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## Chapter 101. Tobacco

### 25 TAC §§101.1-101.6, 101.10

The Texas Department of Health (department) proposes new §§101.1-101.6, and 101.10, concerning the reporting of ingredients and nicotine content of cigarettes and tobacco products. These rules are proposed to implement Chapter 1216 (House Bill 119) 75th Legislature (1997), which added Health and Safety Code, Subchapter N, "Disclosure of Ingredients in Cigarettes and Tobacco Products." This legislation requires manufacturers of these products to report certain information to the department so that it might be available to the public. Specifically the new sections cover the purpose of the rules, definitions, general requirements, ingredient reporting, nicotine yield reporting for cigarettes, nicotine yield reporting for tobacco products, and public information.

Dr. Philip Huang, M.D., Bureau Chief, Bureau of Chronic Disease, has determined that for the first five-year period the sections are in effect, there will be no fiscal implications to state or local government as a result of enforcing or administering the sections as proposed.

Dr. Huang has also determined that for each year of the first five years the sections are in effect, the public benefit anticipated as a result of enforcing the sections will be increased access by the public to information about cigarettes and tobacco products, which will make their decision to use these products better informed. Most manufacturers of cigarettes and tobacco products are large businesses, but to the extent small businesses are involved in manufacturing these products their costs are expected to be between \$740 and \$1575 per brand, based on a price quotation from a large independent lab. These costs may be reduced substantially for those manufacturers who have their own labs. It is estimated that additional costs: costs of the analyzed cigarette or tobacco product, compiling a list of ingredients and preparation and mailing of the report will be between \$20 and \$50 per brand. There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated impact on local employment.

Comments on the proposal may be submitted to Dr. Philip Huang, M.D., Bureau Chief, Bureau of Chronic Disease, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756. Comments will be accepted for 30 days following publication of this proposal in the *Texas Register*.

The new sections are proposed under Health and Safety Code §161.251 which requires the department by rule to establish the time and form for reports of ingredients, §161.253 which requires the department to develop standards for assigning a nicotine yield rating, and §12.001 which provides the Texas Board of Health (board) with the authority to adopt rules for the performance of every duty imposed by law on the board the department, and the commissioner of health.

The new sections affect the Health and Safety Code Chapter 161.

#### §101.1. Purpose.

The purpose of these rules is to implement Texas Health and Safety Code, Chapter 161, Subchapter N, "Disclosure of Ingredients in Cigarettes and Tobacco Products."

#### §101.2. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise.

Annual report- A tobacco manufacturer's annual report to the department, which provides the ingredient information and nicotine yield ratings.

Chewing or snuff tobacco nicotine yield rating- A composite of information intended to show the range of nicotine that each chewing or snuff tobacco product can be expected to provide the average consumer, based on the amount of nicotine in the brand, the pH of the tobacco, and the amount of unionized (free) nicotine in the product.

Cigar- A roll for smoking, made of fermented tobacco that is wrapped in tobacco and the main stream of smoke from which produces an alkaline reaction to litmus paper.

Cigarette- A roll for smoking, made of tobacco or tobacco mixed with another ingredient and wrapped or covered with a material other than tobacco and that is not a cigar.

Cigarette nicotine yield rating- A composite of information to show the range of nicotine that each cigarette brand can be expected to deliver to the average consumer based on the expected range of nicotine delivery under average smoking conditions based on machine testing parameters that reflect actual smoking behavior as accurately as possible, and the potential for increased nicotine delivery or increase rate of nicotine delivery based on cigarette design features such as filter ventilation and pH.

Department- The Texas Department of Health.

Ingredient- Any ingredient, substance, chemical or compound other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco, which is added to the product including but not limited to, flavorants, processing aides, casing sauces, contaminants, combustion modifiers, and packing materials, to the full extent the manufacturer is aware of the presence of any such ingredient.

Manufacturer- A person who manufactures or produces tobacco products and sells tobacco products to a distributor.

Risks to public health- The possibility or actuality of adverse health effects associated with tobacco use, including but not limited to nicotine addiction and adverse health effects associated with exposure to environmental tobacco smoke.

Tobacco product- Smoking tobacco, including granulated, plug-cut, crimp-cut, ready rubbed, and any form of tobacco suitable for smoking in a pipe or as a cigarette; chewing tobacco, including cavendish, twist, plug, scrap, and any kind of tobacco suitable for chewing; snuff or other preparations of pulverized tobacco; or an article or product that is made of tobacco or a tobacco substitute and that is not a cigarette.

#### §101.3. General Requirements for Annual Reports by Manufacturers.

(a) On or after June 1, 1998, and every June 1 thereafter, the manufacturer of any cigarettes or tobacco product, excluding cigars, sold in the state of Texas shall report to the department, in accordance with these regulations, the ingredients and nicotine yield rating of any such cigarette or tobacco product, excluding cigars.

(b) Nothing in this section shall prohibit a manufacturer or distributor of cigarettes or tobacco products from selling such products to an in-state merchant for sale or distribution outside the state.

§101.4. Ingredient Reporting Requirements.

In each annual report, a manufacturer shall provide, at a minimum, the following for each brand, sub-brand, and generic unbranded cigarette or tobacco product, including cigars, distributed in the State of Texas.

(1) A list of all ingredients in the cigarette or tobacco product listed in descending order according to weight, measure, or numerical count, other than tobacco, water, or a reconstituted tobacco sheet made wholly from tobacco. Each ingredient shall be reported by its chemical name and chemical abstract service registry number, if available, on the following ingredient reporting form.

Figure 1: 25 T.A.C. §101.4(a)(1)

(2) The name, job title, address, and telephone number of the individual designated by the manufacturer as the department's contact person concerning these regulations.

§101.5. Cigarette Nicotine Yield Rating Reporting Requirements.

(a) Cigarette manufacturers shall include in their annual report a rating for nicotine yield for each brand, sub-brand and generic unbranded cigarettes sold in the State of Texas, which shall include:

(1) total nicotine content of the cigarette, reported in milligrams of nicotine. The protocol for measuring nicotine content in cigarettes is described in "Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products," as announced in the *Federal Register* of May 2, 1997, Volume 62, number 85, pages 24115-24116;

(2) percent filter tip ventilation; that is, the amount of air dilution in the whole smoke provided by the perforations in the cigarette filter, described in percent. This shall be measured using the Filter Dilution (Ventilation) Testing Instrument (FDT) from Fidus Instrument Corporation, product no. FDT 232; or FIAL Tip and Envelope Ventilation/Pressure Drop QTM5U machine; or equivalent approved by the department, and shall be used in accordance with manufacturer instructions. Two cigarettes shall be randomly selected from each sampled pack, conditioned, and tested for percent filter ventilation. The average percent filter ventilation shall be computed for the 100 cigarettes tested;

(3) pH of cigarette smoke as determined under the method described in Harris, J.L., Hayes, L.E., "A method for measuring the pH of whole smoke", *Tobacco Science*, 1977: 60: 81-83, or equal method approved by the department with the puff volume and interval adjusted as described in subsection (a)(4) of this section; and

(4) nicotine delivery under average smoking conditions, reported in milligrams of nicotine per cigarette. Nicotine delivery under average smoking conditions shall be evaluated using the Cambridge Method, which has been approved by the Federal Trade Commission as the standard for nicotine testing since 1966 and adopted for international purposes by the International Organization for Standardization (ISO). See *Federal Register* of August 1, 1967, Volume 32, number 147, page 11178, as modified in *Federal Register* of July 10, 1980, Volume 45, number 134, pages 46483-46487; and ISO 10315, 91-08-01 entitled *Cigarettes-Determination of Nicotine in Smoke Condensates-Gas-Chromatographic Method*, ISO 3308, third edition, 1991-10-15, *Routine Analytical cigarette-Smoking Machine-Definition of Standard Conditions* and ISO 7201, second edition, 1997-01-15, *Routine Analytical Smoking Machine Additional Test Methods*. Two cigarettes shall be randomly selected from each pack

for a sample of 100 cigarettes. The following changes shall be made to the method described in the publications cited:

(A) puff volume adjusted to 45 milliliters;

(B) puff interval adjusted to 30 seconds;

(C) puff duration shall remain two seconds; and

(D) 50% of the ventilation holes must be blocked by placing a strip of mylar adhesive tape, Scotch brand product no. 600 transparent tape (acetate) or other method approved by the department. The tape shall be cut so that it covers 50% of the circumference and is tightly secured from the end of the filter to the tipping overwrap seam.

(b) Manufacturers shall classify each brand, sub-brand, or generic unbranded cigarette for nicotine yield according to the following standards:

(1) "High Nicotine." Cigarettes yielding more than 1.2 milligrams per cigarette (mg/cigarette);

(2) "Moderate Nicotine." Cigarettes yielding greater than .2 and less than or equal to 1.2 mg/cigarette;

(3) "Low Nicotine." Cigarettes yielding greater than or equal to .01 and less than or equal to .2 mg/cigarette; or

(4) "Nicotine Free." Cigarettes yielding less than .01 mg/cigarette.

(c) The cigarette nicotine index shall be reported to the department as specified in the following "Cigarette Nicotine Yield Rating Form".

Figure 1: 25 T.A.C. §101.5(c)

(d) Sampling and conditioning of Cigarettes. Conditioning for testing of cigarettes shall be done in accordance with the ISO, 3402, third edition, 1991-07-01 entitled *Tobacco and Tobacco Products-Atmosphere for Conditioning and Testing*. Cigarettes shall be sampled using international standard ISO 8243:98 (E) entitled *Cigarette-Sampling*, with samples collected at point of sale and at a single point in time. At a minimum, for each brand sampled, four packages each of cigarettes should be purchased from five retailers located in five separate counties in Texas, for a total of 100 packages purchased. If some varieties are not available in certain locations, additional packages will be purchased where they are available. In measuring nicotine content, the cigarette manufacturer shall use the following sampling method: two cigarettes shall be randomly selected from each pack and conditioned, the tobacco rod split open, and the cigarette tobacco mixed thoroughly before weighing. The minimum sample size shall be 100 grams of tobacco. If the weight of the tobacco is less than 100 grams, additional cigarettes shall be randomly selected from each pack.

§101.6. Tobacco Products - Excluding Cigars, Nicotine Reporting Requirements.

(a) Manufacturers of tobacco products excluding cigars shall include in their annual report a rating for nicotine yield for each brand, sub-brand, or generic unbranded chewing and/or snuff tobacco product sold in the state of Texas, which shall include:

(1) pH of tobacco;

(2) moisture content as percent of weight of tobacco;

(3) nicotine in milligrams per gram of tobacco;

(4) nicotine as a percent of dry weight of tobacco;

(5) percent of unionized (free) nicotine; and

(6) total unionized (free) nicotine in milligrams per gram of tobacco.

(b) Manufacturers of chewing and/or snuff tobacco products shall classify each brand, sub-brand and generic unbranded chewing and/or snuff tobacco product for nicotine delivery, according to the following standard:

(1) "High Nicotine." Smokeless tobacco yielding more than 2.0 milligrams of total free nicotine per gram;

(2) "Moderate Nicotine." Smokeless tobacco yielding greater than 0.5 and less than or equal to 2.0 milligrams of total free nicotine per gram;

(3) "Low Nicotine." Smokeless tobacco yielding greater than or equal to .01 and less than or equal to 0.5 milligrams of total free nicotine per gram; or

(4) "Nicotine Free." Smokeless tobacco yielding less than 0.01 milligrams of total free nicotine per gram.

(c) The chewing and/or snuff tobacco nicotine yield shall be reported to the department as specified in Figure 1 "Cigarette Nicotine Yield Rating Form" .

#### §101.10. Public Information .

(a) Except as provided in subsections (b)-(d) of this section, information included in a report filed under this chapter is public information and is not confidential unless it is determined to be confidential under this section.

(b) The department may not disclose information under subsection (a) of this section until the department has obtained the advice of the attorney general under this section with respect to the particular information disclosed. If the attorney general determines that the disclosure of particular information would constitute an unconstitutional taking of property, the information is confidential and the department shall exclude that information from disclosure.

(c) Information included in a report filed under this subchapter is confidential if the department determines that there is no reasonable scientific basis for concluding that the availability of the information could reduce risks to public health.

(d) Information included in a report filed under this subchapter is confidential under Government Code, Chapter 552, if the information would be excepted from public disclosure as a trade secret under state or federal law.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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For further information, please call: (512) 458-7236



## Chapter 115. Home and Community Support Services Agencies

The Texas Department of Health (department) proposes amendments to §§115.1, 115.11, 115.12, 115.21, 115.25, 115.27, 115.28, 115.51, and 115.52 concerning the licensing

of home and community support services agencies (HCSSAs). The amended sections cover purpose; application and issuance of initial license; issuance and renewal of license; licensure requirements and standards for agencies providing licensed home health, licensed and certified home health or hospice services; standards for hospice services; standards for branch offices; standards for alternate delivery sites; survey procedures; and enforcement action.

The most significant amendments to the rules implement changes to the Health and Safety Code, Chapter 142 as added by Acts of the 75th Legislature, 1997. Specifically, Senate Bill (SB) 1247 added new statutory requirements under §142.004(c) relating to an HCSSA's provision of certain documentation when applying for a license and §§142.017-142.0175 relating to the assessment of administrative penalties against an HCSSA. House Bill (HB) 3075 added new Health and Safety Code, §§142.061-142.063 relating to an HCSSA's possession of sterile water or saline, possession of certain vaccines or tuberculin, and possession of certain dangerous drugs. House Bill 3100 amended the Human Resources Code, Chapter 102 relating to rights of the elderly, requiring the department to amend the current rule reference to this statute.

The administrative penalty requirements mandated by SB 1247 are unique from other licensing statutes authorizing the department to assess penalties (e.g., hospitals). The unique requirements are that the department may only assess an administrative penalty under rules adopted by the Texas Board of Health: 1) for any number of days a violation occurred before the day on which an HCSSA receives notice of the violation counting as one violation; 2) for each day of a continuing violation occurring after the day the HCSSA receives notice of the violation counting as a separate violation; 3) according to a list of each violation for which a penalty may be assessed; 4) if the department has considered the seriousness of the violation (including the nature, circumstances, extent, and gravity of the violation and the hazard or safety of clients), the history of previous violations, and whether the HCSSA had identified the violation through its quality assurance process, and had made appropriate progress on correction; 5) if the department has provided an HCSSA with a reasonable time to correct the violation prior to assessing a penalty; 6) for minor violations, if these violations are of a continuing nature or not corrected; 7) if the violation is a hazard to the health or safety of an HCSSA client; and 8) according to a schedule of appropriate and graduated penalties.

The Home and Community Support Services Advisory Committee (committee) held two meetings to review the proposed rules: October 14, 1997, and October 22, 1997 (conference call). At their meeting on October 14, 1997, the committee voted to approve the amendments to §§115.1, 115.11, 115.12, 115.21, 115.25, 115.27, 115.28, 115.51, 115.52(a), 115.52(c), and 115.52(d). The committee voted to substantially reformat and change certain language in §115.52(b) relating to administrative penalties and to review the changes via conference call meeting on October 22, 1997. On October 22, 1997, the department presented the reformat and revised language to the committee. The committee did not approve certain revised language. The committee voted to delete §115.52(b)(4)(D)(i)(III) from the level II penalty schedule, move the deleted text to the level I penalty schedule, and to move the text "or substantially limits the agency's capacity to provide care" from §115.52(b)(3)(A)(i) to §115.52(b)(3)(A)(ii). The committee further voted to add the word "calendar" between the