and a biennial inspection fee from fifty to two hundred dollars per

ultraviolet radiation device. The proposed amendments will impose costs, in terms of lost revenue, for those tanning facility operators who allowed seventeen-year-old patrons to use their tanning devices with parental or guardian consent prior to the law change; however, not all tanning facilities allowed minors to tan prior to the PHL amendment, and the revenue loss for those that did is expected to be minimal. There could also be an expense to tanning facilities that will now be required to comply with the regulation due to the law amendment which now defines a tanning facility as an establishment with ultraviolet radiation devices for human beings whether or not a fee is charged; however, no such facilities are known to the State Health Department.

Cost to State and Local Government:

State and local governments will incur no additional costs for enforcement. The printing and distribution of the new regulation and the corresponding program inspection report, warning sign, tanning hazard information sheet, and acknowledgement form will be a minimal State Health Department expense. There will be additional costs for providing training and technical guidance to staff of local health departments that are authorized to be the Permit Issuing Official (PIO). No State or local governments are known to operate tanning facilities.

Paperwork:

The proposed amendments will impose minimal additional paperwork on tanning facility operators, including the maintenance of Tanning Facilities Statement of Acknowledgement forms.

Local Government Mandates:

The regulations will not impose any local government mandates. City and county health departments are not mandated to act as the PIO to enforce these regulations.

Duplication:

The proposed regulation does not duplicate any existing state or federal regulation.

Alternatives Considered:

The proposed regulation meets the requirements established by the PHL and effectuates the provisions of the article as intended. Consideration was given to not making clarifying amendments to the regulation; however, this was rejected because of the need to improve the clarity and consistency of the regulation.

Federal Standards:

There are federal standards governing the labeling and performance requirements of ultraviolet radiation devices specified in 21 CFR 1040.20. The proposed regulations do not conflict with or duplicate these requirements.

Compliance Schedule:

The proposed regulation will be effective upon publication of the Notice of Adoption in the *New York State Register*.

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Regulatory Flexibility Analysis for Small Business and Local Government

Effect of Rule:

There are approximately 644 tanning facilities in New York State, all of which will be affected by the proposed regulations. No tanning facilities are operated by local governments.

Compliance Requirements:

Chapter 194 of the Laws of 2018 amended PHL Article 35-A prohibiting children under 18 years old from using tanning facilities and changing the definition of Tanning Facility to include all facilities, whether or not a fee is charged, directly or indirectly. The regulatory amendments pertaining to the minimum age of patrons and applicability of the regulation conform with PHL Article 35-A. Additionally, the amendments require a larger warning sign to accommodate the required notification and enhance the consistency and clarity of the regulations.

Professional Services:

The proposed regulations do not impose any additional burden for professional services.

Compliance Costs:

The proposed amendments increase the biennial registration fee from thirty dollars to one hundred and twenty dollars and a biennial inspection fee from fifty to two hundred dollars per ultraviolet radiation device. The proposed amendments will impose costs, in terms of lost revenue, for those tanning facility operators who allowed seventeen-year-old patrons to use their

tanning devices with parental or guardian consent, prior to the law change; however, not all tanning facilities allowed minors to tan prior to the PHL amendment, and the revenue loss for those that did is expected to be minimal. There could also be an expense to tanning facilities that will now be required to comply with the regulation due to the law amendment which now defines a tanning facility as an establishment with ultra violet radiation devices for human beings whether or not a fee is charged; however, no such facilities are known to the State Health Department.

Economic and Technological Feasibility:

The proposal is technologically feasible because it requires the use of existing technology that facility operators already utilize to document the age of patrons.

Minimizing Adverse Economic Impact:

The proposed amendments pertaining the minimum age of patrons and application of tanning facilities are dictated by PHL; therefore, the aforementioned costs associated with lost revenue for those tanning facility operators who allowed seventeen year old patrons to use their tanning devices with parental or guardian consent are necessary to follow this mandate. The proposed amendments to improve the clarity and consistency of the regulation have no associated costs. The Department will provide the larger warning signs, required under the proposed regulations, at no cost to the operators of tanning facilities.

Small Business and Local Government Participation:

The amendments pertaining the minimum age of patrons and the definition of tanning facilities are dictated by PHL; therefore, outreach to these entities was not conducted.

The amendments to improve the clarity and consistency of the regulation is, in part, based on questions by the operators of tanning facilities, and on questions received from local health departments on regulatory interpretation. These amendments will improve consistency in interpretation and implementation of the regulation.

The proposed regulations are published in the State Register to provide Small Business and Local Government a review and comment period, which is an opportunity for comment and to participate in the regulatory process. No regulated facilities commented on the proposed regulations.

Rural Area Flexibility Analysis

Types and Estimated Number of Rural Areas:

There are approximately 644 regulated tanning facilities operating in New York State. Any of these facilities will be affected by the proposed rule. There are an estimated 249 tanning facilities operating in the 44 counties that have population less than 200,000. There are an additional 176 tanning facilities operating in the nine counties identified to have townships with a population density of 150 persons or less per square mile.

Reporting and Recordkeeping and Other Compliance Requirements:

Reporting and Recordkeeping:

The obligations imposed on Tanning Facilities in rural areas are no different from those imposed on facilities generally. Operators will be required to maintain complete Statement of Acknowledgement forms for each patron. Operators will be required to maintain records of each patron tanning visit, records of certain patron injuries and illnesses, records of annual timer tests for each timer, and records of equipment maintenance. Each record must be maintained for a minimum of two years.

Other Compliance Requirements:

Operators will be required to obtain a biennial Tanning Facility Permit from the Permit Issuing Official.

The revised rule modifies the minimum age that individuals are allowed to use commercial ultraviolet (UV) indoor tanning devices. Public Health Law Article 35-A now

prohibits the use of indoor tanning facilities by individuals less than 18 years of age. The laws previously prohibited children less than 17 years of age from using UV tanning devices and required those between 17 - 18 to obtain written parental consent. The revised rulemaking to Subpart 72-1 also clarifies existing language to improve understanding and consistent implementation.

Professional Services:

The proposed regulations do not impose any additional burden for professional services.

Cost to Regulated Parties:

The costs imposed on Tanning Facilities in rural areas are no different from those imposed on facilities in other locations. The proposed amendments increase the biennial registration fee from thirty dollars to one hundred and twenty dollars and a biennial inspection fee from fifty to two hundred dollars per ultraviolet radiation device. The proposed amendments will impose costs, in terms of lost revenue, for those tanning facility operators who allowed seventeen-year-old patrons to use their tanning devices with parental or guardian consent prior to the law change; however, not all tanning facilities allowed minors to tan prior to the PHL amendment, and the revenue loss for those that did is expected to be minimal. There could also be an expense to tanning facilities that will now be required to comply with the regulation due to the law amendment which now defines a tanning facility as an establishment with ultraviolet radiation devices for human beings whether or not a fee is charged; however, no such facilities are known to the State Health Department.

Economic and Technological Feasibility:

The proposal is technologically feasible because it requires the use of existing technology. The proposal is believed to be economically feasible because it imposed little or no cost to Tanning Facilities.

Minimizing Adverse Economic Impact on Rural Area:

No alternatives were considered for the minimum patron age and tanning facility definition as mandated by Public Health Law Article 35-A. The proposed regulation meets the requirements established by the PHL and effectuate the provisions of the article as intended.

Rural Area Participation:

The proposed amendments pertaining the minimum age of patrons and the definition of tanning facilities are dictated by PHL; therefore, outreach to rural areas was not conducted.

The proposed amendments to improve the clarity and consistency of the regulation is, in part, based on questions by the operators of tanning facilities, and on questions received from local health departments on regulatory interpretation. These amendments will improve consistency in interpretation and implementation of the regulation.

The proposed regulations are published in the State Register to provide the public a review and comment period, which is an opportunity for comment and to participate in the regulatory process. No regulated facilities commented on the proposed regulations.

Job Impact Statement

No Job Impact Statement is required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent from the nature of the proposed amendment that it will not have a substantial adverse impact on jobs and employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The Department of Health (Department) received one comment regarding the proposed amendments to Subpart 72-1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York.

The comment, from the New York State Society of Dermatology & Dermatologic Surgery (NYSSDDS), supports the proposed regulations. The Department acknowledges this support.