

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 229. Food and Drug
Subchapter T. Licensure of Tanning Facilities
Amendments §§229.341 - 229.357

Adoption Preamble

The Executive Commissioner of the Health and Human Services Commission (commission), on behalf of the Department of State Health Services (department) adopts amendments to §§229.341 - 229.357, concerning the licensure of tanning facilities without changes to the proposed text as published in the June 25, 2010, issue of the *Texas Register* (35 TexReg 5470) and, therefore, the sections will not be republished.

BACKGROUND AND PURPOSE

The Health and Safety Code, Chapter 145, was amended by House Bill (HB) 1310, 81st Legislature, Regular Session, 2009, to prohibit a minor younger than 16.5 years of age from using a tanning device and a person younger than 18 years of age from using a tanning device unless the person's parent or legal guardian, in person at the facility, consents in writing for the person to use the device. The amendments to §229.353 and §229.354 are necessary to implement legislative changes to the Health and Safety Code, Chapter 145, the Tanning Facility Regulation Act.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 229.341 - 229.357 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed. As a result of the four-year review of the rules, §§229.341 - 229.357 have been revised to update and clarify the requirements for operating tanning facilities.

SECTION-BY-SECTION SUMMARY

Amendments to §§229.341 - 229.347, 229.353, 229.354, and 229.357 add references to "this subchapter" and deletes "these sections" in order to clarify the rules.

An amendment to §229.341 adds the language "including the terms and conditions under which tanning devices at such facilities may be operated, pursuant to applicable" is added and the language "using ultraviolet lamps as required by applicable" is deleted in order to update the purpose of the subchapter.

Amendments to §229.341 and §229.342 add the term "rules" to supplement the reference to applicable state and federal laws and regulations, in order to clarify the applicability of state and federal rules to the regulation of tanning facilities that use tanning devices.

An amendment to §229.342(a) adds the language "governs and applies to the rules in this subchapter" and deletes the language "requires rules to regulate tanning facilities" in order to accurately describe the authority of the Tanning Facility Regulation Act with respect to the rules under the subchapter.

New §229.342(b) is added to reflect that the Executive Commissioner of the Health and Human Services Commission may adopt rules necessary to implement the Tanning Facility Regulation Act. Subsequent subsections (b) - (f) are relettered to reflect the addition of new §229.342(b).

An amendment to §229.343(1) deletes the language "Texas Civil Statutes, Article 8910 (House Bill 2352, 71st Legislature, 1989" in order to update the reference to Health and Safety Code, Chapter 145.

An amendment to §229.343(2), (10) and (17) adds "department" and deletes the word "board" to update the reference to rules used to interpret the meaning of the term "adulterated" in the Texas Food, Drug and Cosmetic Act.

An amendment to §229.343(4) adds language to clarify the definition of "change of ownership" to include the transfer of all or part of the ownership in a tanning facility held by one person to another person.

An amendment to §229.343(5) revises the name of the department and deletes the language "or his successor" in order to update the definition of "commissioner."

Section 229.343(6) is deleted in its entirety, since the definition of "date of issuance" is no longer necessary when used in the context of the current licensing procedures for tanning facility licenses. Subsequent definitions in this section are renumbered as a result of this deletion.

An amendment to §229.343(8) replaces the title "Sunburning and Tanning History" in Figure: 25 TAC §229.343(8) with "Reaction to Sun Exposure" to the Figure in order to clarify the language in the Fitzpatrick scale as it relates to the skin's reaction to sun exposure.

An amendment to §229.344(a) deletes the term "devices" with respect to the exemption for phototherapy devices and the term "device" is added in order to accurately reflect that this subchapter does not apply to a phototherapy device used by or under the supervision of a licensed physician who is trained to use such a device.

An amendment to §229.345(c) adds the term "for" and "of" is deleted in order to clarify the need for a license prior to beginning operation.

An amendment to §229.345(d) deletes the reference to a one-year license in order to conform the subsection to the requirements for a two-year license in Health and Safety Code, §12.0112.

An amendment to §229.345(g) adds the word "a" prior to the term "license application" in order to reflect a minor grammatical correction.

New §229.345(h) is added to clarify the procedures for requesting a replacement license when a license is lost, stolen or destroyed. In addition, new §229.345(h) establishes the conditions under which the department will issue a replacement license. Subsequent paragraphs of this section are relettered as a result of this new subsection.

An amendment to §229.345(i) adds references to subsections (c), (g), (h), (k), and (l) and deletes existing references in order to reflect that applications required in those subsections must be completed on forms provided by the department and shall contain all the information required by such forms and any accompanying instructions.

An amendment to §229.345(j) adds the term "initial" to the reference to an application for a license to clarify that this information is required for all initial applications for a tanning facility license.

An amendment to §229.345(k) adds a reference to subsection (i) and deletes the reference to subsection (h) in order to reflect the relettering of the subsections due to the addition of new subsection (h) to the section.

An amendment to §229.346(a) deletes the reference in subsection (a)(1) to the one-year license fee order to conform the subsection to the amendments proposed in §229.345(d) and to conform the requirements in §229.346(a) to those required for a two-year license in Health and Safety Code, §12.0112. The paragraph is renumbered as a result of this deletion.

New §229.346(a)(2) is added to reflect the department's current fee of \$440 associated with a license that is amended due to a change in ownership.

New §229.346(a)(3) is added to reflect the department's current fee of \$220 for a license that is amended due to minor changes.

New §229.346(a)(4) is added to reflect the department's current fee of \$100 for a replacement license and to conform the language in this subsection to the requirement for replacement licenses in new §229.345(h) of the section.

An amendment to §229.346(b) deletes subsection (b)(2), relating to delinquency fees, as the requirement is no longer representative of the current procedures for assessing fees associated with licenses amended due to a change in location, name or ownership of a tanning facility. The paragraph is restructured and numbering is eliminated as a result of this deletion.

An amendment to §229.346(c) add references to "texas.gov" and delete references to "Texas Online" in order to reflect the new name and Internet site for the online licensing authority. In addition, "and pay the required fees" is added to reflect that fees must be submitted with an online application.

An amendment to §229.347(b) deletes the reference to §229.345(m) and adds a reference to §229.345(n) due to the relettering of the subsections required by the addition of new §229.345(h).

An amendment to §229.347(e) deletes the reference to §229.345(k) and adds a reference to §229.345(l) due to the relettering of the subsections required by the addition of new §229.345(h).

An amendment to §229.347(f) deletes the reference to §229.345(i) and adds a reference to §229.345(j) due to the relettering of the subsections required by the addition of new §229.345(h).

An amendment to §229.348 adds the term "working" to clarify references in the section to the number of days required for licensees to notify the department of certain changes which would render the information containing in the initial license application no longer accurate.

An amendment to §229.349(c) deletes the reference to §229.345(m) and adds a reference to §229.345(n) due to the relettering of the subsections required by the addition of new §229.345(h).

An amendment to §229.350 adds the term "facility" and deletes the term "establishment" to clarify the location of warning signs posted in the entry area of the tanning facility. Also, the word "by" is replaced with the word "to" for better clarity.

An amendment to §229.351(b) adds the language "for the device" in conjunction with references to the manufacturer's maximum recommended exposure time in order to clarify requirements for timers used on a tanning device.

Amendments to §§229.351 - 229.354, and 229.356 adds "customer" and deletes "consumer" to more accurately reflect the use of the term in the Tanning Facility Regulation Act.

An amendment to §229.352(a) adds the language "agree to" and "at all times while using the device" with reference to the use of protective eyewear in order to conform the section to the requirements for protective eyewear in HB 1310. Furthermore, the language "that meets the requirements of the United States Food and Drug Administration" is deleted in order that it be added to §229.352(d) for clarification purposes.

An amendment to §229.352(d) adds the language "the United States Food and Drug Administration, including the requirements" to clarify the protective eyewear standards that are required by FDA and federal regulations.

An amendment to §229.353(c) adds the terms "instruct" and "assist" in order to conform the requirements for operators assisting customers with the use of a tanning device for the first time to the language in the Tanning Facility Regulation Act.

An amendment to §229.353(c)(2) adds the language "at all times" in reference to the use of protective eyewear in order to conform the section to the requirements for protective eyewear in HB 1310, 81st Legislative Session, 2009.

New §229.353(f) is added to prohibit an operator from allowing a person under 16.5 years of age from using a tanning device.

New §229.353(g) is added to prohibit an operator from allowing a person at least 16.5 years of age and younger than 18 years of age to use a tanning device for the first time unless a written consent that meets the requirements of the department to use the device is obtained from the person's parent or legal guardian, in person at the facility.

New §229.353(h) is added to prohibit an operator from allowing a person younger than 18 years of age to use a tanning device for the first time unless the person has displayed a driver's license or other form of identification containing the person's photograph and indicating that the person is 16.5 years of age or older.

An amendment to §229.354(b)(2) adds the language "younger than 18" and deletes "16 or 17" to reflect the age requirements for written informed consent for minors who use tanning devices in order to implement changes required by HB 1310. In addition, the language "person and the" is added to clarify that both the person and the person's parent or legal guardian are required under HB 1310 to sign a written informed consent statement. The language "The informed consent statement shall state" is added to restructure the subsection for easier comprehension. Furthermore, the language "advisory statement issued by the Texas Medical Board, and available online at <http://www.dshs.state.tx.us/dmd>, warning of the dangers of indoor and outdoor tanning and its association with skin cancer, eye damage, and other health risks, provided" is added in order to clarify the requirement in HB 1310 for the person and parent or legal guardian to read and understand the advisory statement. Finally, the language "at all times while using the tanning device" and "A written informed consent statement may be revoked at any time." is added to reflect requirements under HB 1310 for use of protective eyewear and duration of informed consent statements, respectively.

Section 229.354(b)(3) is deleted in its entirety in order to conform the section to the new requirements under HB 1310 for use of tanning devices by minors under the age of 18. The paragraph is renumbered as a result of this deletion.

An amendment to §229.354(b)(4) adds the age of "16.5" and deletes the term "13" to reference the correct age of the customer. Additionally, the language in subparagraphs A and B was deleted in order to reflect the changes necessary to conform the section to the statutory provisions under HB 1310 that prohibit a person under 16.5 years of age from using a tanning device.

An amendment to §229.355(5) adds the word "location" of the tanning device to the information required to be reported to the department when an injury or illness associated with the use of a tanning device has occurred.

An amendment to §229.357(a) adds the language "compliance with" and deletes the language "are being violated" with respect to the department's inspection authority under the Tanning

Facility Regulation Act. These changes are made in order to conform the language in the paragraph to the statutory language in the Act.

COMMENTS

The department, on behalf of the commission, did not receive any comments regarding the proposed rules during the comment period.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the rules, as adopted, have been reviewed by legal counsel and found to be a valid exercise of the agencies' legal authority.

STATUTORY AUTHORITY

The amendments are authorized under Health and Safety Code, §145.011, which provides the department with authority to adopt rules to enforce the Tanning Facility Regulation Act; and Government Code §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration and enforcement of the Health and Safety Code, including Chapter 145, the Tanning Facility Regulation Act. The amendment regarding fees for replacement licenses is adopted under Health and Safety Code, §12.0111, which requires the department to charge a fee for issuing or renewing a license in an amount to cover the costs to the department for administering its licensing programs; and Health and Safety Code, §12.0112, which requires that the term of each license issued by the department to be two years. Review of the rules implements Government Code, §2001.039, requiring the review every four years of department rules previously adopted.

Legend: (Final Amendments - No additional changes from proposed version)
Regular print = Final language incorporating all proposed changes for final adoption
(No change) = No changes are being considered for the designated subdivision

§229.341. Purpose. This subchapter provides for the licensing and regulation of tanning facilities, including the terms and conditions under which tanning devices at such facilities may be operated, pursuant to applicable state and federal laws, rules, and regulations.

§229.342. Applicable Laws and Regulations.

(a) The Tanning Facility Regulation Act, Health and Safety Code, Chapter 145, governs and applies to the rules in this subchapter.

(b) The Executive Commissioner of the Health and Human Services Commission may adopt rules as necessary to implement the Tanning Facility Regulation Act, Health and Safety Code, Chapter 145.

(c) Tanning devices are both electronic products and devices as defined by the Federal Food, Drug and Cosmetic Act, 21 United States Code, et seq. and as such are subject to the provisions of that act as well as those of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, which requires the department to adopt rules regulating devices, i.e., tanning devices.

(d) Tanning devices used in tanning facilities are required to comply with the following applicable laws and regulations which are adopted by reference and include, but are not limited to:

(1) 21 Code of Federal Regulations (CFR), Part 801, Labeling;

(2) 21 CFR, Subchapter J, Radiological Health;

(3) 21 CFR, Part 1010, Performance Standards for Electronic Products - General;

and

(4) 21 CFR, §1040.20, Sunlamp Products and Ultraviolet Lamps Intended for Use in Sunlamp Products.

(e) Reconditioned tanning devices must comply with applicable provisions of the Federal Food, Drug and Cosmetic Act and the regulations adopted thereunder and are subject to the provisions of the Texas Food, Drug, Device and Cosmetic Salvage Act, Health and Safety Code, Chapter 432.

(f) Nothing in this subchapter shall relieve any person of responsibility for compliance with other pertinent Texas and federal laws, rules, and regulations.

(g) Copies of these laws and rules are indexed and filed at the department, 1100 West 49th Street, Austin, Texas 78756, and are available for inspection during normal working hours.

Electronic copies of these laws, rules, and regulations are available online at <http://www.dshs.state.tx.us/license.shtm>.

§229.343. Definitions. The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Tanning Facility Regulation Act (Act), codified as Health and Safety Code, Chapter 145.

(2) Adulterated--Has the meaning given in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §431.111, as interpreted in the rules of the department and judicial decision.

(3) Authorized agent--An employee of the department designated by the commissioner to enforce the Act.

(4) Change of ownership--The transfer of all or part of the ownership in a tanning facility held by one person to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership; a corporate sale, transfer, reorganization, or merger of the corporation which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership; or if any other type of association, the removal, addition, or substitution of a person or persons as a principal of such association.

(5) Commissioner--The Commissioner of the Department of State Health Services.

(6) Department--The Department of State Health Services.

(7) Fitzpatrick scale--A scale for classifying a skin type, based on the skin's reaction to the first 10 to 45 minutes of sun exposure after the winter season.

Figure: 25 TAC §229.343(7)

(8) Health authority--A physician designated to administer state and local laws relating to public health.

(9) Misbranded--Has the meaning given in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §431.112, as interpreted in the rules of the department and judicial decision.

(10) Operate--To own, manage, or control a tanning facility, or to offer tanning services to the public.

(11) Operator--A tanning facility owner, or an agent of a tanning facility owner, or a person who operates a tanning facility.

(12) Person--An individual, partnership, corporation, or association.

(13) Phototherapy device--A piece of equipment that emits ultraviolet radiation and that is used by a health care professional in the treatment of disease.

(14) Radiation--Ultraviolet radiation.

(15) Radiation machine--Any device capable of producing radiation.

(16) Reconditioning--Has the meaning given in the Texas Food, Drug, Device, and Cosmetic Salvage Act, Health and Safety Code, §432.003, as interpreted in the rules of the department in §229.603 of this title (relating to Definitions) and judicial decision.

(17) Tanning device--A device, as defined in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §431.002, that emits electromagnetic radiation with wavelengths in the air between 200 and 400 nanometers and that is used for tanning of human skin, including a sunlamp, tanning booth, or tanning bed. A tanning device is also classified as a device, as defined in the Federal Food, Drug and Cosmetic Act and the applicable Code of Federal Regulations. The term also includes any accompanying equipment, including protective eyewear, timers, and handrails.

(18) Tanning facility--A business that provides persons access to or use of tanning devices.

Figure: 25 TAC §229.343(7)

Skin Type	Reaction to Sun Exposure
1	Always burns easily; never tans
2	Always burns easily; tans minimally
3	Burns moderately; tans gradually
4	Burns minimally; always tans well
5	Rarely burns; tans profusely
6	Never burns; deeply pigmented

§229.344. Exemptions.

(a) This subchapter does not apply to a phototherapy device used by or under the supervision of a licensed physician who is trained in the use of a phototherapy device.

(b) Personal use of a tanning device by an individual is exempt from the provisions of this subchapter to the extent that such individual owns the tanning device exclusively for personal use and no fee or other compensation is involved in the use of the tanning device.

§229.345. Licensing of Tanning Facilities.

(a) A person shall not operate a tanning facility without a current and valid license to operate the facility that is issued by the department. A separate license is required for each tanning facility.

(b) The license shall be displayed in an open public area of the tanning facility.

(c) Each person acquiring or establishing a tanning facility after the effective date of this subchapter shall apply to the department for a license for such facility prior to beginning operation.

(d) Unless the license is amended as provided in subsection (g) of this section or is revoked or suspended as provided in §229.347 of this title (relating to Revocation, Cancellation, Suspension and Probation of a License), the license is valid for two years as determined by the department.

(e) Licenses shall not be transferable from one person to another or from one tanning facility to another.

(f) A license issued under this subchapter shall be returned to the department if the tanning facility:

- (1) ceases business or otherwise ceases operation on a permanent basis;
- (2) relocates;
- (3) changes the name of the business under which the tanning facility operates; or
- (4) changes ownership.

(g) A license that is amended, including a change in location, name, or ownership of a tanning facility, will require submission of a license application and fee as outlined in subsection (j) of this section and §229.346(a) of this title (relating to Licensing Fees).

(h) In the event a current and valid license is lost, stolen or destroyed, the licensee shall request a replacement license from the department by submitting an application and non-refundable fee as outlined in subsection (j) of this section and §229.346(a) of this title. A replacement license shall only be issued if the lost, stolen or destroyed license was current and valid at the time of the request, and no changes in business name, location or ownership have occurred.

(i) License application forms may be obtained from the department, 1100 West 49th Street, Austin, Texas, 78756 or online at <http://www.dshs.state.tx.us/license.shtm>.

(j) The application required in subsections (c), (g), (h), (k), and (l) of this section shall be completed on forms provided by the department and shall contain all the information required by such forms and any accompanying instructions.

(k) Each tanning facility shall provide the following information upon initial application for a license:

(1) the name of the legal entity to be licensed, including the name under which the business is conducted, physical address, mailing address, and telephone number of the tanning facility;

(2) if a proprietorship, the name of the proprietor; if a partnership, the names of all partners; if a corporation, the names of the corporate officers and/or directors, the corporation charter number, and the name and address of its registered agent in the state; or if any other type of association, the names of the principals of such association;

(3) the name(s), mailing address(es), telephone number(s), and valid driver's license number(s) of:

(A) the proprietor in the case of a sole proprietorship;

(B) the managing partner in the case of a partnership;

(C) the officers and/or directors in the case of a corporation;

(D) the principals in the case of an association;

(E) the operator in charge of the tanning facility;

(4) hours of operation of each tanning facility; and

(5) signature of the owner verifying all information on the initial application form.

(l) The renewal application for licensure as a tanning facility shall be made on a form furnished by the department and can be obtained as referenced in subsection (i) of this section.

(m) Failure to complete the application form may result in the denial of a license.

(n) The department will not issue a license under this subchapter with respect to a facility that:

(1) is operated under a license or permit as a sexually oriented business issued in accordance with Government Code, §243.007;

(2) offers, as its primary business, a service or the sale, rental, or exhibition of a device or other item that is intended to provide sexual stimulation or sexual gratification to a customer; or

(3) is owned or operated by a person who has been convicted of an offense under Penal Code, Chapter 21 or 43; or Penal Code, §71.02(a)(3).

(o) A current license or renewal license shall only be issued when all past due fees and delinquency fees are paid.

§229.346 Licensing Fees.

(a) All applicants for a tanning facility license or renewal license shall pay a license fee for each place of business. All fees are nonrefundable. The license fees are as follows:

(1) \$440 for a two-year license;

(2) \$440 for a two-year license that is amended due to a change of ownership;

(3) \$220 for a license that is amended during the current licensure period due to minor changes; and

(4) \$100 for a replacement license.

(b) A tanning facility shall pay a \$100 delinquency fee if the license renewal fee is paid after the expiration date of the current license.

(c) www.texas.gov. Applicants may submit applications and renewal applications and pay the required fees for a license under this subchapter electronically by the Internet through www.texas.gov at www.texas.gov. The department is authorized to collect fees, in amounts determined by the www.texas.gov Authority, to recover costs associated with license application and renewal application processing through www.texas.gov.

(d) A licensee with multiple licenses under this subchapter may request, in writing, a prorated license fee to consolidate the expiration dates of multiple licenses.

§229.347. Revocation, Cancellation, Suspension, and Probation of a License.

(a) The department may revoke, cancel, suspend, suspend on an emergency basis, or probate by an emergency order of the commissioner, or the commissioner's designee a license to operate a tanning facility if the facility has:

(1) failed to pay a license fee or a renewal fee for a license;

(2) obtained or attempted to obtain a license by fraud or deception;

(3) violated any of the provisions of the Act; or

(4) violated any of the provisions of this subchapter.

(b) The department shall revoke a license issued with respect to a facility if the license may not be renewed under §229.345(n) of this title (relating to Licensing of Tanning Facilities).

(c) Prior to revoking, canceling, suspending or probating a license, the department shall give the license holder written notice of the proposed action, including the reasons and an opportunity for a hearing.

(d) Any hearing for the revoking, canceling, suspending, or probating of a license are governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(e) If the department suspends a license, the suspension shall remain in effect until the department determines that the reason for suspension no longer exists. If the suspension overlaps a renewal date, the suspended license holder shall comply with the renewal procedures in §229.345(l) of this title and the payment of appropriate fees in §229.346 of this title (relating to Licensing Fees); however the department may not renew the license until the department determines that the reason for the suspension no longer exists.

(f) If the department revokes or does not renew a license, a person may reapply for a license by complying with the requirements and procedures in §229.345(j) of this title and §229.346 of this title at the time of reapplication. The department may refuse to issue a license if the reason for revocation or nonrenewal continues to exist. A license holder named in a revocation action is not eligible for licensing under this subchapter for a period of one year from the date of the revocation.

§229.348. Report of Changes. The license holder shall notify the department in writing within ten working days of any change, including a change in location, name, or ownership of a tanning facility, which would render the information contained in the initial license application, reported pursuant to §229.345 of this title (relating to Licensing of Tanning Facilities), no longer accurate. Failure to inform the department within ten working days of a change in the information required in the license application may result in enforcement action as described in §229.357 of this title (relating to Enforcement and Penalties).

§229.349. Advertising.

(a) No person, in any advertisement, shall refer to the fact that the person or the person's facility is licensed with the department pursuant to the provisions of §229.345 of this title (relating to Licensing of Tanning Facilities), and no person shall state or imply that any activity under such license has been approved by the department.

(b) A tanning facility shall not claim, or distribute promotional materials that claim, that using a tanning device is safe or free from risk or that using the device will result in medical or health benefits. The only claims that may be made for tanning are cosmetic.

(c) A business described in §229.345(n) of this title shall not use the word "tan" or "tanning" in a sign or any other form of advertising.

§229.350. Warning Signs.

(a) A tanning facility operator shall post a warning sign in a conspicuous location where it is readily visible to persons entering the facility. The sign shall have the following wording and appearance.

Figure: 25 TAC §229.350(a) (No change.)

(b) A tanning facility operator shall post a warning sign, one sign for each tanning device, in a conspicuous location that is readily visible to a person about to use the device. The sign shall have the following wording and appearance.

Figure: 25 TAC §229.350(b) (No change.)

(c) Warning signs shall meet the following requirements.

(1) The sign shall be printed on white 80 pound gloss coated cover stock and shall be 17 inches wide by 22 inches long.

(2) The lettering on each warning sign shall be brilliant red (Pantone 185) or equivalent on white background.

(3) The major sign heading entitled "DANGER" shall be a minimum of Helvetica Bold 110 point or equivalent.

(4) The subheading entitled "ULTRAVIOLET RADIATION" shall be a minimum of Helvetica Bold 84 point or equivalent.

(5) Body copy shall be Helvetica 36 point or equivalent.

(6) Remaining capitalized copy shall be a minimum of Helvetica Bold 60 point or equivalent.

(d) Camera ready copies of each sign shall be available for reproduction purposes upon written request to the department, 1100 West 49th Street, Austin, Texas 78756-3182.

(e) The department shall include with a license application a description of the design standards required for signs in this section.

§229.351. Tanning Devices.

(a) Only tanning devices manufactured and certified to comply with 21 Code of Federal Regulations (CFR), Part 1040, §1040.20, "Sunlamp products and Ultraviolet Lamps Intended for Use in Sunlamp Products", shall be used by or sold to tanning facilities. Tanning devices that have been reconditioned must comply with federal and state requirements. Tanning device reconditioners must be licensed under the Texas Food, Drug, Device, and Cosmetic Salvage Act, Health and Safety Code, Chapter 432. Compliance shall be based on the standard in effect at the time of manufacture as shown on the device identification label required by 21 CFR, Part 1010, §1010.3. Tanning devices must also comply with the medical device labeling requirements of 21 CFR, Part 801.

(b) All tanning devices shall have a timer which complies with the requirements of 21 CFR, Part 1040, §1040.20(c)(2). The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time for the device. No timer interval shall have an error greater than plus or minus 10% of the maximum timer interval for the product.

(c) The operator shall limit the exposure time of a customer on a tanning device to the maximum exposure time recommended by the manufacturer, taking the customer's skin type into consideration.

(d) Tanning device remote timers shall be installed and located so that the customer may not set or reset the customer's own exposure time. Remote timer systems must comply with the requirements for timers as provided in subsection (b) of this section.

(e) No operator shall sell, or otherwise make available to any user of a tanning device, tokens required to operate the tanning device in quantities greater than the tanning device manufacturer's maximum recommended exposure time for the user.

(f) The operator shall control the temperature of the customer contact surfaces of a tanning device and the surrounding area so that it will not exceed 100 degrees Fahrenheit.

(g) The tanning devices shall be maintained in good repair.

(h) Defective or burned-out lamps or filters shall be replaced with a type intended for use in that device as specified on the device label, or with lamps or filters that are "equivalent" under the United States Food and Drug Administration (FDA) regulations and policies applicable at the time of lamp manufacture. The facility operator shall maintain lamp manufacturer's user instruction labeling at the facility, demonstrating the equivalence of any replacement lamps, if applicable.

(i) A tanning device used by a tanning facility must comply with all applicable state and local electrical code requirements.

(j) When a tanning device is being used by an individual, no other person shall be allowed to remain in the tanning device area.

§229.352. Protective Eyewear.

(a) Each customer shall be provided with protective eyewear and instructions for their use. The operator shall not allow a person to use a tanning device if that person does not agree to use protective eyewear at all times while using the device.

(b) Before each use of a tanning device, the operator shall ensure that each tanning device is accompanied by clean and properly sanitized protective eyewear that protects the eyes from ultraviolet radiation and allows adequate vision to maintain balance.

(c) Protective eyewear shall be located in the immediate proximity of each tanning device, readily visible to a person about to use the device, and shall be provided without charge to each user of a tanning device.

(d) Protective eyewear shall meet the requirements of the United States Food and Drug Administration, including the requirements of 21 Code of Federal Regulations, Part 801 and Part 1040, §1040.20(c)(4).

§229.353. Operators.

(a) A tanning facility shall have an operator present during operating hours.

(b) Each operator must be sufficiently trained and knowledgeable in the correct operation of the tanning devices used at the facility to adequately inform and assist each customer in the proper use of the tanning devices. A record of all training received by each operator shall be kept at the tanning facility where the operator is employed. The record shall be signed by the operator and the owner or owner's designee. The operator must be able to demonstrate such knowledge concerning the:

- (1) requirements of this subchapter and the Tanning Facility Regulation Act;
- (2) procedures for correct operation of the facility;
- (3) recognition of injury or overexposure;
- (4) manufacturer's procedures for operation and maintenance of all tanning devices;
- (5) emergency procedures in case of injury;
- (6) classification of consumer skin types and the recommended exposure times for all skin types; and
- (7) maintenance of records required by §229.354 of this title (relating to Records).

(c) The operator must understand, be competent to explain, and at a minimum, instruct, inform, and assist each customer using a tanning device for the first time of:

(1) the potential hazards and protective measures associated with ultraviolet radiation exposure;

(2) the requirement to wear protective eyewear at all times while using the tanning device;

(3) the possibility of photosensitivity and photoallergenic reaction of some persons to drugs, medicine, and other agents when subjected to sun and ultraviolet radiation exposure;

(4) the correlation between skin type and exposure time; and the maximum exposure time of the facility's devices;

(5) the biological process of tanning;

(6) the dangers and necessity of avoiding overexposure; and

(7) the location and operation of the exposure termination control for the tanning device.

(d) If an operator suspects that possible harm may result from tanning, the customer should be advised to consult their private physician.

(e) Written procedures shall be established and maintained at the tanning facility which describe the requirements operator(s) will follow for the correct use of tanning device(s), to include:

(1) instructions to the customer;

(2) use of protective eyewear;

(3) suitability of prospective customers for tanning device use;

(4) determination of duration of tanning exposures;

(5) periodic testing of tanning device(s) and timer(s);

(6) handling of complaints of injury or illness from customers; and

(7) records to be maintained on each customer.

(f) No operator may permit any person under 16.5 years of age to use a tanning device.

(g) No operator may permit any person at least 16.5 years of age and younger than 18 years of age to use a tanning device for the first time unless such person's parent or legal guardian, in person at the facility, presents the facility with consent in writing for such person to use the device and the consent meets the requirements of §229.354 of this title (relating to Records).

(h) No operator may permit any person younger than 18 years of age to use a tanning device for the first time unless the person has displayed a driver's license or other form of identification containing the person's photograph and indicating that the person is 16.5 years of age or older.

§229.354. Records.

(a) Customer notice.

(1) A tanning facility operator shall give each customer a written statement warning that:

(A) failure to use the eye protection provided to the customer by the tanning facility may result in permanent damage to the eyes;

(B) overexposure to ultraviolet light causes burns;

(C) repeated exposure may result in premature aging of the skin and skin cancer;

(D) abnormal skin sensitivity or burning may be caused by reactions of ultraviolet light to certain:

(i) foods;

(ii) cosmetics; or

(iii) medications, including:

(I) tranquilizers;

(II) diuretics;

(III) antibiotics;

(IV) high blood pressure medicines; or

(V) birth control pills;

(E) any person taking a prescription or over-the-counter drug should consult a physician before using a tanning device;

(F) pregnant women should consult their physicians before using a tanning device;

(G) a person with skin that always burns easily and never tans should avoid a tanning device; and

(H) a person with a family or past medical history of skin cancer should avoid a tanning device.

(2) Compliance with the notice requirements does not affect the liability of a tanning facility operator or a manufacturer of a tanning device.

(b) Signed warning statement.

(1) Each time a customer who is 18 years of age or older uses a tanning facility's tanning device for the first time and each time a person executes or renews a contract to use a tanning facility, the person shall provide photo identification and sign and date a written statement acknowledging that the person has read and understood the required warnings in §229.350 of this title (relating to Warning Signs) and subsection (a) of this section before using the device and agrees to use protective eyewear.

(2) Before any person younger than 18 years of age uses a tanning device for the first time, the person shall give the tanning facility operator a written informed consent statement signed and dated by the person and the person's parent or legal guardian. The informed consent statement shall state that the person and the parent or legal guardian have read and understood the advisory statement issued by the Texas Medical Board and available online at <http://www.dshs.state.tx.us/dmd>, warning of the dangers of indoor and outdoor tanning and its association with skin cancer, eye damage, and other health risks, provided by the tanning facility, and agree that the minor will use protective eyewear at all times while using the tanning device. A written informed consent statement may be revoked at any time.

(3) A tanning facility may not allow a person under the age of 16.5 years to use a tanning device.

(4) For illiterate or visually handicapped persons, the warning statement shall be read by the operator in the presence of a witness. Both the witness and the operator shall sign and date the statement.

(c) Individual customer records.

(1) An individual customer record shall be kept by the facility operator and shall include:

(A) the customer's date of birth;

(B) the total number of tanning visits;

(C) the length of exposure to each tanning device in minutes and the identity of the device responsible for the exposure;

(D) the date and time of each exposure;

(E) any injuries or illnesses resulting from the use of a tanning device;

(F) any written informed consent statement required to be signed in this section;

(G) the customer's skin type, as determined by the customer by using the Fitzpatrick scale;

(H) whether the customer has a family history of skin cancer; and

(I) whether the customer has a past medical history of skin cancer.

(2) The operator must ensure that no individual is allowed to use a tanning device more than once every 24 hours.

(d) Incident log. An operator shall maintain a log at each tanning facility of any incident involving an alleged injury, the use of a tanning device by a customer not wearing protective eyewear, a mechanical problem with a tanning device, or a customer complaint. The log shall contain the nature of the incident, the date the incident occurred, the identity of any tanning device involved in the incident, a description of any corrective action taken in response to the incident, and the signature or initials of the operator responsible for determining whether or not corrective action was required.

(e) Record retention. All records required by this section shall be maintained at the tanning facility at least until the third anniversary of the date of the customer's last use of a tanning device.

(f) Access to records. A person who is required to maintain records under this section or a person who is in charge or custody of those records shall, at the request of an authorized agent or health authority, permit the authorized agent or the health authority at all reasonable times access to and to copy and verify the records.

(g) Disclosure of records.

(1) Except as provided by paragraph (2) of this subsection, an operator or other person may not disclose a customer record required in subsection (c) of this section.

(2) An operator or other person may disclose a customer record:

(A) if the customer, or a person authorized to act on behalf of the customer, requests the record;

(B) if the commissioner or an authorized agent or health authority requests the record under subsection (f) of this section;

(C) if the customer consents in writing to the disclosure to another person;

(D) in a criminal proceeding in which the customer is a victim, witness, or defendant;

(E) if the record is requested in a criminal or civil proceeding by court order or subpoena; or

(F) as otherwise required by law.

(h) Electronic records. Records required by this subchapter which are maintained by the tanning facility on computer systems shall be regularly copied, at least monthly, and updated on storage media other than the hard drive of the computer. An electronic record must be retrievable as a printed copy.

(i) Forms. Forms that have been developed by the department for use by tanning facilities will be provided upon request as camera ready copies for reproduction purposes.

§229.355. Injury Reports. A written report of any injury or illness associated with a tanning device shall be forwarded to the department within five working days of its occurrence or knowledge thereof. The report shall include:

(1) the name of the affected individual;

(2) the name and location of the tanning facility involved;

(3) the date of the injury or illness;

(4) the nature of the injury or illness;

(5) identification of the tanning device involved in the injury or illness, including brand, model, and location;

(6) the name and address of health care provider, if any;

(7) the name of the operator on duty at the time of injury or illness; and

(8) any other information considered relevant to the situation.

§229.356. Sanitation.

(a) The tanning facility shall be kept clean and sanitary at all times. The interior of a tanning facility shall be maintained in good repair and in a safe, clean, sanitary condition, free from all accumulation of dirt and rubbish.

(b) The operator shall clean and properly sanitize any reusable protective eyewear before each use with a sanitizer registered with the United States Environmental Protection Agency (USEPA). Exposure to the ultraviolet radiation produced by the tanning equipment itself is not considered a sanitizing agent.

(c) The operator shall clean and properly sanitize the body contact surfaces of a tanning device after each use with a sanitizer registered with the USEPA.

(d) A test kit or other device that accurately measures the concentration of the sanitizing solution in parts per million shall be used to measure the strength of the sanitizing solution at least once per day of tanning facility operation or more frequently as needed to ensure sufficient strength of the sanitizing solution. All measurements of the sanitizing solution shall be recorded in a log that includes the date of the measurement, the strength of the sanitizing solution measured in accordance with manufacturer's directions, and the initials of the operator responsible for measuring the strength of the sanitizing solution.

(e) The operator shall provide the customers of the tanning facility access to toilet and handwashing facilities with hot and cold running water.

(f) Each tanning facility shall provide to its customers cloth towels or disposable paper towels which may not be shared. Cloth towels must be laundered with soap or detergent after each use.

(g) Floors in rooms containing tanning devices are to be constructed of nonabsorbent, easily cleanable materials. Tanning facilities shall not include carpeting in rooms containing tanning devices.

(h) Floors are to be made dry prior to each customer's use.

(i) Dogs, cats, birds, reptiles, and other pets shall not be permitted in tanning facilities. This exclusion does not apply to guide dogs or fish in aquariums.

§229.357. Enforcement and Penalties.

(a) Inspections. The commissioner or an authorized agent shall have access at all reasonable times to any tanning facility to inspect the facility to determine compliance with the Tanning Facility Regulation Act (Act) or this subchapter.

(b) Administrative penalties. Administrative penalties, as provided in Health and Safety Code, §145.0122, and in §229.261 of this title (relating to Assessment of Administrative Penalties), may be assessed for violation of this subchapter.

(c) Criminal penalty.

(1) A person, other than a customer, commits an offense if the person violates the Act or rules adopted under the Act.

(2) Except as provided by paragraph (3) of this subsection, an offense under the Act is a Class A misdemeanor.

(3) An offense under §229.349(c) of this title (relating to Advertising) is a Class C misdemeanor, unless it is shown on the trial of an offense under this subsection that the person has previously been convicted of an offense under this subsection, then the offense is a Class A misdemeanor.

(d) Civil penalty; Injunction. If it appears that a person has violated or is violating Health and Safety Code, Chapter 145, or an order issued or a rule adopted under authority of Health and Safety Code, §145.011, the commissioner may request the attorney general or the district or county attorney or the municipal attorney of a municipality in the jurisdiction where the violation is alleged to have occurred or may occur to institute a civil suit for:

(1) an order enjoining the violation;

(2) a permanent or temporary injunction, a temporary restraining order, or other appropriate remedy if the department shows that the person has engaged in or is engaging in a violation;

(3) the assessment and recovery of a civil penalty; or

(4) both injunctive relief and a civil penalty.

(e) Venue. Venue for a suit brought under the Act shall be in the county in which the violation or the threat of violation is alleged to have occurred or in Travis County.

(f) Adulterated or misbranded tanning device. If the department identifies an adulterated or misbranded tanning device, the department may enforce the applicable provisions of Subchapter C of the Texas Food, Drug, and Cosmetic Act (Health and Safety Code, Chapter 431) including, but not limited to: detention, emergency order, recall, condemnation, destruction, injunction, civil penalties, criminal penalties and/or administrative penalties. Administrative and civil penalties will be assessed using the Severity Levels contained in §229.261 of this title.

(g) Emergency order. The commissioner or the commissioner's designee may issue an emergency order relating to the operation of a tanning facility in the department's jurisdiction if the commissioner or the commissioner's designee determines:

(1) operation of the tanning facility creates or poses an immediate and serious threat to human life or health; and

(2) other procedures available to the department to remedy or prevent the threat will result in unreasonable delay.