

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

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §§229.341 - 229.357, concerning the Licensure of Tanning Facilities.

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 readoption 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 §229.342(g) adds "rules" to the description of electronic copies of documents that are available online through the department's website.

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."

§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) deletes "Sunburning and Tanning History" in Figure: 25 TAC §229.343(8) and adds "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) adds the term "devices" is deleted 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 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 §229.346(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 §229.346(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, §229.353, §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, 81st Legislative Session, 2009. 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.

§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 "16.5" and deletes "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 "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.

FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five-year period that the sections are in effect, there will be fiscal implications to state government in the form of an estimated increase in revenue of \$1,000 from fees resulting in administering and enforcing §229.346(a)(4) as proposed. These fees will be used to cover the costs of producing and issuing replacement licenses authorized under the section. Further, Ms. Tennyson has determined that there will be no fiscal implications to local governments as a result of administering and enforcing §229.346(a)(4) as proposed. Ms. Tennyson has also determined that there will be no fiscal implications to state and local governments as a result of administering and enforcing §§229.341 – 229.345 and §§229.347 – 229.357 as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there are costs to small businesses or micro-businesses required to comply with §229.353 and §229.354 as proposed. It is estimated that 1,884 tanning facilities are small or micro-businesses. Prior to the enactment of HB 1310, it is believed that several factors, including the complex nature of the requirements for a minor's use of a tanning device, contributed to the use of tanning devices by relatively few minors under the age of 16.5 years. However, tanning facilities will no longer be able to permit persons under the age of 16.5 years to use a tanning device and as a result, it is estimated that tanning facilities will experience an average of \$1,235 per facility in reduced annual revenue associated with the loss of customers under the age of 16.5 years.

Although the department acknowledges that small and micro-businesses who allowed minors under the age of 16.5 years will be impacted by the sections as proposed, alternatives were not considered due to the express prohibition in HB 1310 against allowing persons under the age of 16.5 years to use a tanning device.

There are no anticipated significant economic costs to persons who are required to comply with the sections as proposed. There is no anticipated impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Tennyson has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as the result of administering and enforcing the sections is to ensure tanning facilities meet licensing standards necessary for the safe and effective use of tanning devices.

REGULATORY FLEXIBILITY ANALYSIS

Government Code, §2006.002, requires the agency to consider using regulatory methods that accomplish the objectives of the rules while minimizing the adverse impacts on small business, if doing so is legal and feasible considering the purpose of the statute under which the rule is to be adopted, namely the health and safety of Texas residents.

The proposed rules implement HB 1310, a statute which prohibits all those younger than 16.5 from using tanning devices and permitting those 16.5 years old but younger than 18 to do so, as long as parental consent is obtained as required. As HB 1310 does not authorize or justify any exceptions to these prohibitions and conditions based upon the business size of the entity, there is no legal or feasible method to accomplish the objectives of the rules.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225(g)(3). "Major environmental rule" is defined as a rule, the specific intent of which, is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or public health and safety of the state or sector of the state.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Tom Brinck, Manager, Drugs and Medical Devices Group, Policy, Standards and Quality Assurance Unit, Environmental and Consumer Safety Section, Division for Regulatory Services, P.O. Box 149347, Mail Code 1987, Austin, Texas 78714-9347, (512) 834-6755 extension 2388, or by email to tom.brinck@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments to these rules are authorized by 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 authorized by 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.

The amendments affect the Health and Safety Code, Chapters 12, 145, and 1001; and the Government Code, Chapter 531.