



Florida State Laws Affecting Dental Laboratories

March 2010 Edition

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Florida Dental Laboratory Association

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Florida State Laws Affecting Dental Laboratories

March 2010 Edition

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**** Information in italics is interpretation by the Florida Dental Laboratory Association based upon discussions with Florida Board of Dentistry personnel. ****

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Preface

Florida's dental laboratories are governed by the Florida Statutes (sometimes referred to as "laws") and the Florida Administrative Code (sometimes referred to as "rules"). The Florida Statutes are written based upon legislative action during Florida's legislative sessions.

The Florida Administrative Code is developed by the Florida Board of Dentistry and is designed to further expand and explain the Florida Statutes. It is for this reason that the reader of this manual will see some references to both under certain sections.

The enclosed material is provided to assist readers with understanding Florida's requirements and regulations regarding dental laboratories.

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Credits

Much of the information and supporting documents are the result of the work of lawmakers and government employees responsible for the creation and implementation of the law.

Disclaimer

This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is sold with the understanding that the publisher is not engaged in rendering legal, accounting or other professional service. If legal advice or other expert assistance is required, the service of a qualified person should be sought. While every effort has been made to insure the accuracy of the contents of the manual, neither FDLA nor its agents or affiliates take responsibility for its contents and applicability to or interpretation of the laws. Readers are cautioned that laws and regulations are constantly being enacted and amended.

**** Information in italics is interpretation by the Florida Dental Laboratory Association based upon discussions with Florida Board of Dentistry personnel. ****

New Additions to Florida Law Governing Dental Laboratories

Senate Bill 2760 passed the Florida Legislature on Friday, May 2nd, 2008 and the elements of the legislation went into effect on January 1, 2009.

This legislation reflects the goals of the Governor, the Secretary of the Agency for Health Care Administration, and the State Surgeon General to provide greater access to dental care in Florida, especially for the underserved.

The passage of this legislation was the result of three years of work by the Florida Dental Laboratory Association, and was supported by the Florida Dental Association in 2008.

Major Changes to Florida Law that Affect Dental Laboratories

This manual is intended to explain current laws affecting dental laboratories and the changes to these laws that went into effect on January 1, 2009 as a result of the legislation passed in 2008.

In short, the following is a brief overview of the changes passed in 2008. Further details are provided in the rest of this manual.

- Changed the term unlicensed person to “dental laboratory” and the term work order to “prescription”.
- Requires dental laboratories to disclose to dentists where a product was manufactured, what materials were used in each restoration and to provide certificates of authenticity. Although, the law does not address this information going to the patient, under existing patient rights, a patient may request a copy of this information for their records from their dentist.
- Requires every business that is registered as a dental laboratory with the Florida Department of Health after July 1, 2010 to document that the owner of the laboratory, or a dental technician who is employed full time by the laboratory, maintains 18 hours of approved continuing education in dental technology every two years. This does not apply to laboratories located outside of Florida doing business with dentists in the Sunshine State that are not registered with the Florida Department of Health.

Florida was the first state in the country to pass legislation that requires material and point of origin disclosure related to dental devices.

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- South Carolina passed a similar law in June 2008.
- Other states that have filed or are currently working on similar legislation include: New York, New Jersey, Ohio, Alabama, Indiana, Michigan, Minnesota and North Carolina.

Federal law under Food and Drug Administration regulations only requires point of origin disclosure not material disclosure.

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Florida Statutes Governing Dental Laboratories – Interpretations

The following section provides the text from the Florida Statutes that govern dental laboratories, and the interpretation of these statutes by FDLA. For the full language pulled from the Florida Statutes, refer to page 22 of this manual.

Dental Laboratories Working for Dentists, Prescriptions, Material Selection, Material Disclosure and Point of Origin Disclosure

Florida Statutes Chapter 466, Section 466.021

(Full text available on page 22. Also refer to page 27 for Administrative Code information.)

Dental Laboratories Working for Dentists

- Each licensed dentist who uses the services of any dental laboratory for the purpose of constructing, altering, repairing, or duplicating any denture, implant, veneer, partial denture, bridge splint, orthodontic or other prosthetic appliance, or other suitable form of artificial oral restorative device shall be required to furnish the dental laboratory with a written prescription in a form prescribed by rule of the board.
 - *Each dentist must provide a laboratory with a prescription, called a “Laboratory Procedure Prescription”, which contains the minimum amount of information as determined by the Florida Board of Dentistry in the Florida Administrative Code, Chapter 64B5-17.006. See page 27 of this manual for the language from this section of the Florida Administrative Code.*

Prescriptions, Material Selection

- This prescription shall be dated and signed by the dentist and shall include the license number of the dentist, the patient's name or number with sufficient descriptive information to clearly identify each separate and individual piece of work to be performed by the dental laboratory, and a specification of materials to be contained in each work product.
 - *The Florida Board of Dentistry has determined that an electronic signature of the dentist is acceptable for such use as digital prescriptions. See the Florida Administrative Code, Chapter 64B5-17.006 on page 27 of this manual for the outline of requirements and the addendum for a sample Laboratory Procedure Prescription.*
 - *The requirement for the specification of materials is part of the new law that was passed in 2008. See page 9 of this manual for further information.*
 - *According to Florida Administrative Code 64B5-13.0045, it is unlawful for a dentist to pre-sign Laboratory Procedure Prescriptions, and is punishable by a \$500 fine according to Florida Administrative Code 64B5-13.0046.*

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- The original prescription shall be retained in a file by the dental laboratory for a period of 4 years.
 - *The Florida Board of Dentistry has determined that prescriptions may be stored electronically, as long as the laboratory can reproduce the prescription upon request (printed). See the Florida Administrative Code, Chapter 64B5-17.006 on page 27 of this manual for the outline of requirements.*
 - *The failure of a dental laboratory to have the original or electronic copy of each prescription and ensuring the accuracy of material disclosure is a crime. Under the law, it is a second degree misdemeanor.*

Florida's Dental Laboratory Law continued

Laboratory Procedure Prescriptions

From the dentist to the laboratory.

- Approved prescription forms must contain all information necessary from completion of the assigned work and must include a minimum:
 - a. Title – “Laboratory Procedure Prescription”;
 - b. Name, address and license number of the registered dental laboratory;
 - c. Name, address and license number of the Florida licensed dentist who owns the prescription form and is authorizing the procedure;
 - d. Patient's name or number;
 - e. Date sent to the lab;
 - f. Signature of the licensed dentist, which may be an electronic signature;
 - g. Sufficient descriptive information to clearly identify each separate and individual piece of work to be performed by the dental laboratory; and
 - h. Specification of materials to be contained in each work product.
- Copies of prescription forms must be maintained, either on paper or stored electronically in an encrypted data base, by the dentist for a period of four (4) years.



Laws and Rules for Dental Laboratories in Florida

**** Information in italics is interpretation by the Florida Dental Laboratory Association based upon discussions with Florida Board of Dentistry personnel. ****

Florida's Dental Laboratory Law continued

Materials Specification

From the dentist to the laboratory.

- A dentist must provide Florida laboratories with the materials they want each product to be manufactured with on the prescription.
- FDIA has suggested that laboratories provide their dentists with a list of the patient contact materials regularly used by the laboratory and let the dentists check which materials they want to use for each product. See the images to the right and below as examples.



BUCCAL MARGIN DESIGN	METAL CHOICE
METAL MARGIN <input type="checkbox"/>	HIGH NOBLE (YELLOW) <input type="checkbox"/>
NO METAL MARGIN <input type="checkbox"/>	HIGH NOBLE (WHITE) <input type="checkbox"/>
PORCELAIN BUTT <input type="checkbox"/>	NOBLE (YELLOW) <input type="checkbox"/>
	NOBLE (WHITE) <input type="checkbox"/>
	NON-PRECIOUS <input type="checkbox"/>

MATERIAL CHECK LIST	
The Studio	
<input type="checkbox"/>	BioCeram PFG IPS InLine
<input type="checkbox"/>	Captek PFG IPS InLine
<input type="checkbox"/>	Dimension PFG IPS InLine
<input type="checkbox"/>	K.Ceram PFM IPS InLine
<input type="checkbox"/>	M.Ceram PFM IPS InLine
<input type="checkbox"/>	UniCeram PFG IPS InLine
<input type="checkbox"/>	Empress IPS Empress
<input type="checkbox"/>	E.Max IPS e.Max
<input type="checkbox"/>	PFZ Zirconia C-S Zirconium IPS e.Max
<input type="checkbox"/>	Ceramic Shoulder Restoration Initial I.Q. InLine POM <input type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/>	Other _____
Vantage	
<input type="checkbox"/>	Captek PFG IPS d.Sign
<input type="checkbox"/>	V.Ceram PFM IPS d.Sign
<input type="checkbox"/>	Empress IPS Empress
<input type="checkbox"/>	Zirconia Crown Zero Zirconium IPS e.Max
<input type="checkbox"/>	Other _____

Laws and Rules for Dental Laboratories in Florida

**** Information in italics is interpretation by the Florida Dental Laboratory Association based upon discussions with Florida Board of Dentistry personnel. ****


Material Disclosure

- A registered dental laboratory shall disclose in writing at the time of delivery of the final restoration to the prescribing dentist the materials and any available certificates of authenticity that constitute each product manufactured and the point of origin of manufacture of each restoration, including the address and contact information of the dental laboratory.
 - *This is part of the new law that was passed in 2008. See the addendum for a sample disclosure form.*

Florida's Dental Laboratory Law continued

Material Disclosure

- Florida dental laboratories must provide a list of materials used in the manufacture of the final, seated restoration to the dentist upon delivery.
- It is the responsibility of the laboratory to ensure that the proper material disclosure is provided to the dentist when the restoration is delivered, through certificates of authenticity provided by the manufacturer (if available), or other methods such as IdentAlloy stickers, IdentCeram stickers, or MSDS sheets. Failure to provide the available information is considered a criminal act, and punishable as a misdemeanor.
- Under, U.S. Food & Drug Administration quality system regulations, U.S. dental laboratories should be tracking the lot and batch numbers of each material used in a case for their own laboratory records. This went into effect in 1997.



Laws and Rules for Dental Laboratories in Florida

- Special Guidance for Orthodontic Appliances
 - Dental laboratories that manufacture orthodontic appliances such as retainers, typically use a combination of wires to create the finished medical device. The wires generally do not come from the manufacturer/supplier with any material composition as you would see with ceramic powders, porcelain, or metal alloys found in the manufacture of crowns, bridges or dentures. A laboratory should however, be able to provide the dentist with at least the manufacturer or supplier name and possibly a product name or number for the wire purchased and used to create the orthodontic appliance

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Florida's Dental Laboratory Law continued

Material Disclosure

- This can be included on the invoice or as an addendum.
- **A good rule of thumb is to provide as much information about the material as possible.**
- The Department of Health has recommended the following format AS A MINIMUM for each material:
 - Empress Crown by Ivoclar Vivadent



Laws and Rules for Dental Laboratories in Florida

- The file of prescriptions to be kept by the dentist and the dental laboratory shall be open to inspection at any reasonable time by the department or its constituted agent.
 - *If a laboratory chooses to store prescriptions electronically, they must be able to print the specified prescription upon request by an inspector.*
- Failure of a dental laboratory that has accepted a prescription to have the original or electronic copy of each prescription and to ensure the accuracy of each product's material disclosure at the time it is delivered to the prescribing dentist as required by this section is admissible evidence of a violation of this chapter and constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.
 - *It is the responsibility of the laboratory to ensure that the proper material disclosure is provided to the dentist when the restoration is delivered, through certificates of authenticity provided by the manufacturer, IdentAlloy stickers, IdentCeram stickers, other manufacturer provided stickers, lot numbers or other identifying information available. Failure to provide the available information is considered a criminal act, and punishable as a misdemeanor. See the addendum for a sample disclosure form.*

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- *It is recommended that laboratories always provide lot or batch numbers for products used in the restorations, as this is a requirement of the US Food & Drug Administration.*
- *This information will be kept in the patient record, and is intended to allow for quicker tracking in the event of a product recall or manufacturer notice.*
- *If the laboratory outsources pieces of the restoration to another laboratory, either in Florida or outside, the laboratory delivering the final restoration must provide the material disclosure for pieces manufactured by the outsourced laboratory. This applies to 3rd party laboratories that are owned by the originating laboratory or a parent company as well.*

Florida's Dental Laboratory Law continued

What happens if I don't receive the material specification from my dentists?

- FDIA recommends that the laboratory contact the dentist to request the additional material specification information from the dentist in writing. If at all possible, the laboratory should do this via email, as to create a paper trail.
- If the dentist leaves the material selection up to the laboratory, this should be documented. If the laboratory cannot document this by an email or by fax, the laboratory should make a note on the prescription – something to the effect of, “Called Dr. Smith on 3/7/09 to request material selection. Dr. Smith declined and ask the laboratory to select material on 3/8/09 at 2:30 p.m.”



Laws and Rules for Dental Laboratories in Florida

- This section does not preclude a registered dental laboratory from working for another registered dental laboratory if that work is performed pursuant to written authorization, in a form to be prescribed by rule of the board, which evidences that the originating laboratory has obtained a valid prescription and which sets forth the work to be performed and the resulting material certifications to be provided.
 - *See page 27 of this manual for the outline of requirements for the “Laboratory Procedure Prescription”.*
 - *Note: The prescription from the dentist to the initial laboratory is called the “Laboratory Procedure Prescription” and the authorization from one*

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laboratory to another laboratory to perform part of the work from the original prescription is called the "Laboratory Procedure Authorization".

Florida's Dental Laboratory Law continued

Material Disclosure

- If the laboratory outsources pieces of a restoration to another laboratory (either in or outside of Florida), the laboratory delivering the final restoration must provide the material disclosure for the pieces manufactured by the outsourced laboratory to the dentist.



Laws and Rules for Dental Laboratories in Florida

- A dental laboratory accepting prescriptions from dentists is liable for damages caused by inaccuracies in the material disclosure, certificates of authenticity, or point of origin provided by the dental laboratory to the prescribing dentist.
 - *This means that a laboratory can be sued if damages occur because of inaccuracies or lack of information provided in the material disclosure portion that is required to be sent to the dentist with the restoration.*
- This section does not preclude a registered laboratory from providing its services to dentists licensed and practicing in another state if that work is requested or otherwise authorized in written form that clearly identifies the name and address of the requesting dentist and sets forth the work to be performed and otherwise complies with all applicable laws and treaties.
 - *Florida laboratories may work with out of state dentists. As a good business practice, Florida laboratories are advised to maintain incoming prescriptions for the standard period of four years, and to provide the same material and point of origin disclosure to these out of state dentists.*

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Florida's Dental Laboratory Law continued

Material Disclosure

- This is a short list of patient contact materials commonly contained in final dental prosthesis that FDIA recommends laboratories provide material disclosure for:
 - Porcelains (including stain & glaze)
 - Pressable ceramic materials
 - Abutments and implant screws
 - Substructure materials (alloys, RPD frameworks, Zirconia materials, etc.)
 - Denture base materials (acrylic, flexible resin, etc.)
 - Denture teeth
- This list is not meant to be exclusive – any patient contact materials contained in the final prosthesis are encouraged for disclosure.



Laws and Rules for Dental Laboratories in Florida

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Point of Origin Disclosure

Florida's Dental Laboratory Law continued

Point of Origin Disclosure

- Florida dental laboratories must provide information on where any piece of the final restoration was made to the prescribing dentist.
- This can be included on the invoice or as an addendum.
- **Compliance format for restorations manufactured in house is:**
 - Custom made dental appliance manufactured by XYZ Dental Lab, 123 Smith Lane, Tampa, FL 33612, Phone 813-123-LABS
- **Compliance format for a restoration that was either wholly or partially outsourced to a non affiliated entity , a suggested reference is:**
 - Partial framework manufactured by 3rd party provider in Orlando, FL. Contact information provided upon request. Final restoration manufactured by XYZ Dental Lab.
- **Compliance format for a restoration that was either wholly or partially outsourced to an "affiliated" entity (defined as another laboratory that is partially or fully owned or operated by a parent company) , in state, out of state, or out of the country, a suggested reference is:**
 - Custom made dental appliance distributed by XYZ Dental Lab, 123 Smith Lane, Tampa, FL 33612, Phone 813-123-LABS



Laws and Rules for Dental Laboratories in Florida

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Definition of a Dental Laboratory

Florida Statutes Chapter 466, Section 466.031

(Full text available on page 22.)

The term "dental laboratory" as used in this chapter:

1. Includes any person, firm, or corporation who performs for a fee of any kind, gratuitously, or otherwise, directly or through an agent or employee, by any means or method, or who in any way supplies or manufactures artificial substitutes for the natural teeth, or who furnishes, supplies, constructs, or reproduces or repairs any prosthetic denture, bridge, or appliance to be worn in the human mouth or who in any way holds itself out as a dental laboratory.
2. Excludes any dental laboratory technician who constructs or repairs dental prosthetic appliances in the office of a licensed dentist for such dentist only and under her or his supervision and work order.
 - *For the purposes of Florida Statutes Chapter 466, Sections 466.032, 466.033, 466.034, 466.035, 466.036, 466.037, 466.038, and 466.039, any in-office laboratory technician who is provided services exclusively for the dentist(s) in the office, these rules do not apply.*
 - *See page 43 for FDLA's recommendations for in-house laboratories in regards to compliance with Florida's laws.*

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Florida State Laws Affecting Dental Laboratories

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Laboratory Registration with the State of Florida and New Continuing Education Requirements for the 2012 Registration

Florida Statutes Chapter 466, Section 466.032

(Full text available on page 22. Also refer to page 27 for Administrative Code information.)

Laboratory Registration with the State of Florida

1. Every person, firm, or corporation operating a dental laboratory in this state shall register biennially with the department on forms to be provided by the department and, at the same time, pay to the department a registration fee not to exceed \$300 for which the department shall issue a registration certificate entitling the holder to operate a dental laboratory for a period of 2 years.
 - *In order to register with the state initially, a dental laboratory must have registered with the Florida Department of State, Division of Corporations and hold a local business occupational license in their city and/or county.*
 - *The dental laboratory must also have a pre-inspection by the state before conducting business.*
 - *The current registration fee is \$200 (as of March 2010).*
 - *Florida laboratories will be required to renew their registrations in February 2012.*
2. Upon the failure of any dental laboratory operator to comply with subsection (1), the department shall notify her or him by registered mail, within 1 month after the registration renewal date, return receipt requested, at her or his last known address, of such failure and inform her or him of the provisions of subsections (3) and (4).
3. Any dental laboratory operator who has not complied with subsection (1) within 3 months after the registration renewal date shall be required to pay a delinquency fee of \$40 in addition to the regular registration fee.
 - *Laboratory registration renewals not received by the Florida Board of Dentistry by May of the renewal year will be required to pay an additional \$40.*
4. The department is authorized to commence and maintain proceedings to enjoin the operator of any dental laboratory who has not complied with this section from operating a dental laboratory in this state until she or he has obtained a registration certificate and paid the required fees.
 - *The state has the authority to shut down any laboratory not complying with these registration requirements.*

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New Continuing Education Requirements for the 2012 Registration

1. The dental laboratory owner or at least one employee of any dental laboratory renewing registration on or after July 1, 2010, shall complete 18 hours of continuing education biennially. Programs of continuing education shall be programs of learning that contribute directly to the education of the dental technician and may include, but are not limited to, attendance at lectures, study clubs, college courses, or scientific sessions of conventions and research.
 - a. The aim of continuing education for dental technicians is to improve dental health care delivery to the public as such is impacted through the design, manufacture, and use of artificial human oral prosthetics and related restorative appliances.
 - b. Continuing education courses shall address one or more of the following areas of professional development, including, but not limited to:
 - i. Laboratory and technological subjects, including, but not limited to, laboratory techniques and procedures, materials, and equipment; and
 - ii. Subjects pertinent to oral health, infection control, and safety.
 - c. Programs meeting the general requirements of continuing education may be developed and offered to dental technicians by the Florida Dental Laboratory Association and the Florida Dental Association. Other organizations, schools, or agencies may also be approved to develop and offer continuing education in accordance with specific criteria established by the department.
 - d. Any dental laboratory renewing a registration on or after July 1, 2010, shall submit a sworn affidavit, on a form approved by the department, attesting that either the dental laboratory owner or one dental technician employed by the registered dental laboratory has completed the continuing education required in this subsection in accordance with the guidelines and provisions of this subsection and listing the date, location, sponsor, subject matter, and hours of completed continuing education courses. The dental laboratory shall retain in its records such receipts, vouchers, or certificates as may be necessary to document completion of the continuing education courses listed in accordance with this subsection. With cause, the department may request that the documentation be provided by the applicant. The department may also request the documentation from applicants selected at random without cause.
 - e.
 - i. This subsection does not apply to a dental laboratory that is physically located within a dental practice operated by a dentist licensed under this chapter.
 - ii. A dental laboratory in another state or country which provides service to a dentist licensed under this chapter is not required to

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register with the state and may continue to provide services to such dentist with a proper prescription. A dental laboratory in another state or country, however, may voluntarily comply with this subsection.

Florida's Dental Laboratory Law continued

Continuing Education Requirement

- The employee must have been employed for one full year at full time status within the previous two years before the registration renewal. For the February 2012 registration renewal, the employee must have been employed for at least one full year between February 2010 and February 2012.
- Up to 4 hours may be satisfied by the performance of pro bono work to serve the indigent or underserved populations of Florida. Examples of such programs include Project Select in Florida, Donated Dental Services or Give Back a Smile.
- This continuing education requirement does not apply to a dental laboratory physically that is located within the office of a licensed dentist and owned by the dentist. However, if the laboratory provides work for dentists located outside that location, the CE requirement DOES apply.
- Other manufacturers or CE providers can become approved by the Board of Dentistry through an online application process. This process is very easy to complete at www.CEBroker.com.
- As a **Healthcare Professional in Florida** you can search for approved courses at www.CEBroker.com by using their **Courses and Provider Searches** option. Search under "**Dental Labs**" for a listing of authorized educational providers.



Laws and Rules for Dental Laboratories in Florida

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Registration Certificates

Florida Statutes Chapter 466, Section 466.033

(Full text available on page 24.)

The department shall not require an examination, but shall issue a registration certificate upon completion of the registration form and compliance with any rules promulgated by the department under s. 466.038

Change of Laboratory Address or Ownership

Florida Statutes Chapter 466, Section 466.034

(Full text available on page 24.)

When the ownership or address of any dental laboratory operating in this state is changed, the owner thereof shall notify the department within 30 days of such change of ownership or address.

Laboratory Advertising

Florida Statutes Chapter 466, Section 466.035

(Full text available on page 24.)

Dental laboratories shall not solicit or advertise, directly or indirectly, by mail, card, newspaper, pamphlet, radio, television, or otherwise to the general public to construct, reproduce, or repair prosthetic dentures, bridges, plates, or other appliances to be used or worn as substitutes for natural teeth or for the regulation of natural teeth.

- *Laboratories may advertise their services for sale directly to dentists or other laboratories. When advertising to the general public, a dental laboratory is permitted to advertise the services they provide, where they are located and other awareness information. However, dental laboratories are restricted from “advertising or selling their services” direct to patients, advertisements should be constructed to say something in the vain of “Ask Your Dentist to Call XYZ Dental Laboratory”.*

Inspections

Florida Statutes Chapter 466, Section 466.036

(Full text available on page 24.)

The department may require from the applicant for a registration certificate to operate a dental laboratory any information necessary to carry out the purpose of this chapter, including proof that the applicant has the equipment and supplies necessary to operate as determined by rule of the department, and shall require periodic inspection of all

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dental laboratories operating in this state. Such inspections shall include, but not be limited to, inspection of sanitary conditions, equipment, supplies, and facilities on the premises. The department shall specify dental equipment and supplies that are not permitted in a registered dental laboratory.

- *The state may require a dental laboratory to provide proof that certain safety equipment and supplies necessary to operate are in the laboratory and may allow for periodic inspection.*
- *Inspections of a dental laboratory may include inspection of sanitary conditions, equipment, supplies and the facilities on the premises.*
- *The Board of Dentistry has specified that certain dental equipment and supplies are not permitted in the dental laboratory, including dental chairs, x-ray machines, anesthetics, sedatives or medicinal drugs, other than personal prescriptions for employees of the laboratory.*
- *Further details of what is required of the laboratory to operate and what inspectors will be looking for can be found in the Florida Administrative Code, Chapter 64B5-27-1.001 on page 27 of this manual.*

Revocation of Registration and Fines for Dental Laboratories

Florida Statutes Chapter 466, Section 466.037

(Full text available on page 25.)

The department may suspend or revoke the certificate of any dental laboratory registered under s. 466.032, for failing to comply with the provisions of this chapter or rules adopted by the department under this chapter. The department may impose an administrative fine.

Rules – The Florida Administrative Code

Florida Statutes Chapter 466, Section 466.038

(Full text available on page 25.)

The department, upon consultation with the Board of Dentistry and industry representatives of the dental laboratory profession, has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to enforce the provisions of this chapter pertaining to and regulating dental laboratories

- *Florida's dental laboratories are governed by the Florida Statutes (sometimes referred to as "laws") and the Florida Administrative Code (sometimes referred to as "rules"). The Florida Statutes are written based upon legislative action during Florida's legislative sessions.*
- *The Florida Administrative Code is developed by the Florida Board of Dentistry and is designed to further expand and explain the Florida Statutes. It is for this*

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Florida State Laws Affecting Dental Laboratories

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reason that the reader of this manual will see some references to both under certain sections.

Violations of the Florida Statutes

Florida Statutes Chapter 466, Section 466.039

(Full text available on page 25.)

It shall be unlawful for any person, firm, or corporation to operate as a dental laboratory as defined in this chapter, except those registered as provided in s. 466.032. Violation shall constitute a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

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Text of Florida Statutes Governing Dental Laboratories

Florida Statutes 466 – 2010 Version

466.031 "Dental laboratory" defined.--The term "dental laboratory" as used in this chapter:

(1) Includes any person, firm, or corporation who performs for a fee of any kind, gratuitously, or otherwise, directly or through an agent or employee, by any means or method, or who in any way supplies or manufactures artificial substitutes for the natural teeth, or who furnishes, supplies, constructs, or reproduces or repairs any prosthetic denture, bridge, or appliance to be worn in the human mouth or who in any way holds itself out as a dental laboratory.

(2) Excludes any dental laboratory technician who constructs or repairs dental prosthetic appliances in the office of a licensed dentist for such dentist only and under her or his supervision and work order.

History.--ss. 2, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 20, 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 263, ch. 97-103.

466.032 Registration.--

(1) Every person, firm, or corporation operating a dental laboratory in this state shall register biennially with the department on forms to be provided by the department and, at the same time, pay to the department a registration fee not to exceed \$300 for which the department shall issue a registration certificate entitling the holder to operate a dental laboratory for a period of 2 years.

(2) Upon the failure of any dental laboratory operator to comply with subsection (1), the department shall notify her or him by registered mail, within 1 month after the registration renewal date, return receipt requested, at her or his last known address, of such failure and inform her or him of the provisions of subsections (3) and (4).

(3) Any dental laboratory operator who has not complied with subsection (1) within 3 months after the registration renewal date shall be required to pay a delinquency fee of \$40 in addition to the regular registration fee.

(4) The department is authorized to commence and maintain proceedings to enjoin the operator of any dental laboratory who has not complied with this section from operating a dental laboratory in this state until she or he has obtained a registration certificate and paid the required fees.

**** Information in italics is interpretation by the Florida Dental Laboratory Association based upon discussions with Florida Board of Dentistry personnel. ****

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(5) The dental laboratory owner or at least one employee of any dental laboratory renewing registration on or after July 1, 2010, shall complete 18 hours of continuing education biennially. Programs of continuing education shall be programs of learning that contribute directly to the education of the dental technician and may include, but are not limited to, attendance at lectures, study clubs, college courses, or scientific sessions of conventions and research.

(a) The aim of continuing education for dental technicians is to improve dental health care delivery to the public as such is impacted through the design, manufacture, and use of artificial human oral prosthetics and related restorative appliances.

(b) Continuing education courses shall address one or more of the following areas of professional development, including, but not limited to:

1. Laboratory and technological subjects, including, but not limited to, laboratory techniques and procedures, materials, and equipment; and
2. Subjects pertinent to oral health, infection control, and safety.

(c) Programs meeting the general requirements of continuing education may be developed and offered to dental technicians by the Florida Dental Laboratory Association and the Florida Dental Association. Other organizations, schools, or agencies may also be approved to develop and offer continuing education in accordance with specific criteria established by the department.

(d) Any dental laboratory renewing a registration on or after July 1, 2010, shall submit a sworn affidavit, on a form approved by the department, attesting that either the dental laboratory owner or one dental technician employed by the registered dental laboratory has completed the continuing education required in this subsection in accordance with the guidelines and provisions of this subsection and listing the date, location, sponsor, subject matter, and hours of completed continuing education courses. The dental laboratory shall retain in its records such receipts, vouchers, or certificates as may be necessary to document completion of the continuing education courses listed in accordance with this subsection. With cause, the department may request that the documentation be provided by the applicant. The department may also request the documentation from applicants selected at random without cause.

(e)1. This subsection does not apply to a dental laboratory that is physically located within a dental practice operated by a dentist licensed under this chapter.

2. A dental laboratory in another state or country which provides service to a dentist licensed under this chapter is not required to register with the state and may continue to

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provide services to such dentist with a proper prescription. A dental laboratory in another state or country, however, may voluntarily comply with this subsection.

History.--ss. 2, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 21, 23, 24, ch. 86-291; s. 38, ch. 89-162; s. 1, ch. 89-374; s. 1, ch. 89-543; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 7, ch. 96-281; s. 1112, ch. 97-103; s. 10, ch. 2008-64.

466.033 Registration certificates.--The department shall not require an examination, but shall issue a registration certificate upon completion of the registration form and compliance with any rules promulgated by the department under s. 466.038.

History.--ss. 2, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429.

466.034 Change of ownership or address.--When the ownership or address of any dental laboratory operating in this state is changed, the owner thereof shall notify the department within 30 days of such change of ownership or address.

History.--ss. 2, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429.

466.035 Advertising.--Dental laboratories shall not solicit or advertise, directly or indirectly, by mail, card, newspaper, pamphlet, radio, television, or otherwise to the general public to construct, reproduce, or repair prosthetic dentures, bridges, plates, or other appliances to be used or worn as substitutes for natural teeth or for the regulation of natural teeth.

History.--ss. 2, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429.

466.036 Information; periodic inspections; equipment and supplies.--The department may require from the applicant for a registration certificate to operate a dental laboratory any information necessary to carry out the purpose of this chapter, including proof that the applicant has the equipment and supplies necessary to operate as determined by rule of the department, and shall require periodic inspection of all dental laboratories operating in this state. Such inspections shall include, but not be limited to, inspection of sanitary conditions, equipment, supplies, and facilities on the premises. The department shall specify dental equipment and supplies that are not permitted in a registered dental laboratory.

History.--ss. 2, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 2, ch. 89-374; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 3, ch. 98-130.

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466.037 Suspension and revocation; administrative fine.--The department may suspend or revoke the certificate of any dental laboratory registered under s. 466.032, for failing to comply with the provisions of this chapter or rules adopted by the department under this chapter. The department may impose an administrative fine.

History.--ss. 2, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 3, ch. 89-374; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 35, ch. 2001-277.

466.038 Rules.--The department, upon consultation with the Board of Dentistry and industry representatives of the dental laboratory profession, has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to enforce the provisions of this chapter pertaining to and regulating dental laboratories.

History.--ss. 2, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 4, ch. 89-374; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 129, ch. 98-200.

466.039 Violations.--It shall be unlawful for any person, firm, or corporation to operate as a dental laboratory as defined in this chapter, except those registered as provided in s. 466.032. Violation shall constitute a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

History.--ss. 2, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 95, ch. 91-224; s. 4, ch. 91-429.

466.041 Hepatitis B carriers.--

(1) Any licensee or applicant for licensure who is a carrier of the hepatitis B virus is required to so notify the board.

(2) The board shall by rule establish procedures for reporting carrier status and shall establish practice requirements which will protect the public from transmission of the hepatitis B virus in a dental practice setting or during dental procedures.

(3) Any report of hepatitis B carrier status filed by a licensee or applicant in compliance with the requirements established by the board shall be confidential and exempt from the provisions of s. 119.07(1), except for the purpose of the investigation or prosecution of alleged violations of this chapter by the department.

History.--ss. 18, 19, ch. 89-374; ss. 60, 65, ch. 91-137; s. 25, ch. 91-140; ss. 7, 9, ch. 91-156; s. 4, ch. 91-429; s. 320, ch. 96-406.

466.021 Retention of dental laboratories by dentist; penalty.--Each licensed dentist who uses the services of any dental laboratory for the purpose of constructing, altering,

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repairing, or duplicating any denture, implant, veneer, partial denture, bridge splint, orthodontic or other prosthetic appliance, or other suitable form of artificial oral restorative device shall be required to furnish the dental laboratory with a written prescription in a form prescribed by rule of the board. This prescription shall be dated and signed by the dentist and shall include the license number of the dentist, the patient's name or number with sufficient descriptive information to clearly identify each separate and individual piece of work to be performed by the dental laboratory, and a specification of materials to be contained in each work product. A copy of the prescription shall be retained in a file in the prescribing dentist's office for a period of 4 years following the date the prescription was issued, and the original prescription shall be retained in a file by the dental laboratory for a period of 4 years. A registered dental laboratory shall disclose in writing at the time of delivery of the final restoration to the prescribing dentist the materials and all certificates of authenticity that constitute each product manufactured and the point of origin of manufacture of each restoration, including the address and contact information of the dental laboratory. The file of prescriptions to be kept by the dentist and the dental laboratory shall be open to inspection at any reasonable time by the department or its constituted agent. Failure of the dentist to keep records of each prescription shall subject the dentist to suspension or revocation of her or his license to practice dentistry in this state. Failure of a dental laboratory that has accepted a prescription to have the original or electronic copy of each prescription and to ensure the accuracy of each product's material disclosure at the time it is delivered to the prescribing dentist as required by this section is admissible evidence of a violation of this chapter and constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. This section does not preclude a registered dental laboratory from working for another registered dental laboratory if that work is performed pursuant to written authorization, in a form to be prescribed by rule of the board, which evidences that the originating laboratory has obtained a valid prescription and which sets forth the work to be performed and the resulting material certifications to be provided. A dental laboratory accepting prescriptions from dentists is liable for damages caused by inaccuracies in the material disclosure, certificates of authenticity, or point of origin provided by the dental laboratory to the prescribing dentist. This section does not preclude a registered laboratory from providing its services to dentists licensed and practicing in another state if that work is requested or otherwise authorized in written form that clearly identifies the name and address of the requesting dentist and sets forth the work to be performed and otherwise complies with all applicable laws and treaties.

History.--ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 93, ch. 91-224; s. 4, ch. 91-429; s. 258, ch. 97-103; s. 2, ch. 99-183; s. 126, ch. 99-397; s. 6, ch. 2005-189; s. 9, ch. 2008-64.

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**** Information in italics is interpretation by the Florida Dental Laboratory Association based upon discussions with Florida Board of Dentistry personnel. ****

Text of Florida Administrative Code Governing Dental Laboratories

Excerpted from the Florida Administrative Code, current as of March 2010.

Work Order Forms**

Florida Administrative Code, Section 64B5-17.006

1. Approved work order forms must contain all information necessary for completion of the assigned work and must include at a minimum:
 - a. Title – “Laboratory Procedure Authorization;”
 - b. Name, address and license number of the registered dental laboratory;
 - c. Name, address and license number of the Florida licensed dentist who owns the work order form and is authorizing the procedure;
 - d. Name of patient(s);
 - e. Date sent to lab;
 - f. Signature of the licensed dentist, which may be an electronic signature.
2. Copies of work order forms must be maintained, either on paper or stored electronically in an encrypted data base, by the dentist for a period of four (4) years.

Specific Authority 466.021 FS. Law Implemented 466.021 FS. History–New 12-21-99, Amended 3-23-06, 10-9-06.

1. Approved prescription forms must contain all information necessary from completion of the assigned work and must include a minimum:
 - a. Title – “Laboratory Procedure Prescription”;
 - b. Name, address and license number of the registered dental laboratory;
 - c. Name, address and license number of the Florida licensed dentist who owns the prescription from and is authorizing the procedure;
 - d. Patient’s name or number;
 - e. Date sent to the lab;
 - f. Signature of the licensed dentist, which may be an electronic signature;
 - g. Sufficient descriptive information to clearly identify each separate and individual piece of work to be performed by the dental laboratory; and
 - h. Specification of materials to be contained in each work product.
2. Copies of prescription forms must be maintained, either on paper or stored electronically in an encrypted data base, by the dentist for a period of four (4) years.

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Laboratory to Laboratory Procedure Authorization

Administrative Code language released in 2010:

1. A registered dental laboratory may perform work for another registered dental laboratory if that work is performed pursuant to a written authorization form containing all information necessary for completion of the assigned work and must include at a minimum the following information:
 - a. Title – “Laboratory Procedure Authorization”;
 - b. Name, address and license number of the originating registered dental laboratory;
 - c. Name, address and license number of the registered dental laboratory performing the work; (if that lab is required to register)
 - d. Evidence that the originating laboratory has obtained a valid prescription which shall include the name, address and license number of the licensed dentist who wrote the original prescription authorizing the procedure;
 - e. Sufficient descriptive information to clearly identify each separate and individual piece of work to be performed by the dental laboratory; and
 - f. Specification of materials to be contained in each work product.
2. Copies of prescription forms must be maintained, either on paper or stored electronically in an encrypted data base, by the dentist for a period of four (4) years.

Dental Laboratory Biennial Registration

Florida Administrative Code, Section 64B27-1.002

The Department shall issue a registration certificate entitling the holder to operate a dental laboratory for a period of two years, after the Department has received from the registering person, firm, or corporation:

1. The registration form provided by the Department,
2. A biennial registration fee of \$200.00, and
3. The operator of a dental laboratory shall notify the Department of a change in ownership or address within 30 days. The closure of the laboratory constitutes a change of address. Failure to timely notify the Department of a change in ownership or address, including closure of a laboratory, is grounds to deny an application for registration of a laboratory.

Specific Authority 466.038 FS. Law Implemented 466.032(1), 455.033 FS. History—New 2-10-93, Formerly 21-29.002, 61E4-1.002, Amended 10-29-95, Formerly 59CC-1.002, Amended 1-9-02, 10-23-05.

**** Information in italics is interpretation by the Florida Dental Laboratory Association based upon discussions with Florida Board of Dentistry personnel. ****

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Laboratory Inspections, Practice & Procedure for Healthy and Safe Laboratory Operation

Florida Administrative Code, Section 64B27-1.001

1. Each dental laboratory registered by the Department of Health to operate in the State of Florida shall be subject to periodic inspections by Department personnel at least one time during the calendar year. Such inspections shall be conducted during regular business hours and may occur with or without notice.
2. The following practice and procedure shall be implemented by each registered dental laboratory in the State of Florida and be subject to inspection pursuant to subsection (1) of this section. Each registered dental laboratory shall:
 - a. Be clean and orderly and in good repair, with regard to normal fabrication procedures at time of inspection;
 - b. All waste materials properly disposed of at the end of each day according to local restrictions;
 - c. Maintain on the laboratory premises a copy of the laboratory registration so it is readily available for inspection by Department personnel;
 - d. Maintain on the laboratory premises, for each separate appliance and for a period of four years, a work order from a licensed dentist authorizing construction or repair of the specified artificial oral appliance; and
 - e. Maintain on the laboratory premises a written policy and procedure document on sanitation. Said policy shall include, but not necessarily be limited to:
 - i. Intake and disinfection procedure for each appliance, impression, bite, or other material posing a possible contamination risk received by the laboratory; and
 - ii. Separate procedure for handling dental appliances, and impressions previously identified by the dentist, known to have come from carriers of the HBV and/or HIV virus.
3. Each registered dental laboratory shall have a designated receiving area. The following procedure shall be followed in the receiving area:
 - a. Work surfaces and counter tops shall be constructed of non-porous materials which shall be disinfected daily with a chlorine compound, a combination synthetic phenolic, or an iodophor solution that has been diluted according to the manufacturer's directions.
 - b. Employees working in the receiving area shall wear disposable gloves, and as an option may wear a facial mask or protective eyewear.
4. The following dental equipment and supplies shall not be permitted in a registered dental laboratory in this state:
 - a. Dental chairs.
 - b. X-ray machines.
 - c. Anesthetics, sedatives, or medicinal drugs, other than personal prescriptions.

**** Information in italics is interpretation by the Florida Dental Laboratory Association based upon discussions with Florida Board of Dentistry personnel. ****

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Specific Authority 466.038 FS. Law Implemented 466.021, 466.036 FS. History—New 5-26-91, Formerly 21-29.001, 61E4-1.001, 59CC-1.001, Amended 8-6-06.

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Shade Verification

Florida Administrative Code, Section 64B5-17.010

For the purposes of interpreting Sections 466.003(3), 466.026(1)(a) and 466.028(1)(g)(bb), F.S., the Board shall not consider it to be the unlicensed practice of dentistry for an unlicensed person to furnish, supply, construct or reproduce an appliance to be worn in the human mouth or to verify the patient's shade-selection outside the dentist's direct supervision for fixed partial prosthesis if:

1. The appliance is a removable mouth protection device that is inserted and removed by the user without adjustment by a licensed dentist (e.g. athletic mouth guards);
2. A prescription or dentist's order is not required in order to obtain the appliance;
3. The appliance does not adjust or otherwise affect the natural features of the face or mouth or affect any appliance placed in the mouth by a licensed dentist;
4. The appliance or device does not have the potential to cause significant or irreparable damage to the dentition and/or oral tissue;
5. The request for the shade verification is accompanied by a prescription form or work order written by a licensed dentist to meet the requirements of Section 466.021, F.S.;
6. The dentist has previously completed the initial shade selection;
7. The shade verification site is approved by the dentist and meets all requirements of Sections 466.028(1)(u), 466.031(1) and 466.032(1), F.S.;
8. During shade verification, no appliances or prosthetic devices are to be placed, removed or sealed in the oral cavity at the site except by a licensed dentist on a patient of record in accordance with the requirements of Sections 466.024(5) and 466.028(1)(m), F.S.;
9. During shade verification, contact to the patient is limited to visual contact only;
10. During shade verification, soft or hard tissue shall not be manipulated;
11. During shade verification, the patient shall be instructed on how to retract his or her own lip, and the shade tab shall only be held in proximity, but without physical contact to the patient's dentition; and
12. During shade verification, photography shall be limited to the patient's visible dentition during smile and the patient's dentition with the patient retracting their lips.

Specific Authority 466.004(4) FS. Law Implemented 466.026(1)(a), 466.028(1)(g), (bb) FS. History—New 9-5-91, Formerly 21G-17.010, 61F5-17.010, Amended 5-9-95, Formerly 59Q-17.010, Amended 10-8-03.

**** Information in italics is interpretation by the Florida Dental Laboratory Association based upon discussions with Florida Board of Dentistry personnel. ****

Penalties for Violations of Florida Statutes

Florida Statutes Chapter 466, Section 775.082

1. A person who has been convicted of a capital felony shall be punished by death if the proceeding held to determine sentence according to the procedure set forth in s. 921.141 results in findings by the court that such person shall be punished by death, otherwise such person shall be punished by life imprisonment and shall be ineligible for parole.
2. In the event the death penalty in a capital felony is held to be unconstitutional by the Florida Supreme Court or the United States Supreme Court, the court having jurisdiction over a person previously sentenced to death for a capital felony shall cause such person to be brought before the court, and the court shall sentence such person to life imprisonment as provided in subsection (1). No sentence of death shall be reduced as a result of a determination that a method of execution is held to be unconstitutional under the State Constitution or the Constitution of the United States.
3. A person who has been convicted of any other designated felony may be punished as follows:
 - a.
 - i. For a life felony committed prior to October 1, 1983, by a term of imprisonment for life or for a term of years not less than 30.
 - ii. For a life felony committed on or after October 1, 1983, by a term of imprisonment for life or by a term of imprisonment not exceeding 40 years.
 - iii. Except as provided in subparagraph 4., for a life felony committed on or after July 1, 1995, by a term of imprisonment for life or by imprisonment for a term of years not exceeding life imprisonment.
 1. Except as provided in sub-subparagraph b., for a life felony committed on or after September 1, 2005, which is a violation of s. 800.04(5)(b), by:
 - a. A term of imprisonment for life; or
 - b. A split sentence that is a term of not less than 25 years' imprisonment and not exceeding life imprisonment, followed by probation or community control for the remainder of the person's natural life, as provided in s. 948.012(4).
 2. For a life felony committed on or after July 1, 2008, which is a person's second or subsequent violation of s. 800.04(5)(b), by a term of imprisonment for life.

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- b. For a felony of the first degree, by a term of imprisonment not exceeding 30 years or, when specifically provided by statute, by imprisonment for a term of years not exceeding life imprisonment.
 - c. For a felony of the second degree, by a term of imprisonment not exceeding 15 years.
 - d. For a felony of the third degree, by a term of imprisonment not exceeding 5 years.
4. A person who has been convicted of a designated misdemeanor may be sentenced as follows:
- a. For a misdemeanor of the first degree, by a definite term of imprisonment not exceeding 1 year;
 - b. For a misdemeanor of the second degree, by a definite term of imprisonment not exceeding 60 days.

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Fines for Violations of Florida Statutes

Florida Statutes Chapter 466, Section 775.083

2. A person who has been convicted of an offense other than a capital felony may be sentenced to pay a fine in addition to any punishment described in s. 775.082; when specifically authorized by statute, he or she may be sentenced to pay a fine in lieu of any punishment described in s. 775.082. A person who has been convicted of a noncriminal violation may be sentenced to pay a fine. Fines for designated crimes and for noncriminal violations shall not exceed:
 - a. \$15,000, when the conviction is of a life felony.
 - b. \$10,000, when the conviction is of a felony of the first or second degree.
 - c. \$5,000, when the conviction is of a felony of the third degree.
 - d. \$1,000, when the conviction is of a misdemeanor of the first degree.
 - e. \$500, when the conviction is of a misdemeanor of the second degree or a noncriminal violation.
 - f. Any higher amount equal to double the pecuniary gain derived from the offense by the offender or double the pecuniary loss suffered by the victim.
 - g. Any higher amount specifically authorized by statute. Fines imposed in this subsection shall be deposited by the clerk of the court in the fine and forfeiture fund established pursuant to s. 142.01. If a defendant is unable to pay a fine, the court may defer payment of the fine to a date certain.
3. In addition to the fines set forth in subsection (1), court costs shall be assessed and collected in each instance a defendant pleads nolo contendere to, or is convicted of, or adjudicated delinquent for, a felony, a misdemeanor, or a criminal traffic offense under state law, or a violation of any municipal or county ordinance if the violation constitutes a misdemeanor under state law. The court costs imposed by this section shall be \$50 for a felony and \$20 for any other offense and shall be deposited by the clerk of the court into an appropriate county account for disbursement for the purposes provided in this subsection. A county shall account for the funds separately from other county funds as crime prevention funds. The county, in consultation with the sheriff, must expend such funds for crime prevention programs in the county, including safe neighborhood programs under ss. 163.501-163.523.
4. The purpose of this section is to provide uniform penalty authorization for criminal offenses and, to this end, a reference to this section constitutes a general reference under the doctrine of incorporation by reference.

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Florida's Dental Laboratory Law continued

Penalties for Not Following the New Laws

FDLA asked the Florida Board of Dentistry what the penalty would be for a Florida laboratory that was not following the laws and rules governing their business.

The following is guidance based upon these discussions:

- Not following the material disclosure portion of the law is a 2nd degree misdemeanor. The first offense will be prosecuted as determined by law enforcement.
- If other facets of the law are not complied with, the Florida Department of Health has options at its discretion. Those options include, with premise that a request for corrective action for first offense would be the first citation:
 - Sending a letter of guidance with timeline for corrective action
 - If the Department finds that a dental laboratory, “failed to perform any statutory or legal obligations”, they can levy a fine of \$300.00 up to a \$1,000.00, and put a laboratory on probation for up to five years
 - If the Department finds that a dental laboratory “failed to keep prescriptions” they may levy a fine of \$1,000.00 up to \$6,000.00 and revoke the dental laboratory’s registration for up to three years.
 - If the Department finds that a dental laboratory “operated below the minimum standards of performance”, they can bring civil and/or criminal charges depending on the offense



Laws and Rules for Dental Laboratories in Florida

**** Information in italics is interpretation by the Florida Dental Laboratory Association based upon discussions with Florida Board of Dentistry personnel. ****

Advisement from the Florida Department of Revenue in Regards to Sales Tax on Dental Restorations

QUESTION: What is the taxable status of various dental products and what is the proper documentation required for exempt sales?

ANSWER - Based on Facts Below: The purchase by a dentist or a dental lab of raw materials that will become component parts of medical or dental products that will in turn be dispensed to a healthcare patient by a healthcare practitioner is exempt from tax. One-time use products, such as dental impression materials, that contain the FDA warning "Rx-Only" would be included within this category.

For sales of medical products that are to be resold, and which are not "Rx-only", to dental labs and dentists who are registered for sales and use tax purposes, a copy of their Annual Resale Certificate should be obtained. For sales of non-Rx materials to unregistered dental labs and unregistered dentists, an affidavit should be obtained which states that the specified products will be incorporated into a patient pursuant to a doctor's orders and are therefore exempt from tax pursuant to section 212.08(2), Florida Statutes. Form DR-97, titled "Suggested Format for Blanket Exemption Certificate Based on Property's Use", may be used if Taxpayer used the space marked "Other" to insert the justifying language.

Sales to dental labs and dentists of equipment and consumable supplies are not exempt from tax, and the vendor should collect tax from the customer.

Jan 27, 2003

Re: Technical Assistance Advisement 03A-003
Sales and Use Tax - Sales to Dental Labs
Section: 212.08, F.S.
Rules: 12A-1.020, 12A-1.021, F.A.C.
Petitioner: XXX (herein "Taxpayer")
FEI: XX

Dear :

This letter is a response to your petition dated December 3, 2002, for the Department's issuance of a Technical Assistance Advisement ("TAA") concerning the above referenced party and matter. Your petition has been carefully examined and the Department finds it to be in compliance with the requisite criteria set forth in Chapter 12-

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11, F.A.C. This response to your request constitutes a TAA and is issued to you under the authority of s. 213.22, F.S.

FACTS

The petition sets forth the following facts:

[Taxpayer] is in the business of developing, manufacturing and selling dental and dental laboratory products. [Taxpayer] is located outside the state of Florida, but sells to customers within the state of Florida, and has nexus with Florida. Therefore, [Taxpayer] is required to collect applicable [sales and] use tax from Florida customers

Most of [Taxpayer]'s products that are sold to dental laboratories become a component part of the dentures, dental crowns, bridges, and other products manufactured by the dental labs for sale to dentists. A few products, such as impression material and composites, are purchased by the dental labs for resale to dentists without any change in form. The following is a list of the [Taxpayer]'s products that are sold to dental labs:

ALLOYS - metals that are used to make the framework or structure that is the base for a dental crown, cap or bridge. These alloys can be made of a combination of precious metals, mostly a gold and palladium mixture, or of non-precious metals, such as nickel or chrome-cobalt. In some cases, the [Taxpayer] will sell the precious metal in its pure form to dental laboratories for specific applications.

PORCELAIN - material that is applied as a veneer over the metal base of a dental crown, cap or bridge.

COMPOSITES - materials that are used to manufacture bridges, crowns, inlays, etc. (Note: This should not be confused with composites [that] are used by dentists to cement dental work or as a chair-side restorative.)

IMPRESSION MATERIAL - this is used by a dentist or doctor to take an impression of the patient's mouth. From the impression a working model is produced to simulate the patient's upper and lower teeth.

DENTAL OFFICE MATERIALS - Laboratories will rarely purchase dental office composites, impression materials, or bonding agents [that] will then be resold to dentists without a change in form.

The sale of all of the above items by [Taxpayer] is subject to federal regulation by the Food and Drug Administration ("FDA"). Under section 21 of Code of Federal Regulations, these devices must bear the language "Caution: Federal law restricts this

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device to sale by or on the order of a dentist". See 21 C.F.R. 801.109 for this application.

Under proposed rules, currently being treated as FDA regulations by the FDA, this statement can be reduced to "Rx Only".

[Taxpayer] also sells relatively small amounts of supplies to the labs, such as abrasives, which are used by [Taxpayer]'s customers in manufacturing the dental crowns and other dental products, etc. Machinery and equipment are also sold to the dental labs. [Taxpayer] intends to charge the dental labs use tax on the sale of such items.

REQUESTED ADVISEMENT

Advice is requested on the taxability of the various products and proper documentation required for exempt sales.

LAW AND DISCUSSION

Section 212.08(2), Florida Statutes, provides in part:

(2) EXEMPTIONS; MEDICAL.

(a) There shall be exempt from the tax imposed by this chapter any medical products and supplies or medicine dispensed according to an individual prescription or prescriptions written by a prescriber authorized by law to prescribe medicinal drugs....

(f) Sales of drugs to or by physicians, dentists, veterinarians, and hospitals in connection with medical treatment are exempt.

Rule 12A-1.020(6)(a), Florida Administrative Code, provides:

(6)(a) Medical products and supplies used in the cure, mitigation, alleviation, prevention or treatment of injury, illness, disease or incapacity are taxable, unless:

1. Temporarily or permanently incorporated into a patient or client by a practitioner of the healing arts licensed by the State of Florida.
2. Ordered and dispensed by or on the prescription of a duly licensed practitioner authorized by the laws of the state to prescribe medicinal drugs; or
3. Ordered and dispensed by a pharmacist pursuant to the established dispensing procedures determined by the joint committee of medical, osteopathic and pharmacy professions as created by section 465.186, F.S.

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Rule 12A-1.021(1)(b), Florida Administrative Code, provides in part:

*NOTE: Gold, silver and other materials/devices temporarily or permanently incorporated into the human body by physicians or dentists shall be exempt (i.e.: organ implant, dentures, dental bridge work and crowns).

The purchase by a dentist or a dental lab of raw materials that will become component parts of medical or dental products that will in turn be dispensed to a healthcare patient by a healthcare practitioner is exempt from tax. One-time use products, such as dental impression materials, that contain the FDA warning "Rx-Only" would be included within this category.

Such sales to licensed dental labs (and to licensed dentists) would require no further documentation when the medical product being sold is subject to federal regulation or is an "Rx-only" product. These one-time use products that contain the "Rx-Only" labeling would be product specific exempt, and the vendor would not be required to obtain a resale certificate or affidavit.

For sales of medical products that are to be resold, and which are not "Rx-only", to dental labs and dentists who are registered for sales and use tax purposes, a copy of their Annual Resale Certificate should be obtained. For sales of non-Rx materials to unregistered dental labs and unregistered dentists, an affidavit should be obtained which states that the specified products will be incorporated into a patient pursuant to a doctor's orders and are therefore exempt from tax pursuant to section 212.08(2), Florida Statutes. Form DR-97, titled "Suggested Format for Blanket Exemption Certificate Based on Property's Use," may be used if Taxpayer used the space marked "Other" to insert the justifying language. This form is available on the Department's web site, www.myflorida.com/dor.

Sales to dental labs and dentists of equipment and consumable supplies are not exempt from tax, and the vendor should collect tax from the customer.

This response constitutes a Technical Assistance Advisement under Section 213.22, F.S., which is binding on the department only under the facts and circumstances described in the request for this advice, as specified in Section 213.22, F.S. Our response is predicated upon those facts and the specific situation summarized above.

You are advised that subsequent statutory or administrative rule changes or judicial interpretations of the statutes or rules upon which this advice is based may subject similar future transactions to a different treatment from that which is expressed in this response.

You are further advised that this response, your request and related backup documents are public records under Chapter 119, F.S., and are subject to disclosure to the public

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under the conditions of s. 213.22, F.S. Confidential information must be deleted before public disclosure. In an effort to protect confidentiality, we request you provide the undersigned with an edited copy of your request for Technical Assistance Advisement, the backup material and this response, deleting names, addresses and any other details which might lead to identification of the taxpayer. Your response should be received by the Department within 15 days of the date of this letter.

Sincerely,

Sara D. Faulkenberry
Tax Law Specialist
Technical Assistance and Dispute Resolution
850/414-9838

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How to Report Unlicensed Activity

(Note: Under Florida law, e-mail addresses are public records. If you do not want your e-mail address released in response to a public records request, do not send electronic mail to this entity. Instead, contact this office by phone or in writing.)

To report suspected unlicensed health care practice, call 1-877-HALT-ULA (1-877-425-8852), Email the Department at HALTULA@doh.state.fl.us or mail in a completed Uniform Complaint Form. The Uniform Complaint Form is available online at http://www.doh.state.fl.us/mqa/enforcement/enforce_home.htm.

To file a complaint on a non-medical related business or profession, please visit the Department of Business and Professional Regulation online at http://www.myflorida.com/dbpr/os/communications_office/unlicensed_activity/index.shtml

How To File a Complaint of Unlicensed Activity

The division's Enforcement Unit analyzes complaints and reports involving suspected unlicensed health care practice and initiates investigations when appropriate. Effective complaints must include, verifiable information and as many specific details as possible. Anonymous complaints will be reviewed; however, they may be difficult to pursue unless they include evidence of the allegations made. The Enforcement Unit can be contacted online at http://www.doh.state.fl.us/mqa/enforcement/enforce_home.htm.

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Florida's Dental Laboratory Law continued

Penalties for Not Following the New Laws

FDLA asked the Florida Board of Dentistry what the penalty would be for a Florida laboratory that was not following the laws and rules governing their business.

The following is guidance based upon these discussions:

- Not following the material disclosure portion of the law is a 2nd degree misdemeanor. The first offense will be prosecuted as determined by law enforcement.
- If other facets of the law are not complied with, the Florida Department of Health has options at its discretion. Those options include, with premise that a request for corrective action for first offense would be the first citation:
 - Sending a letter of guidance with timeline for corrective action
 - If the Department finds that a dental laboratory, “failed to perform any statutory or legal obligations”, they can levy a fine of \$300.00 up to a \$1,000.00, and put a laboratory on probation for up to five years
 - If the Department finds that a dental laboratory “failed to keep prescriptions” they may levy a fine of \$1,000.00 up to \$6,000.00 and revoke the dental laboratory’s registration for up to three years.
 - If the Department finds that a dental laboratory “operated below the minimum standards of performance”, they can bring civil and/or criminal charges depending on the offense



Laws and Rules for Dental Laboratories in Florida

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“In-House” Technicians and Laboratories

Florida Statutes Chapter 466, Section 466.031 essentially defines “in-house” as “any dental laboratory technician who constructs or repairs dental prosthesis appliances in the office of a licensed dentist for such dentist only and under her or his supervision and work order.”

The Florida Statutes excludes an in-house “technician” from having to register with the state, but not necessarily an in-house “laboratory”.

FDLA recommends the following course of action for in-house technicians or laboratories in an attempt to maintain compliance:

1. Registered with the state as a dental laboratory. It is currently \$200 every two years to maintain registration, and the next renewal is due in February 2010. However, it should be understood that registration with the state will open the laboratory to yearly inspection by the state. Section 64B27-1.001 of the Florida Administrative Code discusses dental laboratory inspections and what is required.
2. Comply with the new laws regarding material specification (going from the dentist to the “technician” or “laboratory” on the Laboratory Procedure Prescription (formerly called the work order). This is a requirement for prescriptions, no matter if the laboratory is required to register or not.
3. Comply with the new laws regarding material & point of origin disclosure, and certificates of authenticity for materials used. Both of these are new requirements under Florida Statutes Chapter 466, Section 466.021, and are required by all laboratories no matter if they are required to register or not.
4. Lastly, since the Florida Statutes Chapter 466, Section 466.032 does specify that, “This subsection does not apply to a dental laboratory that is physically located within a dental practice operated by a dentist licensed under this chapter.” – in-house “technicians” and “laboratories” should NOT have to provide proof that a full time employee has taken 18 hours of continuing education with the biennial registration renewal.

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Resources

For more information visit www.fdla.net for downloadable form and links to the Florida Department of Health information.

Contact the Florida Dental Laboratory Association in Tallahassee at:

Florida Dental Laboratory Association
325 John Knox Road L103 • Tallahassee, Florida 32303
(850) 224-0711 Phone • 850/222-3019 Fax
www.fdla.net

The Florida Board of Dentistry, Department of Health is the regulatory body that oversees the regulation of dental laboratories. The department staff reviews and approves laboratory registrations, compliance with the law and in conjunction with other government agencies has the authority to levy fines or penalties for non compliance with laws and administrative rules.

To contact the Department:

Email: MedicalQualityAssurance@doh.state.fl.us

Telephone: (850) 488-0595

General Mailing Address

Florida Board of Dentistry
4052 Bald Cypress Way
Tallahassee, Florida 32399-3257

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Sample Laboratory Procedure Prescription from FDLA

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Sample Material & Point of Origin Disclosure Form from FDLA

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**Comparison Chart - Florida Department of Health and NBC CDT
Continuing Education Requirements**

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Comparison of Florida Department of Health and NBC CDT Continuing Education Requirements

	Number of Hours	Required Courses	Additional Requirements
NBC – CDT	12 Hours – Annually	1 Hour – Regulatory Standards (Topics include OSHA, FDA, HIPPA) FDA = Food and Drug Administration OSHA = Occupational Safety and Health Administration	6 Hours – Documented Scientific 5 Hours – Professional Development (Or any combination)
State of Florida CE Requirements for Dental Laboratories	18 Hours – Every two years	1 Hour – FL Laws and Rules of Dental Laboratories and Dental Technicians (this topic counts for NBC Professional Development as well) 2 Hours – Prevention of Medical Errors (on either OSHA or FDA)	15 Hours – General Any Combination

What You Need to Know to be in Compliance

NBC – CDT	In order for a Florida CDT to also meet Florida state requirements, they need “1” hour on Florida laws and rules for dental laboratories every two years.
All Florida Labs	<ul style="list-style-type: none"> ▪ Who is responsible for attaining all 18 hours of Continuing Education? Each Florida dental laboratory for their February 2014 state registration renewal must prove that a person employed by the laboratory for one full year at full time status has acquired 18 hour of continuing education credit approved by the Florida Board of Dentistry. Florida requires every business that is registered as a dental laboratory with the Florida Department of Health to document that the owner of the laboratory, or a dental technician who is employed full time by the laboratory, maintains 18 hours of approved continuing education in dental technology every two years. ▪ Can laboratories split up the total continuing education hours between employees? Laboratories may not split the required continuing education credit between employees. ▪ Where can I get my credits and how do I know if the courses I attend will be accepted by the State of Florida? The designated laboratory employee may obtain continuing education credits through online offerings, home study or in person courses. It is the responsibility of the laboratory to ensure a course is approved for Florida credits. <ul style="list-style-type: none"> ○ The Florida Dental Laboratory Association and the Florida Dental Association are automatically accepted as approved providers of acceptable continuing education credits by the Florida Board of Dentistry. ○ Suppliers, schools or other entities may be approved by the Florida Board of Dentistry to provide credits, after completing an application which can currently be found on www.cebroker.com. You may find a list of courses approved by the Florida Board of Dentistry at www.cebroker.com. Online courses and courses outside the state of Florida are eligible for approval. ▪ What is the timeframe in which I must attain all 18 hours? All of the 18 hours that will be required with the February 2014 registration renewal must have been collected between March 2012 and February 2014. Credits earned before March 2012 will NOT be counted towards the required 18 hours of continuing education required in February 2014. ▪ Sworn Affidavit and Certificates of Attendance Florida laboratories will be required to submit a sworn affidavit with their February 2014 registration renewal listing the date, location, sponsor, subject matter and hours of completed continuing education for the designated employee. The laboratory will also be required to keep backup receipts, certificates of completion or vouchers for the submitted courses in case the state requests the information. The state may request this backup information at any time, or may select laboratories at random to audit.

For more information please contact FDLA at 850-224-0711. For a list of FDLA sponsored continuing education courses and events please visit www.fdma.net