

**COLORADO** Department of Public Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

То:	Members of the State Board of Health
From:	Sean Scott, Deputy Director, Division of Environmental Health and Sustainability
	Cary E. Ruble, Regulation Development and Enforcement Coordinator, Division of Environmental Health and Sustainability
Through:	Jeff Lawrence, Director Division of Environmental Health and Sustainability (92)
Date:	February 17, 2016
Subject:	<b>Request for Rulemaking Hearing</b> Proposed Amendments to 6 CCR 1010-20, <i>Rules and Regulations Governing</i> <i>Artificial Tanning Devices in the State of Colorado</i> , with a request for the rulemaking hearing to occur on February 17, 2016

The Division of Environmental Health and Sustainability ("division") is proposing administrative revisions throughout 6 CCR 1010-20, *Rules and Regulations Governing Artificial Tanning Devices in the State of Colorado*, and is requesting that the Board of Health schedule a rulemaking hearing to consider adoption of the proposed amendments at the April 20, 2016, Board of Health meeting.

In compliance with Executive Order D 2012-002 and the State Administrative Procedure Act (24-4-103.3, C.R.S.), the Colorado Department of Public Health and Environment ("department") has conducted a mandatory review of the *Rules and Regulations Governing Artificial Tanning Devices in the State of Colorado*. Based on this review, and in consideration of U.S. Food and Drug Administration's (FDA) proposed changes to the federal indoor tanning standards, it was determined that only administrative amendments to 6 CCR 1010-20 will be proposed at this time. 6 CCR 1010-20 was last amended by the Board of Health in 1993.

The proposed revision includes:

Standardizing the format of the regulation to comply with the Colorado Secretary of State CCR style template.

Although the proposed revisions to the artificial tanning regulations presently include only administrative changes, the department is aware that on December 18, 2015, the FDA issued two proposed changes and opened a 90-day public comment period regarding radiation safety performance standards for electronic products, including sunlamp products (i.e., artificial tanning devices).

The proposed revisions to the Federal standards, if adopted, would:

- > Restrict use of sunlamp products to individuals 18 and older; and
- Require that sunlamp manufacturers and tanning facilities take additional measures to improve the overall safety of these devices.

Indoor tanning is a known contributor to skin cancer, including melanoma (its most deadly form), and other skin damage. Yet, 1.6 million minors indoor tan each year, increasing their risk of skin cancer and other damage (based on data in the 2013 National Youth Risk Behavior Survey). According to the American Academy of Dermatology, those who have been exposed to radiation from indoor tanning are 59 percent more likely to develop melanoma than those who have never tanned indoors. In addition, the effects of exposure to UV radiation add up over one's lifetime. Therefore, UV radiation exposure in children and teenagers puts them at a greater risk for skin and eye damage later in life. The proposed changes to Federal standards would significantly reduce risk by preventing the use of artificial tanning devices by minors and reducing the risk of using these devices for adults.

Section 25-5-1006(1) C.R.S., requires that the standards established in the department's artificial tanning device regulations can be no less stringent than the Federal (FDA) standards. Should these proposed changes to the Federal standards be adopted, the department would initiate a subsequent rulemaking and take other appropriate measures to ensure compliance with the revised FDA rules.

of Colorado

#### Basis and Purpose.

The purpose of the Board of Health's *Rules and Regulations Governing Artificial Tanning Devices in the State of Colorado*, 6 CCR 1010-20, is to establish provisions regulating the registration and regulation of facilities and equipment which employ ultraviolet and other lamps for the purpose of artificially tanning the human skin through the application of ultraviolet radiation.

The amendments to 6 CCR 1010-20, are being implemented pursuant to the statutory authority granted the Board of Health in Sections 25-5-1006(1),(2)(a), and (2)(b), Colorado Revised Statute (C.R.S.). The Division of Environmental Health and Sustainability ("division") is directed by Executive Order D 2012-002 and the State Administrative Procedure Act (24-4-103.3, C.R.S.) to review all regulations at least once every seven years to ensure that they are efficient, effective and essential. The artificial tanning regulations were last amended in 1993.

The proposed revisions to *Rules and Regulations Governing Artificial Tanning Devices in the State of Colorado* include:

Standardizing the format of the regulation to comply with the Colorado Secretary of State CCR style template.

This rulemaking does not propose changes to align with proposed federal standards regarding artificial tanning radiation safety performance standards as the Food and Drug Administration (FDA) has yet to adopt the proposed changes. Should the proposed changes to the Federal standards be adopted, the department would initiate and complete a subsequent rulemaking effort, inclusive of stakeholder engagement, to align with the new FDA rules.

# Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes: Sections 25-5-1006(1), (2)(a), and (2)(b), C.R.S.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

Yes, the bill number is \_\_\_\_\_; rules are \_\_\_ authorized \_\_\_ required. X\_\_\_ No Is this rulemaking due to a federal statutory or regulatory change?

> \_\_\_\_\_Yes \_\_\_\_X\_\_No

Does this rule incorporate materials by reference?

\_\_\_\_\_Yes \_\_\_\_X\_\_No

Does this rule create or modify fines or fees?

\_\_\_\_\_ Yes \_\_\_\_ No

### **REGULATORY ANALYSIS**

#### for Amendments to 6 CCR 1010-20, Rules and Regulations Governing Artificial Tanning Devices in the State of Colorado

1. A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

Establishments providing access to and users of artificial tanning devices and CDPHE are potentially affected and will benefit from the consistency afforded by the proposed administrative changes to the regulations.

No potential costs will be incurred by artificial tanning facilities based on the administrative changes to the regulation.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

As proposed revisions to the current artificial tanning regulation are only administrative and do not include changes to existing language, therefore, no qualitative or quantitative impact on the regulated community is anticipated.

# 3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

The implementation costs of the proposed revised regulation to CDPHE and the Division of Environmental Health and Sustainability are negligible.

# 4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

At no cost to the regulated community and minimal cost to the department, the benefits of the proposed revision will provide consistency in the formatting of the division's regulations and afford greater efficiency in the incorporation of these changes through future rulemaking should the FDA adopt the proposed changes to the Federal standards.

The costs of inaction are minimal, and there are no benefits from inaction. Inaction would be a disservice to the regulated community and would not comply with department policy to review and update, if necessary, all regulations to assure their relevance.

# 5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

There are no less costly or less intrusive methods for achieving the purpose of the proposed revised regulation. The amendments are necessary to update the formatting

of the rules and achieve consistency with other recently revised division regulations.

### 6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

The artificial tanning device regulations were last revised in 1993. Due to department policy regarding the periodic review and updating of all state regulation and the potential for changes to the FDA rules, alternatives to this rulemaking were not considered.

# 7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

During review of the current artificial tanning regulation and the proposed revisions, the following sources of information were reviewed:

- Executive Order D 2012-002 (EO 2), codified by the Colorado General Assembly at Section 24-4-103.3 CRS (2014)
- Colorado Revised Statutes, Title 25, Article 5, Part 10, Section 1001-1011, *Artificial Tanning Device Operation Act* (25-5-1001-1011, C.R.S).
- 5 CCR 1010-20, *Artificial Tanning Device Regulations*, Effective Date: January 20, 1993
- Federal regulations via http://www.regulations.gov/#!home
- https://www.federalregister.gov/articles/2015/12/22/2015-32023/sunlampproducts-proposed-amendment-to-performance-standard

# STAKEHOLDER COMMENTS

### for Amendments to

# 6 CCR 1010-20, Rules and Regulations Governing Artificial Tanning Devices in the State of Colorado

The following individuals and/or entities were included in the development of these proposed rules:

- CDPHE staff:
  - Cary Ruble, CDPHE DEHS
  - Sean Scott, CDPHE DEHS
  - Jeff Lawrence, CDPHE DEHS
  - o Deborah Nelson, Board of Health Administrator

The following individuals and/or entities were notified that this rulemaking was proposed for consideration by the Board of Health:

- CDPHE staff in the Prevention Services Division
- The public via the Department's website

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The division has been tracking opportunities to improve and modernize this regulation since its last amendment in 1993. A question was raised as to whether the board could prohibit artificial tanning by individuals under the age of eighteen. The Department studied the statute and determined that current statute does not authorize a rule that prohibits artificial tanning. However, the statute does require that the board's rules be no less stringent than the Federal (FDA) standards. On December 18, 2015, the FDA issued two proposed changes and opened a 90-day public comment period regarding radiation safety performance standards for electronic products, including sunlamp products (i.e., artificial tanning devices).

The proposed revisions to the Federal standards related to artificial tanning devices, if adopted, would:

- > Restrict use of sunlamp products to individuals 18 and older; and
- Require that sunlamp manufacturers and tanning facilities take additional measures to improve the overall safety of these devices.

Should these proposed changes to the Federal standards be adopted, the Department would initiate a subsequent rulemaking effort, inclusive of stakeholder engagement, and take any other steps needed to align with the Federal requirements as required by 25-5-1006(1), C.R.S.

# Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

The administrative revisions to the regulation will continue to promote the healthy and safe operation, maintenance, and use of artificial tanning devices by Colorado residents regardless of race, color, national origin, or income. The regulation does not have implications for health equity and environmental justice considerations.

# ARTIFICIAL TANNING DEVICE

# REGULATIONS

Effective Date: January 20, 1993



Colorado Department of Public Health and Environment

#### AUTHORITY: SECTION 25-5-106(1),(2)(a),(2)(b), Colorado Revised Statutes, 1989, as Amended

#### COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT 4300 CHERRY CREEK DRIVE SOUTH DENVER, COLORADO 80222-1530 (303) 692-3620

*This title page does not constitute an official part of any regulation. Information contained on the title page is provided by the Consumer Protection Division from sources deemed reliable and is solely for informational and historical purposes.* 

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# COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

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# Division of Environmental Health and Sustainability

# <u>6 CCR 1010-20</u>

RULES AND REGULATIONS GOVERNING ARTIFICIAL TANNING DEVICES IN THE STATE OF COLORADO

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8		ARTIFICIAL TANNING DEVICES
9		IN THE STATE OF COLORADO
10		CICIAL TANNING DEVICE REGULATIONS
11 12	<u>20.1</u>	Authority
13	This r	egulation is adopted pursuant to the authority in Section 25-5-1006(1),(2)(a), and (2)(b),
14	Colora	ado Revised Statute (C.R.S.) and is consistent with the requirements of the State
15	<u>Admir</u>	nistrative Procedures Act, Section 24-4-101, et seq., C.R.S.
16 17	<del>1-101</del>	-20.2 Scope and Purpose
18	1 101	
19 20 21 22	<u>A.</u>	These rules and regulations provide for This regulation shall govern the registration and regulation of facilities and equipment which employ ultraviolet and other lamps for the purpose of artificially tanning the human skin through the application of ultraviolet radiation.
23 24 25 26	<u>B.</u>	This regulation does not apply to the following exempt devices, as provided in Section 25-5-1005(1)(a), (b) and (c), C.R.S.:
27 28 29 30		1. <u>Artificial tanning devices which are used exclusively for personal,</u> <u>noncommercial purposes by the owner, members of the owner's family, or</u> <u>persons authorized by the owner to use the device;</u>
31 32 33 34		a. <u>Phototherapy devices used by or under the supervision of a licensed</u> <u>physician or other licensed health care professional with the scope of</u> <u>such person's practice for the purposes of treating diseases; and,</u>
35 36 37		b. <u>Artificial tanning devices which are in transit or storage and are not</u> made available for the use during such transit or storage.
38 39 40 41 42 43	<u>C.</u>	Nothing in this regulation shall be construed to mean that the Department endorses any type of artificial tanning device, any location of such devices, any business which provides artificial tanning devices for the use by the public, or the use of any such devices.

## 44 20.3 Applicability

45
46 A. The provisions of this section shall be applicable to all artificial tanning devices and
47 facilities as defined in Sections 25-5-1003 and 25-5-1004, C.R.S., and definitions
48 20.4(A)(2) and 20.4(A)(14) of these regulations.

#### 50 <u>1-10220.4 Definitions</u>

- 52 <u>A.</u> For the purpose of these rules and regulations:
  - (a) <u>Approved</u> shall\_means acceptable to the Colorado Department of <u>Public</u> Health <u>and Environment</u>, or its authorized agents, or employees based on determination of conformance with applicable documented standards and good public health practices.
  - 2. (b) <u>Artificial Tanning Device</u> shall means any equipment that as defined in Section 25-5-1003(1), C.R.S. 1989, as amended.
    - 3. (c) <u>Board</u> shall-means the State Board of Health as defined in Section 25-5-1003(2), C.R.S. 1989, as amended.
      - <u>4.</u> <u>(d)</u><u>Consumer</u> <u>shall</u><u>means</u> any individual who is provided access to a tanning facility which is required to be registered as provided in Section 25-5-1004(1), C.R.S. 1989, as amended.</u>
        - 5. <u>(e) Department shall means</u> the Colorado Department of Health, or its authorized agents, or employees.
    - <u>6.</u> (f) <u>Inspection</u> shall means an official examination or observation by the Department including, but not limited to, tests, surveys, and monitoring of artificial tanning devices and tanning facilities.
      - 7. (g) Operator shall means any individual designated by the registrant to operate or to assist and instruct the consumer in the correct operation and use of artificial tanning device(s).
      - 8. (h) Owner shall means a person in possession and in charge of an artificial tanning facility, and/or tanning device(s), except as exempted in 1-10320.2(B) of these regulations.
    - 9. (i) <u>Person</u> shall-means a natural person, partnership, association, company, corporation, or organization or a manager, agent, servant, officer, or employee thereof.
    - <u>10.</u> (j) Phototherapy Device shall means a piece of equipment as defined in Section

		25-5-1003(5), C.R.S1989, as amended.
	<u>11.</u>	<del>(k) <u>Registrant</u> shall means</del> any person who is registered with the Department as provided in Section 25-5-1004(1), C.R.S. <del>1989, as amended.</del>
	<u>12.</u>	<del>(l) <u>Registration</u> shall</del> mean <u>s</u> registration with the Department in accordance with the provisions of Section 25-5-1004(1), C.R.S. <del>1989, as amended.</del>
	<u>13.</u>	(m) <u>Tanning equipment</u> shall-means ultraviolet or other lamps and equipment containing such lamps intended to induce skin tanning through the irradiation of any part of the living human body.
	<u>14.</u>	<del>(n) <u>Tanning Facility</u> shall mean<u>s</u> any location, premises, place, area, structure, or business, as defined in Section 25-5-1003(6), C.R.S. <del>1989, as amended.</del></del>
	<u>15.</u>	<del>(o) <u>Ultraviolet</u> radiation</del> <del>shall</del> -mean <u>s</u> electromagnetic radiation as defined in Section 25-5-103(7), C.R.S. <del>1989, as amended.</del>
<u>1-103</u>		tions. Exemptions shall be as provided in Section 25-5-1005(1)(a)(b) and (c),
	<u>C.R.S.</u>	1989, as amended.
2-201	20 5	Application for Registration of Artificial Tanning Facilities
	20.5	Application for Registration of Artificial Failining Facilities
<u>A.</u>	<del>(a)</del> registr	Each person having an artificial tanning facility on January 1, 1993 shall apply for ation of such facility no later than thirty (30) days from January 1, 1993.
<u>B.</u>	• •	—Each person establishing or acquiring a tanning facility after January 1, 1993, shall for registration of each location for such facility prior to beginning operation of such a y.
<u>C.</u>	compl	—The application <del>required in 2-202(a) and 2-202(b) of this regulation</del> shall be eted on forms provided by the Department and shall contain all the information ed by such forms.
<u>D.</u>	• •	—The Department shall require at least the following information on the forms led when applying for registration of each tanning facility:
	<u>1.</u>	<del>(1)</del> Name, mailing address, location if different than mailing address, and telephone number of the tanning facility;
	<u>2.</u>	<del>(2)</del> ——Name(s), mailing address(es) and telephone number(s) of the owner(s) of the tanning facility;
	<u>3.</u>	(3) The manufacturer(s), model number(s), and type(s) of ultraviolet lamp(s) or tanning equipment located within the facility;
	<u>2-201</u> <u>А.</u> <u>В.</u> <u>С.</u>	$     \begin{array}{c}         12. \\         13. \\         14. \\         15. \\         14. \\         15. \\         14. \\         15. \\         14. \\         15. \\         14. \\         15. \\         14. \\         15. \\         15. \\         15. \\         15. \\         15. \\         15. \\         15. \\         14. \\         15. \\         10. \\         15. \\     $

134		<u>4.</u>	(4)——The geographic areas within the State to be covered, if the facility is mobile;
135			and,
136			
137		<u>5.</u>	(5) A signed and dated application for registration that the applicant will comply
138			with the requirements of these regulations.
139			
140	<u>2-202</u>	20.5.1	Duration of Registration:
141			
142	Α.	<del>(a)</del>	-Registration is valid for a period of one calendar year. Applications for registration
143			be made during the month of December of each year.
144		Shatt	
145	<u>B.</u>	<u>(b)</u>	All registrations shall expire at midnight on December thirty-first of the year for
146	<u>D.</u>	• •	issued.
147		which	
148	<u>C.</u>	(c)	—The annual registration fee shall be prorated on a monthly basis for any initial
149	<u>c.</u>		ration received after January 1 of any year.
150		registi	acion received arter January i or any year.
150	П	(d)	—A registration shall not be granted without prior payment of the tanning equipment
152	<u>D.</u>	• •	
		ree re	quired in <u>Section</u> 25-5-1004(2), C.R.S.
153	2 202	20 E 2	Transfor of Devistration.
154	2-203	20.5.2	Transfer of Registration:
155			
156	<u>A.</u>	-	ration is not transferable from one person to another person or from one tanning
157			
157		Tacilit	y to another tanning facility.
158	/		
158 159	<del>2-204</del>		Report of Change:
158 159 160		<u>20.5.3</u>	Report of Change:
158 159 160 161	<del>2-204</del> <u>A.</u>	<u>20.5.3</u> (a)	Report of Change: —The registrant shall notify the Department in writing before making any change which
158 159 160 161 162		<mark>20.5.3</mark> (a) would	<b>Report of Change:</b> —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer
158 159 160 161 162 163		<u>20.5.3</u> (a)	<b>Report of Change:</b> —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer
158 159 160 161 162 163 164	<u>A.</u>	20.5.3 (a) would accura	<b>Report of Change:</b> —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate.
158 159 160 161 162 163 164 165		20.5.3 (a) would accura (b)	Report of Change: —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate. —Any new or additional tanning equipment which was not previously reported to the
158 159 160 161 162 163 164 165 166	<u>A.</u>	20.5.3 (a) would accura (b)	<b>Report of Change:</b> —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate.
158 159 160 161 162 163 164 165 166 167	<u>A.</u> <u>B.</u>	20.5.3 (a) would accura (b) Depar	Report of Change: —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate. —Any new or additional tanning equipment which was not previously reported to the tment shall be reported at the time of annual registration.
158 159 160 161 162 163 164 165 166	<u>A.</u> <u>B.</u>	20.5.3 (a) would accura (b) Depar	Report of Change: —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate. —Any new or additional tanning equipment which was not previously reported to the
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158 159 160 161 162 163 164 165 166 167 168	<u>A.</u> <u>B.</u>	20.5.3 (a) would accura (b) Depar 20.5.4	Report of Change: —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate. —Any new or additional tanning equipment which was not previously reported to the tment shall be reported at the time of annual registration.
158 159 160 161 162 163 164 165 166 167 168 169	<u>A.</u> <u>B.</u> <del>2-205</del>	20.5.3 (a) would accura (b) Depar 20.5.4 The D	Report of Change: —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate. —Any new or additional tanning equipment which was not previously reported to the tment shall be reported at the time of annual registration. Termination of Registration.
158 159 160 161 162 163 164 165 166 167 168 169 170	<u>A.</u> <u>B.</u> <del>2-205</del>	20.5.3 (a) would accura (b) Depar 20.5.4 The D termin	Report of Change: —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate. —Any new or additional tanning equipment which was not previously reported to the tment shall be reported at the time of annual registration. Termination of Registration.
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158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173	<u>A.</u> <u>B.</u> <del>2-205</del> <u>A.</u>	20.5.3 (a) would accura (b) Depar 20.5.4 The C termin paid f	Report of Change: —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate. —Any new or additional tanning equipment which was not previously reported to the tment shall be reported at the time of annual registration. Termination of Registration. Department may terminate a registration upon receipt of a written request for nation from the registrant. Once a tanning facility is registered and the fee has been or the year, no portion of the fee will be refunded.
158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174	<u>A.</u> <u>B.</u> <del>2-205</del> <u>A.</u> <u>2-206</u>	20.5.3 (a) would accura (b) Depar 20.5.4 The D termin paid f	Report of Change: —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate. —Any new or additional tanning equipment which was not previously reported to the tment shall be reported at the time of annual registration. Termination of Registration. Department may terminate a registration upon receipt of a written request for nation from the registrant. Once a tanning facility is registered and the fee has been or the year, no portion of the fee will be refunded.
158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175	<u>A.</u> <u>B.</u> <del>2-205</del> <u>A.</u>	20.5.3 (a) would accura (b) Depar 20.5.4 The D termin paid f 520.6 (a)	Report of Change: —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate. —Any new or additional tanning equipment which was not previously reported to the tment shall be reported at the time of annual registration. Termination of Registration. Department may terminate a registration upon receipt of a written request for nation from the registrant. Once a tanning facility is registered and the fee has been or the year, no portion of the fee will be refunded. Prohibited Advertisement:
158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176	<u>A.</u> <u>B.</u> <del>2-205</del> <u>A.</u> <u>2-206</u>	20.5.3 (a) would accura (b) Depar 20.5.4 The D termin paid f 520.6 (a) persor	Report of Change: —The registrant shall notify the Department in writing before making any change which render the information contained in the application for registration no longer ate. —Any new or additional tanning equipment which was not previously reported to the tment shall be reported at the time of annual registration. Termination of Registration. Department may terminate a registration upon receipt of a written request for nation from the registrant. Once a tanning facility is registered and the fee has been or the year, no portion of the fee will be refunded. Prohibited Advertisement: —No person, in any advertisement or promotion, shall state or imply that because such

179		activity under such registration has been approved by the Department.
180 181 182 183 184	<u>B.</u>	No person, in any advertisement or promotion, shall indicate that such person's artificial tanning device(s) is safe or free of hazards from ultraviolet radiation, nor imply use as a medical device or treatment.
185	<u>3-301</u> 2	20.7 Construction and Operation of Tanning Facilities
186 187 188 189 190	operate	otherwise ordered or approved by the Department, each tanning facility shall be constructed, ed and maintained to meet the following minimum requirements:
190 191	<del>(d)</del> 20.	7.1 Warning Signs
191 192 193 194 195 196	<u>A.</u>	(1) — The following warning sign shall be posted in the immediate proximity (within one meter) of each tanning station; it shall be readily legible, clearly visible, and not obstructed by any barrier, equipment, or other item present so that the user can easily view the warning sign before activating the tanning equipment.
197		***************************************
198		DANGERULTRAVIOLET RADIATION
199		Follow instructions.
200		<ul> <li>Avoid overexposure. As with natural sunlight, exposure can cause</li> </ul>
200		premature aging of the skin and skin cancer. As with natural
202		sunlight, overexposure can cause eye and skin injury and allergic
203		reactions. Repeated exposure may cause premature aging of the
204		skin and skin cancer.
205		WEAR PROTECTIVE EYEWEAR. FAILURE TO USE PROTECTIVE
206		EYEWEAR MAY RESULT IN SEVERE BURNS OR LONG TERM INJURY
207		TO THE EYES.
208		<ul> <li>Medications or cosmetics may increase your sensitivity to the</li> </ul>
209		ultraviolet radiation. Consult a physician before using sunlamp if
210		you are using medications or have a history of skin problems, or
211		believe yourself especially sensitive to sunlight.
212		• If you do not tan in the sun, you are unlikely to tan from the use
213		of this product.
214		*****
215 216 217	<u>B.</u>	<del>(2)</del> The lettering on each warning sign shall be at least ten millimeters high for all words shown in capital letters and at least five millimeters high for all lower case letters.
218 219 220	<del>(b)</del> 20.	7.2 Physical Facilities
220 221	<u>A.</u>	(1) Only tanning equipment manufactured in accordance with the specifications set forth

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in 1991 21 CFR Part 1040, Section 1040.20, "Sunlamp products and ultraviolet lamps intended
 for use in sunlamp products", shall be used in tanning facilities. The exact nature of
 compliance shall be based on the standard in effect at the time of manufacture as shown on
 the device identification label required by 1991 21 CFR Part 1010, Section 1010.3.

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- 227 —Each assembly of tanning equipment shall be equipped with a timer which complies Β. (2)228 with the requirements of 1991 21 CFR 1040.20 (c) (2). The maximum timer interval shall not 229 exceed the manufacture's maximum recommended exposure time. No timer interval shall 230 have an error exceeding plus or minus 10 percent of the maximum timer interval for the 231 product. The registrant shall ensure that tests are preformed on each assembly of tanning 232 equipment, at least annually, and documented in writing to ensure the timer is accurate to 233 within 10% of the maximum exposure time. A record of timer testing results shall be kept at 234 each tanning facility location.
- 236 <u>C.</u> (3)—The timer intervals shall be numerically indicated, at ten (10) minute intervals to a maximum of thirty (30) minutes.
- 239 D. (4) The timer may not automatically reset and cause radiation emission to resume for a
   240 period greater than the unused portion of the timer cycle, when emission from the tanning
   241 device has been terminated.
   242
- 243 <u>E.</u> (5)—The timer requirements do not preclude a product from allowing a user to reset the
   244 timer before the end of the preset time interval.
   245
- <u>F.</u> (6) Each assembly of tanning equipment shall be provided with a control on the equipment to enable the consumer to terminate manually radiation emission from the equipment at any time without disconnecting the electrical plug or removing any ultraviolet lamp.
   250
- 251G.(7)Tanning equipment shall be provided with ground fault protection on the electrical252circuit, or other methods for preventing shock.
- <u>H.</u> (8) Tanning equipment shall include physical barriers to protect consumers from injury induced by touching or breaking the lamps.
   256
- 257 <u>I.</u> (9) Each tanning device shall be operated to preclude any thermal burns to human skin or cause heat prostration.
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# 260 (c)20.7.3 Additional Requirements for Stand-Up Booths and any Cabinet or 261 Vertical Tanning Device: 262

- A. (1) Tanning booths and cabinets or vertical tanning device(s) designated for stand-up use
   shall also comply with the following additional requirements:
- 266 <u>B.</u> (2) Booths shall have physical barriers or other means, such as handrails or floor

consumer's skin;

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270 271	<u>C.</u>	(3) —Booths shall be constructed with sufficient strength and rigidity to withstand the stress of use and the impact of a falling person;
272 273 274	<u>D.</u>	(4)——Access to booths shall be rigid construction with doors which are non-latching and open outwardly;
275 276 277	<u>E.</u>	<del>(5)</del> Booths shall be equipped with handrails and non-slip floors.
278 279	<del>(d)</del> 20.7	7.4 Protective Eyewear:
280 281 282 283	<u>A.</u>	(1) Registrants are responsible to provide protective eyewear to each consumer during use of tanning equipment however; consumers may use their own protective eyewear if approved by the registrant.
284 285 286	<u>B.</u>	$\frac{(2)}{(2)}$ The protective eyewear in this regulation shall meet the requirements of $\frac{1991}{21}$ CFR 1040.20(c)(4).
287 288 289 290	<u>C.</u>	(3)——Tanning facility operators shall instruct the consumer in the proper utilization of the protective eyewear. Eyewear must be worn when the lamps are energized. The eyepiece must be in place, and must cover the eye sockets of the user.
291 292 293	<u>D.</u>	(4)——Tanning facility operators shall ensure all protective eyewear is clean and sanitized, the eyewear has no defects, the frames and lenses contain no cracks, abrasions and that the lenses are not clouded.
294 295 296	<del>(e)</del> 20.7	7.5 Sanitation <del>:</del>
297 298 299 300 301	<u>A.</u>	(1) The registrant shall ensure that an operator properly sanitizes the tanning equipment and the protective eyewear between every use by a consumer. Exposure to the ultraviolet radiation produced by tanning equipment is not adequate sanitization. The sanitizer used shall be one registered for such use by the U.S. Environmental Protection Agency or the Colorado Department of Agriculture.
302 303 304 205	<u>B.</u>	(2) The floors, walls and fixtures in tanning facilities shall be kept clean and in good repair at all times.
305 306 307 308 309 310	<u>C.</u>	(3) If towels or linens are provided to consumers, they shall be clean and sanitary. Towels and linens shall be washed between each use. Towels shall be stored in a clean place. Soiled towels and linens shall be stored in nonabsorbent containers or washable laundry bags.
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markings, to indicate the proper exposure distance between ultraviolet lamps and the

311 312			Consumer Warning:
312 313 314 315 316	<u>A.</u>	shall	—Prior to initial exposure to ultraviolet radiation at a tanning facility, the consumer be given a copy of the warning statements and must be supplied with at least the ving information:
317 318 319 320 321 322		<u>1.</u>	(a) A representative list of potential photosensitizing drugs and agents. This list should at least include drugs or agents in the product classes of acne treatment, antibacterials, antibiotics, anticonvulsants, antidepressants, antibacterials, antihypertensive, dye, estrogen and progesterones, melanogenics, perfumes and toilet articles, tranquilizers, antihistamines and antimicrobials/antinfectious agents.
323 324 325		<u>2.</u>	(b) Information regarding potential negative health effects related to ultraviolet exposure, including:
326 327 328 329 330			<u>a.</u> (1) The increased risk of skin cancer later in life; and potential detrimental health risks including skin cancer; a significant increased risk of skin cancer/melanoma, when a painful blistering sunburn has occurred prior to the age of eighteen (18).
331 332			<u>b.</u> $(2)$ The increased risk of skin thickening and premature aging;
333			<u>c.</u> (3)—The possible activation of some viral conditions (cold sores); and,
334 335 336 337 338 339 340			<u>d.</u> (4) The possibility of skin burning or rashes, especially if using any of the potential photosensitizing drugs and agents. Potential clients who are using photosensitizing medication, have a history of sun sensitivity or have a history of sun related skin problems should be advised not to use the tanning device.
340 341 342		<u>3.</u>	<del>(c)</del> —Basic information on how different skin types respond to tanning.
343 344 345 346		<u>4.</u>	(d) An explanation of the need to use protective eyewear with both ultraviolet-A (UVA) and ultraviolet-B (UVB) systems, and that closing the eyes is not sufficient to prevent possible eye damage.
347 348 349 350		<u>5.</u>	(e) Information that tanning may be inadvisable during pregnancy and information that tanning is inadvisable for persons with photosensitizing diseases, melanoma or other skin cancers.
351	<u>4-401</u>	20.8	Records
352 353 354 355	<u>A.</u>		—The registrant shall maintain records ensuring that the requirements of <del>3-301(b)(l)</del> <del>2)</del> 20.7.2(A), have been met.

356 357 358	<u>B.</u>	<del>(b)</del> —Each registrant shall keep records showing receipt, transfer, and disposal of all tanning equipment.
359 360	<u>5-50′</u>	1-20.9 Report of Accident or Adverse Reaction
360 361 362 363 364	<u>A.</u>	(a) — The registrant shall submit to the Department a written report, as provided in Section 25-5-1007(6) C.R.S. 1989, as amended, of any accident or adverse reaction to the use of any artificial tanning device within fifteen days after discovery of the event;
365 366	<u>B.</u>	<del>(b)</del> ——The report shall include:
367 368		<u>1.</u> (1)—The name, address, telephone number of the affected individual;
369 370 371		<ul> <li><u>(2)</u> The name, address, telephone number of tanning facility, and identification of the specific tanning device involved;</li> </ul>
372 373 374 375		3. (3) The nature of the actual or alleged accident or adverse reaction, and any other information relevant to the actual or alleged accident or adverse reaction including duration of exposure; and,
375 376 377 378		<u>4.</u> (4)—Name of attending physician, if applicable, medical attention sought and treatment.
379 380	<u>6-60</u>	120.10 Replacement of Ultraviolet Lamps, Bulbs or Filters
381 382 383 384	<u>A.</u>	(a) ——The registrant shall only use lamps which have been certified with the Food and Drug Administration (FDA) as "equivalent" lamps under the FDA regulations and policies applicable at the time of replacement of the lamps.
385 386 387 388	<u>B.</u>	(b) — The registrant shall replace defective or burned out lamps, bulbs or filters with a type intended for use in the affected tanning equipment as specified on the product label and having the same spectral distribution.
389 390 391	<u>C.</u>	<del>(c)</del> The registrant shall maintain manufacturer's literature demonstrating the equivalency of any replacement lamps.
392 393 394	<u>D.</u>	(d) Defective or burned-out lamps or filters shall be replaced before further use of the tanning equipment.
395 396	<u>E.</u>	<del>(e)</del> —Lamps and bulbs designated for medical use only shall not be used.
397 398	<u>7-70′</u>	1-20.11 Inspections
399 400	<u>A.</u>	(a) Agents of the Department, after proper identification, shall be permitted to enter any tanning facility during business hours for the purpose of making inspections,

401	investigating complaints and to determine compliance with these regulations. Agents of the
402	Department shall not inspect any tanning device while in use by consumers.
403	

- 404B.(b)Each registrant shall make available to the Department records and documents, upon405reasonable notice, maintained pursuant to the requirements of these regulations.
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407 Copies of "Code of Federal Regulations" (CFR) are available for reference from the Director,

408 Consumer Protection Division, Colorado Department of Health, 4300 Cherry Creek Drive South,

409 Denver, Colorado 80222-1530. This reference does not include later amendments to or editions

410 of the incorporated material.