

Tanning Facilities

Effective Date: 10/7/09

Summary of Express Terms

The proposed Subpart contains the following provisions:

The term 'tanning facility' is defined and operators are required to obtain a biennial permit to operate from the permit issuing official (PIO) having jurisdiction in the county where the tanning facility is located. This may be the State, or the County or other specified local health officer when such officer requests to be authorized as a PIO. Inspection of facilities and enforcement of the Subpart by the PIO is established by this proposed regulation, as well as specifying operation standards for tanning facilities. The standards include age restrictions for use of ultraviolet radiation devices, requirements for patron identification, warning and consent requirements, operation and maintenance of physical facilities and equipment, use of protective eyewear during tanning and general operator responsibilities.

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, Chapter 2 of the Official Compilation of Codes, Rules and Regulations of the State of New York, is added to be effective upon filing with the Secretary of State, to read as follows:

The proposed Subpart contains the following provisions:

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GENERAL PROVISIONS

Section 72-1.1 Definitions.

(a) Adequate means sufficient to accomplish the purpose for which something is intended, and to such a degree that no reasonable risk to health or safety is presented. An item installed, maintained, designed and assembled, an activity conducted, or act performed, in accordance with generally accepted standards, principles or practices applicable to a particular trade, business, occupation or profession, is adequate within the meaning of this Subpart.

(b) Department means the New York State Department of Health.

(c) FDA means United States Food and Drug Administration.

(d) Permit issuing official (PIO) shall mean the State Commissioner of Health, or where authorization is requested and received from the State Commissioner of Health, the health commissioner or health officer of a city of 50,000 population or over, the health commissioner or health officer of a county or part-county health district, the State regional health director or district director having jurisdiction, or any county or public health director having all the powers and duties prescribed in Section 352 of the Public Health Law. The PIO may designate additional persons to act in his/her behalf to issue permits or perform inspections as required by this Subpart.

(e) Permit means a license issued to a tanning facility operator pursuant to these rules.

(f) Person means an individual, corporation, partnership, joint venture or any business entity.

(g) Protective eyewear means any adequate equipment designed to be worn by users of an ultraviolet radiation-emitting device to reduce exposure of the eyes to radiation emitted by the product.

(h) Qualified health care professional means a physician licensed by the State of New York to practice medicine, or a physician assistant or nurse practitioner licensed to practice in New York in collaboration with and under the supervision of a licensed physician.

(i) Sanitize means adequate antimicrobial treatment by a disinfectant determined to be capable of destroying pathogenic organisms on treated surfaces. Exposure to the ultraviolet radiation produced by the ultraviolet radiation device itself is not considered an adequate sanitizing agent.

(j) 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 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.

(k) Ultraviolet radiation device means any product which is designed to emit

electromagnetic radiation in the wavelength interval of two hundred (200) nanometers to four hundred (400) nanometers in air, and which is intended to induce tanning of the human skin through irradiation, including but not limited to, a sunlamp, tanning booth, or tanning bed.

72-1.2 Application.

The requirements of this Subpart shall apply to all tanning facilities except where ultraviolet radiation devices are used by a qualified health care professional for treatment of medical conditions.

72-1.3 Enforcement, public health hazards and other violations.

(a) Enforcement.

(1) Operation of a tanning facility without a permit is a violation of this Subpart. The PIO may order any tanning facility operating without a permit to close and remain closed until the facility obtains and displays a valid permit.

(2) Operators in violation of these regulations are subject to the enforcement provisions delineated in the Public Health Law. Where a public health hazard is found, the tanning facility or portion of the facility constituting the hazard shall be placarded to prohibit use until the hazard is corrected in order to protect the public health or safety of the patrons. When a placard is used, it shall be conspicuously posted at each entrance to the tanning facility or portion of the facility constituting the hazard. The placard shall state the authority for its placement and indicate that concealment, mutilation, alteration

or removal of it by any person without permission of the PIO shall constitute a violation of this Chapter and the Public Health Law.

(3) Within fifteen (15) days of placarding a facility or portion of the facility, the operator shall be provided with an opportunity to be heard and present proof that continued operation of the facility does not constitute a danger to the public health.

(4) The PIO or his/her designated representative may inspect the premises, within two (2) working days of notification that the hazard has been eliminated, to remove the placards after verifying the correction, or upon notification of correction, may provide verbal authorization for the operator to remove the placard and resume use.

(b) Public health hazards. Any of the following violations are public health hazards, which require the PIO or a designated representative to order immediate correction or to immediately institute action as provided in the law and/or in this Subpart:

(1) The condition of the wiring or electrical system components of tanning equipment is such that an imminent fire or shock hazard exists;

(2) An ultraviolet radiation device does not have an adequate label;

(3) Failure to operate an ultraviolet radiation device in accordance with the label;

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

(5) Failure to ensure that patrons possess adequate protective eyewear;

(6) Failure to provide adequate protective eyewear at no additional charge to patrons not possessing their own adequate protective eyewear;

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

(8) Failure to provide timer lockout or remote timer controls; or

(9) Any other condition determined by the PIO to be an imminent risk to the public's health and safety.

(c) Other violations.

Failure to comply with other sections of this Subpart or other parts of this title may be subject to a penalty.

72-1.4 Permits and fees.

(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 registration fee per biennial registration period and an inspection fee as specified in section 72-1.5(b) of this Subpart.

(b) A permit issued pursuant to these rules shall be issued to a specific applicant for a specified location and shall be effective for no more than two (2) years from the date of issuance.

(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 per month or each portion of a month thereof.

(d) The PIO may stagger biennial registration periods among tanning facilities as needed to effectively administer permits within their jurisdiction. The PIO may choose to stagger periods by date of application, by size of regulated facility, by geographic location, or by some other classification or grouping determined by the PIO.

(e) When registration periods are staggered, the first registration period shall be January 1 through June 30 and the second period shall be July 1 through December 31, or some other scheme may be used as determined by the PIO to effectively administer permits within their jurisdiction.

(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.

(g) Each permit shall include but not be limited to the following: one facility name, one facility location, name of owner/operator, registration period and name of PIO.

(h) A permit is not transferable from one person to another or from one establishment location to another.

(i) The permit shall be conspicuously posted within the tanning facility.

72-1.5 Inspection and inspection fees.

(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.

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

72-1.6 Variances and waivers.

(a) Variance. In order to allow time to comply with certain provisions of this Subpart, an operator may submit a written request to the PIO for a variance from a specific provision(s) when the health and safety of the public will not be prejudiced by the variance, and where there are substantial practical difficulties or substantial fiscal hardships in immediate compliance with the provision(s). An operator must meet all terms of an approved variance including the effective date, the time period for which the variance is granted, the requirements being varied and any special conditions the PIO specifies.

(b) Waivers. In order to obtain a waiver allowing alternative arrangements that do not meet the provisions of this Subpart but do protect the health and safety of the public, an operator may submit a written request to the PIO for a waiver from a specific provision(s) of this Subpart. Such requests must demonstrate that the alternate arrangements provide adequate protection of the health and safety of the public. The PIO shall obtain and be guided by the recommendation of the Department prior to granting or denying a waiver. An operator must meet all terms of an approved waiver. A waiver will remain in effect indefinitely unless revoked by the PIO or the facility changes operators.

72-1.7 Injury and illness reporting and record keeping requirements.

(a) A full report of specific injuries or illnesses occurring as a result of using an ultraviolet radiation device shall be made by the operator to the PIO within twenty-four (24) hours of notification of its occurrence. Reportable injuries and illnesses shall include:

- (1) all eye injuries requiring medical attention;
- (2) all burns requiring medical attention;
- (3) any other injury or illness incident resulting from the use of an ultraviolet radiation device for which medical care has been obtained.

(b) Details of any reportable injury or illness shall be entered on a form prescribed by the Department. Forms shall be maintained at the tanning facility for a minimum of two (2) years and must be available for review by the PIO.

FACILITY OPERATIONS

72-1.8 Patron identification, acknowledgements and consent requirements.

(a) Age verification

(1) The operator shall require each patron to provide a driver's license or other photo identification issued by a government entity or educational institution indicating that the patron is at least eighteen (18) years of age.

(2) No person under fourteen (14) years of age shall be permitted to use an ultraviolet radiation device. Persons fourteen (14) 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 information 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 specified in Section 72-1.9(a)(2) of these rules.

(c) Statement of acknowledgement

(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 and

informational pamphlet has been read and understood prior to using any ultraviolet radiation device, and that the patron agrees to wear adequate protective eyewear.

(2) No person shall undergo ultraviolet radiation exposure without such a signed statement on file.

(3) The operator or a designated employee shall also sign and date the statement.

(d) Consent form

The operator shall not permit persons fourteen (14) years of age to eighteen (18) years of age to use ultraviolet radiation devices until such persons provide the tanning facility operator or an employee responsible for the operation of the ultraviolet radiation device of such facility (per § 3555(2) of PHL) with the written consent form, prescribed by the Commissioner, indicating the following conditions have been met:

(1) Prior to the initial ultraviolet radiation exposure, the parent or legal guardian shall sign and date the consent form in the presence of the operator or an employee responsible for the operation of the ultraviolet radiation device of such facility (per § 3555(2) of PHL).

(2) By signing the consent form, the parent or legal guardian and persons fourteen (14) years of age to eighteen (18) years of age acknowledges that they have read the warnings required in Section 72-1.9(a) of these rules and have received the information specified in Section 72-1.8(b) of these rules.

(3) By signing the consent form, the parent or legal guardian acknowledges that the person(s) fourteen (14) years of age to eighteen (18) years of age has agreed to wear protective eyewear.

(4) The operator or a designated employee shall also sign and date the form.

(5) The written consent form signed by a parent or legal guardian shall expire twelve (12) months from the date it was signed.

72-1.9 Physical facilities and equipment.

Each tanning facility shall be constructed, operated and maintained to meet the following minimum requirements:

(a) Required warning signs

(1) Warning signs 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 inches by 11 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 warnings.

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 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 $\pm 10\%$ 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.

(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 shall be free of electrical hazards.

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

(9) 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) 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) 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 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 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;

(5) 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.

(6) 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 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.

72-1.10 Protective eyewear.

(a) The operator shall assure that each patron using an ultraviolet radiation device possesses adequate protective eyewear.

(b) Adequate protective eyewear shall be provided at no additional charge to patrons not possessing their own protective eyewear.

(c) The operator shall have available for patron use an adequate number of sets of protective eyewear.

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

72-1.11 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.

(b) The operator must 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.

(c) The operator must keep and maintain an equipment maintenance log as detailed in section 72-1.9 (c)(11) of this Subpart.

(d) The operator must 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.

Regulatory Impact Statement Summary

Statutory Authority:

The Commissioner is authorized by Public Health Law (PHL) Article 35-A Sections 3551 and 3554 to promulgate rules and regulations necessary to effectuate the provisions of the Article.

Needs and Benefits:

In July 1990, Article 35-A of the Public Health Law (PHL) was enacted giving the Department of Health the authority and responsibility to license and inspect ultraviolet radiation devices in tanning facilities, effective July 1991. The legislation established a program that includes biennial licensure and inspection of all commercial non-medical tanning operations. The purpose of this program is to license and inspect commercial tanning facilities with the intent of increasing consumer knowledge of the hazards of ultraviolet tanning and minimizing user injuries.

On August 14, 2006, Chapter 573 of Laws of 2006 amended Article 35-A to prohibit children under 14 years old from using tanning facilities and requiring that children between the ages of 14 and 18 have a parent or legal guardian sign a consent form before the child can use the tanning equipment. Adults must sign a similar statement indicating that they have read the Department's warning materials. The amendments to Article 35-A became effective November 14, 2006. The enacting legislation authorized the Commissioner to promulgate regulations to implement the amendments to the law.

Regulated Parties:

There are approximately 1,800 tanning facilities in New York State. Five counties in New York State have established or are in the process of establishing local regulations which provide performance standards and enable them to permit and inspect tanning facilities. The remaining counties and New York City have not enacted local regulations or established programs to regulate and permit tanning facilities as required by PHL Article 35-A.

Costs to Regulated Parties:

The proposed regulation creates no significant cost to tanning facility operators aside from biennial license and inspection fees established within Article 35-A. Minimal expenses may also be incurred by operators who currently do not provide protective eyewear “free of charge” as required by PHL Article 35-A. In these cases, operators will likely provide inexpensive single use disposable eyewear, which most operators currently sell to patrons for about \$1.00 per set of eyewear. This disposable eyewear is readily available through wholesale, retail and internet sales and can be purchased for less than \$0.20 per pair.

Some operators may have equipment that requires retrofitting to achieve compliance with the requirements within this regulation for ultraviolet device timer access controls. Research indicates that even the most expensive remote timer systems

would cost less than \$300 per unit to retrofit ultraviolet radiation devices to meet the requirements of this regulation. A less costly option exists, adding a patron lockout to the existing device timer. Estimates obtained indicate that this option would cost less than \$50 per device to achieve compliance with the regulation for those operators whose equipment does not already meet the requirement.

Government:

The printing and distribution of the new regulation and the corresponding program inspection report, warning sign, information sheet, consent and acknowledgement forms will be a minimal State Health Department expense. There will be additional costs for staff time and travel expenses to train and to provide technical guidance to voluntary local health department (LHD) staff. Costs will be offset by additional revenue generated from permit and inspection fees. It is expected that PIOs will use existing staff to manage the workload because of the relatively low number of tanning facilities in any particular jurisdiction. Reimbursement to PIOs will be at the current State Aid rate of 36% for public health programs.

Alternatives Considered:

No alternatives were considered as compliance is mandated by Public Health Law. The proposed regulation meets the requirements established by PHL Article 35-A and would effectuate the provisions of the article as intended.

Compliance Schedule:

The proposed regulation will be effective upon publication of a notice of adoption in the *State Register*.

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Regulatory Impact Statement

Statutory Authority:

Article 35-A of Public Health Law (PHL) defines requirements for the regulation of ultraviolet radiation devices. The Commissioner is authorized by Sections 3551 and 3554 of PHL Article 35-A to promulgate rules and regulations necessary to effectuate the provisions of the Article. These provisions authorize the regulation of tanning devices within non-medical tanning facilities.

Legislative Objectives:

In enacting Article 35-A in 1990 and subsequent amendments in 2006, the legislative objective was to protect public health and safety. Establishing regulations for tanning facilities will assure safer facility operation, prevent user injuries and increase consumer knowledge of the health risks of ultraviolet radiation devices, and thus these regulations would further the legislative objective.

Needs and Benefits:

In recent years an association has been made between ultraviolet (UV) tanning device use and a significantly elevated risk of developing skin cancer. While exposure to the sun's UV rays appears to be the most important environmental factor involved in the development of skin cancer, exposure to UV rays from artificial sources of light, such as tanning beds and sunlamps, is as dangerous as exposure to rays from the sun. Furthermore, damage from tanning beds and sunlamps is additive upon the damage incurred from natural sunlight.

In the 10th Report on Carcinogens by the National Institutes of Health (NIH), it is stated: “Exposure to sunbeds and sunlamps is known to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in humans, which indicates a causal relationship between exposure to sunbeds and sunlamps and cancer.”

The three primary types of skin cancer are Basal Cell Carcinoma, Squamous Cell Carcinoma and Melanoma. Indoor tanners are at an increased risk for developing any of these three types. Malignant melanoma is the deadliest of the skin cancers, and its incidence rate in the United States has increased rapidly in the past two decades, particularly among young women. Melanoma accounts for approximately three fourths of all skin cancer deaths.

Although death rates from basal cell and squamous cell carcinomas are relatively low compared to melanoma, these cancers can cause considerable damage and disfigurement if they are untreated. The American Cancer Society estimated that during 2005, about one million new cases of basal cell or squamous cell carcinoma and about 59,580 new cases of malignant melanoma were diagnosed. It is also expected that skin cancer will claim the lives of approximately 10,590 Americans each year.

In addition to skin cancer, there are other significant health risks associated with indoor tanning. The Centers for Disease Control and Prevention (CDC) reports an estimated 700 emergency department visits per year secondary to adverse reactions from UV ray exposure in tanning salons. Indoor tanning also increases risks for photoallergic

skin reactions, serious eye damage including cataract formation, reduced immunity, blood vessel damage, skin infections and other skin pathologies.

Indoor tanning may cause persons with certain medical conditions or those who are taking certain drugs to experience photosensitivity, a physical reaction that occurs when the medical condition or drugs cause a reaction with ultraviolet radiation, making the skin much more sensitive to ultraviolet radiation and thus more likely to burn.

The American Academy of Dermatology (AAD) takes the position that damage caused to skin by exposure to radiation in early years is particularly harmful. The AAD is especially concerned about the use of tanning equipment by children and teens who may not be equipped to make an informed decision about possible risks. Along these same lines, the World Health Organization (WHO) has declared that worldwide, no person under 18 years of age should use a sunbed.

There are currently no regulations in place requiring tanning facility operators to sanitize equipment, including protective eyewear, prior to use or between patrons. Protective eyewear is designed to fit snugly and must be adequately sanitized after each use to prevent the transmission of bacterial eye infections like “pinkeye.” In order to maximize tanning, patrons wear little or no clothing while enclosed in the tanning device, providing direct, total body contact on the surfaces of the tanning bed. Lack of sanitizing or inadequate sanitization of tanning devices after each use facilitates the transmission of infectious skin diseases (fungal, bacterial, or viral) between patrons.

The proposed regulations will provide benefits to the public health by requiring operators to provide patrons with factual information from the Department regarding the hazards of using ultraviolet radiation devices. Patrons will be required to acknowledge by their signature that they have read and understood these warnings. The use of tanning equipment by children will be regulated or prohibited depending on their age. Operators will be required to operate tanning facilities in a sanitary manner and to operate equipment according to manufacturer's specifications.

In July 1990, Article 35-A of the Public Health Law (PHL) was enacted giving the Department of Health the authority and responsibility to license and inspect ultraviolet radiation devices in tanning facilities, effective July 1991. The legislation established a program that includes biennial licensure and inspection of all commercial non-medical tanning operations. The purpose of this program is to license and inspect commercial tanning facilities with the intent of increasing consumer knowledge of the hazards of ultraviolet tanning and minimizing user injuries.

On August 14, 2006, Chapter 573 of Laws of 2006 amended Article 35-A to prohibit children under 14 years of age from using tanning facilities and requiring that children from the ages of 14 to 18 have a parent or legal guardian sign a consent form before the child can use the tanning equipment. Adult tanning patrons must sign a similar statement indicating that they have read the Department's warning materials. The enacting legislation authorized the Commissioner to promulgate regulations to implement the amendments to the law. The amendments became effective November 14, 2006.

The proposed regulation contains the following requirements:

General Requirements:

Tanning facility operators must obtain a biennial permit to operate from the permit issuing official (PIO) having jurisdiction. Tanning facilities may be inspected by the PIO prior to the initial issuance of the permit, and all facilities will be inspected at least once in each biennial period. Operators will be required to pay permit and inspection fees.

Injuries and illnesses that occur as a result of using a tanning device and which require medical attention shall be reported to the PIO by the operator within 24 hours of occurrence. A list of reportable injuries and illnesses is included in the proposed regulations. Operators will be required to document these events on a Department-prescribed form to be kept on premises.

Tanning beds and booths shall be adequately sanitized after each use. Any reusable eyewear loaned to the patron by the operator in lieu of providing free eyewear must also be adequately sanitized.

Patron Identification and Acknowledgements:

Patrons of tanning facilities will be required to present a driver's license or other photo-bearing identification issued by a government entity or educational institution to document that they are at least 18 years of age. Further, operators will be required to provide patrons with specified warnings and the Department's information sheet.

Operators will obtain a signed statement from each patron indicating that they have read the information, and also that they agree to wear protective eyewear while tanning.

Access by Minors:

Children from the ages of fourteen to eighteen years must provide written consent in person from a parent or legal guardian allowing the child to use the tanning facility, and acknowledging that the parent or guardian has read the required warnings and information, and that their child agrees to wear protective eyewear. Children under fourteen years of age are prohibited from using tanning devices, regardless of parental consent or any prior use of the device.

Required Warnings:

The proposed regulations require posting of warning signs within a specified proximity of each tanning device. The required language and specifications for type characteristics and size are stated in detail. The warnings inform patrons of the risks of ultraviolet radiation overexposure, of the need to wear protective eyewear and that certain medications may cause increased sensitivity to ultraviolet radiation. The required warnings are essentially identical to those required by the United States Food and Drug Administration (FDA) for labels on ultraviolet radiation devices.

Protective Eyewear:

The proposed regulations require tanning facility operators to assure that patrons possess a pair of adequate protective eyewear. (“Adequate” is defined within the proposed regulations.) Further, if a patron does not possess their own eyewear, operators

must provide such eyewear to the patron at no additional charge. Operators electing to provide reusable eyewear must ensure that it is adequately sanitized prior to use.

Equipment:

Operators will be required to use only equipment that is labeled in accordance with FDA standards. Equipment must be free from electrical hazards. Specifications for ultraviolet radiation device timers are stated in the proposed regulations. Operators must perform annual testing on all timers to ensure that requirements for accuracy are met. Ultraviolet lamps must be replaced with the appropriate type intended for use in the ultraviolet radiation device as specified by the manufacturer. Operators must document all equipment maintenance.

Costs:

Costs to Regulated Parties:

The proposed regulation creates no significant cost to most tanning facility operators aside from biennial license and inspection fees established within Article 35-A. A facility permit fee of \$30 and an inspection fee of \$50 per ultraviolet radiation device will be assessed biennially.

Some operators may have equipment that requires retrofitting to achieve compliance with the requirements within this regulation for ultraviolet device timer access controls. Research indicates that even the most expensive remote timer systems

would cost less than \$300 per unit to retrofit ultraviolet radiation devices with a remote access system to meet the requirements of this regulation. Costs depend largely on prevailing rates charged by electrical contractors. A less costly option exists, adding a patron lockout to the existing device timer. Estimates obtained indicate that this option would cost less than \$50 per device to achieve compliance with the regulation for those operators whose equipment does not already meet the requirement.

Minimal additional expenses may also be incurred by operators who are not currently providing protective eyewear “free of charge” as required by PHL Article 35-A. In these cases, operators will likely provide inexpensive single use disposable eyewear, which most operators currently sell to patrons for about \$1.00 per set of eyewear. This disposable eyewear is readily available through wholesale, retail and internet sales and can be purchased for less than \$0.20 per pair.

Operators may incur a minimal expense to obtain and post warning signs as required by the proposed regulations.

Costs to State Government:

The printing and distribution of the new regulation and the corresponding program inspection report, warning sign, information sheet, consent and acknowledgement forms will be a minimal State Health Department expense. There will be additional costs for staff time and travel expenses to train and to provide technical

guidance to voluntary local health department (LHD) staff. Some costs will be offset by additional revenue generated from permit and inspection fees.

Costs to Local Government:

There will be no cost to city and county health departments unless they choose to be authorized by the State Commissioner of Health to enforce the proposed regulation. If they choose to enforce the regulation, revenues generated from permit and inspection fees may be used to offset costs. PIOs are expected to utilize existing staff to for the workload because of the low number of tanning facilities in each jurisdiction. Reimbursement to PIOs will be at the current State Aid rate of 36% for public health programs.

Paperwork:

Tanning facility operators must obtain a biennial permit. The PIO will provide application forms to operators.

Operators must maintain records of each patron’s tanning visits, recording the date, duration of tanning, and device used in every tanning session. They will be required to maintain records of certain patron injuries and illnesses, and to keep these forms for a minimum of two years. Operators must maintain records of signed patron warning acknowledgments and consent forms for minors. They shall also be required to keep entries in equipment maintenance logs for a period of two years, and to keep records on required annual testing of ultraviolet radiation device timers.

Local Government Mandates:

The regulations will not impose any local government mandates. City and county health departments that wish to act as the PIO to enforce these regulations could request authorization from the State Commissioner of Health.

Duplication:

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

Alternatives Considered:

No alternatives were considered as compliance is mandated by Public Health Law. The proposed regulation meets the requirements established by PHL Article 35-A and would effectuate the provisions of the article as intended.

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 *State Register*.

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Regulatory Flexibility Analysis for Small Business and Local Government

Effect on Small Business and Local Government:

There are approximately 1,800 tanning facilities in New York State, most of which are not currently under regulation. It is believed that most of these tanning facilities may be considered small businesses.

Compliance Requirements:

Reporting and Recordkeeping:

Tanning facility operators will be required to report certain patron injuries and illnesses within 24 hours of occurrence, and to maintain written records of such events for a period of two years. Operators must document the age of patrons and obtain a signed acknowledgement form from every adult patron. Operators must obtain parental consent forms for every minor patron from the ages of 14 to 18 years. These forms expire 12 months from the date of signing. Operators will also be required to test the accuracy of tanning device timers annually, and keep records of this activity. They shall also be required to keep equipment maintenance logs and to keep entries in these logs for a period of two years.

Other affirmative acts:

Tanning facility operators are required to obtain a biennial permit to operate from the permit issuing official (PIO) having jurisdiction in the county that the facility is located. Operators must check the identification of every prospective patron, ensuring that it meets the criteria set forth in PHL 35-A. Operators must also ensure that every

patron has in their possession a set of adequate protective eyewear for use with ultraviolet radiation devices. For patrons without such eyewear, the operator must provide a set at no additional charge to the patron. Operators must also ensure that all ultraviolet radiation devices are adequately labeled, operated and maintained.

Compliance Costs:

The proposed regulation creates no significant cost to most tanning facility operators aside from biennial license and inspection fees established within Article 35-A. A facility permit fee of \$30 and an inspection fee of \$50 per ultraviolet radiation device will be assessed biennially.

Some operators may have equipment that requires retrofitting to achieve compliance with the requirements within this regulation for ultraviolet device timer access controls. Research indicates that even the most expensive remote timer systems would cost less than \$300 per unit to retrofit ultraviolet radiation devices with a remote access system to meet the requirements of this regulation. Costs depend largely on prevailing rates charged by electrical contractors. A less costly option exists, adding a patron lockout to the existing device timer. Estimates obtained indicate that this option would cost less than \$50 per device to achieve compliance with the regulation for those operators whose equipment does not already meet the requirement.

Minimal additional expenses may also be incurred by operators who are not currently providing protective eyewear “free of charge” as required by PHL Article 35-A. In these cases, operators will likely provide inexpensive single use disposable eyewear,

which most operators currently sell to patrons for about \$1.00 per set of eyewear. This disposable eyewear is readily available through wholesale, retail and internet sales and can be purchased for less than \$0.20 per pair.

Operators may incur a minimal expense to obtain and post warning signs as required by the proposed regulations.

Professional Services:

These regulations do not impose any additional burden for professional services.

Economic and Technological Feasibility:

The proposal is technologically feasible because it requires the use of existing technology. The overall economic impact to comply with the requirements of this regulation is expected to be minimal.

Minimizing Adverse Economic Impact:

The proposed regulation establishes standards for operating ultraviolet radiation devices within tanning facilities in such a way as to minimize risk to the public health. Should this regulation have a substantial adverse impact on a particular facility, a waiver of one or more requirements other than those required by Article 35-A of Public Health Law will be considered, so long as alternative arrangements protect public health and safety.

Alternatively, a variance, allowing additional time to comply with one or more requirements, can be granted if the health and safety of the public is not prejudiced by the variance.

Small Business Participation:

During the development of this regulation, Department staff met with representatives of the Indoor Tanning Association, which represents approximately 23 NYS tanning operators, and several small business owners on several occasions and also had numerous telephone conversations to develop a better understanding of tanning facility operations. This information obtained during these outreach activities was incorporated into the proposed regulation. Furthermore, Department staff were invited to observe several small tanning business operations in person, and knowledge gleaned during these on-site observations was critical in the development of the proposed regulations. Small business participation included six operators in Saratoga County and two in Dutchess County.

Rural Area Flexibility Analysis

Types and Estimated Number of Rural Areas:

There are approximately 1800 tanning facilities in New York State.

Approximately forty percent are located in rural areas throughout the state, as determined by a survey of all local health departments in November 2006.

Reporting and Record Keeping and Other Compliance Requirements:

Reporting and Recordkeeping:

Tanning facility operators will be required to report certain patron injuries and illnesses within 24 hours of occurrence, and to maintain written records of such events for a period of two years. Operators must document the age of patrons and obtain a signed acknowledgement form from every adult patron. Operators must obtain parental consent forms for every minor patron from the ages of 14 to 18 years. These forms expire 12 months from the date of signing. Operators will also be required to test the accuracy of tanning device timers annually, and keep records of this activity. They shall also be required to keep equipment maintenance logs and to keep entries in these logs for a period of two years.

Other affirmative acts:

Tanning facility operators are required to obtain a biennial permit to operate from the permit issuing official (PIO) having jurisdiction in the county that the facility is located. Operators must check the identification of every prospective patron, ensuring that it meets the criteria set forth in PHL 35-A. Operators must also ensure that every

patron has in their possession a set of protective eyewear that meets United States Food and Drug Administration standards for use with ultraviolet radiation devices. For patrons without such eyewear, the operator must provide a set at no additional charge to the patron. Operators must also ensure that all ultraviolet radiation devices are adequately labeled, operated and maintained.

Compliance Costs:

The proposed regulation creates no significant cost to most tanning facility operators aside from biennial license and inspection fees established within Article 35-A. A facility permit fee of \$30 and an inspection fee of \$50 per ultraviolet radiation device will be assessed biennially.

Some operators may have equipment that requires retrofitting to achieve compliance with the requirements within this regulation for ultraviolet device timer access controls. Research indicates that even the most expensive remote timer systems would cost less than \$300 per unit to retrofit ultraviolet radiation devices with a remote access system to meet the requirements of this regulation. Costs depend largely on prevailing rates charged by electrical contractors. A less costly option exists, adding a patron lockout to the existing device timer. Estimates obtained indicate that this option would cost less than \$50 per device to achieve compliance with the regulation for those operators whose equipment does not already meet the requirement.

Minimal additional expenses may also be incurred by operators who are not currently providing protective eyewear “free of charge” as required by PHL Article 35-A.

In these cases, operators will likely provide inexpensive single use disposable eyewear, which most operators currently sell to patrons for about \$1.00 per set of eyewear. This disposable eyewear is readily available through wholesale, retail and internet sales and can be purchased for less than \$0.20 per pair.

Operators may incur a minimal expense to obtain and post warning signs as required by the proposed regulations.

Professional Services:

These regulations do not impose any additional burden for professional services.

Minimizing Adverse Economic Impact on Rural Areas:

The proposed regulation establishes standards for tanning facilities to minimize risk to the public health. Should this regulation have a substantial adverse impact on a particular facility, a waiver of one or more requirements other than those required by Article 35-A of Public Health Law will be considered, so long as alternative arrangements protect public health and safety. Alternatively, a variance, allowing additional time to comply with one or more requirements, can be granted if the health and safety of the public is not prejudiced by the variance.

Rural Area Participation:

During the development of this regulation, the Department met with industry representatives on several occasions and had numerous telephone conversations to develop a better understanding of tanning facility operation and incorporated the information obtained during these outreach activities into the proposed regulation.

Furthermore, Department staff were invited to observe several small tanning business operations in person. Some of these facilities were in rural areas. Knowledge gleaned during these on-site observations was critical in the development of 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.