



COMMONWEALTH of VIRGINIA

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Virginia Board of Dentistry Virginia Dental Association Dental Laboratory Work Group Agenda

May 18, 2012

at

Department of Health Professions

Perimeter Center - 9960 Mayland Drive, 2nd Floor Conference Center – Henrico, VA 23233

11:00 am	Call to Order – Dr. Hall	<u>Page</u>
	Roll Call	
	Minutes	P1 – P3
	Modification of the Board’s Work Order Forms	P4 – P5
	Editing of VDA’s Legislation	P6 – P8

Draft - Unapproved

**VIRGINIA BOARD OF DENTISTRY
DENTAL LABORATORY WORK GROUP
MINUTES
April 20, 2012**

TIME AND PLACE: The meeting of the Dental Laboratory Work Group of the Board of Dentistry was called to order at 11:20 a.m. on April 20, 2012 in Training Room 1, Department of Health Professions, 9960 Mayland Drive, Suite 201, Richmond, Virginia.

PRESIDING: Robert B. Hall, Jr., D.D.S, President

MEMBERS PRESENT: Herbert R. Boyd, III, D.D.S.
Dag Zapatero, D.D.S.
Scott Miller, D.D.S., by conference call

MEMBER ABSENT: David C. Sarrett, D.D.S.

STAFF PRESENT: Sandra K. Reen, Executive Director
Elaine J. Yeatts, DHP Policy Analyst
Huong Vu, Operations Manager

**REGISTRATION OF
DENTAL
LABORATORIES :**

Dr. Hall welcomed the members and asked Ms. Reen to begin by explaining the information she provided on the states identified as regulating labs. She stated that understanding what other states were doing may be helpful so she had collected statutes and regulations and some disciplinary orders. She noted that:

- TX and OK dental boards regulate dental labs;
- Departments of health regulate dental labs in FL and PA;
- TX, SC and KY register dental technicians and require out of state labs to employ registered technicians; and
- TX, SC and FL have criminal penalties for dentists who are doing business with unregistered labs and technicians.

Dr. Hall then asked what the work group wants to accomplish at this meeting. Dr. Miller stated that the Virginia Dental Association (VDA) wants labs to be required to disclose point of origin and material content. He added that dentists have no authority to require disclosure so requiring dental labs to register with the Board is needed. Dr. Zapatero agreed and added that the Board's current work order forms have created problems and the Board does not have any authority to address non-compliance. Dr. Miller said that the Board and the VDA need to improve communications with dentists because there is a lot of confusion about what dentists are required to do.

Extensive discussion followed about the business relationship between dentists and labs and the option of not doing business with labs that are unwilling to provide information. It was noted that the impact of one dentist switching labs would be minimal but the Board would be able to prevent a lab from doing business in Virginia. Ms. Yeatts noted that the Board only has authority in Virginia and would not be able to travel out-of-state or out of country to investigate complaints. Dr. Zapatero responded that the Board could do paper investigations and have material assayed. Dr. Boyd addressed patient interests and recourse with general agreement that patients are most likely to file complaints against the dentist and it would be up to the dentist to file a complaint in order for the Board to conduct an investigation. He added that the dentist can already direct his complaint to the lab and decide whether to keep doing business with a lab he does not trust.

Dr. Hall remarked that there appears to be agreement that dental labs need to disclose point of origin and materials used. He asked if the Board's current work order forms address this and meet the meaning of a work order as defined in VDA's proposed legislation, HB 267. Dr. Miller responded yes then added that the current forms require dentists and labs to spend additional time on where work will be performed and what materials to use. Ms. Reen asked for clarification of the VDA's objections to the requirements for advance notice of subcontracting and discussion followed about preventing defective material from being delivered to the patient and the responsibility that dentists have for protecting patients. Referring to the VDA's proposed bill, Ms. Reen asked what the difference is from the current work order forms with those required by the proposed language. Dr. Miller said that there is none and added that VDA members don't want to be the police of the dental labs.

Dr. Hall referred the work group to the Board's concerns about VDA's current proposed bill and said the Board's interest is to understand the problem being experienced in Virginia so a study would be helpful. Ms. Reen noted that the current bill is impossible to implement because the requirement for registration would be in effect before regulations are in place so no one could legally operate a lab. She added there are also the questions of:

- which state agency in Virginia should be responsible for registering labs,
- is it the VDA's intent to require registration by out of state labs,
- is requiring registration of dental technicians a better option, and
- are suppliers of components to be included in registration?

Dr. Zapatero said that there is no need for a study to be done and asked that the Board address what the VDA members voted for virtually unanimously. Dr. Hall said that he has talked to five or six dentists in his area who are members of VDA and who have stated that they do not understand the need for the bill.

Dr. Miller asked what the VDA can do to move this process ahead. Dr. Zapatero suggested that VDA and the Board can work on the language of the bill. Dr. Boyd suggested that the Board might want to consider regulating CDTs as it rewriting all the chapters. Ms. Reen noted that KY moved from registering dental labs to registering dental technicians so it might be helpful to know why. She added that the Board can modify the work order forms quickly to address concerns.

Dr. Miller agreed that the work group should meet again to discuss modification of the Board's work order forms and address editing the VDA's bill. All agreed. Dr. Miller said he would let Ms. Reen know if he is available either May 18 or June 1 so the next meeting could be scheduled.

ADJOURNMENT:

Dr. Hall adjourned the meeting at 1:05 p.m.

Robert B. Hall, Jr., President

Sandra K. Reen, Executive Director

Date

Date

**VIRGINIA BOARD OF DENTISTRY APPROVED
DENTAL LABORATORY WORK ORDER FORM**

This form is prescribed by the Board for use by its licensees as required by §54.1-2719 of the Code of Virginia. A licensee shall provide all the information required to complete the form. A licensee may use a different form only if all the required information on this form is collected and conveyed.

PATIENT NAME, INITIALS or ID#: _____

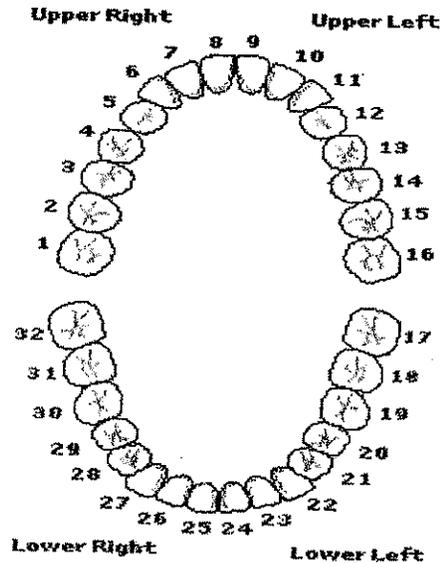
Laboratory Name: _____

Physical Address: _____

E-mail Address: _____

Contact Person: _____

Description of work to be done (include diagrams if needed):



Specify the type and quality of materials to be used:

Dentist's Signature: _____ Date: _____

Dentist's Name Printed: _____ Dental License # _____

Dentist's Address: _____ Telephone: _____

Dentist's Email Address: _____

Instructions to Lab

Laboratory must furnish dentist with subcontractor work order form if the dental lab uses a subcontractor and must comply with all items below:

1. Prior to beginning work, the prescribing dentist must be notified of any foreign subcontractor involved in fabrication or component/materials supply.
2. Prior to beginning work, the prescribing dentist must be notified of any domestic subcontractor involved in fabrication or component/materials supply.
3. Prescribing dentist must be notified of all materials in the delivered appliance/restoration.
4. Prescribing dentist must be notified in writing that materials in the delivered appliance/restoration DO NOT contain more than very small trace amounts (less than 200 ppm) of lead or any other metal not expressly prescribed.
5. Before returning finished case to prescribing dentist, the fabricated appliance/restoration must be cleaned disinfected, and sealed in an appropriate container or plastic bag.

**VIRGINIA BOARD OF DENTISTRY APPROVED
DENTAL LABORATORY SUBCONTRACTOR WORK ORDER FORM**

This form is prescribed by the Board as required by §54.1-2719 of the Code of Virginia for use by dental laboratories to subcontract work orders from dentists licensed and practicing in Virginia. A dental laboratory shall provide all the information required to complete the form. **A different form may be used only if all the required information on this form is collected and conveyed.** A copy of the signed work order received from the prescribing dentist shall be attached.

PATIENT NAME, INITIALS or ID#: _____

Subcontractor Name: _____

Physical Address: _____

E-mail Address: _____

Contact Person: _____

Contact information of the prescribing dentist:

Name: _____

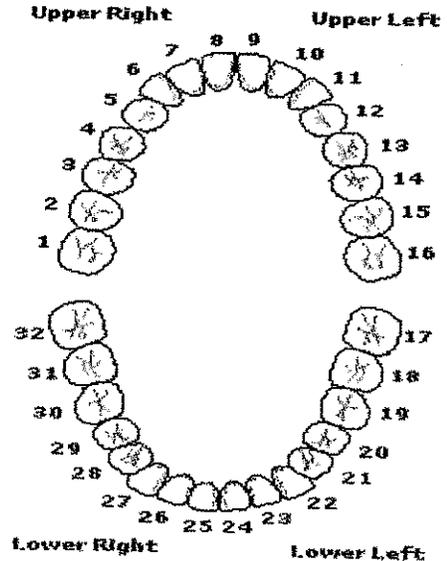
Address: _____

Telephone: _____

Email Address: _____

A copy of the signed work order received from the prescribing dentist is attached.

_____ Yes _____ No



Additional instructions for the handling, construction or repair of the appliance:

Contact information of person, firm or corporation issuing Subcontractor Work Order Form:

Signature: _____ Date: _____

Name Printed: _____ Telephone: _____

Address: _____

Email Address: _____

Instructions to Lab

Subcontractor laboratory must comply with all items below:

1. Prior to beginning work, the prescribing dentist must be notified of any foreign subcontractor involved in fabrication or component/materials supply.
2. Prior to beginning work, the prescribing dentist must be notified of any domestic subcontractor involved in fabrication or component/materials supply.
3. Contracting laboratory must be notified of all materials in the delivered appliance/restoration.
4. Contracting laboratory must be notified in writing that materials in the delivered appliance/restoration DO NOT contain more that very small trace amounts (less than 200 ppm) of lead or any other metal not expressly prescribed.
5. Before returning finished case to prescribing dentist, the fabricated appliance/restoration must be cleaned, disinfected, and sealed in an appropriate container or plastic bag.

12100510D

HOUSE BILL NO. 267
Offered January 11, 2012
Prefiled January 10, 2012

A BILL to amend and reenact §§ 54.1-2700, 54.1-2712, and 54.1-2719 of the Code of Virginia and to amend the Code of Virginia by adding in Article 1 of Chapter 27 of Title 54.1 a section numbered 54.1-2708.4, relating to registration of dental laboratories.

Patron—Peace

Committee Referral Pending

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2700, 54.1-2712, and 54.1-2719 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Article 1 of Chapter 27 of Title 54.1 a section numbered 54.1-2708.4 as follows:

§ 54.1-2700. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Dentistry;

"Dental hygiene" means cleaning and polishing teeth and assisting the members of the dental profession in providing oral health care and oral health education to the public;

"Dental hygienist" means a person trained in the practice of and practicing dental hygiene;

"Dental laboratory" means any individual or business entity engaged in the manufacture or repair of dental prosthetic appliances;

"Dentist" means a person who has been awarded a degree in and is licensed to practice dentistry;

"Dentistry" means the evaluation, diagnosis, prevention, and treatment, through surgical, nonsurgical or related procedures, of diseases, disorders, and conditions of the oral cavity and the maxillofacial, adjacent and associated structures and their impact on the human body;

"License" means the document issued to an applicant upon completion of requirements for admission to practice dentistry or dental hygiene in this Commonwealth or upon registration for renewal of license to continue the practice of dentistry or dental hygiene in this Commonwealth;

"Maxillofacial" means pertaining to the jaws and face, particularly with reference to specialized surgery of this region;

"Oral and maxillofacial surgeon" means a person who has successfully completed an oral and maxillofacial residency program, approved by the Commission on Dental Accreditation of the American Dental Association, and who holds a valid license from the Board;

"Work authorization" means a written instrument executed by a registered dental laboratory by which such dental laboratory subcontracts all or part of the fabrication or repair of a dental prosthetic appliance authorized by a work order to another dental laboratory. A work authorization may be handwritten and may be faxed or sent electronically using an electronic signature, and shall, at a minimum, contain: (i) the name and address of the subcontractor; (ii) a number identifying the work authorization with the original work order; (iii) the date the work authorization was written; (iv) a description of the work to be done by the subcontractor including diagrams, if necessary; (v) a specification of the type and quality of materials to be used; and (vi) the signature of the person issuing the work authorization;

"Work order" means a written instrument executed by a dentist and directed to a registered dental laboratory authorizing the manufacture or repair of a dental prosthetic appliance for such dentist. A work order may be handwritten and may be faxed or sent electronically using an electronic signature and shall, at a minimum, contain: (i) the name and address of the registered dental laboratory; (ii) the patient's name or initials or an identification number; (iii) the date the work order was written; (iv) a description of the work to be done, including diagrams, if necessary; (v) specification of the type and quality of materials to be used; and (vi) the signature and address of the dentist.

§ 54.1-2708.4. Registration of dental laboratories.

No person shall operate a dental laboratory in the Commonwealth without first registering such dental laboratory with the Board. A dental laboratory shall be considered to be operating within the Commonwealth if its work product is prepared pursuant to a work order originating within the Commonwealth.

However, dental laboratories that operate as an in-office lab, under the direct supervision of a licensed dentist, or in an educational institution as part of the institution's educational program, shall be exempt from registration, provided that such laboratories do not also operate pursuant to work orders

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59 *originating from outside the supervising dentist's office or educational institution.*

60 *The Board shall develop regulations governing the operating of dental laboratories, which shall*
61 *require dental laboratories to:*

62 *1. Practice infectious disease control as required by the U.S. Occupational Safety and Health*
63 *Administration;*

64 *2. Disclose to dentists the U.S. Food and Drug Administration registration number of all patient*
65 *contact materials contained in prescribed restorations. Such numbers shall be included in the patient's*
66 *record;*

67 *3. Disclose to dentists the point of origin of the manufacture of the prescribed restoration. If the*
68 *restoration was partially or entirely manufactured by a third-party provider, the point of origin*
69 *disclosure shall identify the portion manufactured by a third-party provider and the city, state, and*
70 *country of such provider;*

71 *4. Perform any manufacture or repair of dental prosthetic appliances only pursuant to a valid work*
72 *order or a valid work authorization from a registered dental laboratory, authorized by a valid work*
73 *order. A subcontractor working pursuant to a valid work authorization, and the dental laboratory*
74 *issuing the work authorization shall retain such authorization, along with the work order from the*
75 *licensed dentist, for three years.*

76 *5. Allow the Board or its agents to inspect its files of work orders or work authorizations during*
77 *ordinary business hours.*

78 *§ 54.1-2712. Permissible practices.*

79 *The following activities shall be permissible:*

80 *1. Dental assistants or dental hygienists aiding or assisting licensed dentists, or dental assistants*
81 *aiding or assisting dental hygienists under the general supervision of a dentist in accordance with*
82 *regulations promulgated pursuant to § 54.1-2729.01;*

83 *2. The performance of mechanical work on inanimate objects only, for licensed dentists, by any*
84 *person employed in or operating a registered dental laboratory;*

85 *3. Dental students who are enrolled in accredited D.D.S. or D.M.D. degree programs performing*
86 *dental operations, under the direction of competent instructors (i) within a dental school or college,*
87 *dental department of a university or college, or other dental facility within a university or college that is*
88 *accredited by an accrediting agency recognized by the United States Department of Education; (ii) in a*
89 *dental clinic operated by a nonprofit organization providing indigent care; (iii) in governmental or*
90 *indigent care clinics in which the student is assigned to practice during his final academic year rotations;*
91 *(iv) in a private dental office for a limited time during the student's final academic year when under the*
92 *direct tutorial supervision of a licensed dentist holding appointment on the dental faculty of the school*
93 *in which the student is enrolled; or (v) practicing dental hygiene in a private dental office under the*
94 *direct supervision of a licensed dentist holding appointment on the dental faculty of the school in which*
95 *the student is enrolled;*

96 *4. A licensed dentist from another state or country appearing as a clinician for demonstrating*
97 *technical procedures before a dental society or organization, convention, or dental college, or performing*
98 *his duties in connection with a specific case on which he may have been called to the Commonwealth;*
99 *and*

100 *5. Dental hygiene students enrolled in an accredited dental hygiene program performing dental*
101 *hygiene practices as a requisite of the program, under the direction of competent instructors, as defined*
102 *by regulations of the Board of Dentistry, (i) within a dental hygiene program in a dental school or*
103 *college, or department thereof, or other dental facility within a university or college that is accredited by*
104 *an accrediting agency recognized by the United States Department of Education; (ii) in a dental clinic*
105 *operated by a nonprofit organization providing indigent care; (iii) in a governmental or indigent care*
106 *clinic in which the student is assigned to practice during his final academic year rotations; or (iv) in a*
107 *private dental office for a limited time during the student's final academic year when under the direct*
108 *supervision of a licensed dentist or licensed dental hygienist holding appointment on the dental faculty*
109 *of the school in which the student is enrolled.*

110 *§ 54.1-2719. Employing registered dental laboratories.*

111 *A. Licensed dentists may employ or engage the services of any ~~person, firm or corporation~~ registered*
112 *dental laboratory to construct or repair, extraorally, prosthetic dentures, bridges, or other replacements*
113 *for a part of a tooth, a tooth, or teeth. A ~~person, firm or corporation~~ so employed or engaged registered*
114 *dental laboratory shall not be considered to be practicing dentistry. No such ~~person, firm or~~*
115 *~~corporation~~ registered dental laboratory shall perform any direct dental service for a patient, but they*
116 *may assist a dentist in the selection of shades for the matching of prosthetic devices when the dentist*
117 *sends the patient to them with a written work order.*

118 *B. Any licensed dentist who employs the services of any ~~person, firm or corporation~~ a dental*
119 *laboratory not ~~working~~ in functioning as part of a dental office under his direct supervision to construct*
120 *or repair, extraorally, prosthetic dentures, bridges, replacements, or orthodontic appliances for a part of a*

121 tooth, a tooth, or teeth, shall furnish such person, firm or corporation *dental laboratory* with a written
122 work order on forms prescribed by the Board which shall, at minimum, contain: (i) the name and
123 address of the person, firm or corporation; (ii) the patient's name or initials or an identification number;
124 (iii) the date the work order was written; (iv) a description of the work to be done, including diagrams,
125 if necessary; (v) specification of the type and quality of materials to be used; and (vi) the signature and
126 address of the dentist.

127 The person, firm or corporation *dental laboratory* shall retain the original work order and the dentist
128 shall retain a duplicate for three years.

129 C. If the person, firm or corporation receiving a written work order from a licensed dentist engages a
130 subcontractor to perform services relative to the work order, a written subwork order shall be furnished
131 on forms prescribed by the Board which shall, at minimum, contain: (i) the name and address of the
132 subcontractor; (ii) a number identifying the subwork order with the original work order; (iii) the date the
133 subwork order was written; (iv) a description of the work to be done by the subcontractor including
134 diagrams, if necessary; (v) a specification of the type and quality of materials to be used; and (vi) the
135 signature of the person issuing the subwork order.

136 The subcontractor shall retain the subwork order and the issuer shall retain a duplicate attached to the
137 work order received from the licensed dentist for three years.

138 D. No person, firm or corporation engaged in the construction or repair of appliances shall refuse to
139 allow the Board or its agents to inspect the files of work orders or subwork orders during ordinary
140 business hours.

141 The provisions of this section shall not apply to a work order for the construction, reproduction, or
142 repair, extraorally, of prosthetic dentures, bridges, or other replacements for a part of a tooth, a tooth, or
143 teeth, done by a person, firm or corporation pursuant to a written work order received from a licensed
144 dentist who is residing and practicing in another state.

Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers

Document issued on: April 19, 2001

This document supersedes *Draft Guidance on Medical Device Patient Labeling*, March 3, 2000.



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Labeling Research and Policy Development Branch
Division of Device User Programs and Systems Analysis
Office of Health and Industry Programs**

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Paula Silberberg at 301-796-5844 or e-mail at paula.silberberg@fda.hhs.gov.

Additional Copies

Additional copies are available from the Internet at:
<http://www.fda.gov/cdrh/ohip/guidance/1128.pdf>. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1128) to identify the guidance you are requesting. Additional information can also be found at <http://www.fda.gov/cdrh/humanfactors.html> and at <http://www.fda.gov/cdrh/designlabel.html>

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Guidance on Medical Device Patient Labeling

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Introduction:

What is the purpose of this guidance?

This guidance serves a dual purpose:

- (1) to assist manufacturers in their development, and
- (2) to assist Center reviewers in their review and evaluation

of medical device patient labeling to help make it understandable to and usable by patients (or family members or other lay persons caring for patients).

The writing style we have adopted in this guidance is targeted to manufacturers, since they will be developing the medical device patient labeling.

When translating the professional label into lay language, take care to ensure that it does not alter the intent of the indications, contraindications, warnings and precautions, or other parts of the professional labeling. The lay translation should also provide a balanced presentation of adverse events and the risks and benefits of the device. It should not introduce new claims that are not in the professional label. Device labeling evolves throughout the review process. Therefore, it is your responsibility to ensure that the patient label is consistent with the final professional label.

What is medical device patient labeling?

Medical device patient labeling is any information associated with a device targeted to the patient or lay caregiver. It is intended to help assure that the device is used safely and effectively. This labeling may pertain to therapeutic, restorative, diagnostic, or cosmetic devices.

Medical device patient labeling is supplied in many formats, for example, as patient brochures, patient leaflets, user manuals, and videotapes. This labeling is intended to be supplied, or given to and used by patients or their lay caregivers with or without accompanying professional counseling. Medical device patient labeling may accompany devices intended solely for physicians to operate, devices for both physicians and patients or lay caregivers to operate, and devices operated solely by patients or their lay caregivers.

Why is medical device patient labeling important?

Medical device patient labeling is essential to assure safe and effective use of many, but not all, devices. It informs patients or their lay caregivers about proper use, risks, and benefits of the device in language they can understand.

Medical device patient labeling assists patients or their lay caregivers in understanding the device; its operation, care, and maintenance; the way it interacts with the body to accomplish its purpose; its place and purpose in the patient care regimen; and any safety or disposal issues.

Patient labeling is important for all devices operated by lay users. Adequate directions for operating the devices are needed to make devices safe and effective. For example, as more patients use complex medical devices at home, medical device patient labeling becomes necessary to better communicate to the lay person how to operate the device.

What are the general types of information that may be included in medical device patient labeling?

There are two general categories of information that may be included in medical device patient labeling:

- (1) risk/benefit information; and
- (2) instructions for use.

Risk/benefit information is information people need to decide to use a device or have it used on them. This information also allows the users to become aware of potential problems with the device. It might include, as appropriate to the device:

- sufficient descriptive information to tell what the device is and what it is used for,
- types of people and situations for whom the device would not be a good choice,
- risks and benefits to the patient or environment associated with the uses of the device,
- information about maintaining the device or identifying potential problems with the device,

- alternative therapeutic and diagnostic choices available, and/or
- other information to enable the person to make an informed decision about the device.

Devices that would have patient labeling consisting primarily or completely of risk/benefit information might be: implants that have no external patient interface once they are implanted, or prescription diagnostic or therapeutic devices that the patient is actively involved in choosing (e.g., laser eye surgery, lithotripsy, intraocular lenses).

Instructions for Use are the procedural steps to follow in setting up, using, cleaning, troubleshooting, and storing a device. This information constitutes the “how to” for the device.

Devices that might have patient labeling that would include instructions for use would be those the patient or lay caregiver has to set up, operate, clean, etc. They might include such devices as suction equipment, intravenous infusion pumps, physical therapy equipment, or transdermal electrical nerve stimulation (TENS) devices.

There are many types of medical devices for which the medical device patient labeling would have both risk/benefit and instructions for use information.

When should you use medical device patient labeling?

Medical device patient labeling should be supplied whenever it can benefit patients or lay caregivers. Patients or lay caregivers benefit from this labeling by increasing their knowledge about the device. Knowledgeable users are more likely to use the device as you intend.

You should know the informational needs of your target audience in order to determine if patient labeling is necessary. Does your audience need or want specific information? Is there something unique about the device (e.g., diagnostic test) that needs to be explained to the patient? Does your audience already know the information?

The following examples illustrate situations where you should consider developing patient labeling. The situations are grouped into risk/benefit information and instructions for use.

You should consider developing risk/benefit information when patients or lay caregivers need to:

- give personal health information to aid their health care practitioner in deciding to use or not use devices in prevention, treatment, or diagnosis of an illness (e.g., magnetic resonance imaging (MRI));
- select among similar devices or device procedures;
- be involved in deciding whether to have a procedure involving the device; and/or

- understand the effect or influence of the device on the patient or others (e.g., orthopedic rods, screws, and fixation devices; genetic screening).

You should consider developing instructions for use when patients or lay caregivers need to:

- maintain the device;
- monitor and report on the operation or output of the device (e.g., pacemakers, glucose monitors);
- explain the operation of the device to others, such as a practitioner caring for another condition of the patient;
- explain the patient's medical situation to others, such as when lay caregivers or others need to understand the requirements of care or the alterations of lifestyle associated with care in the use of the device;
- know how to alter their lifestyles or care regimens to properly integrate the use of the device; and/or
- know how to safely dispose of the device.

You should consider developing both risk/benefit information and instructions for use when patients or lay caregivers need to:

- operate, interpret, and manipulate the device (e.g., programmable implants, home pregnancy test kits, ostomy supplies);
- know how to be careful in using the device, such as understanding the basis for warnings, precautions, and contraindications; and/or
- cooperate with the prevention, treatment, or diagnosis of an illness (e.g., preparation for bone density scan, drugs of abuse test kits).

When is medical device patient labeling not usually necessary?

Medical device patient labeling is not usually necessary when:

- a patient will have no opportunity to benefit from the labeling. The following are typical situations.
 - The device is a tool of the health care practitioner and the patient is not involved in the choice of the device.
 - The device is a tool of the health care practitioner and the patient has no control over or access to the device.
 - The patient can contribute no useful information, such as sensitivities or aversions to materials or abilities to cope with sequelae of device use, that would help the health care practitioner choose or use the device.

Examples of these types of devices include blood pumps, scalpels, or other surgical instruments.

- a patient's opportunity to benefit from patient labeling is outweighed by the risk of allowing him the opportunity in an emergency. The following is a typical situation.
 - Time is of the essence so that involving the patient, family member, or lay caregiver to help decide on whether to use the device or select among several devices or procedures using devices would be more risky to the patient's health than not involving him. In this case, the health care practitioner subordinates the patient's right to know, choose, and decide to his obligation to give prudent care.

Examples include devices and device procedures whose need arises unexpectedly and intraoperatively. The patient has no opportunity to read patient labeling before the procedure, such as in the case of some catheters or drains.

What should you consider when identifying a method to distribute the medical device patient labeling?

To increase the likelihood that the patient labeling will reach the patient and be read by the patient or caregiver, consider:

- When should the patient labeling be provided?
- Must an intermediary, such as a health professional or a supplier, pass along the patient labeling or can it be provided directly to the patient?
- If an intermediary is involved, will there be any logistical difficulties in passing the patient labeling along and can these be overcome?

- What are the obstacles to the patient labeling reaching the patient, and what are the solutions to these obstacles?

If you have a Web site, consider placing patient labeling there to help patients get the most up-to-date information.

During pretesting with your target audience, you can ask what method of distribution the audience would prefer and assess experience they have had in the past with the distribution of patient labeling. (See Appendix F Pretesting.)

Suggested Content of Medical Device Patient Labeling:

Determining Sequence and Content:

We are suggesting the sequence and content of the following headings for patient labeling. We have drawn much of this information from FDA’s Draft Report on Medical Device Labeling: Patients’ and Lay Caregivers’ Medical Device Information and Labeling Needs, Results of Qualitative Research.” (See References – Sequence.)

Medical device patient labeling should flow logically in brief, simple, clear language with highlighting to guide the user to the desired information to meet the need at the moment. The content should be sequenced in a way that is logical for the intended user, with the most important information presented first. Notice that similar information in this suggested sequence is grouped (chunked) together, an organizational technique that participants in FDA’s medical device patient labeling focus groups said they liked. (See References – Sequence.)

A “one size fits all” approach does not work with patient labeling, so the content, and in some cases the sequence, may vary depending on the target audience and the purpose of the medical device patient labeling. Not all of the following headings apply to all medical device labeling. For example, medical device patient labeling presenting only risk/benefit information might not contain headings related to instructions for use.

Through pretesting, such as focus groups, you can systematically gather target audience reactions to your specific medical device patient labeling’s content, sequence, and format. Also, you may find in your pretesting that different wording for the suggested headings is appropriate. (See Appendix F Pretesting.)

Table of Contents:

Include a table of contents if the medical device patient labeling is lengthy and/or complex. This helps readers quickly and easily find the information they need.

Glossary:

If a glossary is used, place it after the table of contents to alert readers that it is there to help them. Whether or not a glossary is used, definitions should appear in the text.

Descriptive Information:

Purpose of the device (indications for use):

Briefly describe the FDA cleared or approved indications for use.

Description of the device:

Give a brief physical description of the device, its parts and accessories. A graphic may be the simplest and clearest way to describe a device. All parts of the device shown in the graphic, such as switches, dials, and meters, should be labeled with numbers, letters, or words. The function or purpose of each labeled item should be briefly described in the text of this section. Also, list materials in the device so patients with hypersensitivities can easily identify their risks.

When the device should not be used (contraindications):

Tell when a device should **not** be used (contraindications). Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit. There may be persons in whom the device should not be used because of their health status. For example, the device may be contraindicated for pregnant women.

List known and reasonably foreseeable hazards, not theoretical possibilities. For example, if hypersensitivity to a material in the device has not been demonstrated, it should not be a contraindication. However, if hypersensitivity to a material has not been sufficiently studied and/or is not scientifically documented, clearly state that information.

Contraindications to the use of a device could include:

- demonstrated hypersensitivity to a material where there is patient contact with the device,
- substantial risk of being harmed because of patient characteristics (e.g., age, gender, accompanying therapy, disease state, health status), or
- continued use in the face of an unacceptably hazardous adverse event.

Risks and benefits:

To make an informed choice about a medical device, a patient must have a thorough understanding of the effects and expectations associated with that device. We characterize this as “risk/benefit” information because the decision making process typically involves the weighing of the positive and negative effects and expectations. It is a global concept that may include a number of specific types of information, depending on the device and the target audience.

The goal of risk/benefit information as applied to medical device patient labeling is to provide the patient with information about the risks and benefits associated with a device or procedure in a manner that is meaningful to the user. Risks and benefits conveyed in an effective and meaningful way to the user should aid the user in deciding whether to use a device, or undergo a procedure that uses a device, and to motivate the user to use the device as labeled.

General guidance for developing risk/benefit information:

- Anticipate and respond to people’s concerns about their personal risk, or any risks to the environment or society from the use or disposal of the device.
- Carefully word messages that may arouse fear and anxiety.
- Tell patients what they can do specifically to avoid risks.
- Describe risks and benefits clearly and specifically.
- State both benefit and risk information in the same way (e.g., qualitative or quantitative), if possible.
- Be positive in the risk messages. For example, state what the patient can do to overcome risk.
(E.g., “In rare cases a sweat rash can develop in the contact area. If a sweat rash develops, take the silicone sheet off for a few days, then start again...”)
- Balance risk and benefit information. Present factual risk and benefit information without any attempt to influence the patient.
- Pretest risk messages to indicate how effective they are. (See Appendix F Pretesting.)
- Use graphs and other visual materials to communicate risk information. Visuals should be colorful enough to attract attention and simple enough to be understandable at a glance. Combining visuals with brief text that contains the “take-home” message can help to ensure more accurate interpretation of risk information.
- Inform and educate people about risks by using risk comparisons that compare risks that are similar or closely related.

The content of risk messages:

Risk messages should closely reflect the perspective, technical capacity, and concerns of the target audience. The message should:

- include specific actions that people can take, even if it is only to tell them where to go to get further information or assistance.
- avoid using vague or unfamiliar terms to characterize the risk (e.g., “some women,” “fourfold,” “lifetime risk”). Word choice greatly influences how people attend to risk information (e.g., “risk” raises alarm, “chance” minimizes alarm).
- respect the audience by addressing people’s values, preferences, and concerns (e.g., Tell patients about a change in their appearance, such as scarring.),
- seek strictly to inform, not influence.
- assume the audience has little technical knowledge when in doubt about the audience.
- show empathy – with statements that illustrate caring.
- provide facts - two to three bits of supporting data.
- use vivid, concrete images, examples, and anecdotes that communicate on a personal level and make technical risk data come alive.
- limit the comparisons to risks that are similar or closely related when making comparisons.
- caution against unwarranted conclusions.
- provide information on consequences of decisions in a balanced manner.

Risk messages:

- should provide a source for more information.
- should acknowledge uncertainties, including lack of currently available scientific knowledge.
- should include analogies.
- may discuss the nature of the risk.
- may include alternatives.
- may discuss benefits.

The content of benefit messages:

- Present balanced benefit information.
 - Identify outcomes.
 - Estimate the magnitude of outcomes in a way that is meaningful for readers to understand.
 - Evaluate the benefit for individuals.

Evaluation of the effectiveness of the risk/benefit information:

It is important to evaluate the effectiveness of the risk/benefit information by testing it. (See Appendix F Pretesting.)

- Is there adequate *awareness* of the risks and benefits, and their potential consequences?
- Is there *knowledge* of the risks and benefits, and what steps can be taken to lessen the risks?
- What are the *attitudes* toward the risks and benefits?
- What is the *behavior* toward the risks and benefits?

Expectations of the device and the procedure associated with the device:

Tell the patient what to expect before, during, and after a surgical procedure and/or the use of the device. If appropriate, give instructions on post-operative or post-procedural care. If the device is one that the patient operates, and the medical device patient labeling has an “Operating Information” section, the information on what to expect could be included in that section.

General warnings and precautions:

Note: Please read the detailed discussion in Appendix E of definitions, purpose, content, format, placement, and other issues related to warnings and precautions.

Embedded in the concept of risk/benefit information is the type of information known as “**general warnings and precautions.**” This is the specific hazard alert information that a user needs to know before using the device. Provide this information early in the labeling. Present it according to the clinical significance of the item to assist the reader in understanding the relative importance of the information. By the time readers get to the information on warnings and precautions in the labeling, they have probably already made the decision to use the device. At this point, the users know the global risks and benefits, but need specific information to avoid or reduce a particular hazard associated with the use or disposal of the device. It may be appropriate to include general warnings and precautions in a presentation of risk/benefit information for a device where that information might have bearing on the decision to use the device as well as on the actual safe use, operation, or disposal of the device.

Warnings and precautions tell the reader about hazards, other than those that are contraindications to device use. Warnings and precautions provide information on how to avoid these hazards, i.e., sources of harm in the use of the device.

Importance of the need to adhere to a care regimen:

State why it is important to follow the care regimen explained in the medical device patient labeling. This will help to motivate the user to follow the instructions.

Operating Information:

The user needs to know what to do, how to do it, and when to do it. The operating instructions should:

- focus on **how to** operate the device. It is usually not necessary to provide a detailed explanation for lay users of the mechanism of action of the device or why it does what it does. That approach can lead to information overload.
- assume that the user does not have device or medical knowledge or ability.
- provide logically ordered steps for the task and make the user aware of the importance of doing the steps in order.
- state the purpose and the expected outcome of each task.
- tell the user what steps are essential and which ones are optional.
- be written at an eighth-grade reading level or below to reach most of the population.
- be clear the first time they are read. Many people do not reread something they do not understand.

Setup instructions:

Give clear setup instructions. If a user is not responsible for the setup of the device, tell the user this and omit the setup instructions.

Include in setup instructions for the lay user:

- a parts list, if appropriate.
- list of materials and tools needed for setup.
- unpacking instructions, if appropriate.
- instructions on proper disposal of packing materials or how to return packaging to you for reuse.
- directions for where the device should be placed, such as a table top or floor. Also state if the device should remain in one place after setup.
- any warnings or safety instructions specifically related to setup, placed right before the corresponding task or instruction.
- results of incorrect setup.
- numbered setup instruction steps in logical order.

- any special preparation required before first use of the device, such as cleaning or disinfecting.
- space to write in user-specific instructions.
- who to call if there is a problem. You may refer users to the assistance section in the medical device patient labeling.

Checkout procedures:

If the device requires any type of checkout procedure for safety and effectiveness, clearly and completely explain this process. This task may be as simple as a visual inspection of the device. Other examples of checkout procedures are calibration and quality control checks.

Include:

- when the checkout should be done, such as at the time of setup and/or before each use.
- step-by-step procedures for checking proper function of necessary parts of the device.
- what to do if the checkout shows that the device is not working properly.
- who to call if there is a problem. You may refer users to the assistance section in the medical device patient labeling.

A clock or calendar graphic may be useful to show the user correct times or days to check the device.

Operating instructions:

Give clear and easy-to-follow operating instructions. These instructions should include:

- special preparation the user needs before operation, such as handwashing or device warm-up procedures.
- any warnings or safety instructions specifically related to operation, placed immediately before the corresponding task or instruction.
- results of incorrect operation.
- operating steps in logical order, with the expected results.
- space for user-specific instructions.
- who to call if there is a problem. You may refer users to the assistance section in the medical device patient labeling.

Importance of the need to monitor the activity of the device:

State the importance of monitoring the activity of the device. This section explains that the user needs to make sure the device is acting the way it should. Give examples of what to check to

make sure the device still works properly. For example, check to see that leads are connected, wires are not damaged, and the power is supplied to the device.

Cleaning instructions:

Give clear and complete cleaning instructions.

- List the supplies needed.
- Give step-by-step procedures.
- State how often to clean the device.
- Tell the user what cleaning accomplishes.
- Tell the user what the results of failure to clean will be.
- Include appropriate warnings and precautions for cleaning agents.
- Describe the results of using improper cleaning solutions or methods.
- Include suggestions for the proper disposal of the suggested cleaning agents, if appropriate.

Description of maintenance and who should do it:

- Clearly describe what maintenance actions are the responsibility of the user.
- If a particular kind of user, such as the lay user at home, is not responsible for maintenance, briefly outline proper maintenance actions, who is responsible, and how often the action should be done. The lay user will then know what to expect and can take action if proper maintenance is not provided.
- If the device has some maintenance procedures to be done by the user and some done by others, such as the biomedical engineer, you may wish to write this section in two parts. The two parts will help make clear to users what they should and should not be doing to maintain the device.

Storage instructions:

Clearly describe proper preparation for storage and storage conditions. State the results of improper storage conditions. If extended storage may affect the device, inform the user. It may be necessary to include information that addresses extended storage in the sections on setup, checkout, operation, and maintenance.

Expected failure time and mode and its effect on the patient:

State how long the device will last. State what to expect when the device fails. Let the user know if it fails safely or dangerously and the effect on the patient. Include this type of information in the Risks and Benefits section of the medical device patient labeling if appropriate.

Instructions on how to safely dispose of the device:

When appropriate, explain how to safely dispose of the device (e.g., mercury containing devices, sharps). Include your take-back information, recycling options, and refurbishment options.

Instructions on accessories:

If the device comes with or is used with accessories, discuss all appropriate content areas for each accessory. You could have a separate accessories section or include information on the accessories in the content areas that apply.

You may need to include a general warning at the beginning of the medical device patient labeling advising users of problems that may occur if they use accessories other than those you recommend.

Instructions on related, additional devices:

If the patient will receive an additional device after an operation or procedure, include information about the additional device in the medical device patient labeling. Describe why this additional device would be needed, what symptoms might be expected post-treatment, and any other information about the additional device that impacts the safe and effective use of the primary device. A typical situation is when a patient who has had a home infusion pump with a peripheral line also receives a central line.

Troubleshooting Information:

Troubleshooting:

Provide an easy-to-find troubleshooting section. When a problem occurs, troubleshooting helps determine if the problem is with the device or with the patient's condition. Anticipate any problems the user may have with setup, operation, or maintenance. Provide solutions for these problems in the troubleshooting section. Group similar problems, such as problems with alarms, and highlight each group heading. Highlighting makes it easy to find each group of problems and the specific problems in it. Put the most life-threatening problems first in each section.

Format this section so that the user can locate specific problems quickly. The troubleshooting section could be a table with a column for signs of trouble and a column for actions.

Clearly describe the symptom of each problem in as few words as possible so that the user can easily match the description to the problem observed. If your device displays error messages, list them and what they mean. Explain the steps necessary to correct the problem. Do not confuse the reader with technical reasons for problems unless the reasons are important to the corrective action.

If there are problems that users cannot or should not try to solve themselves, include warnings or precautions and tell them how to get help.

Instruct users to call their health care professionals for emergency assistance if troubleshooting reveals a patient health problem rather than a device problem.

Note: Putting assistance information in this section does not eliminate the need for a separate assistance section. (User assistance information is discussed in a later section.)

Tell the user how to report undesirable outcomes (adverse events). For example, the user would report malfunctioning of the device, mistakes in using the device, or injury from the use of the device.

Additional Information:

There are certain categories of information that not all patients want in medical device patient labeling. We refer to these categories as "additional information." Additional information includes such categories as clinical studies and adverse events. Whether or not to include a particular category depends on the needs of the target audience of the particular medical device. You may want to include additional information in appendices in the medical device patient

labeling, or advise the reader that it is available on demand. For example, tell the reader to call the user assistance toll-free telephone number, contact the physician, or go to an Internet site.

FDA's medical device patient labeling focus testing has shown that some patients like all the additional information, but most prefer to see it at the end of the document or have it available on demand so they can choose to read it or not. (See References – Additional Information.)

Clinical studies:

When developing clinical study information for patients, whether as part of the patient labeling to accompany the device, or as an “on demand” piece, make sure it is written in simple, plain language.

Disease and self-care information:

Members of some target audiences may benefit from disease and self-care information. For example, a patient undergoing bone densitometry benefits from information about osteoporosis.

Adverse events:

When appropriate, provide information about any adverse events. Devices whose applications are supported by clinical trials will have data about adverse events that occurred during these trials and that may be of value to the device user. Other devices may have adverse event data from other sources, e.g., published literature or experience with similar devices. The detail in and the need to include an Adverse Events section depend on the benefit of these data to the device user. For a device cleared under Premarket Notification, which was not supported by clinical studies, the Adverse Events section might include only potential adverse events and a statement of the source of the information.

Include potentially fatal adverse events in the Warnings and Precautions section, or the Contraindications section.

If appropriate, follow the listing of adverse events with statements directing the reader to other sections of the labeling for additional information regarding these adverse events and any steps to take to avoid them.

Warranty:

When appropriate, provide any warranty information. Also, for devices intended to be implanted in the human body for more than one year, consider providing a card or sticker listing

the manufacturer of the implant, date implanted, model number, lot number, size, type, or any other appropriate descriptive information. Patients can keep this as part of their personal medical records.

Travel or international use:

If a patient could travel with the device, provide appropriate travel instructions. For example, tell the patient if the medical device is not compatible with foreign power systems. The patient will need an adapter, and may need a converter to convert to the proper voltage. Also, tell the patient to check with the carrier to confirm that the device can be carried and/or used on the airplane.

Index:

Provide an index if the medical device patient labeling is lengthy and/or, complex. This helps readers quickly and easily find the information they need.

Date of Printing:

Put the date that the medical device patient labeling is issued or revised where it can be easily found (e.g., cover or last page). FDA requires dated labeling for prescription devices (21CFR801.109(e)) and recommends it for all other devices.

User Assistance Information:

Design a clearly marked section that advises users on how to get help for problems with the device. FDA's medical device patient labeling focus groups indicated that users look at the end of the medical device patient labeling for the user assistance information, although it can be included in other places in addition to the end. (See References – User Assistance Information.) This section should be very easy for the user to find. It may be as simple as putting the customer assistance number near the company name, device name, and model number. The medical device patient labeling can include a toll-free number or the number for customer assistance, as well as an Internet address.

Provide space near the user assistance information, with appropriate identifying terms, for phone numbers of the medical equipment supplier, the home health care agency, the doctor, the referral for disposal of the device, and/or any other appropriate points of contact for the typical user.

Note: Ideally, your toll-free number should be on the device.

Appendix A

Readability:

Readability defined:

Readability is defined as the ease of understanding or comprehension achieved by the style of writing. Reading involves both decoding and comprehension. The reader must be able to recognize (decode) the words in the medical device patient labeling as well as comprehend the meaning of the text. We encourage you to follow the following guidance to assess and enhance readability.

Assessing readability:

To assess readability, analyze qualitative factors (e.g., explanation of jargon, careful organization) in combination with quantitative factors (results of readability formulas). You should test the medical device patient labeling with a sample of likely, representative users of the device.

A qualitative analysis:

Use these qualities in the text to enhance the reader's comprehension of the medical device patient labeling:

- Define complex medical terminology and jargon when it first appears in the text.
- Carefully organize medical device patient labeling from a user's perspective (organized in the way the user will use the information). Repeat important points and summarize important information, to increase the reader's recall and reading comprehension. The reader will remember the message when key points are reinforced.
- Organize sections with headings and questions.

A quantitative analysis (readability formulas):

The reading level of the medical device patient labeling should be no higher than the eighth-grade level, the average reading level among adults. To predict the reading level of the medical device patient labeling, use the readability formulas (manual or software programs) available. (See References: Readability.)

Readability formulas use semantic (vocabulary difficulty) and syntactic (sentence length) factors to predict the readability of the medical device patient labeling. If the reading level is predicted to be above the eighth-grade level, the patient labeling should be rewritten by applying the

principles of writing for increased comprehension (see Appendix B), and qualitative factors that can enhance reading comprehension. These formulas should be used to predict (not measure) the reading level of the text.

The formulas should not be used to write, rewrite, and revise medical device patient labeling to specific readability levels. While readability formulas can predict readability, the reader must actually read the text to determine if it is readable. To

mechanically substitute easier for harder words does not necessarily make the text more readable. Such text could become harder to understand through loss of organization and cohesion and loss of clarity of concepts. As reading expert George Klare explains, merely shortening words and sentences to improve readability is like holding a lighted match under a thermometer when you want to make your house warmer. The thermometer certainly goes up, but the room does not get any warmer.

Testing:

Test the medical device patient labeling with a sample of appropriate users of the device. This is the only way to know if the medical device patient labeling is understandable and useful. User-oriented testing helps to find places where the medical device patient labeling may be inaccurate, incomprehensible, or poorly organized. Since reading is an interactive process between the reader and the text, testing the medical device patient labeling with the target audience is the best way to determine how well the audience understands the labeling.

A summary of readability:

Use qualitative factors in concert with readability formulas to assess the readability of medical device patient labeling. Reader background knowledge and interest, context clues (words that surround a particular word or passage and can throw light on its meaning), text organization, and opportunity for reinforcement are just a few factors other than formula-derived readability that should be used to predict the readability of medical device patient labeling. The best solution is to pretest the medical device patient labeling with the target audience to see if they comprehend it.

Writing for increased comprehension:

The following principles foster the readable writing of medical device patient labeling. We encourage you to follow these principles in order to write for increased comprehension.

General principles:

Write with a specific type of person in mind.

Stress the “need to know” information.

Use concrete examples to clarify abstract ideas.

Consider who will be using the device:

- Are they elderly, disabled, or children?
- Would their vision or hearing likely be impaired?

Consider where the devices will likely be used.

Group (chunk) similar information together.

Use well-mapped, carefully organized writing. Well-organized material provides occasional repetition and thoughtful summary.

Repeat the most important points to increase patient recall and comprehension.

Emphasize and summarize main points.

Use headings and summaries to aid organization and provide message repetition.

Organize medical device patient labeling to meet varied skill and knowledge needs.

- One approach is to provide one well-segmented, highlighted document with a table of contents and the most-desired, basic information up front. Put additional information in appendices to the primary document, or make it available on demand.
- Another approach is to distribute a quick reference card of important reminder information for the experienced user, in addition to the full patient labeling. Also, the experienced user can benefit from an intermediate form (a mini manual) with an expansion of the important

information in the quick reference card, especially key use information, in addition to the full patient labeling.

Locating information in lengthy and/or, complex medical device patient labeling:

Include a summary page with critical information.

Include a table of contents.

Include an index.

Include page numbers to make it easier to locate information.

Include chapter names and numbers, if chapters are used.

Principles for clear, concise writing:

Eliminate unnecessary words:

- Avoid “aware of the fact that.”

Example

Poor: Be aware of the fact that dampness may affect the device and cause rust.

Better: Dampness may affect the device and cause rust.

- Avoid the unnecessary use of make, made, and making.

Example

Poor: Make an attempt to clean your braces twice a day.

Better: Clean your braces twice a day.

- Substitute a single word for a phrase.

Example

Poor: It may take a good deal of practice to operate the device.

Better: It may take much practice to operate the device.

- Use clear and simple phrases whenever possible.

Example

Poor: Endeavor to ascertain the hospital closest to your home.

Better: Try to find the hospital closest to your home.

- Avoid overuse of “it is.”

Example

Poor: It is possible that you may need to use more cleaner.

Better: You may need to use more cleaner.

- Reduce long, complicated phrases.

Example

Poor: You are not able to use another manufacturer’s cable.

Better: You cannot use another manufacturer’s cable.

- Simplify prepositional phrases.

Example

Poor: Store the device in a dry area at all times.

Better: Always store the device in a dry area.

Technical vocabulary:

- Define technical words or use them in context to help increase comprehension. Use lay language first with the technical word in parentheses. In addition to parentheses, use italics or other highlighting techniques to give the reader a signal for the technical vocabulary.

Example

Poor: 65 mm is the tolerance level.

Better: Do not set this gauge above 65 mm (*tolerance level*).

- Define terms the first time they occur in the text. Keep the definitions simple and concise. If you need to define many words on one page, define them in a set off section of the page on which the words first appear. For example, use a sidebar.
- Provide examples to explain technical words.
- Provide a glossary of technical words. If a glossary is used, it should be placed after the table of contents to alert readers that it is there to help them. Whether or not a glossary is used, definitions should appear in the text.

Word choice:

- Personalize the material by using the second person “you” instead of the third person “he,” “she,” or “they.” Using “you” focuses the information directly to the patient, which makes it more important and personal.

Example

Poor: The user should not operate this device near water.

Better: You should not operate this device near water.

- Use terms consistently throughout the text. Use the same term to identify the device and its parts throughout the medical device patient labeling. Avoid synonyms or alternate phrases.

Example

If you start with “dial,” do not call it a “knob” later.

- Put adjectives and adverbs close to the words they modify.

Example

Poor: Use the wire that is covered with green plastic.

Better: Use the green wire.

- Avoid adverbs that are difficult to define or interpret.

Example

Poor: Respond quickly.

Better: Respond within one minute.

- Use active rather than passive verbs.

Example

Poor: The dial should be turned clockwise.

Better: Turn the dial clockwise.

- Use action verbs, not nouns created from verbs.

Example

Poor: Avoidance of cellular phones is necessary when operating the device.

Better: Avoid cellular phones when operating the device.

- Use specific terms. Vague terms may be misinterpreted.

Example

Poor: Device operates poorly in a cool room.

Better: Device will not operate below 60 degrees F.

- Avoid abbreviations or acronyms. If abbreviations or acronyms are necessary, define them the first time. Use them consistently.

Example

Abbreviation: oxygen instead of O₂

Acronym: home medical equipment
instead of HME

Sentences:

- The burden for short-term memory is greater for longer sentences. Use as few words as possible to present an idea or describe an action.

Example

Poor: Find the opaque plastic container that has a blue line on the upper half of it and fill it with any type of water until you reach the blue line.

Better: Fill the plastic container to the blue line with tap water.

- Use no more than one clause in a sentence.

Example

Poor: Check the power cord and do not use it if you find cuts or frays or it is loosely connected to the device.

- Better: 1. Look at the power cord for cuts or frays.
If it is cut or frayed, do not use the device.
2. Tug lightly on the power cord. If it slips out of the device, do not use the device.
 3. Call 1-800-xxx-xxxx if you need help.

- Place phrases that describe or explain at the end of the sentence. Phrases at the beginning or in the middle of a sentence may be confusing.

Example

Poor: Before using this device, you should read the instruction manual.

Better: Read the instruction manual before using this device.

- Write the way you talk. Avoid formal language.

Example

Poor: Insert the blue cable into the blue socket on the anterior section of the machine to form a completed circuit of the electrical system.

Better: Plug the blue cord into the blue hole on the front of the machine.

- Express ideas of similar content in similar form.

Example

Poor: Twist the large dial clockwise until it stops. Turning the small dial, move it 3 notches counterclockwise.

Better: 1. Turn the large dial marked X clockwise until it stops.
2. Turn the small dial marked Y counterclockwise 3 notches from the "Off" position.

- Users should be able to read instructions aloud. Do not use parentheses for information that should be read. Parentheses cause the reader to hesitate, making it hard to read. Use parentheses only for extra information such as technical terms.

- Don't promote the product in the medical device patient labeling. Ads or promotions in the text will interfere with the patient's ability to follow instructions.
- Use bullets, lists, or more than one sentence instead of a long sentence that requires a lot of punctuation.

Paragraphs:

- Begin paragraphs with a simple topic sentence that states the main idea.
- Paragraphs should be cohesive about a single thought.

Motivation:

- Focus on what the target audience should **do** as well as **know**. (For example, "If mercury leaks, call the local authorities for help with the mercury spill. Mercury is toxic.")
- Use questions throughout the text as headings and summary points to encourage active learning.

Writing procedures:

- Write procedures in short, identifiable steps. Put the steps in the order they should be performed.
- Before each set of steps, tell the reader how many steps are in the procedure. This helps the reader avoid missing steps.
- Number each step in Arabic numbers such as 1, 2, 3. Do not use Roman numerals such as I, II, III; letters such as A, B, C; or words such as one, two, three. People most readily identify Arabic numbers with steps in a sequence.
- Limit each step to no more than three logically connected actions. If actions are not related, put them in separate steps.
- Make the instructions for each action clear and definite to prevent misunderstandings. This approach is especially critical for steps that require more than one action.

Example

Poor: Turn the machine on.

Better: To turn the machine on:

1. Plug the power cord into an AC outlet.
 2. Face the front of the machine. Find the black power switch on the right side.
 3. Turn the power switch to the “ON” position.
- Tell the user what to expect from an action.

Example

Poor: Flip the switch to the “ON” position.

Better: Face the front of the machine. Flip the black switch on the left side, marked “ON/OFF,” to the “ON” position.

The green light will go on.

- Discuss common errors at the point in the procedures where they are likely to occur. Provide information to prevent and correct use errors.
- Each step should be contained on one page. If the entire step will not fit on a single page, break the step into smaller substeps, each fitting on a page or less. Put more than one step on a page only if each step and accompanying graphics are complete on that page.

- Avoid referring the user to another place in the manual for other information (cross referencing). It is confusing to the reader and interrupts the flow of the procedures. If cross referencing is absolutely necessary, make sure the reader knows when to return to the original place.

Example

Poor: If the alarm sounds, go back to the beginning of chapter X.

Better: If the alarm sounds:

1. Turn to page X.
2. Repeat steps 1 and 2 on page X.
3. Return to step 1 on page Y.

Appendix C

Appearance of text:

What principles should be applied to the physical features of the text?

The speed by which letters and words can be recognized (legibility) can be enhanced by applying the following principles.

Sections:

Divide the text appropriately into short sections. Use headings or other highlighting/separation devices. Major headings, including captions and subtitles, should capture the main points. Within the text, bullet text is helpful.

When creating headings, it is acceptable to use uppercase letters and bold print.

Type:

Base the type size and font on the needs of the target audience.

Use at least a 12 point type size whenever possible. For elderly or visually impaired users, use at least 14 points. For headings, use ranges from 18-36 points.

Use a serif font for the text. It allows more variation among letters than sans serif. This makes the letters easier to recognize.

Use both upper and lower case letters in the body of the text. It is more difficult to read all capital letters.

Use black type on a white background for best contrast. It is the easiest to read.

Paper:

Avoid glossy paper. It may cause a glare.

Use paper heavy enough to prevent text and graphics from showing through.

Highlighting:

Use highlighting techniques to emphasize important words, thoughts, or phrases. Highlighting techniques include bolding, underlining, italics, capital letters, color, background patterns, and white space.

Do not overdo highlighting. It will decrease the impact of the message.

Be consistent in the highlighting methods used.

White space:

Use white space carefully to keep the medical device patient labeling from looking too cramped or too spread out. White space between blocks of text aids the ease of reading.

Justify the left-hand margin. Use ragged right margins.

Use at least 1/16th of an inch of white space between lines of text.

Increase the amount of white space around important individual words, text and graphics for emphasis.

Formatting and organizing instructions:

Organize instructions with text, flowchart, or list formats as appropriate.

Use tables to present information graphically to simplify complex information.

- It should complement and supplement the text.
- It should condense statistical information.

Note: In instruction manuals, tables are normally not appropriate and their use should be minimized. If a table is necessary to simplify complex information, include instructions on its use. Label each table clearly.

Use lists when the use of the device requires checking off steps that are completed.

Number steps that must be completed in order.

Bullet lists that have no specific order of importance.

Appendix D

Appearance of graphics:

What principles should be applied to the graphics of the medical device patient labeling?

Photographs and line art attract and keep a reader's interest and are often remembered longer than words. Properly chosen and placed illustrations make the text more meaningful and reduce the burden of details in the text. Use the following principles in the graphics of the medical device patient labeling.

Graphics should:

- attract attention,
- re-emphasize the text of the medical device patient labeling,
- be simple and clearly drawn, without clutter, unneeded background, or extraneous detail,
- demonstrate one concept, single idea, or point of information at a time,
- be placed next to corresponding text,
- use cues such as circles or arrows to point out key information,
- be clearly labeled,
- be easy to understand,
- improve understanding of essential information,
- be recognizable to the audience, and
- fit the target audience.

Set off text and graphic that go together by the use of lines, white space, or titles. If a graphic is referred to in the text, it should have a title, for example, Figure 1.

Use accurate and precise graphics.

- When comparing two illustrations, show the difference. If the difference is not distinct, the reader may get confused.
- Represent only simple concepts in your graphics, either of actions or of the device and its surroundings.
- Confine action graphics to a single action whenever possible.
- Use a separate graphic for each distinct idea.

Graphics should be large enough to see the focal point and important words clearly. Use as few words as possible. Captions should tell readers what to look for in the illustration. Eliminate

detail that is not necessary. The clearest graphics have dark, sharp lines for good contrast. Line drawings and illustrations are clearer than photographs. Photos may have distracting extra images and poor contrast. Simple exploded views or cut-away views may be helpful. Use exploded views only for devices that the user should put together or take apart.

In instruction manuals, tables and graphs are normally not appropriate and their use should be minimized. If a table or graph is necessary, include instructions on its use. Label each table or graph clearly.

Apply the following to symbols and icons.

- A symbol is a sign or picture that has been developed to represent an idea. A symbol should be defined or explained because it doesn't mean anything by itself.
- An icon is a drawing that looks like the idea it is meant to represent. Use icons only with text to explain them.
- Use standardized symbols and icons, or those already understood by the general population. Make sure that your population understands the symbols that you use.

Do not use icons with commonly understood usages to illustrate examples inconsistent with those usages (e.g., a red octagon to indicate "go").

Warnings and precautions:

The purpose of this section is to:

- define and explain the terms *warnings* and *precautions*,
- discuss their use in medical device labeling,
- recommend approaches to effective presentation based on literature and research findings, and
- present some of the common issues associated with warnings and precautions.

Note: Labeling a device with warnings and precautions is the least preferable method of controlling accidents and injuries. You should make every effort to design the device so that the hazard is eliminated. Only when this is clearly impossible should you resort to a warning or precaution in the labeling. For instance, if the device may be made without toxic substances, this would be the preferred alternative.

What are warnings and precautions?

Warnings and *precautions* are written, pictorial, and/or audible alerts to a hazard. The term used to identify the particular hazard presents the reader with a cue to the seriousness of the hazard.

A warning alerts the reader about a situation which, if not avoided, could result in death or serious injury. [ANSI Z535.4-1998] It may also describe potential serious adverse reactions and safety hazards. The designation of a hazard alert as a “warning” is reserved for the most significant problems. The term **WARNING** is generally used as the signal word for this type of hazard alert. If a problem may lead to death or serious injury, FDA may expect you to highlight the warning by placing it in a box.

The term precaution is used for the statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. [ANSI Z535.4-1998] It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse. The word **CAUTION** is generally used as the signal word for a precaution statement.

The distinction between warnings and precautions is a matter of degree of likelihood and seriousness of the hazard. The target audience for medical device labeling (health care practitioners and lay users of home use devices) generally recognize a hierarchy of hazard alerts,

with warnings being those of a more serious nature and precautions being of a less serious, but important, nature.

What is the purpose of warnings and precautions in medical device labeling?

The basic purpose of a warning or precaution is twofold:

- to inform users of potential personal and environmental hazards, and
- to persuade them to modify their behavior to avoid injury or device damage.

For a warning or precaution to be effective, readers must:

- perceive the threat to be both severe and relevant to them,
- believe that they can perform the recommended response, and
- believe that response will be effective in avoiding the hazard.

Effective warnings and precautions capture the reader's attention, are understood, are consistent enough with the reader's beliefs and attitudes to be accepted, and are persuasive enough to motivate the reader to comply. They invoke an appropriate level of fear arousal, conveying the nature and extent of the hazard, without being so strong that they backfire, causing the reader to select an alternative action or no action.

What is appropriate content of an effective warning or precaution?

There are four elements generally recognized by the courts and research (See References – Warnings and Precautions) as necessary for an effective warning or precaution:

- **a signal word (WARNING, CAUTION)** to alert the reader that what follows is important hazard information. A symbol or icon may emphasize the effect of the signal word. Additional enhancement, such as bolding, larger type, underlining, italics, or color may help the information stand out from the rest of the text. However, studies have demonstrated that a large difference in font size between the signal word and the text may de-emphasize the importance of the text and therefore reduce the likelihood that the text will be read.
- **a hazard avoidance directive** in the form: **Do Not, Never, Avoid...**” (or **Do**, if more appropriate) followed by the action to avoid (or perform). The objective of this directive is to give clear instructions to the user on how to avoid the hazard.
- **a clear statement of the nature of the hazard** associated with the warning (e.g., allergic reaction to material, strong magnetic field) or precaution (e.g., environmental effect, damage from reesterilization) that characterizes the severity and the likelihood.
- **the consequences**, specifying the serious adverse events, potential safety hazards and limitations in device use that result if users do not follow instructions. The purpose is to

give them a clear idea of the risk, which is likely to increase compliance. Hazard alert research has shown that this element has a significant effect on readers. If the consequences are not included, the alert is likely to be less effective.

The signal word should appear first. The order provided here for the other three elements (hazard avoidance, hazard identification, and consequences) will be appropriate for most instances, but may be altered as necessary to best communicate the information to the reader.

How is an effective warning or precaution formatted?

No magic formula works in every instance. The writer must apply the principles discussed here for writing effective warnings and precautions as appropriate to the user and the device.

We suggest that you present warnings and precautions in “clusters” of issues that provide the reader with the information in the most logical and usable order for the particular device. For instance, a surgical device may have the warnings and precautions grouped, or clustered, into Preoperative Information, Intraoperative Information, and Postoperative Information, with appropriately highlighted headers. A home use device may have warnings and precautions grouped according to Setup, Calibration, Use, Storage, and Disposal. There are many possible groupings of this important hazard avoidance information, including the use of a “Before You Start” subsection for devices deemed to need a select and very limited group of warnings and precautions to be read before the device is handled at all. Within each cluster, we encourage you to prioritize the information by clinical significance. If there are no logical clusters or groupings of the hazard information, arrange warnings and precautions in order of clinical significance.

Warnings and precautions should be as concise and focused as possible while providing sufficient information. We recommend using bullets, rather than full sentences. Each bullet should contain a single item. We recommend against grouping a number of warnings or precautions in paragraph form. Users are more likely to read and comply with warnings or precautions presented in outline form using plenty of white space and consistent indentations, rather than paragraphs.

Additional approaches that can assist readers to notice, understand, and comply with warnings and precautions include:

- Integrating warnings and precautions into the task/hazard-related context. This increases the chance that the reader will encounter the information when he is most receptive to it.
- Using concrete rather than abstract terms and jargon. Frank language makes the writing more interesting and therefore more likely to be remembered. For example, say “Contact with this product will produce severe burns” rather than “Contact with this product will result in serious injury.”
- Using the simplest possible construction.

- Making each warning and precaution conspicuous. The use of white space and simple highlighting techniques can call attention to the warning or precaution. Do not bury this important information in extensive text.
- Standardizing terms and formatting across the labeling and, if possible, across products to increase consumer recognition.

Where should warnings and precautions be placed for maximum effect?

Research shows that hazard alerts are most effective when integrated into the task information at the most relevant location. Medical device labeling has traditionally contained separate sections for warnings and precautions. This approach predates much of the research into hazard alert effectiveness. However, there is a reluctance to abandon the placement of this important information in separate sections in medical device labeling because of user familiarity with this format. Some research has shown that short, well-highlighted warning messages can actually get users to read a set of longer, more detailed warnings in another section of the labeling. We recommend that warnings and precautions included in the separate sections be those that can be taken out of procedural context and still be effective.

Procedurally related warnings and precautions that cannot be taken out of context should be located with the associated procedural step. Research differs on the most effective location relative to relevant text, but placement immediately before the associated procedural task has been shown to be effective. We suggest considering this approach for warnings and precautions that are included in procedural instructions.

What other issues should be considered in designing warnings and precautions?

Because it is difficult to get readers to notice and read warnings and precautions, it is important to know what works with the target audience of the particular device. This is most effectively done by testing draft warnings and precautions on a sample of the target audience. Recommended testing points are when the labeling is being designed and again after it has been implemented. The latter testing can provide information to be used at the next labeling change.

Including too many warnings and precautions, over-warning, dilutes the strength of all of the hazard alerts. We recommend that writers use care in what is designated as a warning or precaution. Careless designation can have the same diluting effect as over-warning (e.g. “WARNING! Batteries not included.”). Repeated exposure to unnecessary hazard alerts (not relevant or already known) reduces the effectiveness of the important warnings and precautions.

We know that readability indexes can predict, but do not measure the reader’s actual ability to comprehend labeling. Because of the complexity of the process by which individuals interact

with hazard alerts, you should not rely on readability indexes to predict warning and precaution comprehension.

Appendix F

Pretesting:

What is pretesting?

Pretesting of medical device patient labeling is the systematic and formal gathering of target audience reactions to medical device patient labeling's content and format, before the medical device patient labeling is issued in final form. It is typically one of the evaluations conducted in the early stages of message development. Pretesting may assist you in:

- determining which of a number of labeling presentations is most effective for the intended audience and in identifying strengths and weaknesses in the presentation,
- identifying sensitive and controversial elements,
- revising and improving materials before distribution to users, and
- identifying the best method to distribute the labeling to the target audience.

What methods of pretesting the medical device patient labeling should be used?

Pretesting methods include methods such as individual in-depth interviews, focus group interviews, self-administered questionnaires, usability testing, and readability testing (See Appendix A Readability).

Pretesting can check the potential users' comprehension of the medical device patient labeling and their ability to follow instructions in the medical device patient labeling in order to operate the device. User-oriented testing helps to find places where the patient labeling may be inaccurate, incomprehensible, or poorly organized.

Individual in-depth interviews:

A potential user provides ideas and impressions of possible ways that the medical device patient labeling could be most effectively written.

Focus group interviews:

A small group of potential users, usually 8 to 10 people, discusses their perceptions, opinions, beliefs, and attitudes (POBAs) toward the medical device patient labeling. The discussion is guided by a skilled moderator.

Self-administered questionnaires:

Potential users are asked to review the medical device patient labeling, complete the written questions in the questionnaire about the medical device patient labeling, and return it within a specified time.

Usability testing:

The concept of *usability* refers to the extent to which people who use a product can use it quickly and easily to accomplish specific tasks. The usability of a product is composed of the combined usability of the product's sub-components, which can include hardware, software, menus, icons, messages, labels, manuals, reference materials, and software-based help. Consideration of the usability of a device may focus on all or some of these sub-components. For medical devices, patient labeling is often an important sub-component of usability considerations.

Usability testing is a technique designed to determine how usable a product is. This technique involves systematic observation of actual users trying out a product (or sub-component) and the collection of information from the users about aspects of the product that are easy and those that are difficult for them. Performing usability testing on medical device patient labeling materials involves the use of the device and its labeling materials by a group of intended users of the device. Data are then collected on how well the labeling materials support the users, how effectively they are able to use the device, how many and what kind of errors they make, and any difficulties they encounter.

From the perspective of medical device patient labeling reviews, it is desirable for you to demonstrate that labeling materials can be used safely and effectively through the application of *usability testing*. If usability test results are submitted, they can be used to assist the process of reviewing patient labeling. To the extent that safety concerns are adequately reflected in the test, these results can be considered an indication of the adequacy of the medical device patient labeling.

Checklist Summary:

Use this checklist to make sure that you have considered all the recommendations in this guidance.

The medical device patient labeling contains the following content:

- ❑ **Table of Contents**
- ❑ **Glossary**
- ❑ **Descriptive Information:**
 - ❑ Purpose of the device (indications for use)
 - ❑ Description of the device
 - ❑ When the device should not be used (contraindications)
 - ❑ Risks and benefits
 - ❑ Expectations of the device and the procedure associated with the device
 - ❑ General warnings and precautions
 - ❑ Importance of the need to adhere to a care regimen
- ❑ **Operating Information:**
 - ❑ Setup instructions
 - ❑ Checkout procedures
 - ❑ Operating instructions
 - ❑ Importance of the need to monitor the activity of the device
 - ❑ Cleaning instructions
 - ❑ Description of maintenance and who should do it
 - ❑ Storage instructions
 - ❑ Expected failure time and mode and its effect on the patient
 - ❑ Instructions on how to safely dispose of the device
 - ❑ Instructions on accessories
 - ❑ Instructions on related, additional devices
- ❑ **Troubleshooting Information:**
 - ❑ Troubleshooting
- ❑ **Additional Information:**
 - ❑ Clinical studies
 - ❑ Disease and self-care information
 - ❑ Adverse events
 - ❑ Warranty
 - ❑ Travel or international use
- ❑ **Index**
- ❑ **Date of Printing**
- ❑ **User Assistance Information**

The medical device patient labeling adheres to the guidance recommended for:

- ❑ Readability
- ❑ Writing for increased comprehension
- ❑ Appearance of text
- ❑ Appearance of graphics
- ❑ Warnings and precautions
- ❑ Pretesting

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VDA/BOD Point of Origin and Material Disclosure

Workgroup Discussion

By Drs. Dag Zapatero, and Scott Miller

1. Both the Virginia Board of Dentistry (BOD) and the Virginia Dental Association (VDA), agree that patient safety in the Commonwealth of Virginia is enhanced when a dentist obtains point of origin and material disclosure for all dental prosthetics prior to insertion. See Appendix 1 for NEW background information.
 - 1.1. The BOD requires dentist to be responsibility for obtaining POO and MD from ALL laboratories (in-state, out of state, and off-shore), in the fabrication of an appliances. BOD then places regulatory penalties on the dentist for failure to obtain POO and MD from the primary dental lab and/or the subcontracting lab selected, which is selected by the primary lab. The BOD advises dentist to document non disclosure by a lab and then asks them to find a new lab, in order to avoid penalties.
 - 1.2. The VDA bill would require ALL primary dental laboratories engaged in the fabrication of a prosthetic to register and provide the POO and MD to the prescribing dentist. The enforcement of the VDA plan is assured through a mandatory dental lab registration process, and by a second statutory requirement that dentist licensed by the Commonwealth of Virginia only do business with a BOD registered dental labs. Failure to comply with these regulation would result in actions being taken by the BOD, against a lab for non disclosure, or a dentist for using a non registered lab. Penalties include a reprimand, fines and potentially the loss of registration for flagrant violations.
2. The BOD approved prescription forms, are required for immediate use by all licensed dentist in Virginia. A secondary work order is now required when a lab subcontracts work to a third party lab (in-state, out-state or off-shore).
 - 2.1. BOD currently has authority to inspect any dental lab.
 - 2.2. The new BOD prescription forms are uniquely different from the standard prescription in use for more than 30 years, while the new work order form is an additional requirement for dentist and labs, expanding the minimum requirements under previous regulations.

- 2.3. Traditionally, dental laboratories have supplied the prescription form to their prescribing dentist. The new BOD regulations rendered hundreds of thousands of dollars in labs forms already printed obsolete, without allowing a transition time for conversion. This placed an undue burden on the laboratory business and drives up cost of doing business, specially for one person labs.
- 2.4. In contrast the VDA bill would allow the continued use of the older standard forms and not place any additional financial burden on dental labs by requiring a second work order form.
- 2.5. VDA Bill does not require subcontracting labs to register. Primary labs are responsible to providing POO and MD for the entire case.
- 2.6. Under the VDA plan, dental labs would be require to disclose POO and MD on the patient invoice accompanying a case as the necessary documentation for statutory compliance and for forensic discovery.
- 2.7. The VDA plan requires ALL primary dental labs to register with the Commonwealth of Virginia. This gives clear regulatory governance by the BOD on the dental labs that have registered. In contrast, the BOD does not currently regulate dental labs and thus it is not clear how they can require any dental lab to use the new work order form for in obtaining POO and MD from a third party lab.
- 2.8. The BOD prescription requires prior notification if any 3rd party labs (subcontractor) is utilized. No such requirement in the VDA bill.
- 2.9. Patient management software generated lab prescriptions, like those from Dentrax, are on the rise and are the future. According to Karen Kraus of Henry Schein Dental there are about 1100 active Dentrax Software users in Virginia, consisting of both single and multi doctor practices. These electronic prescriptions are not customizable and would not be permitted under current BOD regulations. Dentrax prescriptions would be allowed under the VDA bill since it only requires the minimum requirements on a prescription form to obtain POO and MD. SEE APPENDIX 2.
- 2.10. Neither the VDA nor BOD plans specifies what materials need be disclosed by the dental labs. Are all materials used in fabrication to be disclosed? Or just those contacting the patient's tissues or exposed to the oral environment?
- 2.11. BOD forms indicates that no more that 200 ppm of lead should be contained in the dental prosthetic according to FDA guideline. What happens if the FDA changes its number? Will it be necessary to re-issue new forms immediately?

3. Registration requirements and stats in other states;
 - 3.1. Oklahoma and Pennsylvania require lab registration without POO or MD requirements.
 - 3.2. The Ohio and Illinois prescription form require POO and MD without registration requirements SEE APPENDIX 3 for Ohio form.
 - 3.3. Three states; Texas, South Carolina, and Florida currently require laboratory registration, POO and MD. SEE APPENDIX 4
 - 3.4. The following are the numbers of registered labs in the states that require registration:
 - *Texas reported - 950
 - *Florida reported - 1083
 - *South Carolina reported - 125
 - Oklahoma reported - 146
 - Pennsylvania reported - 350
4. Proposed application and registration requirements for dental labs.
 - 4.1. Name of the dental lab or DBA name
 - 4.2. Name and contact information of the dental lab owner.
 - 4.3. Name of any, and all officers if incorporated.
 - 4.4. Copy of the current business license.
 - 4.5. Address of the primary location and any location where work is performed.
 - 4.6. Oath statement
 - 4.7. A fee of no more than \$200 payable every two years.
 - 4.8. SEE APPENDIX 5 FOR DENTAL LAB REGISTRATION APPLICATION FORMS for TX, OK, FL, SC, and PA.
 - 4.9. All registered dental labs would appear on a website maintained by the BOD or an administrator approved by the BOD. SEE APPENDIX 6 FOR SAMPLE OKLAHOMA APPROVED DENTAL LAB REGISTRANTS WEBSITE.

- 4.10. BOD can list newly registered labs and delisted labs on the communications newsletters. It would be up to the BOD to make the de-listing of a lab part of public record.
5. Complaints driven process is used to inspect a lab or dentist for statutory compliance.
 - 5.1. The VDA and BOD agrees that it is the dentist who is ultimately responsible for attaining POO and MD.
 - 5.2. However, if a dentist cannot obtain the required disclosure information from a lab, it would be up to the dentist to file a complaint with the BOD, and provide the BOD with the evidentiary materials for case investigation.
 - 5.3. Labs or patient complaints would not be accepted under the VDA plan since the burden of reporting is up to the dentist. All complaints would be centered on POO or MD. The VDA plan does not require any disclosure, POO or MD to the patient.
 - 5.4. If a dentist were undergoing a BOD investigation and under the normal course of the investigation it were revealed that a lab was not disclosing POO or MD on a patient invoice then both the lab and dentist would be subject to disciplinary action. Same would take place if a dentist were using a non registered lab in the fabrication of a dental prosthetic.
 6. Proposed forensic investigation of dental labs.
 - 6.1. BOD regulation currently allow for inspection of ALL dental labs.
 - 6.2. VDA bill does have a statement on OSHA compliance which is negotiable to VDA member if this will cause compliance issue for the BOD.
 - 6.3. The VDA bill would require registered dental labs to provide POO and MD on the patient invoice accompanying the patient case.
 - 6.4. In the case of a subcontracting lab, the subcontracting lab would not be required to register with the BOD and thus not responsible for providing POO or MD. It would be up to the primary lab to disclose both POO and MD for the subcontracting lab if they are not registered.
 - 6.5. We foresee the investigation of dentist complaints to solely center on the patient invoice.

- 6.5.1. BOD investigator would visit the complaining dentist to start the discovery process and enter the patient invoice as evidentiary material for the lack of POO and/or MD.
- 6.5.2. The BOD investigator would limit the scope of their visit to obtaining evidence solely pertaining to the investigation of the complaint, including reading/copying the patient chart and looking at the lab invoice for the treatment in question.
- 6.5.3. If however a BOD investigator appears at a dental office to investigate a patient complaint then all instances of non compliance by the dentist or a lab are subject to disciplinary review and action.

7. Penalties for non compliant labs.

- 7.1. First offenses can be handles with a registered letter from the BOD asking the lab to comply.
- 7.2. A secondary offense may result in a fine.
- 7.3. The third offense can result in an inspection of labs located within the Commonwealth and/or a fine.
- 7.4. The forth offense may result in the lost of BOD Registration and listing on BOD approved labs. The lab would also loose any fee already paid for prior registration.

8. Penalties for non compliant dentist.

- 8.1. A dentist is subject to the BOD disciplinary action if he/she is found to contract a lab not on the approved BOD registration list.

9. Exemptions

- 9.1. Under the VDA bill any lab located in a dental office doing work for the dental practice of which he is an employee is exempt from these regulations.
- 9.2. Dentist and dental labs in dental school or involved in an educational setting are exempt.
- 9.3. Dentist and dental labs working a a free dental clinic or a public health department is exempt.

10. Re-applying for laboratory registration

10.1. A dental lab will be allowed to re-apply for registration if it is operating under a new name and can no longer use the old name in any form.

10.2. A new application fee would apply.

10.3. If a dental lab loses this registration 3 times it's owner will no longer be able to apply for registration.

11. More work is necessary to determine what procedures and specialities would be required to disclose POO and MD.

11.1. A timeline for the implementation of the regulations once the VDA bill is approved by the legislature.

11.2. Discussion needed to determine if POO and MD is necessary for;

11.2.1. Orthodontist/General Dentist who prescribe or place orthodontic appliances in the mouth, i.e. braces, retainers, Invisalign.

11.2.2. Where do sleep apnea appliances fall?

11.2.3. Would oral surgeons be exempt with they have bone or facial prosthetic fabricated by a third party and inserted in a patient (screws, pins, chin implants etc.)?

11.2.4. What place do proprietary prescription have under the BOD and VDA plan? Particularly with implant/crown/Invisalign milling centers? It seems that electronic prescriptions are more easily integrated under the VDA plan since it does not state and particular form be used.

11.3. What materials need to be included in the MD? Are the FDA material registration numbers the standard?

11.4. What information needs to be revealed about the subcontractors to the dentist on POO?

12. What others have reported about VDA bill.

12.1. See APPENDIX 7 FOR MY CALL LOG.

Appendix 1

The Globalization of the Dental Laboratory Industry

The current state of the American Dental Laboratory industry is of great concern to professional leadership, yet remains vaguely understood by the average clinician.

The purpose of this Perspectives feature is to shed light on the issues affecting patient safety and professional liability.

I have enlisted the expertise of the Executive Director of the National Association of Dental Laboratories (NADL), Mr. Bennet Napier, CAE. He is an expert on this topic and served as an invaluable resource for hard data on this subject.

LABOR SHORTAGE

The rapidly diminishing labor pool of qualified technical talent is at a catastrophic level. This decline has led many larger stateside laboratories to develop in-house training programs to develop their workforce from introductory to advanced levels. Unfortunately, this practice is restricted to the individual lab and has little consequence on the profession overall.

U.S. INDUSTRY STATISTICS—2010

Technicians

- 33,600 dental technicians (down from 43,000 in 2008)
- 6,500 Certified Dental Technicians

Source: NADL Market Research, US Census Data, US Department of Labor/Bureau of Labor Statistics

Average Age of Remaining Techs by Specialty

Unfortunately, there is no good source for this question, although the NADL intends to survey the market in 2012 to gauge the average age. What we do know with certainty is that the smallest pool of dental technicians (trained) are in removable and orthodontic services.

Laboratories

- 10,000 dental laboratories (down from 13,500 in 2008)
- 1,600 NADL members
- Nearly 80% of NADL members are small laboratories
- 6,000 laboratories have a single technician
- \$632,000.00 in average annual gross sales per dental laboratory nationally*

Source: NADL Market Research, US Census Data, US Department of Labor

Disappearing Accredited DLT Programs

This problem is compounded by the fact that no backfill of talent is in the academic pipeline. The number of Accredited Dental Laboratory Programs in the United States has dropped from 58 in 1989 to 18 today, graduating approximately 350 students a year.

Reduced Military Dental Technology Training

According to Col Richard J. Windhorn, Commander of the US Army Dental Laboratory, The US Armed Forces trained an annual average of 800 technicians in 1993. That number today is reduced to 128 new technicians per year for all three federal services.

In the past, many of these individuals retired into the private sector as faculty in accredited programs as well as technicians and managers in many laboratories across the country. Now that strong talent pool has been reduced.

Lack of Adequate Advanced Training

Advanced training has been largely restricted to the area of esthetic dentistry. The manufacturers' interest in marketing and selling products has fostered a great deal of high-level education for ceramists from the well-known specialized institutes and professional

PERSPECTIVES

1 organizations. The Advanced Esthetic Dentistry for
2 Ceramist Technicians program led by Dr. Ed McLaren
3 at UCLA is an excellent example of what can be done.
4 The American Society of Master Dental Technologists
5 program at NYU is a regional effort that provides an
6 opportunity for advanced training. LSU provides a
7 unique learning environment allowing the technician to
8 team with dental students working directly with
9 patients in restoring cases.

10
11 These excellent programs are far too few in number to
12 meet the future needs of the profession.

OFFSHORE PRODUCTION

13
14
15
16 Easily accessible worldwide shipping networks have
17 opened markets for all types of medical devices. As is
18 typical, the dental market trails medicine due to the
19 smaller comparative sales volume. Indirect dental
20 restorations are now a major focus of manufacturers in
21 countries with significantly lower labor costs. Extremely
22 large operations employing up to 4,000 people now
23 exist in Southeast Asia. These entities vary greatly in
24 quality and materials used for fabrication. That being
25 said, it is foolish to assume that all of these laboratories
26 do substandard work.

1ST Major Dental Manufacturer Purchases Offshore Laboratory

27
28
29
30
31 The recent purchase of at least one of these operations
32 by a highly reputable US-based dental manufacturer is
33 of interest. Their reasoning for the purchase was to
34 reverse the loss of sales of their ADA accepted
35 materials in that market. They control all materials used
36 to meet ADA accepted status. The objective is to
37 provide a reliable outsource option exclusively for their
38 dental laboratory customer base in this rapidly
39 developing market segment.

Direct Sale of Offshore Restorations into Local Markets

40
41
42
43 Another, more alarming scenario of definite concern to
44 US laboratories is a Southeast Asian manufacturer that
45 has set up facilities in major US cities and sells directly
46 to dentists only.

FDA REGULATION

47
48
49 The FDA is faced with an overwhelming volume of
50 medical device imports and ridiculously low resources
51 for adequate enforcement.

Import Posture for FDA

- Fiscal Year 2010: 20 million shipments of FDA
regulated imports 52 53 54 55 56
- US Government Accountability Office report to
Congress in 2010 indicated only 8% of shipments
are being inspected 57 58 59
- Budget request for additional \$70 million in funding
to increase at-port inspections of imported products 60 61 62

Appropriate Disclosure

63
64
65 An alarming number of US laboratories are selling
66 offshore work to dentists without proper disclosure.
67 The FDA has regulations in place that require
68 disclosure of the origin of fabrication in the packaging
69 of the restoration in a conspicuous place. The
70 regulations also include any part of the process,
71 preventing laboratories from subcontracting the
72 majority of the process and “finalizing” stateside
73 without proper disclosure.

Dental Crowns Being Made Overseas

- ❖ 2006 Total Domestic Crown and Bridge Market was
33,458,641 units, manufactured offshore 6 million units
(17%) 74 75 76 77 78 79
- ❖ 2008 Total Domestic Crown and Bridge Market was
37,214,886 units, manufactured offshore 10 million
units (26%) 80 81 82
- ❖ 2010 Total Domestic Crown and Bridge Market was
39,476,350, manufactured offshore 15 million units
(38%) 83 84 85
- ❖ *Source on Total Units: iData Research 2010, Import
Trade Data from US FDA* 86 87
- ❖ *Source on Number of Units Manufactured Offshore:
NADL Cost of Doing Business Surveys, 2006, 2008,
2010 (sample of 1,000 US dental laboratories on* 88 89 90

1	offshore production or outsourcing) as conducted by	has put out a mandate that employers increase worker	46
2	Valmont Research	wages by 20% over the next 5 years.	47
3			48
4	Dental Laboratory Data for Import	Two Examples of Many Major Asian Laboratories	49
5	Restorations 2010		50
6		Laboratory 1	51
7	❖ (NAICS) codes comprise the medical devices	The majority of their customer base is Europe. Only	52
8	industry that is covered by the Office of Health and	10% of export sales are to the United States currently.	53
9	Consumer Goods (OHCG) Based on FDA 2010 data,	Their push into the US market started in 2009. Their	54
10	total medical device imports for the U.S. was \$33 billion	sales have reportedly grown 20% since 2010. The	55
11	❖ According to the FDA data, Dental laboratories	business model is to grow their footprint in the U.S.	56
12	(NAIC 339116; account for about 4% of import total	through laboratory acquisition and opening additional	57
13	measured by value of shipment (VOS) include crowns,	sales centers. They currently have operations in	58
14	dentures, bridges, and other orthodontic products.	Washington, California, Massachusetts, and Illinois.	59
15	❖ Four percent equals \$1.32 billion. If you use NADL		60
16	data on US lab sales, the percentage is 20%. Again, this	At the main Asian manufacturing location, there are	61
17	is percentage of sales not units. If you use units as the	reportedly 2,000 technicians working two shifts a day	62
18	measure based on average offshore price point, it is	(last shift ends at 11 pm or midnight). Campus is	63
19	estimated to be 35% of units.	20,000 m ² .	64
20			65
21	The Offshore Outsource Market	To our knowledge, as of September 2011, they had not	66
22		been inspected by the US FDA. Reportedly, they have	67
23	Outsourcing from an Asian perspective started in	been inspected regularly by the French FDA equivalent.	68
24	Singapore with several entrepreneurs developing		69
25	outsourcing labs to meet a market demand for	They recruit technicians primarily from the	70
26	insurance based programs for the German market.	countryside. They have an extensive training process,	71
27	Most export labs in Asia are actually owned by	and students get paid during the training process.	72
28	Taiwanese, not native Chinese. The Chinese	Nearly 50% of students stay on after the initial training.	73
29	government provides tax incentives for export labs.	After 3 years, 30% of the class is still employed there.	74
30	In most cases, gross sales are tax exempt for the first		75
31	2–3 years. The government also provides tax incentives	Laboratory 2	76
32	for employee training and recruitment.	This laboratory reportedly receives 6,500 units per	77
33		week. This laboratory sells PFMs at an average price of	78
34	There are approximately 25 large export labs in Asia.	\$35.00. Other emerging markets like Vietnam are home	79
35	However, with that said, there are over 30 countries	to export labs selling crowns at \$12–15. At a \$12–15	80
36	with foreign dental laboratories importing work into the	price point, one could speculate that FDA-approved	81
37	United States, and there are over 75 export laboratories	materials are not being used.	82
38	in China registered to import into the United States.		83
39		There is discussion of subcontracting cases to	84
40	The majority of dental technicians in this area are	laboratories in lower priced markets (Thailand) to	85
41	female and between the ages of 18–25. A typical career	control their rising labor costs. This practice is further	86
42	duration in the large labs is 7–8 years. After that,	evidence of the globalization of the industry. They	87
43	technicians may leave and go back to their hometowns	also are reportedly planning to acquire several	88
44	to practice dental technology in domestic labs. China is	\$5-million-dollar-sized US labs to be stateside regional	89
45	currently facing 15% inflation. The Chinese government	customer service/distribution centers.	90

PERSPECTIVES

CONCLUSIONS

The factors presented in this paper combined with a sagging global economy and continuously increasing third-party reimbursement sources are creating previously unseen downward price pressure on the world laboratory market. This observation does not bode well for the short-term resolution of the US laboratory academic crisis. Investment from organized dentistry and the manufacturing community are crucial but perhaps unrealistic requirements to turn this tide.

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***Dentistry*, and serves as Director of Professional Services for Drake Precision Dental Laboratory in Charlotte, NC**

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Launch Lab Work into the Cloud with DDX



With today's stable ISP bandwidth and operating platforms, more and more companies are working "in the cloud" and enjoying capabilities like online data storage, instantaneous file sharing across multiple users and geographies and universal access to information that keeps businesses running. For many dentists, however, concerns about security, HIPAA compliance and training are slowing adoption of cloud technologies.

Fortunately for Dentrix users, they are already using cloud-ready Henry Schein products and services like eClaims and, more recently, Dentrix Mobile and Henry Schein DDX.



Henry Schein DDX makes lab case management easier

This powerful tool allows dentists to submit new prescriptions to their labs right from Dentrix. With just a few clicks, they can pull images and files from various networks and create one web-accessible case—then share lab case information, collaborate on case design and manage account details like payments and statements. Even better, all this detail is integrated with digital restoration technologies dentists use every day, like Dental Wings and E4D.

DDX is built and delivered online with no software installation necessary. Dentrix users can start their first case with a DDX-enabled lab in seconds. When they click the **DDX** button in the patient's chart and select **New DDX Lab Case Prescription**, a lab prescription is pre-populated with that patient's info (Figure 1). The digital lab prescription can be sent to any lab from any web browser, with imaging files of any size attached.



Figure 1. Create a lab prescription with just one click in a patient's chart.

Once a dentist submits the prescription, the DDX-enabled lab receives an automatic alert that the case is coming (or, if the practice chooses, the lab receives an automatic pickup request). Practices can even schedule the patient's follow-up appointment right in the chair, as DDX instantly generates an accurate turnaround date based on the lab's real-time production calendar (Figure 2).

Schedule a New Case

Patient Details

First Name: Eric
 Last Name: Crosby
 Gender: Male
 Patient Chart: CR0200
 Birth Date: Nov 11, 1970

Work Requested

Send Date: Apr 11, 2011
 Procedure: Select Procedure
 Enclosures: Select options
 Other: Try-in, Emerg, Files

Notes

I accept all Terms and Conditions
 Submit Case

Figure 2. Prescription information like return date and status is automatically updated online and viewable by your practice and the lab.

With just a few clicks, the lab case and all its related information are viewable by dentist and lab at any time—trackable, transparent, with any needed files attached. The best part? DDX is completely free for dentists.

Digital lab case management with DDX: How is it working?

Dental practices submitted over 35 million lab cases in the US in 2009. Given a total caseload of 20 to 50 cases per month per dentist and hundreds or thousands of cases per month per lab, DDX

improves a critical aspect of the patient experience. It allows for easy case collaboration for both dentist and lab, while significantly reducing phone calls, lost staff time and costly rebookings that slow patient flow for dentists and production for labs. Because many dentists work with multiple labs, and most labs work with many dentists, these teams can now log in and view a centralized case record, with no lost reporting time to patients, lab managers or doctors.

In March 2011, a survey of DDX-enabled practices found that 67% of practices saw around a 30% reduction in phone time for their staff after implementing DDX. That's time those employees can now dedicate to managing their current job responsibilities, improving production and customer service, or even to making outbound marketing efforts to generate new business.

With the responsive, flexible customization platform of DDX, practices and labs can agree on the criteria required for a case and then standardize that criteria so no incomplete prescription can ever be submitted. This partnership has led to better service for both dental practices and labs.

Put DDX and the cloud to work for you today

Using DDX is a smart step toward harnessing the power of cloud computing and delivers needed changes fast, inexpensively and with measurable results. DDX provides dentists and labs with a universal network to communicate using technologies they already have, which will help practices prepare for other changes in the future as they move toward paperless practice management.

It's important to realize that, as with any new service, labs and dentists will need to work together to implement digital processes that enhance, not impede, their current workflow. If your lab doesn't yet use DDX, it's very easy to get them on board. Simply send their info to the DDX team at www.DDXDental.com/Suggest_a_Lab, and the DDX team will follow up. Or, you can search for and send cases to labs in your area that are already DDX-enabled at www.DDXDental.com/Find_a_Lab. To get started today or to suggest that your lab become DDX-enabled, visit www.DDXDental.com/Dentists.

The screenshot displays the DDX Case Manager interface for Case #109. The interface includes a navigation bar with 'Portal', 'Mike's Case Manager Demo Laboratory', 'Cases', and 'Finances'. The main content area shows case details for Case #109, including a 'New case received' notification, a 'Print' button, and a 'Cancel' button. Key information includes: Back from Lab Date (Mar 11, 2011), Send to Lab Date (Feb 10, 2011), Provider (Dr. William Macdonald), Patient (Burns Kimball), Patient Appointment (Not Entered), and Status (Online Case in Progress). A 'Work Requested' table shows 1 unit of Porcelain fused to Metal (*). The interface also features a 'Patient Appointment' section with 'Date' and 'Time' fields, and a sidebar with options like 'Reschedule Case', 'Add Procedure to Case', 'Case Note', and 'Attach Files'.

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Figure 3. Prescription information like return date and status is automatically updated online and viewable by the practice and the lab.

Author: Holly Holm
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APPENDIX 3

Ohio State Dental Board Laboratory Prescription & Point of Origin Form

<u>Today's Date</u>	<u>Try-In Date</u>	<u>Finish Date</u>
<u>Patient Name</u>	<input type="checkbox"/> Male <input type="checkbox"/> Female	<u>Age</u>
<u>Type of Restoration</u>		
<u>Dentist Name</u>	<u>Signature</u>	
<u>DDS/DMD License #</u>	<u>Phone</u>	
<u>Dentist Address</u>	<u>City/State/Zip</u>	
<u>Lab Name</u>	<u>Phone</u>	
<u>Lab Address</u>	<u>City/State/Zip</u>	

TYPE OF RESTORATION

- | | |
|--|--|
| <input type="checkbox"/> Porcelain to High Noble
<input type="checkbox"/> Porcelain to Noble
<input type="checkbox"/> Porcelain to Base Metal (NP)
<input type="checkbox"/> Full Metal High Noble
<input type="checkbox"/> Full Metal Noble
<input type="checkbox"/> Full Metal Base (NP)

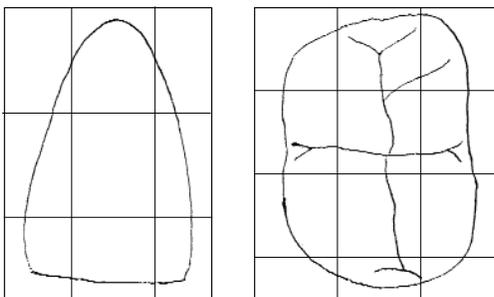
<input type="checkbox"/> Max Full Denture
<input type="checkbox"/> Mand Full Denture
<input type="checkbox"/> Max Partial Denture
<input type="checkbox"/> Mand Partial Denture | <input type="checkbox"/> All Ceramic (specify) _____

<input type="checkbox"/> All Composite (specify) _____

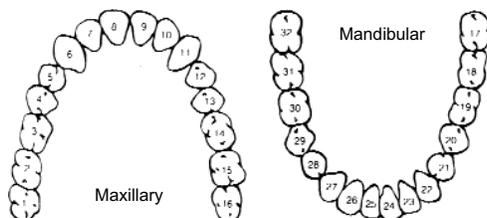
<input type="checkbox"/> Other (specify) _____

Pontic Design (circle)
 |
|--|--|

CUSTOM SHADING



PARTIAL



INSTRUCTIONS

SHADING

DENTAL RESTORATION POINT OF ORIGATION FORM

Attention Lab: Complete this section and return to doctor when case is received.

<u>Doctor Name</u>	<u>Patient Name</u>
--------------------	---------------------

This case will be: Fabricated by technicians at our own dental laboratory.

Sent to another laboratory in the U.S. to be fabricated:

<u>Lab Name</u>	<u>Location</u>
-----------------	-----------------

Sent to an overseas/foreign laboratory to be fabricated:

<u>Lab Name</u>	<u>Location</u>
-----------------	-----------------

Materials to be used in fabrication:



Duplicate copy should be kept in the patient's record

4715-5-02

Written work authorization.

- (A) The Ohio state dental board hereby prescribes that the written work authorization required in division (B) of section 4715.09 of the Revised Code shall be on printed forms for both original and copy and shall contain the following:
- (1) The name and address of the entity or person to whom the written work authorization is directed, hereinafter referred to as "primary contractor".
 - (2) The patient's name and/or identifying number. In the event such identifying number is used, the name of the patient shall be written upon a copy of such written work authorization retained by the dentist.
 - (3) A description of the work to be done, with diagrams if applicable.
 - (4) A description of the type of the materials to be used.
 - (5) The actual date on which the authorization was written.
 - (6) The signature in ink by the dentist issuing the said written work authorization, his state dental license number and his office address.
 - (7) A section to be completed by the primary contractor and returned to the issuing dentist that shall disclose all of the following information and certify that the information is accurate by including the signature of a responsible party of the primary contractor:
 - (a) A list of all materials in the composition of the final appliance;
 - (b) The location where the appliance was fabricated, including the name, address, phone number and FDA registration number, if applicable, of the person or entity performing the work;
 - (c) The location, including name, address, phone number and FDA registration number, if applicable, of any sub-contractors utilized to perform some or all of the services relative to the fabrication of the appliance;
 - (d) A description of all disinfection methods used in the fabrication of the appliance.
- (B) Upon request, the dentist shall provide each patient or authorized patient representative with a duplicate copy of the section of the form described in section (A)(7) of this rule.

~~(B)~~(C) The dentist shall retain a copy of the written work authorization for two years from its date as a part of the patient record.

~~(C)~~(D) The primary contractor~~unlicensed person, partnership, association, or corporation~~ shall retain the original work authorization for two years from its date. Copies of work authorization forms shall be open for inspection by the Ohio state dental board and its investigators.

~~(D)~~(E) If the primary contractor~~unlicensed person, partnership, association, or corporation~~ receiving a written work authorization from a licensed dentist engages another unlicensed person, partnership, association, or corporation (herein referred to as "sub-contractor") to perform some of the services relative to such work authorization, as provided for in division (C) of section 4715.09 of the Revised Code, he or it shall notify the issuing dentist in advance of the fabrication of the appliance of the name and location of the subcontractor and shall furnish a written sub-work authorization with respect thereto on forms prescribed by the state dental board, which shall contain the following:

The sub-contractor shall retain the sub-work authorization and the primary contractor shall retain a duplicate copy, attached to the work authorization received from the licensed dentist, for inspection by the state dental board or its duly authorized agents, for a period of two years. Copies of work authorization forms shall be open for inspection by the Ohio state dental board and its investigators.

~~(1) The name and address of the sub-contracting entity or person to whom the work authorization is directed.~~

~~(2) A description of the work to be done, with diagrams if applicable.~~

~~(3) A description of the type of materials to be used.~~

~~(4) The actual date on which the written work authorization was written to the sub-contractor.~~

~~(5) The name, address, and signature of the entity or person issuing the sub-work authorization.~~

~~(E) The sub-contractor shall retain the original sub-work authorization and the entity engaging the sub-contractor shall retain a duplicate copy of the sub-work authorization, attached to the written work authorization received from the licensed dentist, for a period of two years.~~

~~(F) All written work authorizations and sub-work authorizations required by paragraphs (B), (C), and (E) of this rule, held by the dentist or unlicensed person, partnership,~~

~~association, or corporation shall be open for inspection without a subpoena for two years by the state dental board, its authorized agents, or the prosecuting attorney of a county or the director of law of a municipal corporation wherein the written work authorizations or sub-work authorizations are located.~~

~~(G) The Ohio state dental board hereby prescribes that the demand for a written work authorization in division (D) of section 4715.09 of the Revised Code, be made in writing. The unlicensed person shall retain a copy of the original written demand for a written work authorization form for a period of two years. Copies of work authorization form demands shall be open for inspection by the Ohio state dental board and its investigators.~~

~~(H)~~(F) The foregoing does not prohibit the inclusion of additional information on the written work authorization when the same is necessary or desirable.

~~(G)~~(G) "Unlicensed person, partnership, association or corporation" as used in this rule, includes, but is not limited to, dental laboratory or dental laboratory technician.

(H) "Appliance" as used in this rule, includes, but is not limited to, any denture, plate, bridge, splint, crown, veneer, or orthodontic or prosthetic dental device.

Effective: 10/01/2008

R.C. 119.032 review dates: 07/10/2008 and 02/28/2013

CERTIFIED ELECTRONICALLY

Certification

09/18/2008

Date

Promulgated Under: 119.03
Statutory Authority: 4715.03
Rule Amplifies: 4715.09
Prior Effective Dates: 9-30-70; 4-27-98; 5-15-03

APPENDIX 4

Dental Laboratory Regulations by State		Updated May 2011									
	Texas	Missouri	South Carolina	Kentucky	Illinois	Florida	Oklahoma	Ohio	Pennsylvania		
Year of Initial Enactment	1985	1995	1942	1977	1993	1987	1992	2008	1987		
Laboratory Registration Fee	\$105.00 Annually		\$102.00 Annually	\$50.00 Annually*		\$200.00 Every 2 yrs	\$200.00		\$200.00		
Laboratory Registration	Yes	No	Yes	Yes*	No	Yes	Yes	No	Yes		Yes
Technician Registration Fee	No	No	\$100 initial \$102 on renewal	\$10.00*	No	No	No	No	No		No
Registration of Technician Employees	No	No	No	Yes*	No	No	No	No	No		No
Requirement to Provide # of Employees	Yes	No	No	Yes*	No	No	No	No	No		No
Certificate to Perform Dental Technology	No	No	Yes**	Yes*	No	No	No	No	No		No
CDT or Equivalent Required	Yes	No	Yes	Yes	No	No	No	No	No		No
State Laws and Rules Exam Required	No	No	Yes	No	No	No	No	No	No		No
Out-of-State Laboratories Required to Register	Yes	No	Yes	Yes*	No	No	No	No	No		No
Dentists Required to Use Registered Laboratory	Yes	No	Yes	Yes*	No	No	No	No	No		No
Material Disclosure	No	Yes	Yes	No	Yes	Yes	No	Yes	No		No
Point of Origin Disclosure	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No		No
CE for One Technician in each Laboratory	Yes	No	Yes	Yes	No	Yes	No	No	No		No
Laboratory Registration legislation has previously been filed in: Alabama, Minnesota, New York, New Jersey											
NOTES:											
* Kentucky repealed in 2010 re-enactment anticipated during the 2012 legislative session											
** The certificate to perform dental technological work in SC requires each of the following: HS or GED; 2 year DT degree or 3 years OJT; CDT or pass SC state board; and pass SC laws and rules exam											

APPENDIX 5



Application for Registration of a Dental Laboratory

TEXAS STATE BOARD OF DENTAL EXAMINERS
 333 Guadalupe, Tower 3, Suite 800
 Austin, Texas 78701-3942
 Phone: (512) 463-6400 / Fax: (512) 463-7452
 Website: www.tsbde.state.tx.us
 E-Mail: information@tsbde.state.tx.us

Instructions: Submit a copy of your SBDE Jurisprudence Assessment for Dental Laboratory Initial Registration Certificate of Completion with this application. (www.tsbde.state.tx.us/Jurisprudence)

Mail your application package to the SBDE at the address listed above. All incomplete applications will be returned with no action. Fee is Non-Refundable. Make your payment to the Texas State Board of Dental Examiners.

If a question does not apply, indicate "N/A". **Have Questions?** Visit our website at: www.tsbde.state.tx.us

FEE: \$105

PERSONAL CHECK OR
MONEY ORDER ACCEPTED

DO NOT WRITE IN THIS SPACE

DLCC Review: _____

LABORATORY INFORMATION

Each Lab must register separately. In-house labs which do work ONLY for their employing dentist are not required to register or pay fees to the SBDE.

LAB NAME: _____ DBA: _____ <small>(If Applicable)</small> MAILING ADDRESS: _____ CITY/ COUNTY: _____ STATE: _____ ZIP: _____ LABORATORY TELEPHONE: _____ LABORATORY IS: _____ SOLE OWNER _____ DENTAL OFFICE _____ PARTNERSHIP _____ *CORPORATION	OWNER NAME: _____ MAILING ADDRESS: _____ CITY/ COUNTY: _____ STATE: _____ ZIP: _____ OWNER'S TELEPHONE: _____ DATE LAB OPENED OR WILL OPEN FOR BUSINESS: _____
---	---

IF CORPORATION THE STATE IN WHICH INCORPORATED: _____

IF SUBSIDIARY CORPORATION, GIVE NAME OF PARENT COMPANY, STATE IN WHICH CORPORATED, AND PERCENT OF STOCK PARENT COMPANY OWNS IN SUBSIDIARY

Parent Company	State Incorporated	% Stock Owned
----------------	--------------------	---------------

EMPLOYEE INFORMATION	NUMBER OF TECHNICIANS EMPLOYED: _____	NUMBER OF SUPERVISORS: _____
	NUMBER OF NON-TECHNICAL EMPLOYEES: _____	TOTAL NUMBER OF EMPLOYEES: _____

OWNER / MANAGER INFORMATION

• **Has the owner or manager ever been convicted of a misdemeanor or felony?** Yes _____ No _____ If Yes, explain and provide court disposition documents:

• **Has the applicant ever held a laboratory registration in Texas?** If Yes, provide the following information:

Owner Name: _____	Manager Name: _____	Texas Lab Registration #: _____
Lab Name: _____	DBA (If applicable): _____	
Lab Address: _____	City	State
Number and Street		Zip Code

I, the applicant herein, state that all the facts, statements, and answers contained in this application are true and correct. I am not omitting any information which might be of value to the Board in determining my qualifications, whether it is called for or not. I agree that any falsification, omission, or withholding of pertinent information or facts concerning my qualifications as an applicant shall be sufficient to bar me from registration by the State Board of Dental Examiners and such falsification, omission or withholding shall serve as sufficient grounds for the revocation, cancellation, or suspension of my Texas Laboratory Registration if it is not discovered until after issuance.

STATE OF _____	Name and Title _____	Notarized Signature of Laboratory Owner or Manager (Required) _____	Date _____
COUNTY OF _____			

Before me, the undersigned authority, on this day personally appeared the applicant whose signature appears above and who being by me sworn upon oath says that all the facts, statements and answers contained in this application are true and correct.

Sworn and subscribed to before me, the said _____ this the _____ day of _____, 20____, to certify which witness my hand and seal of office.

(Seal)

NOTARY PUBLIC SIGNATURE

CERTIFIED DENTAL TECHNICIAN INFORMATION

(This section to be completed by the CDT of Record)

Section 266 of the Dental Practice Act requires that in order to qualify for registration by the SBDE, a commercial laboratory must employ a Certified Dental Technician, who must be on premises at least thirty (30) hours per week.

ACCEPTABLE PROOF OF CDT WILL BE A COPY OF THE CURRENT CDT CERTIFICATION CARD WITH THE EXPIRATION DATE INDICATED.

I, _____, will be the designated
(NAME)

Certified Dental Technician (CDT) of record for the following dental laboratory:

(NAME OF DENTAL LABORATORY)

I understand that the Texas State Board of Dental Examiners (SBDE) Rules and Regulations require that I, as a the designated CDT, must be on premises of this laboratory a minimum of thirty (30) hours per week and that I may be asked to attest that I meet the requirement.

My CDT credential is active and currently registered with the National Board of Certification (NBC).

I am attaching a copy of my card with this application and acknowledge that it will be verified by a member of the SBDE staff.

If I cease employment with the laboratory, I understand it is in my best interest to immediately notify the SBDE of the change so my CDT credential can be removed from this laboratory registration.

All facts stated herein are true and correct to the best of my knowledge.

Date

Certified Dental Technician Signature

STATE OF _____

COUNTY OF _____

Before me, the undersigned authority, on this day personally appeared the applicant whose signature appears above and who being by me sworn upon oath says that all the facts, statements and answers contained in this application are true and correct.

Sworn and subscribed to before me, the said _____ this the _____ day of _____, 20 _____, to certify which witness my hand and seal of office.

(Seal)

Notary Public Signature



PROTOCOL FOR DENTAL LABORATORY APPLICATION REGISTRATION

Upon receipt of a completed dental laboratory application, fee and required documents, an applicant will receive an acknowledgment letter.

If the application is complete our office will schedule an inspection to be completed within 30 business days.

For questions and concerns call (850) 245-4444 ext. 3491 or email Susan_Angel@doh.state.fl.us



DENTAL LABORATORY REGISTRATION APPLICATION
FEE: \$200.00 NON-REFUNDABLE

Pursuant to Chapter 466.033, Florida Statutes, this is the official registration form made referenced. Failure to complete this application or failure to provide the requested documents shall prevent any further consideration of your registration request. Make check payable to Board of Dentistry & mail to address below.

1. Laboratory Name: _____

Laboratory Address: _____

Owner's Name: _____

Owner's Telephone: Office: _____ Home: _____

Birth Date: _____ Social Security No.: _____
2. Have you ever registered a dental lab? _____ If yes, please provide the registration number: _____
3. Business type: _____ Sole Proprietorship _____ Partnership _____ Corporation*
(*Must submit certified copies of all articles of incorporation)
4. Fictitious Name Statement: If the laboratory is operating under a name other than the owner, please provide a copy of the "fictitious name" registration from the Secretary of State – (850) 488-9000. Please attach to this completed application.
5. Has any owner, partner, officer, director, stockholder or employee ever been a party to any civil, criminal or administrative proceeding involving any violation of Chapter 466, Florida Statutes, or any regulation governing the practice of the dental profession? _____
6. Has any owner, partner, officer, director, stockholder or employee ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest to, a crime in any jurisdiction other than a minor traffic offense? You must include all misdemeanors and felonies, even if the court withheld adjudication so that you



would not have a record or conviction. Driving under the influence or driving while impaired is not a minor traffic offense for purposes of this question. _____

7. Has any owner, partner officer, director, stockholder or employee ever had a professional license or registration revoked, suspended, or disciplined? _____
8. Is the laboratory equipment modern and does the laboratory meet the requirements for sanitation & safety as outlined in the attached rule?

Note: "Yes" answers for questions #5, #6 & #7 require official documents of the occurrence which must include date, jurisdiction (state and county), offense, disposition, and all other relevant information. "No" answer for question #8 requires an explanation.

OWNER'S NAME (PRINT OR TYPE)

OWNER'S SIGNATURE DATE

Revised 2/21/2006

SC Dept of Labor, Licensing and Regulation - Board of Dentistry

110 Centerview Drive, Suite 202
P.O. Box 11329, Columbia, South Carolina 29211-1329
(803) 896-4599; fax (803) 896-4719
www.llr.state.sc.us

APPLICATION FOR REGISTRATION – DENTAL / ORTHODONTIC TECHNICIAN

Application must be fully completed with all requested information and documentation supplied. Application fee of \$100.00 (check or money order only) must accompany application. **Application fee is non-refundable and non-transferable.** The application form itself is a public document obtainable under the Freedom of Information Act.

For Dental Technician Registration

Orthodontic Technician Registration

Dental Technician Applicants Apply By:

- Registration by State Board Examination
- Registration by CDT Certification - must submit copy of current certification
- Registration by Written Comprehensive Examination of the National Board for Certification in Dental Laboratory Technology (NBC) - must submit proof of successful completion

I. Applicant Identifying Information
Complete this section of the form by providing all of the requested information. You must notify the Board office, in writing, of any address changes after you file this application in order to receive further information.

Applicant's Name _____
Last First Middle Suffix (Jr., III)

*Social Security Number _____ U.S. Citizen: ___ Yes ___ No

Preferred Mailing Address _____
Street City State Zip

Home Address _____
Street City County State Zip

Current Office Address _____
Street City County State Zip

Email Address: _____

Home Phone () _____ Business Phone () _____ Business Fax () _____

Place of Birth (City, State or Country) _____ Date of Birth MM/DD/YYYY _____ Gender M/ F _____ Race (not required) _____

Military Service: _____ Dates of Service: _____

Honorable / Dishonorable Discharge: _____ If other than Honorable, attach a copy.

Have you ever been known by any names other than what is listed above? ___ Yes ___ No.
If yes, state in full every other name by which you have been known. If change was made by a Court order, enclose notarized copy of order.

Do you need special accommodations in order to take an examination? ___ Yes ___ No. If yes, please specify: _____

APPLICATION FEE: Check or Money Order in the amount of \$100.00 to be made payable to: LLR – Board of Dentistry. Application fee is non-refundable and non-transferable. Submit application and fee to: SC Department of Labor, Licensing and Regulation – Board of Dentistry, PO Box 11329, Columbia, SC 29211-1329.

*The Social Security Number (SSN) is not subject to disclosure as public information. The disclosure of the SSN for identification purposes is authorized and mandated by federal statutes requiring state dental boards to report to the Healthcare Integrity and Protection Data Bank (HIPDB) and the National Practitioner Data Bank (NPDB), among others.

**APPLICATION FOR A PERMIT TO OPERATE A DENTAL
LABORATORY**

IN THE STATE OF OKLAHOMA

FROM THE STATE DENTAL ACT:

"Annually - before the first day of January, every dental laboratory within the state of Oklahoma shall apply for and receive a permit by the Board of Dentistry to operate a dental laboratory for that calendar year."

"Any change in ownership or location of a dental laboratory shall immediately be communicated to the Board of Dentistry."

NAME OF LABORATORY: _____

ADDRESS: _____

CITY/STATE/ZIP: _____

I, _____, herewith enclose a \$20.00 fee for an annual permit to operate a Dental Laboratory in the State of Oklahoma for the calendar year 2012.

DATE

SIGNATURE OF OWNER

State of _____
County of _____

Subscribed and sworn to before me this _____ day of _____, _____.

Notary Public

My commission expires: _____
Commission number: _____

PLEASE COMPLETE AND FORWARD TO:

**BOARD OF DENTISTRY
201 N.E. 38TH TERR., SUITE 2
OKLAHOMA CITY, OK 73105
405/524-9037**

****PLEASE COMPLETE AFFIDAVIT ON BACK****

AFFIDAVIT OF ELIGIBILITY

Pursuant to Section 8-29-10 SC Code of Law, ALL applicants for a South Carolina license after July 1, 2008 are required to complete and sign this Affidavit of Eligibility.

Section A: LAWFUL PRESENCE in the United States.

I, (please print your full name) _____, swear or affirm under penalty of perjury under the laws of the State of South Carolina that (check 1, 2 or 3 below):

1. ___ I am a United States citizen or legal permanent resident eighteen years of age or older; or
2. ___ I am not a US citizen but am lawfully present in the US as evidenced by one of the following
 - a. ___ I am a qualified alien as defined in 8 U.S.C. sec 1641, eighteen years of age or older.
 - b. ___ I am a nonimmigrant under the "Immigration and Nationality Act," Federal Public Law 82-414 as amended, eighteen years of age or older.
3. ___ I am not physically present in the US under 8 U.S.C. sec 1621 (c) (2) (c) or employed in the US pursuant to 8 U.S.C. 1621 (c) (2) (a) (check either a or b below):
 - a. ___ I am a US citizen, not physically present or employed in the United States.
 - b. ___ I am a Foreign National, not physically present or employed in the United States.

If you selected either 3.a. or 3.b., you do not need to complete Section B. Skip to Section C.

Section B: Secure and Verifiable Document. This section must be completed if you checked number 1 or 2 in Section A.

1. Please check one of the following acceptable secure and verifiable documents. Complete documentation must be provided upon request only.
 - Any South Carolina Driver License, South Carolina Driver Permit or South Carolina Identification Card, expired less than one year.
 - Out-of-state issued photo Driver's License or photo identification card, photo driver's permit expired less than one year. State: _____
 - Valid Temporary Resident Card
 - Certificate of Naturalization with intact photo
 - Certificate of (US) Citizenship with intact photo
 - Other: (Name of verifiable document) _____

_____/_____/_____
Social Security Number

2. Enter the state or the federal agency name where this secure and verifiable document was issued.

(If issued by a state agency, include both the state and agency name.)

3. What is the secure and verifiable document number? _____

4. What is the expiration date of your secure and verifiable document? ____/____/____ (month/day/year)

(If you hold a document without an expiration date, such as a military ID or naturalization certificate, please write N/A.)

Section C: Attestation.

- I understand that this sworn statement is required by law because I have applied for or hold a professional or commercial license regulated by 8 U.S.C. sec. 1621. I understand that state law requires me to provide proof that I am lawfully present in the United States. I may also be required to provide proof of lawful presence.
- I understand that in accordance with section 8-29-10 false statements made herein are punishable by law. I state under penalty of perjury that the above statements are true and correct.
- I am the person identified above and the information contained herein is true and correct to the best of my knowledge. I understand that under South Carolina law, providing false information is grounds for denial, suspension or revocation of a license, certificate, registration or permit.
- I understand that the above information must be disclosed to the Department of Labor, Licensing and Regulation upon request and is subject to verification.

Signature

Date

Please print your name as shown on your secure and verifiable document.

Professional License Type: _____

License Number (if already licensed): _____

The South Carolina Code of Laws requires that every individual who applies for an occupational or professional license provide a social security or alien identification number for use in the establishment, enforcement and collection of child support obligations and for reporting to certain databanks established by law. Failure to provide your social security number for these mandatory purposes will result in the denial of your licensure application. Social security numbers may also be disclosed to other governmental regulatory agencies and for identification purposes to testing providers and organizations involved in professional regulation. Your social security number will not be released for any other purpose not provided for by law.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH

Application for Registration under the Drug, Device and Cosmetic Act and Licensure under the Wholesale Prescription Drug Distributor's Act

Pay fee with check or money order payable to "Pennsylvania Department of Health." Major Credit card payment, provide information below. Only one fee, the highest amount, is due regardless of the number of applicable category types unless your business involves distribution sales of prescription drugs, controlled substances, or medical gas then both, the distributor license and registration are due. Return form along with fee(s) to:

PENNSYLVANIA DEPARTMENT OF HEALTH: DRUG & DEVICE REGISTRATION SECTION

132 KLINE PLAZA, SUITE A, HARRISBURG, PENNSYLVANIA 17104

PHONE (717) 783-1379 FAX (717) 772-0232

Check all blocks which apply (If fee-exempt mark only fee-exempt boxes)

Check	Type of Enterprise	Fee
<input type="checkbox"/>	Manufacturer or Re-packager/labeler of Prescription Drugs, Controlled Substances, and/or Medical Gas Transfiller	\$400
<input type="checkbox"/>	Manufacturer or Re-packager/labeler of Non-prescription Drugs or Cosmetics*	\$100
<input type="checkbox"/>	Wholesaler/Distributor of Prescription Drugs and/or Controlled Substances, and/or Medical Gases (License)	\$10
<input type="checkbox"/>	Distributor of Prescription drugs and/or Controlled Substances, and/ or any seller of Med. Gases (Registration)**	\$100
<input type="checkbox"/>	Distributor of Non-prescription Drugs or Cosmetics*	\$25
<input type="checkbox"/>	Devices-Medical: Manufacturer, Reprocessor, Distributor, or Retailer	\$25
<input type="checkbox"/>	Retailer of Non-prescription drugs, Medicated Cosmetics, or Medicated Over-the-Counter Products*	\$10
<input type="checkbox"/>	Fee-exempt *** Distributor, Manufacturer, Retailer of Drugs (all types) and/or Devices (Registration)	None
<input type="checkbox"/>	Fee-exempt ***Distributor of Prescription and/or Controlled Substance Products (License)	None

*[Some OTC, Cosmetics, & Herbal Products are Drugs and may require registration] **(direct/consumer sales or indirect/distribution sales)

***[Tax-exempt- Some examples are charitable nonprofit organizations and certain government affiliated organizations.]

Name of Establishment: _____

Facility Address/City/Zip Code/County: _____

Telephone no. (including area code) for facility: _____

Billing address if different from above: _____

Contact person for entity and Telephone number: _____

Contact Person's Address if different than above: _____

List other trade/business names used: _____

Type of ownership (corporation, partnership, sole proprietorship, etc): _____

Ownership Name(s): Individual, Partners, or Corporate Officers (and title): _____

(If change of ownership please list previous registration no. or name: _____)

If incorporated, State in which establishment is incorporated and date of incorporation: _____

Has the applicant or have any of the officers, agents or employees of the establishment ever been convicted of any violation of federal or Pennsylvania laws dealing with controlled substances? No Yes If yes, fully describe on other side.

Has the applicant or have any of the officers, agents or employees of the establishment had a license or equivalent authorization previously held for the manufacture of distribution of any drugs denied, suspended, revoked, restricted or subjected to any other sanction for disciplinary reasons by a government authority? No Yes If yes, fully describe on other side

Please indicate an e-mail address for your business: _____
(optional, for Internet Renewal/Notification and information)

Corporate Federal Tax ID (optional, for purposes of renewing multiple registrations): _____ - _____ - _____

If Payment by Credit card: _____ - _____ - _____ Exp. Date: ____/____/____

Applicant Name/Title _____ Date: _____
Address and Telephone number: (If different than above) _____

Oklahoma Board of Dentistry

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LABORATORIES WITH PERMITS

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Laboratory Name: A and J Dental Lab

Address: 601 W. 17th

City / State / Zip: Sulphur OK 73086

Owner Name: Audrey Caudle

Laboratory Name: A X-Ceptional Quality Denture Lab

Address: P.O. Box 472064

City / State / Zip: Tulsa OK 74147

Owner Name: Tracy Ann Davis

Laboratory Name: Adams Partial Denture Laboratory

Address: 3912 S. Oak Ave.

City / State / Zip: Broken Arrow OK 74011

Owner Name: Gregory D. Adams

Laboratory Name: Advanced Dental Arts

Address: RR 1 Box 2600

City / State / Zip: Thackerville OK 73459

Owner Name: Pat Dowdell

Laboratory Name: Agee Dental Laboratory

Address: P.O. Box 227

City / State / Zip: Glenpool OK 74033

Owner Name: Brian Agee

Laboratory Name: Alexander Dental Lab

Address: 12324 E. 86th St. N., #232

City / State / Zip: Owasso OK 74055

Owner Name: Geoffrey L. Alexander

Laboratory Name: Anderson Dental Lab

Address: 2521 S. 124th E. Ave.

City / State / Zip: Tulsa OK 74129

Owner Name: James Anderson

Laboratory Name: Au Dental Laboratory

Address: 1219 W. Frank Phillips Blvd.

City / State / Zip: Bartlesville OK 74003

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Laboratory Name: B & B Dental Studio of Ardmore

Address: 182 Sierra St.

City / State / Zip: Ardmore OK 73401

Owner Name: Brett Neher

Laboratory Name: B.M. Ortho Lab

Address: 824 24th Ave. N.W.

City / State / Zip: Norman OK 73069

Owner Name: Brandon McCune

Laboratory Name: B.R.B. Dental Lab

Address: 805 E Hobson, #C

City / State / Zip: Sapulpa OK 74067

Owner Name: Billy R. Battle

Laboratory Name: Bair Dental Lab

Address: 910 Stoneridge Dr.

City / State / Zip: Stillwater OK 74074

Owner Name: Bob Bair

Laboratory Name: Baker Crown & Bridge

Address: 301 Choctaw

City / State / Zip: Bartlesville OK 74003

Owner Name: Charles R. & Michelle Baker

Laboratory Name: Barnett Dental Lab

Address: 174 E. Brooken Rd.

City / State / Zip: Stigler OK 74462

Owner Name: Paul Barnett

Laboratory Name: Baron Dental Lab, Inc.

Address: 6565 South Yale, #907

City / State / Zip: Tulsa OK 74136

Owner Name: Aaron D. Hutchison

Laboratory Name: Barton Dental Laboratory

Address: 3015 E. Skelly Dr., #327

City / State / Zip: Tulsa OK 74105

Owner Name: Harvey Barton

Laboratory Name: Bella Denti Dental Laboratory

Address: 3817 N. Asbury Ave., #C

City / State / Zip: Bethany OK 73008

Owner Name: Nathan Graham

Laboratory Name: Bezalel Dental Lab

Address: 215 East 2nd

City / State / Zip: Skiatook OK 74070

Owner Name: Cimberly F. Fowler

Laboratory Name: Bill's Dental Lab, Inc.

Address: 30270 E. 69th St. S.

City / State / Zip: Broken Arrow OK 74014

Owner Name: Billy L. Morris

Laboratory Name: Blue Star Dental, Inc.

Address: 624 S.W. 'D' Ave.

City / State / Zip: Lawton OK 73501

Owner Name: Dr. Wavel Wells

Laboratory Name: Bob's Dental Lab

Address: P.O. Box 396

City / State / Zip: Duncan OK 73534

Owner Name: Bobby Moore

Laboratory Name: Brooks Dental Lab

Address: 1933 Quail Run

City / State / Zip: Newcastle OK 73065

Owner Name: Brooks C. DeMunbrun

201 N.E. 38th Terr., #2 - Oklahoma City, OK 73105

TEL: (405) 524-9037 FAX: (405) 524-2223

Email: dentist@oklaosf.state.ok.us

Business Hours: Monday-Friday 8:30am to 4:30pm

APPENDIX 7

Virginia Dental Statue Call Log

1) I just got a call today from Barbara Smith, she indicated that her husband has a practice in Danville and she was looking for help to report a Smith Dental Lab in Danville who she says was seeing patients and practicing dentistry without license. Barbara said she called the BOD and was told they do not regulate labs but that she could file a report since the lab was practicing dentistry without a license. She said the report is gear to complaints against dentist and not labs so she did not know what to do.

I asked her to file the complaint and to also contact the VDA for help. I also asked her to call her state representatives and a tell them her story. Not the smoking gun but perhaps a great representation about why we need registration.

Barbara Smith
434 250-0689

2) Ron Emmons - Triangle Dental Labs in Triangle VA (703) 221-1555 shares concern and likes HB267. Long time coming and was stunned to hear the bill was defeated by the BOD. Was concerned over the thousands of dollars he has in prescription pads. Does not feel fair that they should be worthless and would call BOD and delegates.

3) James Hartzell DDS and CDT - Lab owner in California (661) 904-7421. Supportive and believes that its was needed to help US labs compete more fairly on a level playing field. He lets me labs in CA doing PFMs for \$16.00 (or \$60.00) a unit. Feels garage labs are ruining the business.

4) Jaryd Royer (boudicious@gmail.com) from JDL Laboratory in Port Neches TX. I have recently read the article in pertaining to the VDLSA in the newest edition of "iDT- Inside Dental Technology" and as was Dr. Zapatero, I am compelled by this story. My family owns a dental lab in the town of Port Neches, TX, called JDL Laboratories. We have noticed a dramatic drop in business in the realm of restorative dentistry as a whole, and being an aspiring dental student I am immediately drawn to this. I was curious if there is any more text related to this act that could better educate me and our company on this act to possibly present it at our next seminar?!?!? I feel that passing a "U.S.A.DLSA" would be more appropriate due to our economic drop etc. Please contact me if you have any additional information and also if there is any way that we could help or get more involved.