



# Oregon

John A. Kitzhaber, MD, Governor

## *Health Licensing Agency*

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**WHO:** Oregon Health Licensing Agency  
Board of Cosmetology

**WHEN:** October 24, 2011 – 9 am

**WHERE:** Oregon Health Licensing Agency  
Rhoades Conference Room  
700 Summer St NE, Suite 320  
Salem, Oregon

### **What is the purpose of the meeting?**

The purpose of the meeting is to conduct regular board business. Please use appropriate language, manners and protocols when conducting board business. A working lunch may be served for board members and designated staff in attendance. A copy of the agenda is printed with this notice. Please visit <http://egov.oregon.gov/OHLA/COS/meetings.shtml> for current meeting information.

### **Is the public or licensees allowed to attend the meeting?**

Yes. Members of the public are invited and encouraged to be in attendance at all board/council meetings. All public audience members are asked to sign-in on the attendance roster prior to the meeting. Comments may be heard under public comment at the end of the meeting. Please wait to be recognized by the Chairperson prior to commenting.

### **Is it possible to watch the meeting live on the internet?**

Yes. You may access the meeting at <https://oregon.ilinc.com/join/wwvjcc> (Link provided is specific to this meeting date) If you need assistance accessing the meeting contact the iLinc Join Help Desk at 1-800-799-4510, and select option "1."

### **What if the board/council enters into executive session?**

Prior to entering into executive session the board/council chairperson will announce the nature of and the authority for holding executive session, at which time all audience members are asked to leave the room with the exception of news media and designated staff. Executive session would be held according to ORS 192.660.

No final actions or final decisions will be made in executive session. The board/council will return to open session before taking any final action or making any final decisions.

### **Who do I contact if I have questions or need special accommodations?**

The meeting location is accessible to persons with disabilities. A request for accommodations for persons with disabilities should be made at least 48 hours before the meeting. For questions or requests contact a board specialist at (503) 373-2049.

All members are asked to please give at least 24-hour notice if they are unable to attend the meeting so arrangements may be made.



Oregon Health Licensing Agency  
Board of Cosmetology



9 am, Monday, October 24, 2011  
700 Summer Street N.E., Suite 320  
Salem, Oregon

Revised 10/23/2011

**Call to Order**

**Introduction of new board member Peggy Zepp**

1. **Approval of Agenda**
2. **Approval of Minutes**
  - ◆ July 25, 2011
3. **Reports**
  - ◆ Director's Report
    - 2013 Legislative Concept Discussion
    - 2012 Chair Summit
  - ◆ Statistical and Budget Report
  - ◆ Regulatory Report
    - FDA Warning Letter Sent to Brazilian Blowout
  - ◆ Policy, Legislation & Administrative Rules
    - OHLA Permanent Administrative Rules
4. **Executive Session** - ORS 192.660 (2)(f) for the purpose of considering information or records exempt from public inspection.
  - a. Airbrush Tanning
  - b. Skin micro-needling
  - c. Tattoo Removal

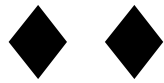
**Working Lunch**

5. **Items for Board Action**
  - ◆ Approve Administrative Rulemaking Schedule and Proposed Administrative Rules
    - Temporary Administrative Rule – Civil Penalty & American Disabilities Act
  - ◆ 2012 Chair/Vice-Chair
  - ◆ 2012 Committees
  - ◆ 2012 Board Meeting Dates
6. **Public Comment**
7. **Other Board Business**
  - ◆ Practical Examination by Career Schools

**Agenda is subject to change.**

**For the most up to date information visit [www.oregon.gov/OHLA](http://www.oregon.gov/OHLA)**

# **Approval of Minutes**



**July 25, 2011**



Oregon Health Licensing Agency  
Board of Cosmetology



9 am, Monday, July 25, 2011  
700 Summer Street NE, Suite 320  
Salem, Oregon

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**MINUTES**

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**MEMBERS PRESENT**

Debora Masten, Chair  
Sharon Wisner, Vice-Chair  
Shelly Couch  
Tiffany Galvan  
Heidi Zuniga  
Lisa Bonner Brown

**STAFF PRESENT**

Randy Everitt, Director  
Katherine Lozano, Assistant Attorney General  
Sylvie McMillan, Fiscal Services and Licensing Manager  
David Sparks, Regulatory Operations Manager  
Callie Zink, Administrative Services Manager  
Samie Patnode, Policy Analyst  
Sinnamon Harris, Board Specialist

**MEMBERS ABSENT:**

Herb Hirst

**GUESTS PRESENT:**

Mike Snook  
Peggy Zepp

\*This meeting was live video streamed.

**Call to Order**

Debora Masten, Chair, called the meeting of the Board of Direct Cosmetology to order at 9:03 am, Monday, July 25, 2011, at the Oregon Health Licensing Agency (OHLA), Rhoades Conference Room, 700 Summer Street NE, Salem, Oregon. Roll was called.

Debora Masten welcomed new board member Lisa Bonner Brown to the Board of Cosmetology. Bonner Brown said she is a practitioner and a salon owner.

**1. Approval of Agenda**

**MOTION:**

Shelly Couch made a motion with a second by Heidi Zuniga to approve the agenda. Motion passed unanimously.

## **2. Approval of Minutes**

### **MOTION:**

Shelly Couch made a motion with a second by Tiffany Galvan to approve the minutes for April 25, 2011. Motion passed unanimously.

## **3. Reports**

### **◆ Directors Report**

Randy Everitt, Director, welcomed new board member Lisa Bonner Brown. Everitt also thanked Debora Masten for her years of service to the Board of Cosmetology as her terms ends with this board meeting. He said it had been a pleasure working with Masten as board chair and she has contributed greatly to the profession.

Everitt explained that due to staffing issues and a full slate of administrative rulemaking scheduled for this summer through the rest of 2011, rulemaking for certain OHLA regulated professions have been postponed. This allows the agency to focus on rulemaking for those professions with the most immediate and significant issues related to public health, safety and risk.

Everitt stated that the agency has developed a strategic plan that prioritizes administrative rulemaking for the next 18 months. He noted the plan is flexible and subject to change depending upon the agency's ability to address staffing issues. Everitt pointed out the agency is undergoing major changes to the makeup of its boards and councils and added the Board of Licensed Dietitians to the agency as a result of the 2011 Legislative Session.

Everitt stated that new professions, those with a temporary rule already in place, or those that are experiencing a significant risk to public safety, are top priority to undergo rulemaking in this strategic plan. Those that fall within these categories are assigned a Level 1 priority. It was noted that the Board of Cosmetology does not currently meet the criteria for immediate rulemaking. The Board of Cosmetology has just finished a primary revision of the administrative rules. The agency will address emergency issues as they arise.

Everitt asked the board to begin thinking about legislative concepts for 2013 as the agency would like to begin discussions in late September or early October. The agency will advise the board of any statutory issues that may need to be addressed.

### **◆ Statistical Report**

Sylvie McMillan, Fiscal Services and Licensing Manager, presented an overview of statistics related to the board. Statistics included licensing, examination and regulatory statistics, active license trends, complaints, and website traffic.

### **◆ 2010-2011 Budget**

McMillan presented the statements of cash flow for the 7/1/2009 – 6/30/2011 biennium, the 7/1/2011 – 12/31/2011 end of the year and 7/1/2011 – 6/30/2013 biennium. McMillan spoke about offering discounts for facility owners who renew their facility licenses online. She presented information about the "Platinum" cost allocation model for the 7/1/2011 – 12/31/2011 which breaks down the percentages of the services provided to the board. Please see chart below:

OREGON HEALTH LICENSING AGENCY COSMETOLOGY FUND 7520 STATEMENT OF CASH FLOW FOR THE PERIOD 07/01/11- 06/30/13	
11-13' Beginning Cash Balance	\$ 213,508.02
Revenues	\$ 5,857,702.41
Dept of Education Transfers In	\$ 8,400.00
Expenditures	\$ 5,203,800.76
Less: Accrued Expenditures	\$ -
Less: Total Expenditures	\$ (5,203,800.76)
Subtotal: Resources Available	\$ 875,809.67
Change in (Current Assets)/Liabilities	\$ -
<b>Ending Cash Balance (Estimate)</b>	<b>\$ 875,809.67</b>
<b>Ending Cash Balance Goal</b>	<b>\$ 660,000.00</b>
<b>COSMETOLOGY, Platinum Allocation, 07/1/11 - 12/31/11</b>	
License Volume Rate	91.95%
Small Board / Council Assessments	- 6.00%
<b>Shared Cost Rate for ADMIN, FISCAL/LICENSING, REGULATORY</b>	<b>85.95%</b>
<b>Educational Services, Cost Rate</b>	<b>26.32%</b>
<b>Frontline and Customer Support, Cost Rate</b>	<b>91.95%</b>
<b>Cosmetology Support Staff, Direct</b>	<b>100.00%</b>
<b>Inspections, Cost Rate</b>	<b>93.24%</b>
<b>Cosmetology Investigations, Direct</b>	<b>100.00%</b>
<b>Cosmetology Regulatory Admin, Direct</b>	<b>100.00%</b>
<b>Other Direct Cosmetology Expenditures</b>	<b>100.00%</b>

◆ **Regulatory Operations Division Report**

David Sparks, Regulatory Operations Manager, reported on enforcement activity. Sparks stated between July 2009 and June 2011, 381 complaints were filed with the agency. Twelve percent of those 381 remain open. The current regulatory reporting period is July 1, 2011, through July 25, 2011. The agency had received 12 complaints during this period. Sparks noted seventy-seven notices went out since the last April 25, 2011, board of Cosmetology meeting for approximately \$34,500 in civil penalties.

Sparks said the regulatory staff was working on developing a civil penalties matrix so fines could be assessed more objectively. McMillan noted that if a contested case hearing is lost by the respondent during disciplinary proceedings, the respondent can be assessed the agency's attorney fees up to \$5,000.

Below is a table of complaints and the complaint type:

Open complaints	
Complaint Count	Complaint Type Description
1	Critical Complaint regarding licensing
21	Licensing Concern
13	Safety/Sanitation Issues
10	Services Provided

◆ **Policy, Legislation & Administrative Rules**

Samie Patnode, Policy Analyst, presented the permanent administrative rules certificate and order for filing. It includes protocols for authorization holders who are in active military status, definition of “appearance,” incompetence and negligence as used in the law. The administrative rule will become effective August 15, 2011.

**4. Items for Board Action**

The board was asked to determine additional training requirements for applicant Long Truong, prior to his taking the Nail Technology written examination for his eighth attempt. The recommendation of additional training hours was 33% or 115 hours of the initial 350 hours of training. Training hours would be reported via certification of completed hours signed by an authorized representative at a licensed career school.

The 33% or 115 hours would be as follows:

- 6% or 21 hours of Chemicals
- 2% or 7 hours of Standards
- 6% or 21 hours of Diseases
- 8% or 24 hours of Definitions
- 6% or 21 hours of Equipment
- 6% or 21 hours of General

**MOTION:**

Shelly Couch made a motion with a second by Tiffany Galvan to approve the agency’s recommendation to require Long Truong to complete the training hours as listed above, prior to taking the nail technology written examination for his eighth attempt. The motion passed unanimously.

The board was asked to determine additional training requirements for applicant Tuoi Nguyen, prior to her taking the Nail Technology written examination for her eighth attempt. The recommendation of additional training hours was 55% or 194 hours of the initial 350 hours of training. Training hours would be reported via certification of completed hours signed by an authorized representative at a licensed career school.

The 55% or 194 hours would be as follows:

- 11% or 39 hours of Chemicals
- 2% or 7 hours of Standards
- 9% or 32 hours of Diseases

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10% or 35 hours of Definitions  
11% or 39 hours of Equipment  
12% or 42 hours of General

**MOTION:**

Shelly Couch made a motion with a second by Lisa Bonner Brown to approve the agency's recommendation to require Tuoi Nguyen to complete the training hours as listed above, prior to taking the nail technology written examination for her eighth attempt. The motion passed unanimously.

**5. Public Comment**

Mike Snook commented he had been contacted by a law firm regarding providing the state individual field-of-practice and Oregon Laws and Rules examinations in languages other than English.

**6. Other Board Business/Board Interest**

Patnode discussed two emails received from cosmetology stakeholders. One was an inquiry and suggestions made by Connie McArtor regarding various issues. Patnode responded with information regarding the Oregon Students Assistance Commission scholarship program for cosmetology students, as well as links to Family Health Insurance Assistance Program (FHIAP) and the Department of Education (DOE).

Renee Ford inquired how to "challenge" the state board to receive a certificate to only braid hair. Patnode responded noting the legal requirement to be certified in barbering or hair design is written in Oregon Revised Statutes Chapter 690, and cannot be changed by the Health Licensing Agency or by the Board of Cosmetology. Patnode provided Ms. Ford the relevant statutes ORS 690.005(1)(a) through (d) and ORS 690.005(10)(a) through (c). She also provided the information related to the Oregon State Legislature.

Sinnamon Harris, Board Specialist, presented four articles of interest to the board: *Program Helps Prevent Foot Infections, Dirt Under the Nails, Chemicals May Be Risky to Nail Salon Workers, and Calls for FDA to Regulate Hair Straighteners.*

**7. Executive Session-Place Holder**

Debora Masten called the committee into executive session under ORS 192.660(2)(f) "for the purpose of considering information or records exempt from public inspection" at 10:17 am.

Debora Masten reconvened open session at 11: 25 am and welcomed any audience members back into the room. No recommendations or decisions were made during executive session.

Patnode stated face-painting and temporary tattoos were found, by the agency's Assistant Attorney General Katharine Lozano, *not to be within the esthetics scope of practice* and thus did not require certification. Hair braiding is included in hair design scope of practice requiring certification. Since these are frequently asked questions from practitioners the agency will decide how best to communicate the legal advice to certificate holders and the public.

The meeting adjourned at approximately 11:26 am.

# **Director's Report**



# 2013 Legislative Concepts

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## OREGON HEALTH LICENSING AGENCY

The Oregon Health Licensing Agency (OHLA) begins the legislative process more than a year before the actual legislative session.

To begin the process the agency has compiled a list of possible legislative concepts for each program. Members are asked to review the list and make comments as well as add additional changes. As part of that process the agency will consider all comments and suggestions and may call on the individual boards and councils Legislative & Rules Committees to fine tune language or to act as experts in a particular profession.

### **OHLA ORS 676 – Streamline the following among all OHLA professions:**

- Continuing education authority;
- Renewal requirements;
- Fee structure;
- Complaint and investigation confidential;
- Disclosure of confidential information to other public entity; and
- Charitable events exception for all programs or relevant programs;

### **Board of Athletic Trainers ORS 688:**

- Remove NATA references; and
- Standardized definition of “Physician Extender”.

### **Board of Body Art Practitioners Oregon Laws 2011, Chapter 715 (ORS 690):**

- Ear lobe piercing only field of practice with grandfathering provision;
- Make tattooing a minor illegal;
- Add freelance authorization for electrology allowing electrologists to be mobile licensees.

### **Board of Cosmetology ORS 690:**

- Add work performed on the “face” related to esthetics;
- Practice standards and requirements for legend drugs and devices such as lasers and hydroquinone (skin lightening agent);
- Streamline public records confidentiality regarding complaints (690.195(2)); and
- Clarify authority to assess civil penalty to the Board (690.992) for violations of (676.612)

### **Board of Denture Technology ORS 680:**

- Perform X-rays part of scope of practice.

**Board of Licensed Dietitians ORS 691:**

- Mandatory licensure.

**Environmental Health Registration Board ORS 700:**

- Exempt individuals under a supervised internship from registration with guidelines by rule;
- Define duties and parameters of an environmental health specialist;
- Designate title for waste water specialist as RWWS; and
- Elimination of waste water field of practice.

**Advisory Council on Hearing Aids ORS 694:**

- Council membership – designate four hearing aid specialists licensed under 694.065(a) and (c) and one audiologist licensed under ORS 681; and
- Add temporary licensure provisions by rule.

**Board of Direct Entry Midwifery ORS 678:**

- Mandatory licensing including exemptions;
- Broaden legend drugs and devices;

**Nursing Home Administrators Board ORS 678:**

- Standards for directors/administrators for Assisted/Residential Living Facilities.

**Respiratory Therapist and Polysomnographic Technologists Licensing Board Oregon Laws 2011, Chapter 346 (ORS 690):**

- Add training to requirements for licensure under polysomnography; and
- Add language related to the practice of respiratory care to include:  
*“the insertion of devices to draw, analyze, infuse or monitor pressure in arterial, capillary or venous blood as prescribed by medical director” and emergent intraosseous placement.*

**Sex Offender Treatment Board ORS 675:**

- Designate titles for use by only a certified or associate sex offender treatment therapist as CCSOT and CASOT.
- Require that only certified or associate sex offender treatment therapists may treat minors or developmentally disabled;
- Mandatory licensure for all sex offender treatment therapists.

**Other Issues:**

- Durable medical equipment; and
- Home caregiver registry;

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**Oregon Health Licensing Agency**

700 Summer Street NE, Suite 320  
Salem, Oregon 97301-1287  
(503) 378373-1904



# **Statistical & Budget Reports**



# Oregon Health Licensing Agency

## Board of Cosmetology

*Licensing and Regulatory Division Statistics as of October 17, 2011*

**2011 - 2013 Biennium**

### *Authorizations Issued*

Quarter	Barber Certificates	Hair Design Certificates	Esthetics Certificates	Nail Technology Certificates	Facility Licenses	Independent Contractor Registrations	Freelance Certificates	Total Authorizations
<b>1st</b>	18	292	267	186	169	252	71	1255
<b>2nd</b>	4	41	35	28	18	36	9	171
<b>Total:</b>	22	333	302	214	187	288	80	1426

### *Renewals Processed*

Quarter	Barber Certificates	Hair Design Certificates	Esthetics Certificates	Nail Technology Certificates	Facility Licenses	Independent Contractor Registrations	Freelance Certificates	Total Renewals	% Renewed Online
<b>1st</b>	323	1377	898	835	870	1078	9	5390	76.09%
<b>2nd</b>	19	124	102	90	154	140	5	634	66.88%
<b>Total:</b>	342	1501	1000	925	1024	1218	14	6024	75.12%

# Oregon Health Licensing Agency

## Board of Cosmetology

*Examination Statistics as of October 17, 2011*

*2011 - 2013 Biennium*

Quarter	OR Laws and Rules			Barber			Hair Design			Esthetics			Nail Technology		
	Passed	Failed	% Passed	Passed	Failed	% Passed	Passed	Failed	% Passed	Passed	Failed	% Passed	Passed	Failed	% Passed
<b>1st</b>	494	108	82%	20	25	44%	293	50	85%	271	37	88%	189	101	65%
<b>2nd</b>	80	10	89%	5	0	100%	44	9	83%	35	6	85%	29	10	74%
<b>Total:</b>	574	118	83%	25	25	50%	337	59	85%	306	43	88%	218	111	66%

# Oregon Health Licensing Agency

## Board of Cosmetology

*Regulatory Division Statistics as of October 17, 2011*

*2011 - 2013 Biennium*

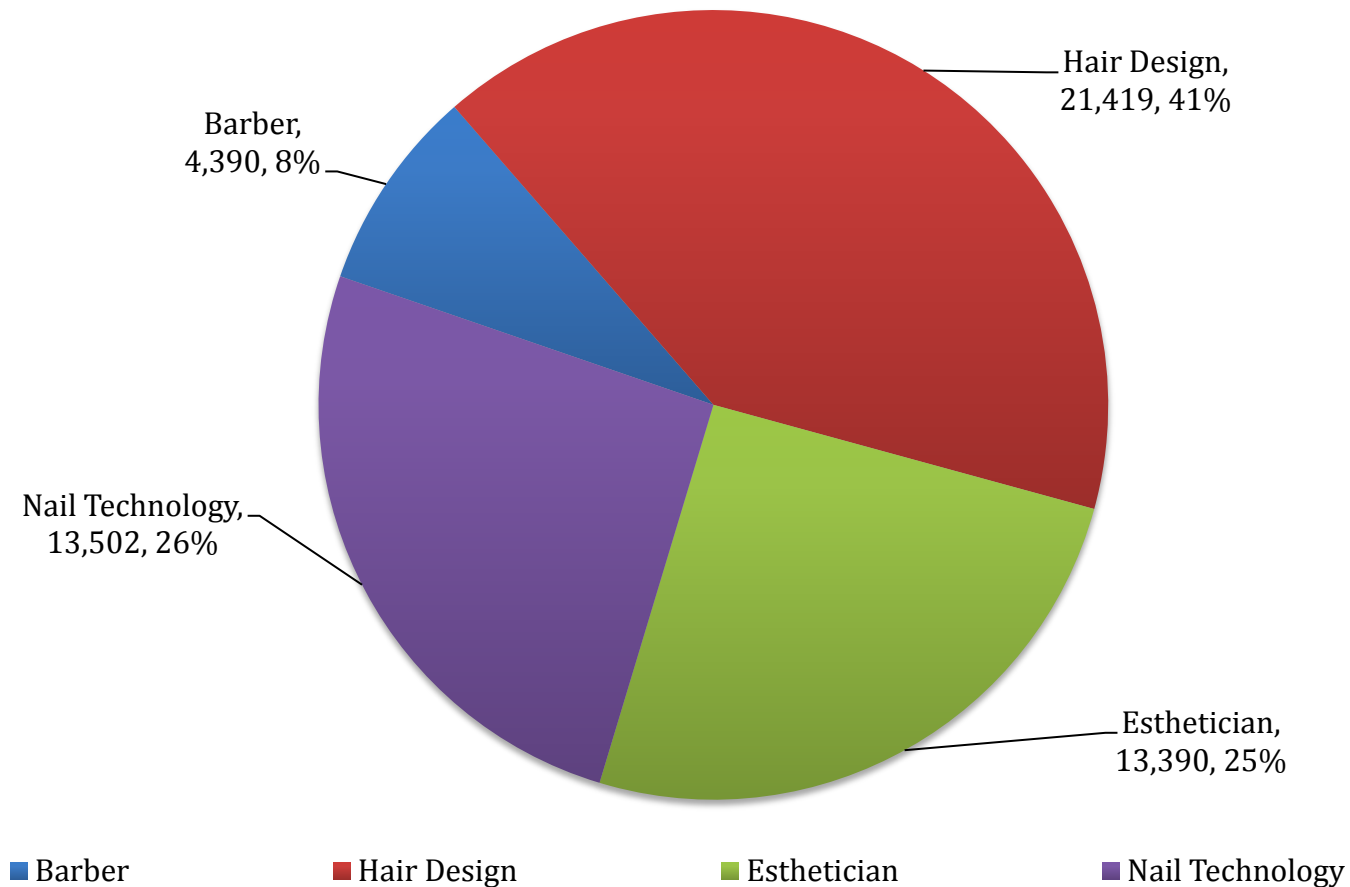
<b>Quarter</b>	<b>Complaints Received</b>	<b>Complaints Closed</b>	<b>Proposed Sanctions</b>	<b>Final Orders</b>	<b>Facility and Independent Contractor Inspections</b>
<b>1st</b>	54	13	80	89	1763
<b>2nd</b>	4	5	8	11	174
<b>Total:</b>	58	18	88	100	1937

# Oregon Health Licensing Agency

## Board of Cosmetology

Cosmetology Practitioners as of October 17, 2011

2011 - 2013 Biennium

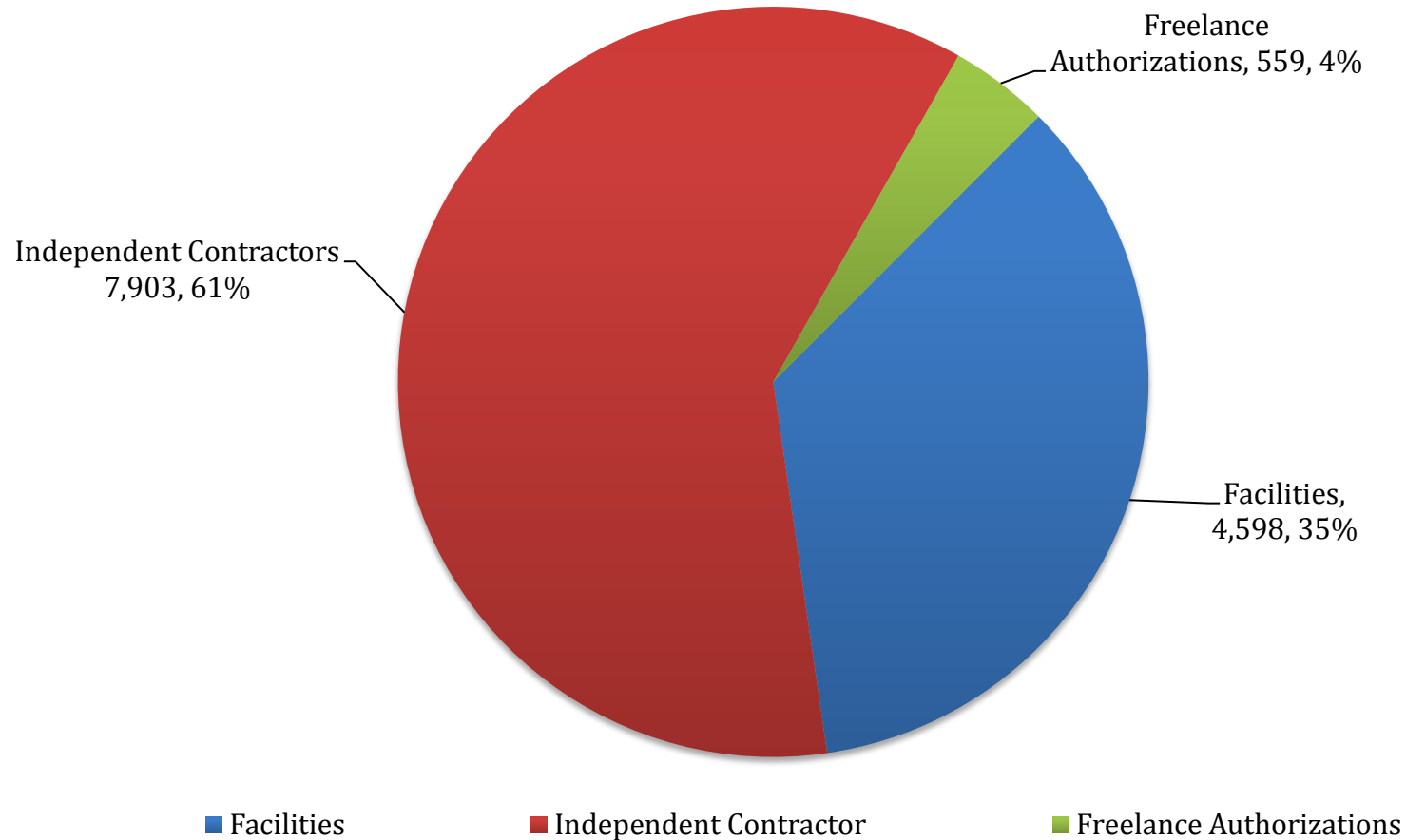


# Oregon Health Licensing Agency

## Board of Cosmetology

Cosmetology Business Authorizations as of October 17, 2011

2011 - 2013 Biennium

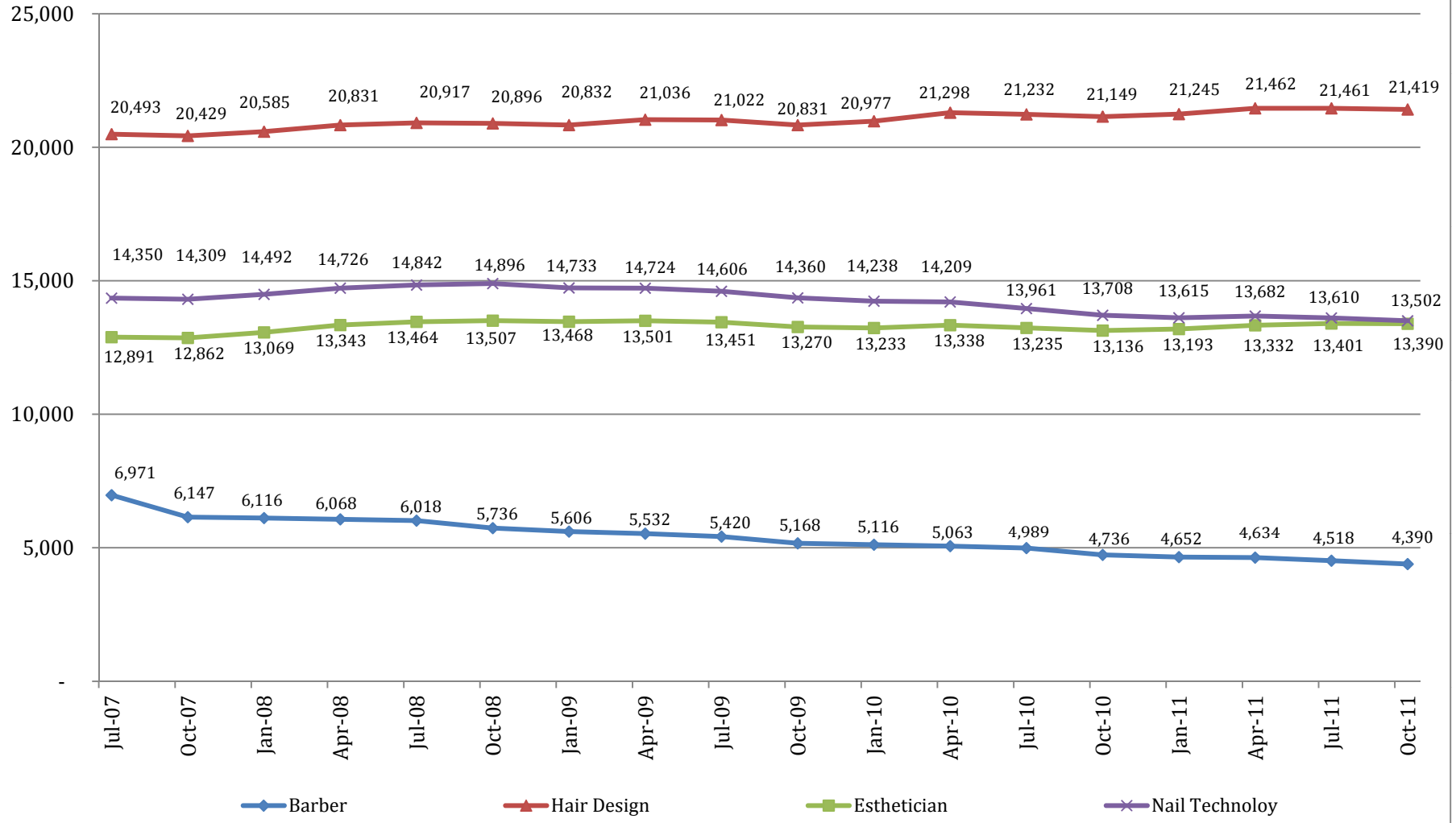


# Oregon Health Licensing Agency

## Board of Cosmetology

### Practitioner Certificate Volume

#### July 2007 - October 2011

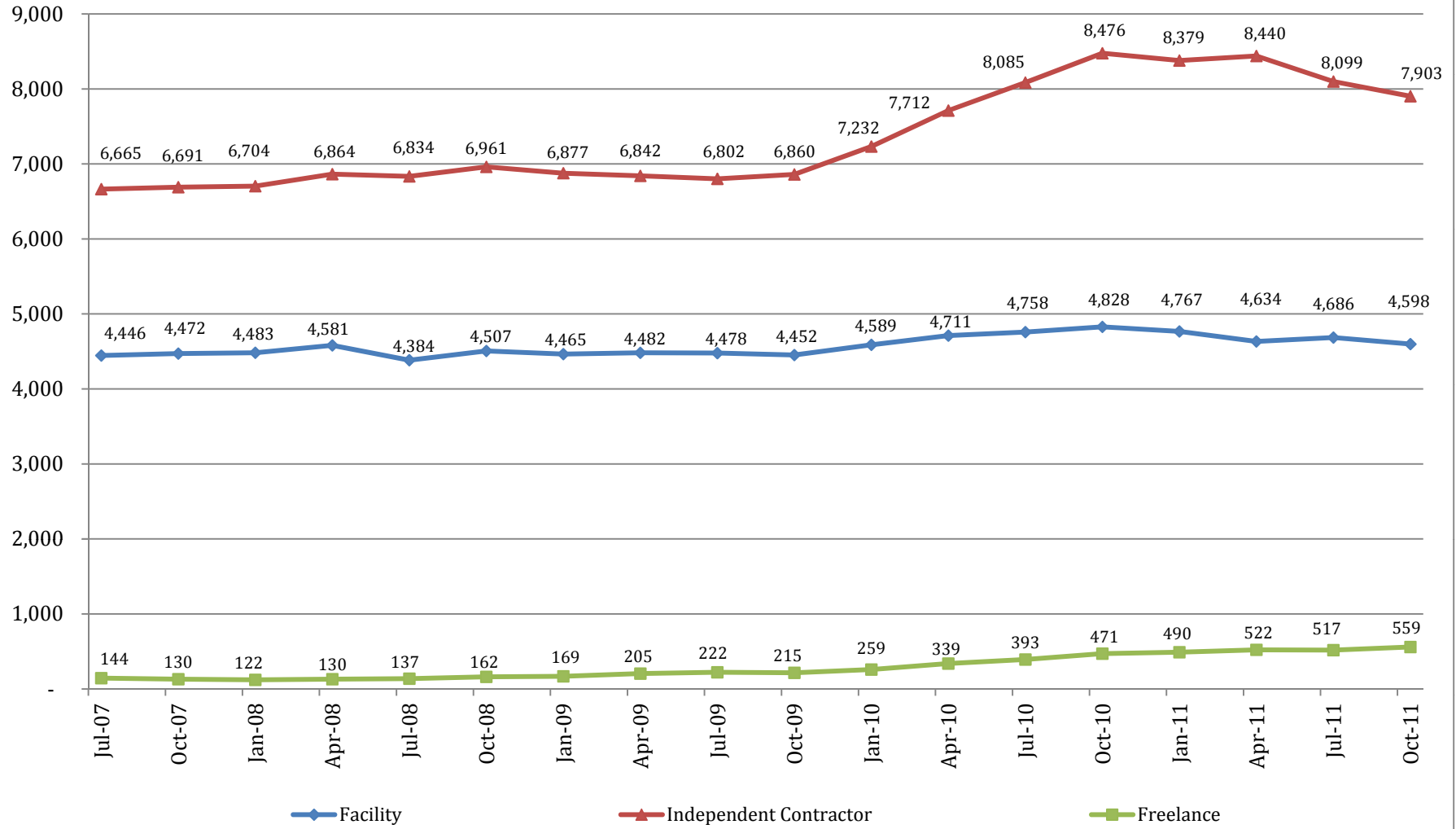


# Oregon Health Licensing Agency

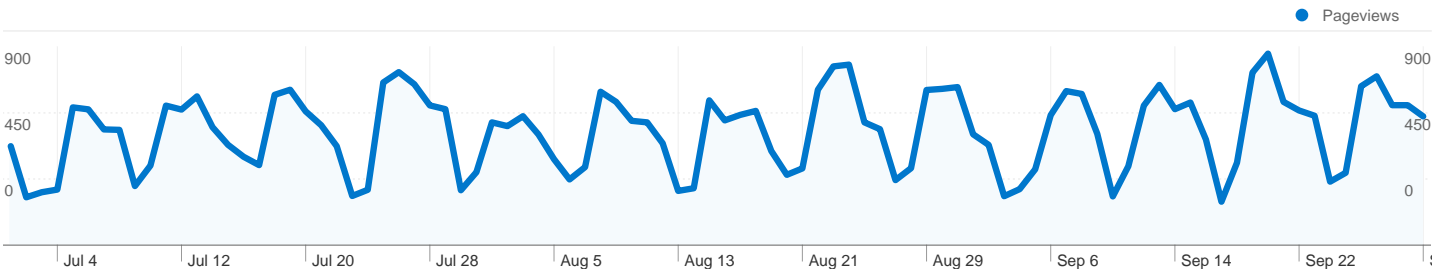
## Board of Cosmetology

### Business Authorization Volume

#### July 2007 - October 2011



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## 78 pages were viewed a total of 49,043 times

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### Content Performance

<b>Pageviews</b> <b>49,043</b> % of Site Total: <b>35.75%</b>	<b>Unique Pageviews</b> <b>39,026</b> % of Site Total: <b>35.56%</b>	<b>Avg. Time on Page</b> <b>00:01:31</b> Site Avg: <b>00:01:13 (23.54%)</b>	<b>Bounce Rate</b> <b>37.57%</b> Site Avg: <b>47.28% (-20.54%)</b>	<b>% Exit</b> <b>35.04%</b> Site Avg: <b>37.68% (-7.02%)</b>	<b>\$ Index</b> <b>\$0.00</b> Site Avg: <b>\$0.00 (0.00%)</b>
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Page	Total Pageviews	google Pageviews	oregon.gov Pageviews	bing Pageviews	yahoo Pageviews	(direct) Pageviews
/OHLA/COS/index.shtml	11,895	7,200	521	904	1,113	556
/OHLA/COS/COSlaws_rules.shtml	4,834	2,886	382	278	452	243
/OHLA/COS/how_to_get_licensed.shtml	4,486	2,226	417	486	382	104
/OHLA/COS/contact_us.shtml	3,895	2,608	104	173	173	243
/OHLA/COS/forms.shtml	3,304	1,078	1,391	208	69	104
/OHLA/COS/COSfees.shtml	2,678	1,321	173	208	173	173
/OHLA/COS/Reciprocity.shtml	2,295	1,426	69	278	104	34
/OHLA/COS/cosoverview.shtml	1,669	904	104	173	139	139
/OHLA/COS/Features/Bacterial_Skin_Infections.shtml	1,217	869	0	34	104	0
/OHLA/COS/	1,182	278	0	139	34	486

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# Oregon Health Licensing Agency

## Board of Cosmetology

### Statement of Cash Flow 2009-2011 Biennium

<b>OREGON HEALTH LICENSING AGENCY COSMETOLOGY FUND 7520 STATEMENT OF CASH FLOW FOR THE PERIOD 07/01/09- 06/30/11</b>	
09-11' Beginning Cash Balance	\$ (99,912.46)
Revenues	\$ 5,062,890.47
Dept of Education Transfers In	\$ 8,100.00
Transfer Cash Out / Allocation Adjustment	\$ (67,378.21)
Expenditures	\$ 4,705,021.54
Less: Accrued Expenditures	\$ -
Less: Total Expenditures	\$ (4,705,021.54)
Subtotal: Resources Available	\$ 198,678.26
Change in (Current Assets)/Liabilities	\$ -
<b>Ending Cash Balance (Actual) as of 9/30/2011</b>	<b>\$ 198,678.26</b>
<b>Cost Allocation_7/1/2009 - 1/31/2010</b>	
Indirect Cost %	76.39%
<b>Cost Allocation_2/1/2010 - 9/30/2010</b>	
Indirect Cost %	75.35%
<b>Cost Allocation_10/1/2010 - 6/30/2011</b>	
Indirect Cost %	78.27%
Direct Cost %	100.00%

Agency Divisions	Shared Cost Categories	FTE ALLOCATION	Cosmetology	Board of Body Art	Denturists, Hearing Aids, Nursing Home Administrators and Environmental Health Specialists	Athletic Trainers, Respiratory Therapists and Polysmonographic Technologists , Direct Entry Midwives, Sex Offender Treatment Therapists and Dietitians
			Cosmetology Plan	Small Board Gold Plan	Small Board Silver Plan	Small Board Bronze Plan
Administrative Services Division	Management, Rules and Legislation and Board Support	10.00 FTE	X	X	X	X
	Education Services	1.00 FTE	X	X	X	
Fiscal Services / Licensing Division	Fiscal Services and Information Technologies	7.00 FTE	X	X	X	X
	Cosmetology Direct Support	1.00 FTE	X			
	Small Board Qualifications and Licensing	1.00 FTE		X	X	X
	Front Line	4.00 FTE	X	X	X	X
Regulatory Operations Division	Inspections	4.00 FTE	X	X		
	Investigations	4.00 FTE	X	X	X	X
	Admin Support	1.00 FTE	X	X	X	X
<b>TOTAL FTE / COST CATEGORIES</b>		<b>33.00 FTE</b>	<b>8</b>	<b>8</b>	<b>7</b>	<b>6</b>

# Oregon Health Licensing Agency

## Board of Cosmetology

### Statement of Cash Flow 2011-2013 Biennium

<b>OREGON HEALTH LICENSING AGENCY COSMETOLOGY FUND 7520 STATEMENT OF CASH FLOW FOR THE PERIOD 07/01/11- 09/30/11</b>		
11-13' Beginning Cash Balance <i>as of 9/30/2011</i>	\$	198,678.26
Revenues	\$	775,119.00
Dept of Education Transfers In	\$	-
Expenditures	\$	630,210.52
Less: Accrued Expenditures	\$	(5,768.06)
Less: Total Expenditures	\$	(624,442.46)
Subtotal: Resources Available	\$	349,354.80
Change in (Current Assets)/Liabilities	\$	273.16
<b>Ending Cash Balance (Actual)</b>	\$	<b>349,627.96</b>
<b>Ending Cash Balance Goal, Projected to reach goal approx. July 2012</b>	\$	<b>660,000.00</b>
<b>Platinum Allocation, 07/1/11 - 12/31/11</b>		
Shared Services Rate		85.95%
Educational Services Rate		26.32%
Frontline and Customer Support Rate		91.95%
Inspections		93.24%
Direct Cost		100.00%

# Oregon Health Licensing Agency

## Board of Cosmetology

### Statement of Cash Flow 2011-2013 Biennium

<b>OREGON HEALTH LICENSING AGENCY</b> <b>COSMETOLOGY FUND 7520</b> <b>STATEMENT OF CASH FLOW</b> <b>FOR THE PERIOD 07/01/11- 06/30/13</b>	
11-13' Beginning Cash Balance <i>as of 9/30/2011</i>	\$ 198,678.26
Revenues	\$ 5,657,993.19
Dept of Education Transfers In	\$ 8,400.00
Expenditures	\$ 5,088,695.53
Less: Accrued Expenditures	\$ -
Less: Total Expenditures	\$ (5,088,695.53)
Subtotal: Resources Available	\$ 776,375.92
Change in (Current Assets)/Liabilities	\$ -
<b>Ending Cash Balance (Projection)</b>	<b>\$ 776,375.92</b>
<b>Platinum Allocation</b>	
Shared Services Rate	85.95%
Educational Services Rate	26.32%
Frontline and Customer Support Rate	91.95%
Inspections	93.24%
Direct Expenditures	100.00%

**Regulatory  
Operations Division  
Report**



Oregon Health Licensing Agency  
Regulatory Division

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**BOARD OF COSMETOLOGY**

***2009 – 2011 Biennium***

Between July 2009 and June 2011, 387 complaints were received by the Agency. Of the 387 complaints, 24 remain open.

Below is a detailed list of the 24 open complaints with an ongoing investigation:

<b>Case #</b>	<b>Received Date</b>	<b>Complaint Allegations</b>
09-5785	9/2/2009	Possible Fraud
10-6067	7/23/2010	Unlicensed Employees
10-6100	8/21/2010	Unlicensed Facility
10-6103	8/25/2010	Providing services with dormant license
10-6165	10/4/2010	Practicing without IC license
10-6218	11/17/2010	Unlicensed Facility
10-6245	11/24/2010	Safety & Sanitation
11-6288	1/13/2011	Using Brazilian Blowout
11-6289	1/13/2011	Services provided
11-6291	1/25/2011	Using Brazilian Blowout
11-6335	2/24/2011	Services provided/possible incompetence
11-6337	3/11/2011	Services provided
11-6338	3/11/2011	Services provided
11-6322	4/7/2011	Pet in facility
11-6400	4/14/2011	Possibility of obtaining license fraudulently
11-6390	5/2/2011	Services provided/possible incompetence
11-6399	5/2/2011	Barber Pole in front of facility/No licensed barbers
11-6474	5/3/2011	Received license without passing exam
11-6408	5/22/2011	Safety & Sanitation
11-6409	5/24/2011	Safety & Sanitation
11-6417	5/26/2011	Unlicensed employee
11-6445	5/31/2011	Unlicensed employees
11-6447	5/31/2011	Safety & Sanitation
11-6439	6/6/2011	Unlicensed Employee

Below is a summary of the closed complaints categorized by investigation result. These 24 complaints were closed out since the last Board meeting.

<b>Investigation Result</b>	<b>Count</b>
Civil Penalty	9
Referred	1
Unfounded	14

Below is a summary of all other closed complaints categorized by investigation result. These 339 complaints were closed out prior to the last Board meeting.

<b>Investigation Result</b>	<b>Count</b>
Civil Penalty	109
Pending	1
Refer Other CMPL	1
Referred	4
Revoked	4
Suspended	52
Unfounded	135
Verbal Warning	2
W/D	1
W/O Action	30

### ***2011 – 2013 Biennium***

Between July 1, 2011 and October 17, 58 complaints were received by the Agency. Of the 58 complaints, 40 remain open.

Below is a detailed list of the 40 open complaints with an ongoing investigation:

<b>Case #</b>	<b>Received Date</b>	<b>Complaint Allegations</b>
11-6464	7/5/2011	Unlicensed Facility
11-6493	7/21/2011	Safety & Sanitation
11-6495	7/21/2011	Safety & Sanitation
11-6523	7/21/2011	Safety & Sanitation
11-6482	7/27/2011	Safety & Sanitation
11-6483	7/28/2011	Unlicensed Facility
11-6490	7/28/2011	Unlicensed Facility
11-6492	7/28/2011	Unlicensed Facility
11-6481	7/28/2011	Services Provided
11-6527	8/4/2011	Unlicensed Practitioner

11-6528	8/8/2011	Unlicensed Employees
11-6529	8/9/2011	Unlicensed Facility
11-6530	8/9/2011	Services Provided
11-6531	8/9/2011	Safety & Sanitation
11-6532	8/10/2011	Unlicensed Facility
11-6525	8/10/2011	Unlicensed Practitioner
11-6515	8/16/2011	Unlicensed Practitioners
11-6517	8/16/2011	Unlicensed Practitioners
11-6518	8/16/2011	Unlicensed Practitioners
11-6519	8/16/2011	Unlicensed Practitioners
11-6511	8/17/2011	Safety & Sanitation
11-6512	8/17/2011	Safety & Sanitation
11-6536	8/18/2011	Unlicensed Facility
11-6537	8/18/2011	Unlicensed Facility
11-6506	8/23/2011	Unlicensed Facility
11-6507	8/23/2011	Unlicensed Facility
11-6505	8/24/2011	Unlicensed Facility
11-6539	8/26/2011	Unlicensed Facility
11-6526	8/30/2011	Inactive Facility License
11-6540	8/31/2011	Safety & Sanitation
11-6565	9/12/2011	Working outside facility w/o Freelance License
11-6559	9/13/2011	Services Provided
11-6561	9/15/2011	Safety & Sanitation
11-6562	9/19/2011	Unlicensed Facility
11-6548	9/19/2011	Safety & Sanitation
11-6563	9/22/2011	Unlicensed Practitioner
11-6572	9/22/2011	Safety & Sanitation
11-6576	9/29/2011	Unlicensed Practitioners
11-6575	10/10/2011	Safety & Sanitation
11-6569	10-13/2011	Expired Facility License

Below is a summary of the closed complaints categorized by investigation result. These 18 complaints were received and closed out since the last Board meeting.

Investigation Result	Count
Civil Penalty	8
Unfounded	4
W/O Action	6

**Interagency Agreement  
between the  
Oregon Health Licensing Agency  
and  
Oregon OSHA**

**I. Purpose**

This agreement is entered into between the Oregon Health Licensing Agency (OHLA) and the Oregon Department of Consumer and Business Services, Occupational Safety and Health Division (Oregon OSHA) for the purpose of delineating the responsibilities and activities to be performed by each agency pursuant to its authority to regulate hair-smoothing products containing formaldehyde. This agreement is intended to promote cooperative efforts between OHLA and Oregon OSHA and effective regulation of formaldehyde hazards in Oregon.

**II. Roles and Authorities**

Under ORS 654, and as the Federal Occupational Safety and Health Administration's (OSHA) designee, Oregon OSHA is responsible for protecting workers in the State of Oregon, having implemented workplace formaldehyde rules. OHLA regulates hair salons in Oregon, and adopted by reference Oregon OSHA's formaldehyde rules (OAR437/Subdivision Z-1910.1048), effective May 5, 2011.

**III. Enforcement**

**A. Referrals**

1. OHLA and Oregon OSHA will refer formaldehyde compliance or enforcement situations involving hazards and possible violations of laws or regulations enforced by either agency to the other.
2. Referrals will be provided within the week, and may be accomplished in person, by telephone, FAX, or email.
3. A copy of the report by the enforcing agency will be provided to the other agency on completion.

## **B. Common Inspections**

1. When inspecting or responding to a complaint relating to the same project or situation, OHLA and Oregon OSHA will assist each other to the extent possible and allowed by law by sharing information regarding potential violations of formaldehyde regulations.
2. Both OHLA and Oregon OSHA will maintain strict confidentiality concerning the other agency's inspection, compliance or enforcement plans or actions. As required by law, Oregon OSHA confidential information will not be communicated to OHLA.
3. During inspections and compliance meetings, OHLA and Oregon OSHA representatives will each clearly communicate their regulatory responsibilities to the inspected party. For example, an OHLA inspector will only communicate violations of OHLA regulations, and refer all potential worker protection violations to Oregon OSHA personnel, and vice versa.
4. Where indicated, all sample(s) will be collected using established protocols and chain of custody procedures established by the Oregon OSHA Laboratory. Analysis will be completed by the Oregon OSHA Laboratory to support compliance with these rules. For sample analyses submitted by OHLA, they agree to reimburse Oregon OSHA for such analyses when the aggregate cost (\$25 per sample analysis) exceeds \$500.00 in a calendar year, billable one time annually.

## **IV. Transfer of Information**

### **A. Enforcement Information**

1. OHLA and Oregon OSHA may, upon request, provide each other with copies of enforcement actions relating to formaldehyde. These actions may include, but are not limited to, Notices of Intent to Assess Civil Penalty and Citations, respectively.
2. Upon request, OHLA and Oregon OSHA will provide each other, as allowed by law, with relevant historical enforcement information such as database reports and file copies.

## **V. Public Information**

### **A. Communication with the News Media**

1. When communicating with the news media concerning formaldehyde violations or hazards, representatives of OHLA and Oregon OSHA will clearly state that Oregon OSHA exercises jurisdiction over worker protection issues, and that OHLA exercises jurisdiction over public safety/consumer protection health issues.
2. Representatives of OHLA and Oregon OSHA will not make statements to the news media concerning the other agency's formaldehyde regulations, inspections or possible violations. Statements that a situation has been referred to OHLA or Oregon OSHA are appropriate.

### **B. Issuing Press Releases**

OHLA and Oregon OSHA will notify and gain approval from the other agency's Public Information Officer prior to issuing any press release containing information on the other agency's formaldehyde regulations, inspections or possible violations.

## **VI. Training**

### **A. Interagency Training**

Representatives from OHLA and Oregon OSHA will conduct training sessions to educate the other agency's affected staff on formaldehyde regulations, policies and procedures.

### **B. Legislation**

1. OHLA and Oregon OSHA will communicate proposed legislation affecting formaldehyde regulation to each other as early in the legislative process as possible.
2. In developing formaldehyde legislation, both OHLA and Oregon OSHA will strive for interagency compatibility and avoid unnecessary duplication.

### C. Rulemaking

1. OHLA and Oregon OSHA will provide each other with drafts of proposed Oregon Administrative Rules on formaldehyde as early as possible in the rulemaking process, but in all cases prior to the beginning of the public notice and comment period.
2. In developing formaldehyde regulations, both OHLA and Oregon OSHA will strive for interagency compatibility and avoid unnecessary duplication.

### VII. Oregon Health Licensing Agency

A designee of Oregon OSHA will participate in the meetings and decisions of the Oregon Health Licensing Agency.

### VIII. Effective Date

This agreement will be effective upon signature by the Director of the Oregon Health Licensing Agency and the Administrator of the Oregon Occupational and Safety Division of the Department of Consumer and Business Services.

### IX. Provisions for Review and Updating

OHLA and Oregon OSHA will meet to discuss items contained in this agreement, to update it where necessary, and to exchange relevant program information.

### X. Agreement Termination

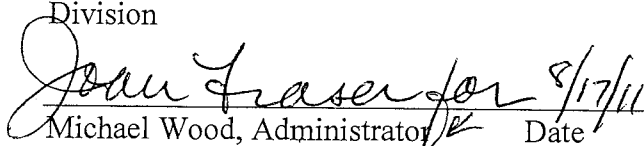
This agreement will remain in force until terminated by either party given thirty days' notice by the other.

AGREED:

AGREED:

Oregon Department of Consumer and Business  
Services, Occupational Safety and Health  
Division

Oregon Health Licensing Agency

  
Michael Wood, Administrator

  
Randall Everitt, Director

8/15/2011  
Date

# Appendix A

## **Oregon Health Licensing Agency Contacts**

David Sparks, Manager, Regulatory Operations Division,  
Kraig Bohot, Public Information Officer

### Main Office:

Oregon Health Licensing Agency (OHLA)  
700 Summer St. NE, Suite 320  
Salem, OR 97301-1287  
Phone: 503-378-8667  
Fax: 503-370-9004

## **Oregon OSHA Contacts:**

Chris Ottoson, Statewide Health Enforcement Manager  
Trena VanDeHey, Health Enforcement Analyst  
Marilyn Schuster, Policy Manager  
Melanie Mesaros, Public Information Officer

### Main Office:

Oregon OSHA  
350 Winter St. NE, Rm. 430  
PO Box 14480  
Salem, OR 97309-0405  
Phone: 503.378.3272  
Fax: 503.947.7461



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## Inspections, Compliance, Enforcement, and Criminal Investigations

### Brazilian Blowout 8/22/11



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

#### WARNING LETTER

**AUG 22 2011**

**VIA OVERNIGHT-DELIVERY  
RETURN RECEIPT REQUESTED**

Mr. Mike Brady, CEO  
GIB, LLC dba Brazilian Blowout  
6855 Tujunga Avenue  
North Hollywood, CA 91605-6312

Re: 207094

Dear Mr. Brady:

The U.S. Food and Drug Administration (FDA) has reviewed the regulatory status of your product, Brazilian Blowout Acai Professional Smoothing Solution (Brazilian Blowout). As Brazilian Blowout is intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance, it is a cosmetic within the meaning of Section 201(i) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(i)]. As described below, Brazilian Blowout is adulterated within the meaning of Section 601 (a) of the Act [21 U.S.C. § 361 (a)] and is misbranded within the meaning of Section 602(a) of the Act [21 U.S.C. § 362(a)]. It is a violation of Section 301(a) of the Act [21 U.S.C. § 331(a)] to introduce or deliver for introduction into interstate commerce any cosmetic that is adulterated or misbranded. You can find copies of the Act and its implementing regulations through links on FDA's home page at <http://www.fda.gov><sup>1</sup>.

#### **Adulterated Cosmetic**

Under Section 601(a) of the Act [21 U.S.C. § 361(a)], a cosmetic is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual. Brazilian Blowout is an adulterated cosmetic because it bears or contains a deleterious substance that may render it injurious to users under the conditions of use prescribed in your labeling. Specifically, based on FDA sample analysis, Brazilian Blowout contains methylene glycol, the liquid form of formaldehyde, which, under the conditions of use prescribed in the labeling, releases formaldehyde when hair treated with the product is heated with a blow dryer and then with a hot flat iron. Methylene glycol is a deleterious substance, which at the levels present in this product, may harm users under the conditions of use prescribed in the labeling thereof. FDA analysis of approximately 50 mg samples of Brazilian Blowout confirmed the presence of methylene glycol, the liquid form of formaldehyde, at levels ranging from 8.7 to 10.4%.

The primary route of exposure to formaldehyde, when using Brazilian Blowout under the conditions of use prescribed in the

labeling, is through inhalation. Formaldehyde is a highly reactive chemical that readily reacts with biological tissues, particularly the mucous tissues lining the respiratory tract and the eyes. Adverse events have reported the following injuries associated with Brazilian Blowout: eye disorders (irritation, increased lacrimation, blurred vision, hyperaemia); nervous system disorders (headache, burning sensation, dizziness, syncope), and respiratory tract (dyspnea, cough, nasal discomfort, epistaxis, wheezing, rhinorrhea, throat irritation, nasopharyngitis). Other reported symptoms included nausea hypotrichosis, chest pain, chest discomfort, vomiting, and rash.

Brazilian Blowout is targeted primarily for use by salon professionals in a salon setting. The product may also be used in home salon settings as Brazilian Blowout is also available for purchase in beauty retail stores and via the internet by the general public.

### **Misbranded Cosmetic**

In addition, under Section 602(a) of the Act [21 U.S.C. § 362(a)], a cosmetic is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the Act [21 U.S.C. § 321(n)] provides that, in determining whether a product's labeling or advertising is misleading "there shall be taken into account (among other things) the extent to which the labeling or advertising fails to reveal facts material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual."

Brazilian Blowout is misbranded because its label and labeling (including instructions for use) makes misleading statements regarding the product's ingredients and fails to reveal material facts with respect to consequences that may result from the use of the product. Specifically, Brazilian Blowout contains the liquid form of formaldehyde, methylene glycol; however, the product label declares that the product contains "No Formaldehyde" or is "Formaldehyde Free." This declaration renders your product misbranded because it is a false and misleading statement. In addition, the failure to include information about the release of formaldehyde into the air during the heating process on the product's label or labeling makes your product misbranded because you fail to reveal material facts with respect to consequences that may result from the use of your product under the conditions of use prescribed in the labels or labeling.

The violations cited in this letter are not intended to be an all-inclusive list of the violations that exist in connection with your product. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility as a manufacturer to ensure that the products your firm markets are safe and otherwise in compliance with all applicable legal and regulatory requirements.

You should take prompt action to correct the violations cited in this letter. Failure to do so may result in enforcement action without further notice, including, but not limited to, seizure and/or injunction.

Please advise this office in writing within fifteen (15) working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur in the future. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and the date by which each item will be corrected and documented.

Please direct your written reply to Rob Genzel Jr., Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/s/

Michael W. Roosevelt  
Acting Director  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition

## Cosmetic Ingredient Review Expert Panel 119<sup>th</sup> Meeting (June 27-28, 2011) - Findings

### June 30, 2011

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- **Final Safety Assessment**
  - 1,2 – Glycols
- **Revised Tentative Amended Safety Assessments**
  - Diethanolamine (DEA) and Its Salts
  - Formaldehyde and Methylene Glycol
- **Tentative Safety Assessments and Tentative Amended Safety Assessments**
  - Benzyl Alcohol and Benzoic Acid and Its Salts and Benzyl Ester
  - Crosslinked Alkyl Acrylates
  - DEA Amides
  - Pentaerythrityl Tetraisostearate and Other Pentaerythrityl Esters
  - Triethanolamine (TEA) and TEA-containing Ingredients
  - Silylates and Surface Modified Siloxysilicates
- **Insufficient Data Announcements**
  - Decyl Glucoside and Other Alkyl Glucosides
- **Re-Reviews**
  - HC Red No. 1
  - Glutaral
- **New Data**
  - Sodium Lauraminodipropionate
  - PEGs-Cocamine
- **119<sup>th</sup> Meeting Notes**
  - **Director's Report**
  - **2012 Priorities**
  - **CIR Boilerplate Language**
    - Hair Dye Epidemiology
    - Aerosols Inhalation
  - **Scientific Literature Reviews released in May/June 2011**
    - Alkyl Glyceryl Ethers
    - 2-Amino-4-Hydroxyethylaminoanisole and its Sulfate Salt
    - Citric Acid and Its Inorganic Salts and Alkyl and Glycol Esters
    - Panax Ginseng Root Extract and Other Ginseng Root-Derived Ingredients as Used in Cosmetics
    - Trisodium Sulfosuccinate and Alkyl PEG Sulfosuccinates
  - **Scientific Literature Reviews Under Development**
    - Chlorphenesin
    - Diisostearyl Malate
    - Distearidimonium Hectorite
    - Galactomannans (Guar Hydroxypropyltrimonium Chloride)
    - Nylon 12
    - Polyquaternium-22
    - Synthetic Fluorophlogopite
    - Xanthan Gum
  - **Re-reviews under Development**
    - MEA and Related MEA-Containing Ingredients
    - Sodium Lauraminopropionate
  - **Next CIR Expert Panel Meeting**
    - Monday and Tuesday, September 26-27, 2011

## Final Safety Assessment

Any interested person who believes that a final safety assessment or final amended safety assessment is incorrect may petition the CIR Expert Panel to amend/further amend the safety assessment. Unpublished data cited as references in CIR safety assessments are available for review at the CIR office. Final safety assessments and final amended safety assessments are available - see the order form.

### 1,2-Glycols

These 1,2-glycol ingredients are used mostly as skin and hair conditioning agents and viscosity increasing agents in cosmetic products, although caprylyl and pentylene glycol are also described as preservatives. While dermally absorbed, modeling data predicts decreased skin penetration of longer-chain 1,2-glycols. Negative oral toxicity data on shorter-chain 1,2-glycols and genotoxicity data support the safety of all of the 1,2-glycols reviewed in this safety assessment. The Expert Panel concluded that all 16 of the 1,2 glycols listed below are safe for use in cosmetics in the present practices of use and concentration described in the safety assessment. Were the ingredients not in current use (as indicated by \*) to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.

Caprylyl Glycol  
Arachidyl Glycol\*  
Cetyl Glycol\*  
Hexacosyl Glycol\*  
Lauryl Glycol\*  
Myristyl Glycol\*  
Octacosanyl Glycol\*  
Stearyl Glycol\*

Decylene Glycol  
Pentylene Glycol  
1,2-Butanediol\*  
1,2-Hexanediol  
C14-18 Glycol\*  
C15-18 Glycol  
C18-30 Glycol\*  
C20-30 Glycol\*

## Revised Tentative Amended Safety Assessments

The CIR Expert Panel changed its conclusions for these two safety assessments and is providing the opportunity for interested persons to provide comment on those revisions. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, posted on the CIR website, and are available at the CIR office for review by any interested party. **Please submit data to CIR by September 2, 2011, or sooner if possible.** These ingredient reports will be scheduled for review by the CIR Expert Panel at its **September 26-27, 2011 meeting.** Tentative safety assessments are available - see the order form.

### Diethanolamine (DEA) and Related DEA-Containing Ingredients

Previously, the Expert Panel issued a tentative amended safety assessment with a conclusion that these ingredients were safe as used when formulated to be non-irritating, but that these ingredients should not be used in cosmetic products in which *N*-nitroso compounds are formed. The discussion of that tentative conclusion included a concern that Sodium Lauraminopropionate (a component of DEA-Lauraminopropionate) had previously been determined to have insufficient data to support safety. That concern, however, was not reflected in the conclusion.

Therefore, the Expert Panel is issuing a revised Tentative Amended Report with the conclusion of safe as used when formulated to be non-irritating for the 17 ingredients in the list provided below. Were the ingredients not in current use (as indicated by \*) to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group. These ingredients should not be used in cosmetic products in which *N*-nitroso compounds are formed.

Diethanolamine  
Diethanolamine Bisulfate  
DEA-C12-13 Alkyl Sulfate\*  
DEA-C12-15 Alkyl Sulfate\*  
DEA-C12-13 Pareth-3 Sulfate\*  
DEA-Cetyl Sulfate\*  
DEA-Cocoamphodipropionate  
DEA-Dodecylbenzenesulfonate\*  
DEA-Isostearate\*

DEA-Laureth Sulfate  
DEA-Lauryl Sulfate  
DEA-Linoleate  
DEA-Methyl Myristate Sulfonate\*  
DEA-Myreth Sulfate\*  
DEA-Myristate\*  
DEA-Myristyl Sulfate\*  
DEA Stearate

The Expert Panel concluded that the available data or information are insufficient to make a determination that DEA-Lauraminopropionate is safe under the intended conditions of use. The types of data needed include:

- chemical characterization (impurities/purity data)
- chemical and physical properties
- method of manufacture
- 28-day dermal toxicity
- dermal reproductive and developmental toxicity
- ocular irritation at concentration of use, if available
- dermal irritation and sensitization at concentration of use
- two different genotoxicity studies (one using a mammalian system); if positive, a dermal carcinogenesis assay by National Toxicology Program standards will be required

Depending on the results of these studies, additional data may be required.

### Formaldehyde and Methylene Glycol

The Expert Panel received additional input from the Nail Manufacturers Council of the Professional Beauty Association, the Professional Keratin Smoothing Council, the American Chemistry Council, the Personal Care Products Council, and the National Healthy Nail Salon Alliance (comprised of the California Healthy Nail Salon Collaborative, Women's Voices for the Earth, and the National Asian Pacific American Women's Forum).

After reviewing the comments and additional data received, the Expert Panel determined that revision of the previous tentative conclusion was appropriate and that issuing a revised tentative amended safety assessment for public comment was appropriate.

In particular, the Expert Panel determined that the proposed safe level of formaldehyde and methylene glycol of 0.2% formaldehyde equivalents was based on dermal safety testing using formalin, which contains only 37% (w/w) formaldehyde equivalents. Accordingly, the level that should have been given as the safe level for formaldehyde and methylene glycol is 0.074% (w/w) formaldehyde equivalents.

While concern had been expressed in comments that the term formaldehyde equivalents was not the best term to convey the Expert Panel's intent, all parties agree that it is critical to use terminology that expresses the dynamic equilibrium between formaldehyde and methylene glycol in aqueous media. The Expert Panel considered that the term formaldehyde equivalents best captures the idea that methylene glycol is continuously converted to formaldehyde and vice versa even at equilibrium, which can be easily shifted by heating, drying, and other conditions to increase the amount of formaldehyde. Any other term would not distinguish the rapid, reversible formaldehyde/methylene glycol equilibrium from the slow release of formaldehyde from so-called formaldehyde releaser preservatives that are not addressed in this safety assessment, yet are widely used.

The Expert Panel reviewed the available data on air measurements of formaldehyde in nail salon settings and determined that the levels were consistent with the absence of adverse reaction reports to manufacturers and to the FDA. The National Healthy Nail Salon Alliance provided a previously published study suggesting that air concentrations may not be low in all settings. In considering this question, the Expert Panel noted that the FDA inspection guide that describes 5% formaldehyde as a level below which action is not needed during inspections of nail hardener products/manufacturing sites, does not have a clear basis. Available data suggest current use of formaldehyde/methylene glycol at only 1 – 2% in nail hardeners. Given the rapid reaction on the nail surface and the use of nail hardeners at room temperature, the Expert Panel did not consider that formaldehyde/methylene glycol at 1 – 2% in nail hardeners would present a risk of sensory irritation to the eyes, nose, or throat of users.

However, recent clinical experience of eyelid dermatitis was reported with 2 patients using one brand of formaldehyde-containing nail hardener and the National Healthy Nail Salon Alliance provided other self-reported adverse events after use of that same brand. Eyelid dermatitis is a common phenomenon seen by dermatologists and can be related to contact of the patient's hands with the eyelid area after application of a cosmetic to the nails. The Expert Panel was concerned that a better understanding of the current use concentrations of formaldehyde/methylene glycol in nail hardeners is needed. The FDA indicated that some testing to address this issue already has been done and could be extended to include the brand in question. Until such data and any additional relevant data are submitted, the Expert Panel determined that the data are insufficient to evaluate the safety of formaldehyde and methylene glycol in nail hardeners.

The Expert Panel was concerned about sensory irritation adverse reports consistent with measured air levels of formaldehyde in salons using hair smoothing products containing formaldehyde/methylene glycol. Because the use of hair smoothing products involves the application of heat, the Expert Panel remained concerned that substantial amounts of formaldehyde vapor can be released. The reported levels of formaldehyde gas measured in the air around salon work stations can be below occupational exposure standards and guidelines, but also may be at or only marginally below occupational exposure standards and guidelines. These findings raised a concern that use of hair smoothing products with formaldehyde/methylene glycol may not be safe, even in salons where some ventilation appears to be in place. The Expert Panel noted that the Professional Keratin Smoothing Council suggested that these products are manufactured with the expectation that adequate ventilation would be provided when used; i.e., safe use requires adequate ventilation. OSHA inspections from some states report a range of ventilation controls, many of which were simply opened shop doors or fans used to distribute the air around the room. The Expert Panel also heard anecdotal information that hair smoothing products are used in home environments for which adequate ventilation cannot be assured.

Based on the unique circumstance of formaldehyde/methylene glycol use in hair smoothing products intended to be heated, the likely production of substantial amounts of formaldehyde gas, and the absence of any assurance that adequate ventilation could/would be available, the Expert Panel determined such use of formaldehyde and methylene glycol to be unsafe.

During the discussion, the Expert Panel noted that some hair smoothing products may be labeled as "formaldehyde-free" and yet contain methylene glycol. Because the presence of methylene glycol ensures that formaldehyde will be present, such a product with a "formaldehyde-free" label should be considered to be misbranded under the provisions of the Food, Drug, and Cosmetic Act.

To summarize the Expert Panel's revised tentative amended conclusion:

1. formaldehyde and methylene glycol are safe for use in cosmetics applied to the skin when formulated to ensure use at the minimal effective concentration, but in no case should formaldehyde equivalents exceed 0.074% (w/w).
2. the available data are insufficient to determine the safety of formaldehyde and methylene glycol as used in nail hardening products, until additional data on use concentrations are available from FDA or industry.
3. formaldehyde and methylene glycol are unsafe for use in hair smoothing products, the use of which involves application of high temperatures.

## **Tentative Safety Assessments and Tentative Amended Safety Assessments**

*For tentative safety assessments, interested persons are given 60 days to comment, provide information and/or request an oral hearing before the CIR Expert Panel. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, posted on the CIR website, and are available at the CIR office for review by any interested party. **Please submit data to CIR by September 2, 2011, or sooner if possible.** These ingredient reports will be scheduled for review by the CIR Expert Panel at its **September 26-27, 2011 meeting.** Tentative safety assessments are available - see the order form.*

### **Benzyl Alcohol and Benzoic Acid, and its Salts and Benzyl Ester**

The Expert Panel concluded that the newly available inhalation toxicity data and the safety test data already available support the safety of benzyl alcohol, benzoic acid, calcium benzoate, magnesium benzoate, potassium benzoate, sodium benzoate, and benzyl benzoate, and agreed that a tentative amended safety assessment with the conclusion that these 7 ingredients are safe in the present practices of use and concentration should be issued.

The Expert Panel discussed the finding of adenomas of the adrenal cortex of B6C3F<sub>1</sub> mice receiving a high dose of benzyl alcohol in an oral carcinogenicity study. Such tumors were considered benign and benzyl alcohol was not considered carcinogenic. In earlier safety assessments, a 5% concentration limit for benzyl alcohol, benzoic acid, and sodium benzoate and a 10% concentration limit for benzyl alcohol in hair dyes were established. Currently available information demonstrates that the present practices of use and concentration of these ingredients are below those levels and that the limits are no longer needed. The Expert Panel did note the presence of benzene as an impurity due to photo-degradation of benzoic acid, but at current use concentrations, the levels of benzene in cosmetic products would be negligible.

## Crosslinked Alkyl Acrylates

The Expert Panel noted there were very little published data available on the crosslinked alkyl acrylates. The Panel discussed that these ingredients are macromolecules that are not expected to pass through the stratum corneum. Systemic toxicity, reproductive and developmental toxicity, genotoxicity, and carcinogenicity were not expected endpoints with topical application of products containing these ingredients, because significant dermal absorption is not expected. The Panel was not concerned that residual monomer would cause toxicity because the amount of residual monomer that would be available was low, as were the concentrations of use for these ingredients.

For ingredients polymerized in benzene, however, concern was expressed that residual benzene would be present. The Expert Panel determined, therefore, that the available data are insufficient to make a determination of safety on the crosspolymers for which benzene was used as the solvent. The Panel would need confirmation of which ingredients were polymerized in benzene and to have a margin of safety estimated for those ingredients, considering the amount of residual benzene present in the ingredient, the ingredient concentration of use, the NOEL for benzene, and the usage patterns of cosmetics containing the ingredient.

The Panel issued a tentative report with a conclusion of safe as used for the 23 crosslinked alkyl acrylates in the list below, provided that they are not polymerized in benzene. If polymerized in benzene, see previous paragraph. Were the ingredients not in current use (as indicated by \*) to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.

Acrylates/C10-30Alkyl Acrylate Crosspolymer  
Acrylates/C12-13 Alkyl Methacrylates/Methoxyethyl Acrylate Crosspolymer\*  
Acrylates Crosspolymer  
Acrylates/Ethylhexyl Acrylate Crosspolymer  
Acrylates/Ethylhexyl Acrylate/Glycidyl Methacrylate Crosspolymer\*  
Acrylates/PEG-4 Dimethacrylate Crosspolymer\*  
Acrylates/Steareth-20 Methacrylate Crosspolymer  
Acrylates/Vinyl Isodecanoate Crosspolymer  
Acrylates/Vinyl Neodecanoate Crosspolymer  
Allyl Methacrylate/Glycol Dimethacrylate Crosspolymer\*  
Allyl Methacrylates Crosspolymer  
Butyl Acrylate/Glycol Dimethacrylate Crosspolymer\*  
C8-22 Alkyl Acrylates/Methacrylic Acid Crosspolymer\*  
Glycol Dimethacrylate/Vinyl Alcohol Crosspolymer\*  
Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer  
Lauryl Methacrylate/Sodium Methacrylate Crosspolymer  
Methacrylic Acid/PEG-6 Methacrylate/PEG-6 Dimethacrylate Crosspolymer\*  
PEG/PPG-5/2 Methacrylate/Methacrylic Acid Crosspolymer\*  
Potassium Acrylates/C10-30 Alkyl Acrylate Crosspolymer\*  
Sodium Acrylates Crosspolymer-2  
Sodium Acrylates/C10-30 Alkyl Acrylate Crosspolymer  
Sodium Acrylates/Vinyl Isodecanoate Crosspolymer\*  
Stearyl/Lauryl Methacrylate Crosspolymer\*

## DEA Amides

The Expert Panel has expanded the original safety assessment of cocamide DEA to include other DEA amides. The Expert Panel determined that other DEA amides should include the alkyl amides (with branched and with partially unsaturated structures) and natural source mixtures. Some of the DEA amides have been reviewed, and it is appropriate to include them in this family for completeness; additionally, read-across data are provided.

While the Panel noted gaps in the available safety data for many of the ingredients included in this group, the Expert Panel relied on the safety assessments of previously reviewed ingredients. The available data were sufficient due to similar structure activity relationships, biological function, and cosmetic product usage. For example, while reproductive and developmental toxicity data on the diethanolamides were not found, the Panel relied on reproductive data from the DEA report, as well as from reports on the other amide "components."

The Panel was concerned with levels of free DEA that could be present as an impurity in a DEA amide ingredient and limited the amount of free DEA to no more than was considered safe in the CIR safety assessment of DEA and its salts.

Accordingly, a tentative amended safety assessment was issued with a conclusion of safe as used when formulated to be non-irritating for the 33 ingredients in the list provided below. Were the ingredients not in current use (as indicated by \*) to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group. These ingredients should not be used in cosmetic products in which *N*-nitroso compounds are formed.

Almondamide DEA\*  
Apricotamide DEA\*  
Avocadamide DEA\*  
Babassuamide DEA\*  
Behenamide DEA\*  
Capramide DEA  
Cocamide DEA  
Cornamide DEA\*

Cornamide/Cocamide DEA\*  
Hydrogenated Tallowamide DEA\*  
Isostearamide DEA  
Lanolinamide DEA\*  
Lauramide DEA  
Lauramide/Myristamide DEA  
Lecithinamide DEA\*  
Linoleamide DEA

Minkamide DEA\*  
Myristamide DEA  
Oleamide DEA  
Olivamide DEA\*  
Palm Kernelamide DEA  
Palmitamide DEA\*  
Palmitamide DEA\*  
Ricebranamide DEA\*

Ricinoleamide DEA\*  
Sesamide DEA\*  
Shea Butteramide/Castoramide DEA\*

Soyamide DEA  
Stearamide DEA  
Tallamide DEA\*

Tallowamide DEA\*  
Undecylenamide DEA\*  
Wheat Germamide DEA\*

### Pentaerythrityl Tetrastearate and Other Pentaerythrityl Esters

The Expert Panel noted that pentaerythrityl cocoate, tetraisononanoate, and tetrapelargonate previously were reviewed and considered to be safe as used in cosmetics, and should be included in this list to provide support for the safety of the entire group. While pentaerythrityl cocoate is undefined as to the number of cocoate moieties esterified to pentaerythritol, it could also be a tetra ester.

A previous review of pentaerythrityl rosinatate in which insufficient data were available to support safety was not considered relevant to this safety assessment because the safety questions related to the rosin component. Because pentaerythrityl tetraacetate presents different chemical and physical properties, it was not considered as part of this family. Available data did not suggest any safety concerns for the parent alcohol, pentaerythritol.

Accordingly, the Expert Panel issued a tentative safety assessment for 17 pentaerythrityl esters, finding them to be safe in cosmetics in the present practices of use and concentration. Were the ingredients not in current use (as indicated by \*) to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group. The ingredients included in this safety assessment are:

Pentaerythrityl Tetrastearate  
Pentaerythrityl Tetra C5-9 Acid Esters\*  
Pentaerythrityl Tetra C5-10 Acid Esters\*  
Pentaerythrityl Tetracaprylate/Tetracaprate  
Pentaerythrityl Tetralaurate  
Pentaerythrityl Tetramyristate\*  
Pentaerythrityl Tetrastearate  
Pentaerythrityl Tetrabehenate  
Pentaerythrityl Tetracocoate\*

Pentaerythrityl Tetraoleate\*  
Pentaerythrityl Tetraethylhexanoate  
Pentaerythrityl Tetraethylhexanoate/Benzoate  
Pentaerythrityl Tetrabehenate/Benzoate/Ethylhexanoate  
Pentaerythrityl Tetrabenzoate\*  
Pentaerythrityl Tetraisononanoate\*  
Pentaerythrityl Tetrapelargonate  
Pentaerythrityl Cocoate

### Triethanolamine (TEA) and Related TEA-Containing Ingredients

The Panel reviewed the list of proposed ingredients for the TEA family. The sulfate esters, for example, are included in this re-review because some of the sulfates have been reviewed previously, thus providing read-across data. The phosphate esters, however, have not yet been reviewed and the Expert Panel concluded that including them in the tentative amended safety assessment would not be appropriate. In addition, the structures, properties, and metabolism of certain amine and amide acid salts, ester acid salts, sulfonates, polysaccharide and protein salts, and polymer salts are likely to be different from triethanolamine; therefore, these families of ingredients will not be included.

While there were gaps in the available safety data for many of the ingredients included in this group, the Expert Panel relied on the safety assessments of previously reviewed ingredients. The available data were sufficient due to similar structure activity relationships, biological function, and cosmetic product usage. For example, myristic acid has been found safe as used; therefore, the Panel was able to extrapolate those data to support the safety of TEA-Myristate (i.e., the TEA salt of myristic acid).

The Panel was concerned with levels of free DEA that could be present as an impurity in a TEA and related TEA-containing ingredients and limited the amount of free DEA to no more than was considered safe in the CIR safety assessment of DEA and its salts.

A tentative amended safety assessment was issued for public comment, with a conclusion of safe as used when formulated to be non-irritating for the 32 ingredients in the list provided below. Were the ingredients not in current use (as indicated by \*) to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group. These ingredients should not be used in cosmetic products in which *N*-nitroso compounds are formed.

Triethanolamine  
Magnesium/TEA-Coco-Sulfate\*  
Sodium/TEA C12-13 Pareth-3 Sulfate\*  
TEA-C10-15 Alkyl Sulfate\*  
TEA-C11-15 Alkyl Sulfate\*  
TEA-C12-13 Alkyl Sulfate\*  
TEA-C12-14 Alkyl Sulfate\*  
TEA-C12-15 Alkyl Sulfate\*  
TEA-C11-15 Pareth Sulfate\*  
TEA-C12-13 Pareth-3 Sulfate\*  
TEA-Canolate\*

TEA-Cocoate  
TEA-Coco-Sulfate\*  
TEA-Glycerol Dimaleate\*  
TEA-Hydrochloride  
TEA-Hydrogenated Cocoate\*  
TEA-Isostearate  
TEA-Lactate  
TEA-Laurate  
TEA-Laurate/Myristate\*  
TEA-Laureth Sulfate  
TEA-Lauryl Sulfate

TEA-Myristate  
TEA-Oleate\*  
TEA-Oleyl Sulfate\*  
TEA-Palmitate  
TEA-PEG-3 Cocamide Sulfate\*  
TEA-Sorbate\*  
TEA-Stearate  
TEA-Sulfate  
TEA-Tallate\*  
TEA-Undecylenate\*

### Silylates and Surface Modified Siloxysilicates

The Expert Panel considered newly available data provided by industry that addressed the chemical and physical properties of these ingredients. Certain examples of these data appeared to suggest that the physical form of surface modified siloxysilicates could be that of particulates with effective diameters at 10 microns or lower. The Expert Panel recognizes that the particle size produced by cosmetic aerosols is larger than this size and particles from cosmetic aerosols are generally not respirable. In this case, however, because these ingredients exist as particulates with lower particle sizes, the Expert Panel was concerned that no inhalation toxicity data were available. Data on a trade name ingredient, Antifoam A, were determined not to be relevant to the safety of these ingredients and have been removed from the safety assessment.

The Expert Panel concluded that these ingredients are safe as used in leave-on and rinse-off products. However, there are insufficient data to support the safety of these ingredients in products that might be inhaled. The additional data needed are an inhalation study using the smallest particle size used in cosmetics, targeting the effects on the nasopharyngeal cavity. Ingredients included are:

Silica Silylate,  
Silica Dimethyl Silylate,

Trimethylsiloxysilicate,  
Trifluoropropylidimethyl/Trimethylsiloxysilicate

## Insufficient Data Announcements

For insufficient data announcements, interested persons are given 60 days to comment, provide information and/or request an oral hearing before the CIR Expert Panel. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, posted on the CIR website, and are available at the CIR office for review by any interested party. **Please submit data to CIR by September 2, 2011, or sooner if possible.** These ingredient reports will be scheduled for review by the CIR Expert Panel at its **September 26-27, 2011** meeting.

### Decyl Glucoside and Other Alkyl Glucosides

As with many ingredients, alkyl glucosides are provided to formulators at less than 100% active substance. The Expert Panel requested clarification as to whether the reported use concentrations of decyl glucoside, as well as the other alkyl glucosides, relate to the active ingredient. The Expert Panel noted the absence of dermal sensitization data at an active ingredient concentration of 11% and issued an insufficient data announcement requesting human dermal sensitization data (HRIPT) for decyl glucoside at 11% active ingredient, the maximum reported leave-on use concentration reported. If it is determined that the 11% reported use concentration of decyl glucoside is actually use at 11% with only <100% decyl glucoside, then appropriate modifications may be made to the testing protocol. Those submitting data should note that the percent active ingredient should be identified in all data submissions.

## Re-Reviews/New Data

### HC Red No. 1 – not reopened.

In 1996, the CIR Expert Panel concluded that HC Red No. 1 was safe for use in hair dye formulations at concentrations up to 0.5%. The Panel reviewed new data that was published in the opinion released by the European Commission's Scientific Committee on Consumer Products in 2006. The Panel noted that use of HC Red No. 1 in hair dyes has decreased from 47 uses to 9 and that the current use concentration is 0.07%, well below the limit from the original conclusion. Based on this new information, the Expert Panel determined to not reopen the safety assessment of HC Red No. 1.

### Glutaral – reopened

In 1996, the CIR Expert Panel concluded that glutaral was safe for use at concentrations up to 0.5% in rinse-off products; however, the data were insufficient to determine the safety of glutaral in leave-on products. The Panel also concluded that glutaral should not be used in aerosolized products. Since the original conclusion, numerous studies have been published, including a 2-year NTP study on inhalation. While the number of uses for glutaral has decreased from 60 to 13, this ingredient is used in leave-on products and may be used in an aerosol product. The current concentration of use is  $6 \times 10^{-6}\%$ . The Panel has reopened this report to incorporate the new data and to get clarification on uses and concentration. A draft tentative amended safety assessment will be prepared for consideration at the **September 26-27, 2011** meeting.

### Sodium Lauriminodipropionate – reopened

In 1997, the CIR Expert Panel reviewed the safety of Sodium Lauraminopropionate and Sodium Lauriminodipropionate and found that the available data were insufficient to support the safety for use of either ingredient in cosmetics and listed the following additional data that were needed:

- concentration of Use
- chemical characterization (impurities/purity data)
- chemical and physical properties
- method of manufacture
- 28 day dermal toxicity
- dermal teratogenicity
- ocular irritation at concentration of use, if available
- dermal irritation and sensitization at concentration of use
- two different genotoxicity studies (one using a mammalian system)

The Personal Care Products Council's CIR Science and Support Committee provided an extensive submission of data and comments that address these data needs for Sodium Lauriminodipropionate, but not Sodium Lauraminopropionate.

The Expert Panel recommended splitting the two reports to separate the two ingredients and reopening Sodium Lauriminodipropionate only. In addition, the Panel supported the idea that the newly available data also would support the safety of Disodium Lauriminodipropionate and Lauriminodipropionic Acid, such that the acid, the monosodium salt, and the disodium salt would all be safe in the present practices of use and concentration. A draft tentative amended safety assessment will be prepared for consideration at the **September 26-27, 2011** meeting.

### PEGs Cocamine – not reopened

In 1999, the CIR Expert Panel concluded that the available data were insufficient to support the safety of PEGs Cocamine (PEG-2, -3, -5, -10, -15, and -20 Cocamine). Additional data needed were:

- physical and chemical properties, including impurities (especially N-nitrosamines);
- genotoxicity in a mammalian system
- 28-day dermal toxicity using PEG-2 Cocamine
- dermal sensitization data on PEG-2 Cocamine

The Personal Care Products Council's CIR Science and Support Committee submitted data and structure/activity analyses for these PEGs Cocamine ingredients.

The Expert Panel determined that the structure/activity analysis approaches were not well enough established to substitute for actual study data that had been requested. The Panel recognized the potential of such analyses and recommended that a part of an upcoming meeting agenda (on the order of ½ day) be devoted to discussing how such approaches might be used by CIR in the future.

# 119<sup>th</sup> Meeting Notes

## Director's Report

Dr. Andersen announced that Carla Jackson is CIR's new administrative assistant, replacing Josephine Robinson. He also announced that this will be Halyna Breslawec's last meeting as the CIR Deputy Director. Dr. Breslawec has accepted the Personal Care Products Council's offer to become the new Executive Vice-President for Science when Dr. John Bailey retires at the end of July.

CIR efforts under the leadership of Kevin Fries continue to ensure the publication of 3 issues per year of the International Journal of Toxicology containing CIR safety assessments.

## 2012 Priorities

Based on frequency of use data from FDA's Voluntary Cosmetic Registration Program and input received from the Personal Care Products Council, CIR proposed a list of 2012 priorities and asked for both Panel and public comments. At this meeting three specific suggestions were made:

- combining all amino acids into one report that would acknowledge that these chemicals are natural components of human cells/tissue and focusing on safety data related to dermal application.
- consider a safety assessment that would address the Compositae plant family. Also referred to as the aster, daisy, or sunflower family, the Compositae are the largest family of vascular plants and dermal irritation and sensitization data often are available.
- note that dermal penetration/metabolism data on the oligopeptide ingredient would be useful.

At the September, 2011 meeting, the Panel will make a final determination regarding 2012 priorities.

The draft CIR 2012 priority list currently includes:

- Talc
- Matricaria Chamomilla Flower Extract
- Anthemis Nobilis Flower Extract
- Chamomilla Recutita (Matricaria) Flower/Leaf Extract
- Lauroyl Lysine (And Related Ingredients)
- Arginine (And Related Ingredients)
- Hydrolyzed Soy Protein
- Hydrolyzed Silk
- Dimethicone/Vinyl Dimethicone Crosspolymer
- Dimethicone Crosspolymer
- Boron Nitride
- Vitis Vinifera (Grape) Seed Extract
- Nitrocellulose
- Polyethylene Terephthalate
- Tromethamine
- Palmitoyl Oligopeptide
- Stearamidopropyl Dimethylamine
- Peg-120 Methyl Glucose Dioleate
- 6-Hydroxyindole

## CIR Boilerplate Language

**Hair Dye Epidemiology** – Dr. Julie Skare, the Chair of the Personal Care Products Council's Hair Colorants Technical Committee, reviewed the several epidemiology studies that investigated associations between hair dye use and cancer and other endpoints. She emphasized that studies of personal use of hair dyes may have a minimum amount of information on exposures (e.g., ever/never use of hair dyes) or a great deal of information (e.g., hair dye type, color, duration and frequency of use) and everywhere in between. She asserted that, the more exposure information provided, the better the resultant study. She also reminded the Expert Panel that studies on occupation as a hairdresser/barber/cosmetologist lack information on actual exposure to hair dyes and that these subjects have exposure to multiple products in their occupational setting.

Just published a matter of weeks before this presentation, Koutros et al. 2011 examined the association between personal use of hair dyes and bladder cancer. The exposure assessment was excellent and genotyping of NAT2, NAT1, GSTM1, and GSTT1 was done. The overall finding was that there was no association between ever use of hair dyes and bladder cancer. Looking at subcategories, a statistically significant lower risk of bladder cancer in women was associated with use of red color hair dyes and with medium/dark brown and medium/dark red shades. Use of hair dyes in the 10-19 years of use range and total lifetime applications in the 100-199 range also were associated with a lower risk of bladder cancer. Other stratifications of the data produced a statistically significant association of bladder cancer with permanent hair dye use in college-educated women, but the numbers of individuals in this group were low and the confidence interval was large. Further stratification by NAT2 (slow) also produced a statistically significant association with bladder cancer in college-educated women using permanent hair dyes and a statistically significant lower risk of bladder cancer in non-college-educated women using permanent hair dyes exclusively with NAT2 (rapid) genotype. Among three studies over the past 8 years, she noted that no pattern of association of NAT2 and NAT1 genotype/phenotype with bladder cancer and hair dye use has emerged.

Dr. Skare also summarized the following studies that examined personal use of hair dyes and cancer endpoints:

- Shakhssalim et al. 2010 – case-control study of bladder cancer in Iran – poor exposure information, OR of 1.99 (CI 1.02 – 3.82)
- Lv et al. 2010 - hospital-based case-control study of myelodysplastic syndromes in China - minimal exposure information, OR of 1.46 (CI 1.03 – 2.07)
- Wong et al. 2009 – hospital-based case-control study of acute myeloid leukemia in Shanghai – exposure information from structured interview, OR 0.98 (CI 0.80 – 1.2)

- Wong et al. 2010 - hospital-based cancer case-control study in Shanghai – exposure information from structured interview, OR 0.93 (CI 0.75 – 1.16) for NHL; OR 0.37 (CI 0.18 – 0.76) for CLL/SLL
- Zhang et al. 2009 – reanalysis of Connecticut NHL case-control study
- Chang et al. 2009 – re-evaluation of tissue samples from case-control study in males from Iowa and Minnesota

Dr. Skare summarized the following studies that examined personal use of hair dyes and non-cancer endpoints:

- Prince et al. 2010 - primary biliary cirrhosis
- Corpechot et al. 2010 – primary biliary cirrhosis
- Gross et al. 2010 – aplastic anemia

Additional new studies were described in which occupations as a hairdresser/barber/cosmetologist were examined for association with cancer and non-cancer endpoints.

Overall, she suggested that the newly available studies do not change the position established by the CIR Expert Panel that there is insufficient evidence to support a causal relationship between personal hair dye use and cancer or other toxicological endpoints, based on lack of strength of the associations and inconsistency of findings. She recommended that the pace at which new data are being developed would suggest that the CIR boilerplate could be updated to use the 2008 IARC Working Group meeting (basis for the IARC 2010 monograph) as the baseline and add discussion of studies published after that date.

**Aerosol/inhalation toxicity** - The CIR Expert Panel reviewed an updated version of the aerosol/inhalation toxicity boilerplate. In some circumstances, inhalation toxicity data are not available for a particular ingredient, yet that ingredient may be used in cosmetic aerosols. In such a case the Panel may use the aerosol boilerplate language that explains respirable particle sizes in comparison with particle sizes in cosmetic products. The Expert Panel offered comments to tighten the language before posting on the website. An additional technical issue was raised regarding particles that do not penetrate deeply into the respiratory system, but once further passage is blocked, may allow the ingredient in question to vaporize and pass all the way to the lungs. Such an issue would be addressed on a case by case basis and would use the ingredient's vapor pressure as a starting point to evaluate the situation.

## Scientific Literature Reviews issued in May/June 2011 and scheduled for consideration at the September 26-27, 2011 meeting:

*Interested persons are given 60 days to comment, provide information and/or request an oral hearing before the CIR Expert Panel. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings and are available at the CIR office for review by any interested party. **Please submit data to CIR by August 24<sup>th</sup>, or sooner, if possible.** Scientific Literature Reviews are available - see the order form.*

### Alkyl Glyceryl Ethers

The ingredients included in this review are alkyl glyceryl ethers. Structurally, this means that an alkyl or alkenyl chain is terminated with glycerin at one end. The following ingredients as used in cosmetics are reviewed:

- Ethylhexylglycerin
- Caprylyl Glyceryl Ether
- Glyceryl Capryl Ether
- Cetyl Glyceryl Ether/Chimyl Alcohol
- Glyceryl Allyl Ether
- Glyceryl Lauryl Ether
- Isodecyl Glyceryl Ether
- Isostearyl Glyceryl Ether
- Oleyl Glyceryl Ether
- Batyl Alcohol

These ingredients function mostly as surfactants or skin conditioning agents in cosmetic products. Cetyl glyceryl ether and chimyl alcohol are listed in The International Cosmetic Ingredient Dictionary and Handbook as discrete chemicals. However, these two ingredients are identical chemicals. Accordingly, there are 11 ingredients listed in this review, but two of them represent the same entity.

### 2-Amino-4-Hydroxyethylaminoanisole and Its Sulfate Salt

This literature review addresses the safety of the cosmetic ingredient 2-amino-4-hydroxyethylaminoanisole and 2-amino-4-hydroxyethylaminoanisole sulfate. These two ingredients function as coupling agents in oxidative hair dyes, although only the more highly soluble sulfate salt is in use. Purity for 2-amino-4-hydroxyethylaminoanisole sulfate has been reported to be 99.3-100% with HPLC at 210-304 nm.

### Citric Acid and Its Inorganic Salts and Alkyl and Glycol Esters

This literature review addresses the safety of citric acid, an  $\alpha$ -hydroxy tricarboxylic acid, as used in cosmetics. Citric acid may function in cosmetics as a chelating agent, pH adjuster, or fragrance ingredient. This report also addresses the safety of the following 12 inorganic salts, 20 alkyl esters, and 13 glycol esters of citric acid as used in cosmetics:

#### Inorganic Salts

Aluminum Citrate  
Calcium Citrate  
Copper Citrate  
Diammonium Citrate

Disodium Cupric Citrate  
Ferric Citrate  
Magnesium Citrate  
Manganese Citrate  
Monosodium Citrate

Potassium Citrate  
Sodium Citrate  
Zinc Citrate

#### Alkyl Mono-, Di-, and Triesters

Isodecyl Citrate  
Isopropyl Citrate  
Stearyl Citrate  
Dilauryl Citrate  
Distearyl Citrate  
Tributyl Citrate

Tri-C 12-13 Alkyl Citrate  
Tri-C14-15 Alkyl Citrate  
Tricaprylyl Citrate  
Triethyl Citrate  
Triethylhexyl Citrate  
Trihexyldecyl Citrate  
Trisocetyl Citrate

Triisopropyl Citrate  
Trilauryl Citrate  
Trioctyldecyl Citrate  
Trioleyl Citrate  
Triisostearyl Citrate  
Tristearyl Citrate  
Ethyl Citrates

#### Glycol Mono-, Di-, and Triesters

Disodium Laureth-7 Citrate  
Laureth-6 Citrate  
Laureth-7 Citrate  
Propylene Glycol Citrate

Dilaureth-7 Citrate  
Sodium Dilaureth-7 Citrate  
PEG-5 Tricapryl Citrate  
PEG-5 Trilauryl Citrate  
PEG-5 Trimyristyl Citrate

PEG-5 Tricetyl Citrate  
PEG-5 Tristearyl Citrate  
Trilaureth-9 Citrate  
Tripropylene Glycol Citrate

While some of the inorganic salts of citric acid may function as a pH adjuster or chelating agent, as citric acid does, these salts also have many diverse functions, including skin conditioning agent, buffering agent, cosmetic astringent, oral care agent, cosmetic biocide, or pesticide. The alkyl esters function primarily as skin conditioning agents, but a few have other possible functions, including plasticizer, solvent, and fragrance ingredient. The glycol esters of citric acid are reported to function mostly as skin conditioning agents or surfactants. Citric acid and a number of the ingredients in this safety assessment are generally recognized as safe (GRAS) direct food additives. Because the safety of the oral intake of these ingredients has been well established, only dermal data are being considered for these GRAS ingredients.

### **Panax Ginseng Root Extract and Other Ginseng Root-Derived Ingredients as Used in Cosmetics**

Many ginseng-derived materials are used in cosmetics. At this time, the CIR review is focusing on ginseng-derived ingredients that are derived from the root portion of the plant, and is not addressing ginseng derived ingredients that are prepared using other plant parts. The ingredients being considered are:

- Panax Ginseng Root Extract,
- Hydrolyzed Ginseng Root,
- Hydrolyzed Ginseng Root Extract,
- Hydrolyzed Ginseng Saponins,
- Panax Ginseng Root,
- Panax Ginseng Root Powder,
- Panax Ginseng Root Water,
- Panax Ginseng Root Oil,
- Panax Ginseng Root Protoplast,
- Panax Japonicus Root Extract,
- Panax Notoginseng Root,
- Panax Notoginseng Root Powder,
- Panax Quinquefolium Root Extract.

The cosmetic uses of these ingredients include: skin-conditioning agents - miscellaneous, fragrance ingredients, skin-conditioning agents - miscellaneous, skin conditioning agent-humectant, skin-conditioning agents - emollient, and cosmetic astringent.

### **Trisodium Sulfosuccinate and Alkyl PEG Sulfosuccinates**

The ingredients in this review share a sulfo-substituted, succinic acid core. Accordingly, the salts of these materials are sulfosuccinates. With the exception of the trisodium salt (i.e. trisodium sulfosuccinate), the ingredients in this review are the salts of alkyl polyethylene glycol (PEG), mono-esters of sulfosuccinic acid. The ingredients included are:

- Disodium Laureth Sulfosuccinate
- Disodium Laureth-6 Sulfosuccinate
- Disodium Laureth-9 Sulfosuccinate
- Disodium Laureth-12 Sulfosuccinate
- Disodium Deceth-5 Sulfosuccinate
- Disodium Deceth-6 Sulfosuccinate
- Magnesium Laureth-3 Sulfosuccinate
- Disodium C12-14 Pareth-1 Sulfosuccinate
- Disodium C12-14 Pareth-2 Sulfosuccinate
- Disodium C12-15 Pareth Sulfosuccinate
- Disodium Coceth-3 Sulfosuccinate
- Disodium Laneth-5 Sulfosuccinate
- Disodium C12-14 Sec-Pareth-3 Sulfosuccinate
- Disodium C12-14 Sec-Pareth-5 Sulfosuccinate
- Disodium C12-14 Sec-Pareth-7 Sulfosuccinate
- Disodium C12-14 Sec-Pareth-9 Sulfosuccinate
- Disodium C12-14 Sec-Pareth-12 Sulfosuccinate
- Disodium Oleth-3 Sulfosuccinate
- Trisodium Sulfosuccinate

These ingredients function mostly as surfactants-cleansing agents in cosmetic products. An amended CIR final safety assessment on alkyl PEG ethers with a safe as used conclusion was issued previously, and data on laureths from this preceding review could be used to fill pertinent data gaps (i.e., carcinogenicity and reproductive and developmental toxicity) in the current safety assessment. The potential for using these data is based on the assumption that, if these ingredients have the ability to penetrate the skin, the first level metabolites would likely include the corresponding alkyl PEG ethers (e.g., magnesium laureth-3 sulfosuccinate may be metabolized to laureth-3 and sulfosuccinic acid). While acknowledging the uncertainty as to whether data on laureths can be used to assess the safety of sulfosuccinates, these data should not be ignored in the safety evaluation. Accordingly, data on laureths are included while further consideration of their relevance continues.

### **Scientific Literature Reviews under Development**

Chlorphenesin

Diisostearyl Malate  
Disteardimonium Hectorite  
Galactomannans (Guar Hydroxypropyltrimonium Chloride)  
Nylon 12  
Polyquaternium-22  
Synthetic Fluorophlogopite  
Xanthan Gum

### **Re-reviews under Development**

MEA and Related MEA-Containing Ingredients  
Sodium Lauraminopropionate

### **Next CIR Expert Panel meeting**

Monday and Tuesday, September 26-27, 2011  
The Madison Hotel  
1177 Fifteenth St. NW  
Washington, DC, 20005  
Phone: (202) 862-1600  
Fax: (202) 785-1255

# Order Form

## Name & Mailing Address:

Please print carefully or attach business card

## Cosmetic Ingredient Review

1101 17th Street, NW, Suite 412

Washington, DC 20036-4702

Phone 1-202-331-0651

Fax 1-202-331-0088

Email [cirinfo@cir-safety.org](mailto:cirinfo@cir-safety.org)

Personal Care Council member: \_\_\_ no \_\_\_ yes if a subsidiary, member company name \_\_\_\_\_

Date:

Quantity	Description	Unit Price*	Total
	Final Safety Assessment – 1,2-Glycols		
	Revised Tentative Amended Safety Assessment – Formaldehyde and Methylene Glycol		
	Revised Tentative Amended Safety Assessment – DEA and related DEA-containing ingredients		
	Tentative Safety Assessment - Crosslinked Alkyl Acrylates		
	Tentative Amended Safety Assessment – Benzyl Alcohol and Benzoic Acid and Its Salts and Benzyl Ester		
	Tentative Safety Assessment - Pentaerythrityl Tetraisostearate and Other Pentaerythrityl Esters		
	Tentative Amended Safety Assessment - DEA Amides		
	Tentative Amended Safety Assessment - Triethanolamine (TEA) and TEA-containing Ingredients		
	Tentative Safety Assessment - Silylates and Surface Modified Siloxysilicates		
	Scientific Literature Review - Alkyl Glyceryl Ethers		
	Scientific Literature Review - 2-Amino-4-Hydroxyethylaminoanisole and its Sulfate Salt		
	Scientific Literature Review - Citric Acid and Its Inorganic Salts and Alkyl and Glycol Esters		
	Scientific Literature Review - Panax Ginseng Root Extract and Other Ginseng-Root Derived Ingredients		
	Scientific Literature Review - Trisodium Sulfosuccinate and Alkyl PEG Sulfosuccinates		
Shipping (see below)			
5.75% sales tax (for Washington, DC pickups/addresses only)			
Total Enclosed			

ORDERS MUST BE PREPAID • NO WIRE TRANSFERS • CHECKS DRAWN ON US BANKS • PAYMENT IN US DOLLARS ONLY

Check #:	<input type="checkbox"/> Visa <input type="checkbox"/> MasterCard <input type="checkbox"/> American Express	Signature:
	Number: _____ Exp. Date: _____	

\*Prices

	List Price	Personal Care Products Council Member Price
Scientific Literature Review	\$80.00	\$40.00
Tentative Safety Assessment	\$90.00	\$50.00
Final Safety Assessment	\$100.00	\$60.00

Domestic: Reports ship free to U.S.A. and Canada; \$10.00 for each Compendium  
 International: \$5.00 for each report; \$57.00 for each Compendium

\* **IMPORTANT NOTE:** Payment must accompany order. Sending order and payment separately can delay fulfillment of order.

# **Policy, Legislation & Administrative Rules**

Secretary of State  
Certificate and Order for Filing  
**PERMANENT ADMINISTRATIVE RULES**

I certify that the attached copies\* are true, full and correct copies of the PERMANENT Rule(s) adopted on August 15, 2011 by the \_\_\_\_\_  
Date prior to or same as filing date

<u>Oregon Health Licensing Agency</u>	<u>OAR 331</u>
<b>Agency and Division</b>	<b>Administrative Rules Chapter Number</b>
<u>Samantha Patnode, Policy Analyst</u>	<u>700 Summer St. NE, Suite 320, Salem, Oregon 97301-1287</u>
<b>Rules Coordinator</b>	<b>Address</b>
	<u>503-373-1917</u>
	<b>Telephone</b>

to become effective August 15, 2011. Rulemaking Notice was published in the June 2011 Oregon Bulletin.\*\*  
Date upon filing or later Month and Year

**RULE CAPTION**

Define terms used in ORS 676.612 and active military status protocols for authorization holders.

**Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.**

**RULEMAKING ACTION**

List each rule number separately (000-000-0000)

Secure approval of new rule numbers (Adopted or Renumbered rules) with the Administrative Rules Unit prior to filing.

**ADOPT:** 331-010-0050

**AMEND:** 331-020-0040, 331-020-0070

**REPEAL:**

Stat. Auth.: ORS 676.615

Other Auth.: ORS 408.450

Stats. Implemented: ORS 676.607, 676.608, 676.612, 408.450

**RULE SUMMARY**

Adopt 331-010-0050 allowing authorization holders in active military status waiver of renewal, fees and continuing education requirements, as well as protocols for restoration of former authorization status.

Define and clarify what constitutes an appearance before the agency during investigations of alleged violations of statutes or rules under the authority of the Oregon Health Licensing Agency (OHLA), its boards or councils.

Define and clarify the terms incompetence and negligence used in ORS 676.612 in relation to the boards or councils under the OHLA.

<u>Randall Everitt, Director</u>	<u>8/11/11</u>
<b>Authorized Signer</b>	<b>Printed name</b>
	<b>Date</b>

\*With this original, file one photocopy of certificate, one paper copy of rules listed in Rulemaking Actions, and electronic copy of rules. \*\*The Oregon Bulletin is published the 1st of each month and updates rules found in the OAR Compilation. For publication in Bulletin, rule and notice filings must be submitted by 5:00 m on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, when filings are accepted until 5:00 pm on the preceding workday.  
ARC 930-2005

**OREGON HEALTH LICENSING AGENCY**

**DIVISION 10**

**AGENCY GENERAL ADMINISTRATION RULES**

**331-010-0050**

**Authorization Holders; Military Leave**

**(1) A practitioner authorized to practice under a program listed in ORS 676.606 is not required to renew the authorization or pay renewal fees while in active military service unless required by the authorization holders branch of the military.**

**(2) To be restored to former authorization status the authorization holder must notify the agency in writing within 60 days of being honorably discharged.**

**(3) No fees will be due until the following renewal period.**

**(4) Requirements for completing continuing education hours during an authorization holder's active duty period shall be evaluated on a case by case basis.**

## DIVISION 20

### AGENCY REGULATORY OPERATIONS RULES

#### 331-020-0040

##### Complaint Processing and Investigation

Pursuant to ORS 676.608, complaints filed with the Oregon Health Licensing Agency will be handled as follows:

(1) The agency will determine if the complaint is related to a profession or occupation regulated and administered by the agency and the complaint falls within authority delegated to the agency by statute.

(2) The agency investigator(s):

(a) Will review the information and as applicable, interview parties and witnesses, and examine physical evidence relating to the complaint;

(b) Will advise on whether an authorization holder or other individual practiced within the acceptable standards of the particular program;

~~(c) May attempt to informally resolve the matter;~~

~~(d)~~ (c) Will make recommendations for agency action.

(3) After receiving advice from the investigator(s), the agency will determine what action will be taken in accordance with ORS 676.608.

**(4) As used in ORS 676.608(8), to "appear before the agency" includes: an investigative interview conducted under oath, under subpoena or otherwise compelled; an interview or hearing before a board, council, or subcommittee of a board or council; any depositions authorized by the agency; pre-hearing conferences; and contested case hearings. It does not include interrogatories, written admissions, other written communications, or voluntary communications.**

Stat. Auth.: ORS 183, 676.605, 676.608, 676.615  
Stats. Implemented: ORS 183, 676.605, 676.608, 676.615  
Hist.: HLO 1-2004, f. & cert. ef. 2-13-04; HLA 1-2009, f. & cert. ef. 6-1-09

## 331-020-0070

### Discipline

(1) The Oregon Health Licensing Agency may discipline authorization holders for violations of laws and rules, in accordance with ORS 676.612 and 676.992.

(2) Failure to cooperate with the agency or its agent is unprofessional conduct and is subject to disciplinary sanctions, which may include suspension or revocation and refuse to issue or renew or place on probation and assessment of civil penalties. Failure to cooperate with the agency or its agent includes, but is not limited to, the following:

(a) Failing to provide information within the specified time allotted and as requested by the agency;

(b) Failing to temporarily surrender custody of original client records to the agency upon request, which includes treatment charts, models, health histories, billing documents, correspondence and memoranda;

(c) Interference, use of threats or harassment which delays or obstructs any person in providing evidence in any investigation, contested case, or other legal action instituted by the agency;

(d) Interference, use of threats or harassment which delays or obstructs the agency in carrying out its functions under individual programs administered and regulated by the agency as listed in ORS 676.606 and rules adopted thereunder;  
or

(e) Deceiving or attempting to deceive the agency regarding any matter under investigation including altering or destroying any records.

(3) The agency, at its discretion, may require supplemental training in an appropriate area of study as determined by the agency, board or council, as a disciplinary sanction. Supplemental training may be in addition to assessment of a monetary penalty or the agency, board or council may waive or reduce a penalty, in cases requiring supplemental training.

**(4) As used in ORS 676.612(2)(j) incompetence means engaging in conduct which evidences a lack of ability or fitness to perform the holder's professional functions.**

**(5) As used in ORS 676.612(2)(j) negligence means engaging in conduct detrimental to the client.**

Stat. Auth.: ORS 676.607, 676.612, 676.992  
Stats. Implemented: ORS 676.607, 676.612, 676.992  
Hist.: HLO 1-2004, f. & cert. ef. 2-13-04; HLA 1-2009, f. & cert. ef. 6-1-09

# **Executive Session**

# **Items for Board Action**

**ISSUE:**

Approve proposed administrative rules and approve rulemaking schedule.

**DISCUSSION:**

**Temporary Rulemaking**

On September 13, 2011, the Agency filed temporary administrative rules related to civil penalties and prohibitions. Temporary administrative rules are used in situations which warrant immediate action and are only good for 180 days (approximately 6 months).

During a review of the Board of Cosmetology’s (Board) Oregon Administrative Rules (OAR) it was determined that temporary rules be filed to amend the following OARs:

**OAR 817-090-0025, 817-090-0035, and 817-090-0045** because the Oregon Health Licensing Agency (Agency) and the Board do not have statutory authority to assess civil penalties for violations of ORS chapter 676 or OAR chapter 331 under OAR chapter 817.

**OAR 817-090-0105 and 817-120-0005** because it is unlawful under the ADA for a state to prevent an individual from practicing cosmetology based on that individual’s HIV/AIDS (communicable disease) status.

**Proposed Administrative Rules**

In order to permanently adopt the temporary rules, the Agency must go through the regular rulemaking process. Upon approval of the proposed administrative rules by the Board, the public comment period will begin on December 1, 2011 and end on December 28, 2011. The Board is scheduled to permanently adopt administrative rules on January 23, 2012. Effective date for permanent rules is scheduled for February 1, 2012.

Date	Action	Time
September 13, 2011	Temporary administrative rule effective	
October 24, 2011	Board meeting notification of temporary rule. Approve proposed rules and rulemaking schedule	9 am
December 1, 2011	Notice of proposed rules –Oregon Bulletin	
December 28, 2011	Last day for public comment	
January 23, 2012	Board meeting adopt permanent rules	9 am
February 1, 2012	Permanent rules effective	
March 11, 2012	Temporary rule expires	

Other administrative rules to be revised include facility application requirements allowing only a natural person to apply for a facility license. This will allow the Agency to track facilities by “one” individual rather than a “corporation” which is easily dissolved or changed.

**RECOMMENDATION:**

Recommend approval of proposed administrative rules and the rulemaking schedule for 2012.

Secretary of State  
Certificate and Order for Filing  
**TEMPORARY ADMINISTRATIVE RULES**  
A Statement of Need and Justification accompanies this form.

I certify that the attached copies\* are true, full and correct copies of the TEMPORARY Rule(s) adopted on September 13, 2011 by the \_\_\_\_\_ Date prior to or same as filing date

Oregon Health Licensing Agency (OHLA), Board of Cosmetology OAR Chapter 817  
Agency and Division Administrative Rules Chapter Number

Samantha Patnode, Policy Analyst 700 Summer St NE, Suite 320, Salem, OR 97301-1287 (503)373-1917  
Rules Coordinator Address Telephone

to become effective September 13, 2011 through March 11, 2012  
Date upon filing or later A maximum of 180 days including the effective date.

**RULE CAPTION**

Amend civil penalty assessment rules.  
Amend rules related to practicing as on or an individual with a communicable disease.

**Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.**

**RULEMAKING ACTION**

List each rule number separately, 000-000-0000.

Secure approval of new rule numbers (Adopted rules) with the Administrative Rules Unit prior to filing

**ADOPT:**

**AMEND:** 817-090-0025, 817-090-0035, 817-090-0045, 817-090-0105, 817-120-0005

**SUSPEND:**

**REPEAL:**

Stat. Auth.: ORS 676.607, 676.615, 676.992, 690.165, 690.167, 690.205

Other Auth.:

Stats. Implemented: ORS 676.992, 690.015

**RULE SUMMARY**

It is necessary to amend OAR 817-090-0025, 817-090-0035, and 817-090-0045 because the agency and the board do not have statutory authority to assess civil penalties for violations of ORS chapter 676 or OAR chapter 331 under OAR chapter 817.

It is necessary to amend OAR 817-090-0105 and 817-120-0005 because it is unlawful under the ADA for a state to prevent an individual from practicing cosmetology based on that individual's HIV/AIDS (communicable disease) status.

\_\_\_\_\_  
Authorized Signer Randall Everitt, Director September 13, 2011  
Printed name Date

\*With this original and Statement of Need, file one photocopy of certificate, one paper copy of rules listed in Rulemaking Actions, and electronic copy of rules. ARC 940-2005

Secretary of State  
**STATEMENT OF NEED AND JUSTIFICATION**

A Certificate and Order for Filing Temporary Administrative Rules accompanies this form.

Oregon Health Licensing Agency (OHLA), Board of Cosmetology  
Agency and Division

OAR Chapter 817  
Administrative Rules Chapter Number

In the Matter of: Amendment of 817-090-0025, 817-090-0035, 817-090-0045, 817-090-0105, 817-120-0005

Rule Caption:

Amend civil penalties and requirements for practice of or on individuals with communicable diseases.

Stat. Auth.: ORS 676.607, 676.615, 676.992, 690.165, 690.167, 690.205

Other Auth.:

Stats. Implemented: ORS 676.992, 690.015

**Need for the Temporary Rule(s):**

It is necessary to amend OAR 817-090-0025, 817-090-0035, and 817-090-0045 to align administrative rules with the statutory authority of OHLA and the Board of Cosmetology for administration of cosmetology regulation and setting of civil penalty amounts for violations of cosmetology rules.

It is necessary to amend OAR 817-090-0105 and 817-120-0005 to bring the administrative rules into compliance with the Americans with Disabilities Act.

**Documents Relied Upon, and where they are available:**

Oregon Revised Statutes Chapters 676, 690 and 28 CFR parts 35 and 36.

All documents except information exempt from public disclosure are available at the Oregon Health Licensing Agency 700 Summer Street NE, Suite 320, Salem, OR 97301-1287. To obtain information or copies of information please contact Samantha Patnode, Policy Analyst, at (503) 373-1917, during normal business hours Monday Through Friday between 7:30am to 4:30pm. Email: [samie.patnode@state.or.us](mailto:samie.patnode@state.or.us)

**Justification of Temporary Rule(s):**

The temporary administrative rule is justified because the agency and the Board of Cosmetology are required to act within their statutory authority and may not adopting or enforcing rules that are inconsistent with the requirements of the ADA.

	Randall Everitt, Director	September 13, 2011
Authorized Signer	Printed name	Date

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310. ARC 945-2005

**DIVISION 90**  
**CIVIL PENALTIES**

**817-090-0025**

**Schedule of Penalties for Facility and Independent Contractor Registration Violations**

The Agency has adopted the following presumptive penalty schedule for the 1st, 2nd, and 3rd violation of facility license and independent contractor registration laws and rules. This schedule applies, except at the discretion of the agency pursuant to OAR 331-020-0060. For the 4th and subsequent offenses, the provisions of OAR 331-020-0060 apply.

(1) Operating or purporting to operate a facility without a valid facility license is a violation of ORS 690.015(2)(b) ~~or and~~ **690.015(2)(e)**:

(a) **Never licensed:**

(A) 1st offense: \$500;

~~(B)(b)~~ 2nd offense: \$1000;

~~(C)(c)~~ 3rd offense: \$2500

(b) **Inactive or expired license:**

(A) 1st offense: \$200;

(B) 2nd offense: \$500;

(C) 3rd offense: \$1,000

(c) **Certificate, Authorization, or Registration Suspended or Revoked:**

(A) 1st offense: \$2,500;

(B) 2nd offense: \$5,000;

(C) 3rd offense: Monetary penalty and any other actions allowed by law including revocation of suspended authorization to practice and refusal to issue a new authorization to practice to a revoked authorization holder.

(2) Operating or purporting to operate as an independent contractor without **independent contractor registration** or with a dormant independent contractor registration is a violation of ORS 690.015 (2)(d) **or and 690.015(2)(e)**:

- (a) 1st offense: \$200
- (b) 2nd offense: \$500
- (c) 3rd offense: \$1,000

~~(3) Operating a facility with an inactive or expired license is a violation of ORS 676.612 (2)(r):~~

- ~~(a) 1st offense: \$200;~~
- ~~(b) 2nd offense: \$500;~~
- ~~(c) 3rd offense: \$1,000~~

~~(3)~~(4) Allowing an uncertified person **employee or uncertified individual under a person's supervision and control** to practice in a field of practice is a violation of ORS 690.015(2)(g):.

**(a) Employee or individual with suspended who has never been certified:**

- ~~(A)~~(a) 1st offense: \$500;
- ~~(B)~~(b) 2nd offense: \$1,000;
- ~~(C)~~(c) 3rd offense: \$2,500

**(b) Employee or individual with inactive, suspended, revoked, or expired certification:**

- (a) 1st offense: \$200**
- (b) 2nd offense: \$500**
- (c) 3rd offense: \$1000**

~~(5) Failing to allow the Agency to inspect the premises when the facility is open or obstructing or hindering the normal progress of the inspection, threatening or exerting physical harm, or enabling another individual to impede the inspection progress is a violation of OAR 817-0200006(9) and will result in monetary penalties and any other actions allowed by law.~~

~~(6) Allowing an employee to practice with an inactive or expired practitioner certificate is a violation of ORS 676.612(2)(h):~~

~~(a) 1st offense: \$200~~

~~(b) 2nd offense: \$500~~

~~(c) 3rd offense: \$1000~~

~~(4)(7) Failing to meet the specifications and standards required under OAR 817-010-0007 in a facility is a violation of OAR 817-020-0006 (1)(e) and may result in an emergency suspension of the facility license until the violation is corrected.~~

Stat. Auth.: ORS 676.605, 676.615, 676.992, 690.165 & 690.167

Stats. Implemented: ~~ORS 676.605, 676.615, 676.992,~~ **690.015**, 690.165 & 690.167

Hist.: BH 3-1984(Temp), f. & ef. 6-27-84; BH 4-1984, f. & ef. 12-7-84; BH 1-1985, f. & ef. 3-28-85; BH 1-1988, f. & cert. ef. 7-1-88; BH 2-1990, f. & cert. ef. 10-29-90; BH 1-1992, f. 6-1-92, cert. ef. 7-1-92; BH 3-1994, f. 6-23-94, cert. ef. 7-1-94; BH 1-1996, f. 5-31-96, cert. ef. 7-1-96; Renumbered from 817-090-0020; BBH 1-1998, f. 6-24-98, cert. ef. 6-30-98; BOC 1-2000, f. 5-12-00, cert. ef. 5-15-00; BOC 1-2002, f. 5-31-02 cert. ef. 6-1-02; BOC 1-2004, f. 6-29-04, cert. ef. 7-1-04; BOC 1-2006, f. & cert. ef. 3-15-06; BOC 2-2011, f. & cert. ef. 5-5-11

## **817-090-0035**

### **Schedule of Penalties for Practitioner Violations**

The Agency has adopted the following presumptive penalty schedule for the 1st, 2nd, and 3rd violation of practitioner licensing laws and rules. This schedule applies, except at the discretion of the agency pursuant to OAR 331-020-0060. For the 4th and subsequent offenses, the provisions of OAR 331-020-0060 apply.

~~(1) Operating~~ **Performing, attempting to perform, or purporting to perform services in a field of practice without proper certification, authorization, registration or permit with an inactive or expired practitioner certificate** is a violation of ORS **690.015(2)(a) or 690.015(2)(e)**. ~~676.612(2)(r):~~

**(a) Certificate, authorization, registration, or permit inactive or expired:**

~~(A)(a)~~ 1st offense: \$200;

~~(B)(b)~~ 2nd offense: \$500;

~~(C)(c)~~ 3rd offense: \$1000.

**(b) Certificate, authorization, registration, permit never held:**

~~(2) Practicing or purporting to practice in a field of practice without a certificate, is a violation of ORS 690.015(2)(a)~~

~~(A)(a)~~ 1st offense: \$1,000;

**(B)**~~(b)~~ 2nd offense: \$2,500;

**(C)**~~(c)~~ 3rd offense \$5,000.

**(c) Certificate, authorization, or registration suspended or revoked:**

**(A) 1st offense: \$2,500;**

**(B) 2nd offense: \$5,000;**

**(C) 3rd offense: Monetary penalty and any other actions allowed by law including revocation of suspended authorization to practice and refusal to issue a new authorization to practice to a revoked authorization holder.**

**(2)**~~(3)~~ Performing **or attempting to perform** services in a field of practice in an unlicensed facility is a violation of ORS 690.015(2)(c):

(a) 1st offense: \$200;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1,000

~~(4) Practicing or purporting to practice in a field of practice with a suspended certificate is a violation of 676.612 (4)~~

~~(a) 1st offense: \$2,500;~~

~~(b) 2nd offense: \$5,000;~~

~~(c) 3rd offense: Monetary penalty and any other actions allowed by law including refusal to issue an authorization to practice~~

**(3)**~~(5)~~ Performing in a field of practice by a student when not on the premises of an educational institution in which he or she is enrolled is a violation of OAR 817-100-0005:

(a) 1st offense: \$500;

(b) 2nd offense: \$1,000;

(c) 3rd offense: \$2,500.

Stat. Auth: ORS 676.605, 676.615, 676.992, 690.165 & 690.167

Stats. Implemented: ORS 676.605, 676.615, 676.992, 690.165 & 690.167

Hist.: BH 3-1984(Temp), f. & ef. 6-27-84; BH 4-1984, f. & ef. 12-7-84; BH 1-1985, f. & ef. 3-28-85; BH 1-1988, f. & cert. ef. 7-1-88; BH 2-1990, f. & cert. ef. 10-29-90; BH 1-1992, f. 6-1-92, cert. ef. 7-1-92; BH 3-1994, f. 6-23-94, cert. ef. 7-1-94; BH 1-1996, f. 5-31-96, cert. ef. 7-1-96, Renumbered from 817-090-0020; BOC 1-2000, f. 5-12-00, cert. ef. 5-15-00; BOC 2-2001, f. 2-16-01, cert. ef. 3-1-01; BOC 1-2004, f. 6-29-04, cert. ef. 7-1-04; BOC 1-2006, f. & cert. ef. 3-15-06; BOC 2-2011, f. & cert. ef. 5-5-11

## 817-090-0045

### Schedule of Penalties for Certificate/License/Registration/Permit Violations

The Agency has adopted the following presumptive penalty schedule for the 1st, 2nd, and 3rd violation of certificate/license/registration/permit laws and rules. This schedule applies, except at the discretion of the agency pursuant to OAR 331-020-0060. For the 4th and subsequent offenses, the provisions of OAR 331-020-0060 apply.

(1) Altering with fraudulent intent or fraudulent use of a license, certificate, registration, permit or authorization issued by the agency is a violation of ORS 690.015(2)(j) or ORS 690.015(2)(k):

(a) 1st offense: \$1,500;

(b) 2nd offense: \$3,500;

(c) 3rd offense: \$5,000.

(2) Failing to post a valid license, registration, certificate, permit or authorization issued by the agency in public view is a violation of ORS 690.095 and OAR 817-035-0110:

(a) 1st offense: \$100

(b) 2nd offense: \$200

(c) 3rd offense: \$500

(3) Failing to post the most recent inspection certificate in public view within the facility is a violation of OAR 817-035-0110:

(a) 1st offense: \$100;

(b) 2nd offense: \$200;

(c) 3rd offense: \$500.

~~(4) Failing to return or surrender a certificate, license, registration, permit or authorization upon demand by the Agency is a violation of OAR 331-030-0020:~~

~~(a) 1st offense: \$1,000;~~

~~(b) 2nd offense: \$2,500;~~

~~(c) 3rd offense: \$5,000.~~

~~(5) Failing to provide appropriate photographic identification upon request by the Agency is a violation of OAR 331-030-0020(4):~~

~~(a) 1st offense: \$500;~~

~~(b) 2nd offense: \$1,000;~~

~~(c) 3rd offense: \$2500.~~

~~(6) Failing to inform the Agency within 30 calendar days of a change work location, home or mailing address, or other notification requirement listed in OAR 331-010-0040 is a violation of OAR 331-010-0040~~

~~(a) 1st offense: \$100;~~

~~(b) 2nd offense: \$200;~~

~~(c) 3rd offense: \$500.~~

Stat. Auth.: ORS 676.605, 676.615, 676.992, 690.165 & 690.167

Stats. Implemented: ORS ~~676.605, 676.615, 676.992,~~ **690.015**, 690.165 & 690.167

Hist.: BH 3-1984(Temp), f. & ef. 6-27-84; BH 4-1984, f. & ef. 12-7-84; BH 1-1985, f. & ef. 3-28-85; BH 1-1988, f. & cert. ef. 7-1-88; BH 2-1990, f. & cert. ef. 10-29-90; BH 1-1992, f. 6-1-92, cert. ef. 7-1-92; BH 3-1994, f. 6-23-94, cert. ef. 7-1-94; BH 1-1996, f. 5-31-96, cert. ef. 7-1-96; Renumbered from 817-090-0020; BBH 1-1998, f. 6-24-98, cert. ef. 6-30-98; BOC 1-2000, f. 5-12-00, cert. ef. 5-15-00; BOC 1-2004, f. 6-29-04, cert. ef. 7-1-04; BOC 1-2006, f. & cert. ef. 3-15-06; BOC 2-2011, f. & cert. ef. 5-5-11

## **817-090-0105**

### **Schedule of Penalties for Client Health and Safety Violations**

The Agency has adopted the following presumptive penalty schedule for the 1st, 2nd, and 3rd violation of safety and infection control laws and rules. This schedule applies, except at the discretion of the agency pursuant to OAR 331-020-0060. For the 4th and subsequent offenses, the provisions of OAR 331-020-0060 apply.

(1) Failing to use a neck strip or a towel to prevent contact between the skin of a client's neck and a hair cloth or cape is a violation of OAR 817-010-0040(1):

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

(2) Failing to use a disposable cover on the head of a client who is trying on a hairpiece or to clean and label used hair goods as "used" prior to resale is a violation of OAR 817-010-0085:

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

(3) Failing to wear single-use disposable protective gloves while having open sores or skin lesions during any performance of service on a client is a violation of OAR 817-015-0030(2):

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

~~(4) Performing services while diagnosed with a communicable disease or condition in a transmittable form is a violation of OAR 817-120-0005(4) and (5) and shall incur the following penalty for any violation: Emergency suspension until the disease or condition is no longer communicable.~~

~~(5) Treating any disease or knowingly serving any client having a communicable disease or condition except head lice is a violation of OAR 817-120-0005(4) and (5):~~

~~(a) 1st offense: \$300;~~

~~(b) 2nd offense: \$500;~~

~~(c) 3rd offense: \$1000.~~

~~(4)~~(6) Performing services without washing one's hands immediately before and after serving each client is a violation of OAR 817-015-0030(1):

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

~~(5)~~(7) Failing to maintain client records for each client receiving esthetics or nail technology services, maintain client records on the premises of the facility or allow an

enforcement officer access to review client records upon request is a violation of OAR 817-015-0065 or OAR 817-015-0070:

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

~~(6)(8)~~ Failing to maintain required documentation of an FDA Class I or Class II manual or mechanical device or equipment, or to provide required documentation upon request is a violation of OAR 817-010-0065(10) or (14):

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

Stat. Auth.: ORS 676.605, 676.615, 676.992, 690.165, 690.167, 690.205

Stats. Implemented: ORS 676.605, 676.615, 676.992, 690.165, 690.167 & 690.205

Hist.: BH 1-1985, f. & ef. 3-28-85; BH 1-1988, f. & cert. ef. 7-1-88; BH 2-1990, f. & cert. ef. 10-29-90; BH 3-1994, f. 6-23-94, cert. ef. 7-1-94; BH 1-1996, f. 5-31-96, cert. ef. 7-1-96; Renumbered from 817-090-0030; BBH 1-1998, f. 6-24-98, cert. ef. 6-30-98; BOC 1-2000, f. 5-12-00, cert. ef. 5-15-00; BOC 4-2001(Temp), f. & cert. ef. 11-1-01 thru 4-29-02; BOC 1-2002, f. 5-31-02 cert. ef. 6-1-02; BOC 1-2004, f. 6-29-04, cert. ef. 7-1-04; BOC 1-2006, f. & cert. ef. 3-15-06; BOC 2-2011, f. & cert. ef. 5-5-11

## **DIVISION 120 CODE OF PROFESSIONAL CONDUCT**

### **817-120-0005 Practice Standards**

(1) Practitioners must be guided by the highest standards of professional conduct.

(2) Practitioners shall act and practice in a manner which safeguards the public's health, safety, and welfare.

(3) All practitioners shall be appropriately clothed while providing services and shall be subject to public decency laws.

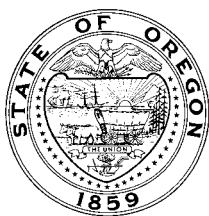
~~4) Practitioners shall not perform services while diagnosed with a communicable disease or condition in a transmittable form.~~

~~(5) Practitioners shall not treat any disease or knowingly serve any client having a communicable disease or condition, except head lice.~~

Stat. Auth.: ORS 676.605, 676.615 & 690.165

Stats. Implemented: ORS 676.605, 676.615 & 690.165

Hist.: BH 1-1988, f. & cert. ef. 7-1-88; BH 3-1994, f. 6-23-94, cert. ef. 7-1-94; BH 1-1996, f. 5-31-95, cert. ef. 7-1-96; Renumbered from 817-120-0010, BOC 1-2000, f. 5-12-00, cert. ef. 5-15-00; BOC 1-2004, f. 6-29-04, cert. ef. 7-1-04; BOC 1-2006, f. & cert. ef. 3-15-06



# Administrative Rule Schedule

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## OREGON HEALTH LICENSING AGENCY

### Board of Cosmetology

Date	Action	Time
September 13, 2011	Temporary administrative rule effective	
October 24, 2011	Board meeting notification of temporary rule. Approve proposed rules and rulemaking schedule	9 am
December 1, 2011	Notice of proposed rules –Oregon Bulletin	
December 28, 2011	Last day for public comment	
January 23, 2012	Board meeting adopt permanent rules	9 am
February 1, 2012	Permanent rules effective	
March 11, 2012	Temporary rule expires	

Under ORS 676.607(f) the Oregon Health Licensing Agency (Agency) has authority and responsibility to approve and collect all fees for the programs under ORS 676.606 including the Board of Cosmetology. The Agency has final rulemaking authority under ORS 676.615. All comments including recommendations from board members will be considered by the Agency.

All meetings are held at the Oregon Health Licensing Agency, Rhoades Conference Room, 700 Summer St, Suite 320, Salem, OR 97301, unless otherwise specified.

Members of the public are invited and encouraged to attend all board and committee meetings. However, audience members will not be allowed to participate, unless there is a dedicated placeholder on the agenda and/or the chairperson designates an allotted time.

Invited technical experts may be invited to participate in meetings regarding their knowledge and expertise in specific areas.

Please send all public comment to:

Samie Patnode, Policy Analyst  
700 Summer St NE, Suite 320  
Salem, OR 97301-1287  
[samie.patnode@state.or.us](mailto:samie.patnode@state.or.us)  
Work: (503) 373-1917

For current information regarding administrative rules or the rulemaking process visit the Web at [http://www.oregon.gov/OHLA/COS/COSlaws\\_rules.shtml](http://www.oregon.gov/OHLA/COS/COSlaws_rules.shtml).

Secretary of State  
Certificate and Order for Filing  
**TEMPORARY ADMINISTRATIVE RULES**  
A Statement of Need and Justification accompanies this form.

I certify that the attached copies\* are true, full and correct copies of the TEMPORARY Rule(s) adopted on September 13, 2011 by the \_\_\_\_\_ Date prior to or same as filing date

Oregon Health Licensing Agency (OHLA), Board of Cosmetology OAR Chapter 817  
Agency and Division Administrative Rules Chapter Number

Samantha Patnode, Policy Analyst 700 Summer St NE, Suite 320, Salem, OR 97301-1287 (503)373-1917  
Rules Coordinator Address Telephone

to become effective September 13, 2011 through March 11, 2012  
Date upon filing or later A maximum of 180 days including the effective date.

**RULE CAPTION**

Amend civil penalty assessment rules.  
Amend rules related to practicing as on or an individual with a communicable disease.

**Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.**

**RULEMAKING ACTION**

List each rule number separately, 000-000-0000.

Secure approval of new rule numbers (Adopted rules) with the Administrative Rules Unit prior to filing

**ADOPT:**

**AMEND:** 817-090-0025, 817-090-0035, 817-090-0045, 817-090-0105, 817-120-0005

**SUSPEND:**

**REPEAL:**

Stat. Auth.: ORS 676.607, 676.615, 676.992, 690.165, 690.167, 690.205

Other Auth.:

Stats. Implemented: ORS 676.992, 690.015

**RULE SUMMARY**

It is necessary to amend OAR 817-090-0025, 817-090-0035, and 817-090-0045 because the agency and the board do not have statutory authority to assess civil penalties for violations of ORS chapter 676 or OAR chapter 331 under OAR chapter 817.

It is necessary to amend OAR 817-090-0105 and 817-120-0005 because it is unlawful under the ADA for a state to prevent an individual from practicing cosmetology based on that individual's HIV/AIDS (communicable disease) status.

\_\_\_\_\_  
Authorized Signer Randall Everitt, Director September 13, 2011  
Printed name Date

\*With this original and Statement of Need, file one photocopy of certificate, one paper copy of rules listed in Rulemaking Actions, and electronic copy of rules. ARC 940-2005

Secretary of State  
**STATEMENT OF NEED AND JUSTIFICATION**

A Certificate and Order for Filing Temporary Administrative Rules accompanies this form.

Oregon Health Licensing Agency (OHLA), Board of Cosmetology  
Agency and Division

OAR Chapter 817  
Administrative Rules Chapter Number

In the Matter of: Amendment of 817-090-0025, 817-090-0035, 817-090-0045, 817-090-0105, 817-120-0005

Rule Caption:

Amend civil penalties and requirements for practice of or on individuals with communicable diseases.

Stat. Auth.: ORS 676.607, 676.615, 676.992, 690.165, 690.167, 690.205

Other Auth.:

Stats. Implemented: ORS 676.992, 690.015

**Need for the Temporary Rule(s):**

It is necessary to amend OAR 817-090-0025, 817-090-0035, and 817-090-0045 to align administrative rules with the statutory authority of OHLA and the Board of Cosmetology for administration of cosmetology regulation and setting of civil penalty amounts for violations of cosmetology rules.

It is necessary to amend OAR 817-090-0105 and 817-120-0005 to bring the administrative rules into compliance with the Americans with Disabilities Act.

**Documents Relied Upon, and where they are available:**

Oregon Revised Statutes Chapters 676, 690 and 28 CFR parts 35 and 36.

All documents except information exempt from public disclosure are available at the Oregon Health Licensing Agency 700 Summer Street NE, Suite 320, Salem, OR 97301-1287. To obtain information or copies of information please contact Samantha Patnode, Policy Analyst, at (503) 373-1917, during normal business hours Monday Through Friday between 7:30am to 4:30pm. Email: [samie.patnode@state.or.us](mailto:samie.patnode@state.or.us)

**Justification of Temporary Rule(s):**

The temporary administrative rule is justified because the agency and the Board of Cosmetology are required to act within their statutory authority and may not adopting or enforcing rules that are inconsistent with the requirements of the ADA.

Authorized Signer	Randall Everitt, Director Printed name	September 13, 2011 Date
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Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310. ARC 945-2005

**DIVISION 90**  
**CIVIL PENALTIES**

**817-090-0025**

**Schedule of Penalties for Facility and Independent Contractor Registration Violations**

The Agency has adopted the following presumptive penalty schedule for the 1st, 2nd, and 3rd violation of facility license and independent contractor registration laws and rules. This schedule applies, except at the discretion of the agency pursuant to OAR 331-020-0060. For the 4th and subsequent offenses, the provisions of OAR 331-020-0060 apply.

(1) Operating or purporting to operate a facility without a valid facility license is a violation of ORS 690.015(2)(b) ~~or and~~ **690.015(2)(e)**:

(a) **Never licensed:**

(A) 1st offense: \$500;

~~(B)(b)~~ 2nd offense: \$1000;

~~(C)(c)~~ 3rd offense: \$2500

(b) **Inactive or expired license:**

(A) 1st offense: \$200;

(B) 2nd offense: \$500;

(C) 3rd offense: \$1,000

(c) **Certificate, Authorization, or Registration Suspended or Revoked:**

(A) 1st offense: \$2,500;

(B) 2nd offense: \$5,000;

(C) 3rd offense: Monetary penalty and any other actions allowed by law including revocation of suspended authorization to practice and refusal to issue a new authorization to practice to a revoked authorization holder.

(2) Operating or purporting to operate as an independent contractor without **independent contractor registration** or with a dormant independent contractor registration is a violation of ORS 690.015 (2)(d) **or and 690.015(2)(e)**:

- (a) 1st offense: \$200
- (b) 2nd offense: \$500
- (c) 3rd offense: \$1,000

~~(3) Operating a facility with an inactive or expired license is a violation of ORS 676.612 (2)(r):~~

- ~~(a) 1st offense: \$200;~~
- ~~(b) 2nd offense: \$500;~~
- ~~(c) 3rd offense: \$1,000~~

~~(3)~~**(4)** Allowing an uncertified person **employee or uncertified individual under a person's supervision and control** to practice in a field of practice is a violation of ORS 690.015(2)(g):.

**(a) Employee or individual with suspended who has never been certified:**

- ~~(A)~~**(a)** 1st offense: \$500;
- ~~(B)~~**(b)** 2nd offense: \$1,000;
- ~~(C)~~**(c)** 3rd offense: \$2,500

**(b) Employee or individual with inactive, suspended, revoked, or expired certification:**

- (a) 1st offense: \$200**
- (b) 2nd offense: \$500**
- (c) 3rd offense: \$1000**

~~(5) Failing to allow the Agency to inspect the premises when the facility is open or obstructing or hindering the normal progress of the inspection, threatening or exerting physical harm, or enabling another individual to impede the inspection progress is a violation of OAR 817-0200006(9) and will result in monetary penalties and any other actions allowed by law.~~

~~(6) Allowing an employee to practice with an inactive or expired practitioner certificate is a violation of ORS 676.612(2)(h):~~

~~(a) 1st offense: \$200~~

~~(b) 2nd offense: \$500~~

~~(c) 3rd offense: \$1000~~

~~(4)(7) Failing to meet the specifications and standards required under OAR 817-010-0007 in a facility is a violation of OAR 817-020-0006 (1)(e) and may result in an emergency suspension of the facility license until the violation is corrected.~~

Stat. Auth.: ORS 676.605, 676.615, 676.992, 690.165 & 690.167

Stats. Implemented: ~~ORS 676.605, 676.615, 676.992,~~ **690.015**, 690.165 & 690.167

Hist.: BH 3-1984(Temp), f. & ef. 6-27-84; BH 4-1984, f. & ef. 12-7-84; BH 1-1985, f. & ef. 3-28-85; BH 1-1988, f. & cert. ef. 7-1-88; BH 2-1990, f. & cert. ef. 10-29-90; BH 1-1992, f. 6-1-92, cert. ef. 7-1-92; BH 3-1994, f. 6-23-94, cert. ef. 7-1-94; BH 1-1996, f. 5-31-96, cert. ef. 7-1-96; Renumbered from 817-090-0020; BBH 1-1998, f. 6-24-98, cert. ef. 6-30-98; BOC 1-2000, f. 5-12-00, cert. ef. 5-15-00; BOC 1-2002, f. 5-31-02 cert. ef. 6-1-02; BOC 1-2004, f. 6-29-04, cert. ef. 7-1-04; BOC 1-2006, f. & cert. ef. 3-15-06; BOC 2-2011, f. & cert. ef. 5-5-11

## **817-090-0035**

### **Schedule of Penalties for Practitioner Violations**

The Agency has adopted the following presumptive penalty schedule for the 1st, 2nd, and 3rd violation of practitioner licensing laws and rules. This schedule applies, except at the discretion of the agency pursuant to OAR 331-020-0060. For the 4th and subsequent offenses, the provisions of OAR 331-020-0060 apply.

~~(1) Operating~~ **Performing, attempting to perform, or purporting to perform services in a field of practice without proper certification, authorization, registration or permit with an inactive or expired practitioner certificate** is a violation of ORS **690.015(2)(a) or 690.015(2)(e)**. ~~676.612(2)(r):~~

**(a) Certificate, authorization, registration, or permit inactive or expired:**

~~(A)(a)~~ 1st offense: \$200;

~~(B)(b)~~ 2nd offense: \$500;

~~(C)(c)~~ 3rd offense: \$1000.

**(b) Certificate, authorization, registration, permit never held:**

~~(2) Practicing or purporting to practice in a field of practice without a certificate, is a violation of ORS 690.015(2)(a)~~

~~(A)(a)~~ 1st offense: \$1,000;

**(B)**~~(b)~~ 2nd offense: \$2,500;

**(C)**~~(c)~~ 3rd offense \$5,000.

**(c) Certificate, authorization, or registration suspended or revoked:**

**(A) 1st offense: \$2,500;**

**(B) 2nd offense: \$5,000;**

**(C) 3rd offense: Monetary penalty and any other actions allowed by law including revocation of suspended authorization to practice and refusal to issue a new authorization to practice to a revoked authorization holder.**

**(2)**~~(3)~~ Performing **or attempting to perform** services in a field of practice in an unlicensed facility is a violation of ORS 690.015(2)(c):

(a) 1st offense: \$200;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1,000

~~(4) Practicing or purporting to practice in a field of practice with a suspended certificate is a violation of 676.612 (4)~~

~~(a) 1st offense: \$2,500;~~

~~(b) 2nd offense: \$5,000;~~

~~(c) 3rd offense: Monetary penalty and any other actions allowed by law including refusal to issue an authorization to practice~~

**(3)**~~(5)~~ Performing in a field of practice by a student when not on the premises of an educational institution in which he or she is enrolled is a violation of OAR 817-100-0005:

(a) 1st offense: \$500;

(b) 2nd offense: \$1,000;

(c) 3rd offense: \$2,500.

Stat. Auth: ORS 676.605, 676.615, 676.992, 690.165 & 690.167

Stats. Implemented: ORS 676.605, 676.615, 676.992, 690.165 & 690.167

Hist.: BH 3-1984(Temp), f. & ef. 6-27-84; BH 4-1984, f. & ef. 12-7-84; BH 1-1985, f. & ef. 3-28-85; BH 1-1988, f. & cert. ef. 7-1-88; BH 2-1990, f. & cert. ef. 10-29-90; BH 1-1992, f. 6-1-92, cert. ef. 7-1-92; BH 3-1994, f. 6-23-94, cert. ef. 7-1-94; BH 1-1996, f. 5-31-96, cert. ef. 7-1-96, Renumbered from 817-090-0020; BOC 1-2000, f. 5-12-00, cert. ef. 5-15-00; BOC 2-2001, f. 2-16-01, cert. ef. 3-1-01; BOC 1-2004, f. 6-29-04, cert. ef. 7-1-04; BOC 1-2006, f. & cert. ef. 3-15-06; BOC 2-2011, f. & cert. ef. 5-5-11

## 817-090-0045

### Schedule of Penalties for Certificate/License/Registration/Permit Violations

The Agency has adopted the following presumptive penalty schedule for the 1st, 2nd, and 3rd violation of certificate/license/registration/permit laws and rules. This schedule applies, except at the discretion of the agency pursuant to OAR 331-020-0060. For the 4th and subsequent offenses, the provisions of OAR 331-020-0060 apply.

(1) Altering with fraudulent intent or fraudulent use of a license, certificate, registration, permit or authorization issued by the agency is a violation of ORS 690.015(2)(j) or ORS 690.015(2)(k):

(a) 1st offense: \$1,500;

(b) 2nd offense: \$3,500;

(c) 3rd offense: \$5,000.

(2) Failing to post a valid license, registration, certificate, permit or authorization issued by the agency in public view is a violation of ORS 690.095 and OAR 817-035-0110:

(a) 1st offense: \$100

(b) 2nd offense: \$200

(c) 3rd offense: \$500

(3) Failing to post the most recent inspection certificate in public view within the facility is a violation of OAR 817-035-0110:

(a) 1st offense: \$100;

(b) 2nd offense: \$200;

(c) 3rd offense: \$500.

~~(4) Failing to return or surrender a certificate, license, registration, permit or authorization upon demand by the Agency is a violation of OAR 331-030-0020:~~

~~(a) 1st offense: \$1,000;~~

~~(b) 2nd offense: \$2,500;~~

~~(c) 3rd offense: \$5,000.~~

~~(5) Failing to provide appropriate photographic identification upon request by the Agency is a violation of OAR 331-030-0020(4):~~

~~(a) 1st offense: \$500;~~

~~(b) 2nd offense: \$1,000;~~

~~(c) 3rd offense: \$2500.~~

~~(6) Failing to inform the Agency within 30 calendar days of a change work location, home or mailing address, or other notification requirement listed in OAR 331-010-0040 is a violation of OAR 331-010-0040~~

~~(a) 1st offense: \$100;~~

~~(b) 2nd offense: \$200;~~

~~(c) 3rd offense: \$500.~~

Stat. Auth.: ORS 676.605, 676.615, 676.992, 690.165 & 690.167

Stats. Implemented: ORS ~~676.605, 676.615, 676.992,~~ **690.015**, 690.165 & 690.167

Hist.: BH 3-1984(Temp), f. & ef. 6-27-84; BH 4-1984, f. & ef. 12-7-84; BH 1-1985, f. & ef. 3-28-85; BH 1-1988, f. & cert. ef. 7-1-88; BH 2-1990, f. & cert. ef. 10-29-90; BH 1-1992, f. 6-1-92, cert. ef. 7-1-92; BH 3-1994, f. 6-23-94, cert. ef. 7-1-94; BH 1-1996, f. 5-31-96, cert. ef. 7-1-96; Renumbered from 817-090-0020; BBH 1-1998, f. 6-24-98, cert. ef. 6-30-98; BOC 1-2000, f. 5-12-00, cert. ef. 5-15-00; BOC 1-2004, f. 6-29-04, cert. ef. 7-1-04; BOC 1-2006, f. & cert. ef. 3-15-06; BOC 2-2011, f. & cert. ef. 5-5-11

## **817-090-0105**

### **Schedule of Penalties for Client Health and Safety Violations**

The Agency has adopted the following presumptive penalty schedule for the 1st, 2nd, and 3rd violation of safety and infection control laws and rules. This schedule applies, except at the discretion of the agency pursuant to OAR 331-020-0060. For the 4th and subsequent offenses, the provisions of OAR 331-020-0060 apply.

(1) Failing to use a neck strip or a towel to prevent contact between the skin of a client's neck and a hair cloth or cape is a violation of OAR 817-010-0040(1):

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

(2) Failing to use a disposable cover on the head of a client who is trying on a hairpiece or to clean and label used hair goods as "used" prior to resale is a violation of OAR 817-010-0085:

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

(3) Failing to wear single-use disposable protective gloves while having open sores or skin lesions during any performance of service on a client is a violation of OAR 817-015-0030(2):

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

~~(4) Performing services while diagnosed with a communicable disease or condition in a transmittable form is a violation of OAR 817-120-0005(4) and (5) and shall incur the following penalty for any violation: Emergency suspension until the disease or condition is no longer communicable.~~

~~(5) Treating any disease or knowingly serving any client having a communicable disease or condition except head lice is a violation of OAR 817-120-0005(4) and (5):~~

~~(a) 1st offense: \$300;~~

~~(b) 2nd offense: \$500;~~

~~(c) 3rd offense: \$1000.~~

~~(4)(6)~~ Performing services without washing one's hands immediately before and after serving each client is a violation of OAR 817-015-0030(1):

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

~~(5)(7)~~ Failing to maintain client records for each client receiving esthetics or nail technology services, maintain client records on the premises of the facility or allow an

enforcement officer access to review client records upon request is a violation of OAR 817-015-0065 or OAR 817-015-0070:

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

~~(6)(8)~~ Failing to maintain required documentation of an FDA Class I or Class II manual or mechanical device or equipment, or to provide required documentation upon request is a violation of OAR 817-010-0065(10) or (14):

(a) 1st offense: \$300;

(b) 2nd offense: \$500;

(c) 3rd offense: \$1000.

Stat. Auth.: ORS 676.605, 676.615, 676.992, 690.165, 690.167, 690.205

Stats. Implemented: ORS 676.605, 676.615, 676.992, 690.165, 690.167 & 690.205

Hist.: BH 1-1985, f. & ef. 3-28-85; BH 1-1988, f. & cert. ef. 7-1-88; BH 2-1990, f. & cert. ef. 10-29-90; BH 3-1994, f. 6-23-94, cert. ef. 7-1-94; BH 1-1996, f. 5-31-96, cert. ef. 7-1-96; Renumbered from 817-090-0030; BBH 1-1998, f. 6-24-98, cert. ef. 6-30-98; BOC 1-2000, f. 5-12-00, cert. ef. 5-15-00; BOC 4-2001(Temp), f. & cert. ef. 11-1-01 thru 4-29-02; BOC 1-2002, f. 5-31-02 cert. ef. 6-1-02; BOC 1-2004, f. 6-29-04, cert. ef. 7-1-04; BOC 1-2006, f. & cert. ef. 3-15-06; BOC 2-2011, f. & cert. ef. 5-5-11

## **DIVISION 120 CODE OF PROFESSIONAL CONDUCT**

### **817-120-0005 Practice Standards**

(1) Practitioners must be guided by the highest standards of professional conduct.

(2) Practitioners shall act and practice in a manner which safeguards the public's health, safety, and welfare.

(3) All practitioners shall be appropriately clothed while providing services and shall be subject to public decency laws.

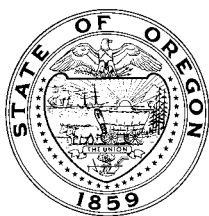
~~4) Practitioners shall not perform services while diagnosed with a communicable disease or condition in a transmittable form.~~

~~(5) Practitioners shall not treat any disease or knowingly serve any client having a communicable disease or condition, except head lice.~~

Stat. Auth.: ORS 676.605, 676.615 & 690.165

Stats. Implemented: ORS 676.605, 676.615 & 690.165

Hist.: BH 1-1988, f. & cert. ef. 7-1-88; BH 3-1994, f. 6-23-94, cert. ef. 7-1-94; BH 1-1996, f. 5-31-95, cert. ef. 7-1-96; Renumbered from 817-120-0010, BOC 1-2000, f. 5-12-00, cert. ef. 5-15-00; BOC 1-2004, f. 6-29-04, cert. ef. 7-1-04; BOC 1-2006, f. & cert. ef. 3-15-06



# Administrative Rule Schedule

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## OREGON HEALTH LICENSING AGENCY

### Board of Cosmetology

Date	Action	Time
September 13, 2011	Temporary administrative rule effective	
October 24, 2011	Board meeting notification of temporary rule. Approve proposed rules and rulemaking schedule	9 am
December 1, 2011	Notice of proposed rules –Oregon Bulletin	
December 28, 2011	Last day for public comment	
January 23, 2012	Board meeting adopt permanent rules	9 am
February 1, 2012	Permanent rules effective	
March 11, 2012	Temporary rule expires	

Under ORS 676.607(f) the Oregon Health Licensing Agency (Agency) has authority and responsibility to approve and collect all fees for the programs under ORS 676.606 including the Board of Cosmetology. The Agency has final rulemaking authority under ORS 676.615. All comments including recommendations from board members will be considered by the Agency.

All meetings are held at the Oregon Health Licensing Agency, Rhoades Conference Room, 700 Summer St, Suite 320, Salem, OR 97301, unless otherwise specified.

Members of the public are invited and encouraged to attend all board and committee meetings. However, audience members will not be allowed to participate, unless there is a dedicated placeholder on the agenda and/or the chairperson designates an allotted time.

Invited technical experts may be invited to participate in meetings regarding their knowledge and expertise in specific areas.

Please send all public comment to:

Samie Patnode, Policy Analyst  
700 Summer St NE, Suite 320  
Salem, OR 97301-1287  
[samie.patnode@state.or.us](mailto:samie.patnode@state.or.us)  
Work: (503) 373-1917

For current information regarding administrative rules or the rulemaking process visit the Web at [http://www.oregon.gov/OHLA/COS/COSlaws\\_rules.shtml](http://www.oregon.gov/OHLA/COS/COSlaws_rules.shtml).

**Issue:**

With the end of 2011 approaching it is necessary for the Board of Cosmetology to elect a Chair and Vice-Chair for the year 2012.

**Discussion:**

Debra Masten has served as Chair during the year of 2011.  
Sharon Wisser has served as Vice-Chair during the year of 2011.

**Recommendation:**

Board of Cosmetology nominates and elects a board Chair and Vice-Chair for the year 2012.

CHAIRPERSON

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VICE-CHAIRPERSON

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**Issue:**

With the end of the year 2011 approaching, it is necessary for the Board of Cosmetology to review the make up of committees and designated members to each committee.

**Discussion:**

The purpose of committees is to allow for review and discussion of specific issues, which usually require more in-depth fact-finding and deliberation than can be scheduled at periodic board meetings. Committees also serve as a resource to staff in the daily administration of the program with members providing technical expertise and direction, particularly in scope of practice, practice standards, education and regulatory aspects.

A committee may be comprised of one member acting, as liaison between the board and office staff, but must include a total number of members that equates to less than an a quorum.

Committee	Committee Purpose/Description
Legislation/Rules	Gain consensus on rule development and make recommendations for action to the board/agency. Committee work is centered on "fact-finding"-discussion of facts, perspectives and concerns.
Education/Examination	Establish requirements for training and education, equivalencies and continuing education.
Enforcement	Advise agency during investigation or review of disciplinary cases.
Customer Connection	Advises agency on areas affecting all board/councils uniformly. Projects may include Website review, agency publications and agency rulemaking.
Practice & Procedures Standards	Review and discuss inquiries received regarding scope of practice

**Recommendation:**

The Board of Cosmetology designates committee members for the year of 2012.

**Oregon Health Licensing Agency  
BOARD OF COSMETOLOGY**

**2011 COMMITTEE LIST**

<b>Enforcement</b>	Herb Hirst, Sharon Wiser, Alt: Shelley Couch
<b>Legislation &amp; Rules</b>	Herb Hirst, Debora Masten, Sharon Wiser
<b>Practice/Procedure Standards</b>	Heidi Zuniga, Debora Masten, Sharon Wiser
<b>Education/Examination</b>	Heidi Zuniga, Sharon Wiser, Shelley Couch
<b>Customer Connection:</b>	Shelley Couch

**2012 SUBCOMMITTEE NOMINEES**

<b>Enforcement</b>	<hr/> <hr/> <hr/> <hr/>
<b>Legislation &amp; Rules</b>	<hr/> <hr/> <hr/> <hr/>
<b>Practice &amp; Procedures Standards</b>	<hr/> <hr/> <hr/> <hr/>
<b>Education / Examination</b>	<hr/> <hr/> <hr/> <hr/>
<b>Customer Connection</b>	<hr/> <hr/> <hr/> <hr/>

**Issue:**

With the end of 2011 approaching it is necessary for the Board of Cosmetology to approve meeting dates for the year 2012.

**Discussion:**

The following dates are proposed for the Board of Cosmetology to conduct regular council business:

January 23, 2012 at 9am

April 23, 2012 at 9am

July 23, 2012 at 9 am

October 1, 2012 at 9am

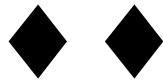
**Recommendation:**

The Board of Cosmetology approves meeting dates for the year 2012. Approved meeting dates:

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# **Public Comment**

# **Other Board Business**



**Board Interest File**

