

BOARDS AND COMMISSIONS

Board of Dentistry

(Amendment)

201 KAR 8:016. Registration of dental laboratories.

RELATES TO: KRS 313.021, 313.022, 313.550

STATUTORY AUTHORITY: KRS 313.021(1)(a), (c), 313.022(1)(c), 313.080, 313.090, 313.100

NECESSITY, FUNCTION, AND CONFORMITY: KRS 313.021(1)(a) requires the board to govern dental laboratories. KRS 313.021(1)(c) requires the board to promulgate administrative regulations for any license or registration created by the board. KRS 313.022(1) requires the board to promulgate administrative regulations to prescribe a reasonable schedule of fees, charges, and fines. This administrative regulation establishes requirements for the issuance and renewal of dental laboratory registration with the board. This administrative regulation establishes fees for the issuance, renewal, and reinstatement of registrations of dental laboratories with the board.

Section 1.

(1) Each commercial dental laboratory operating, doing business, or intending to operate or do business in Kentucky~~[the state]~~ shall register with the board~~[- and pay the fee established in Sections 4 and 8 of this administrative regulation].~~

(2) A dental laboratory shall be considered operating or doing business in Kentucky~~[within this state]~~ if its work product is prepared pursuant to a written authorization originating within this state.

Section 2. The board shall not issue a registration to a commercial dental laboratory unless the applying dental laboratory is operated under the supervision of at least one (1) certified dental technician (CDT) or dentist licensed in this state in accordance with KRS 313.550.

Section 3. If the dental laboratory has violated any provision of KRS Chapter 313 or 201 KAR Chapter 8, the dental laboratory shall be subject to disciplinary action pursuant to KRS 313.080 and 313.100.

Section 4. ~~[Each commercial dental laboratory shall pay a fee of \$150 to the board before a registration shall be issued to the applicant.]~~

~~[Section 5.]~~ Upon the granting of a registration, the board shall assign to that laboratory a dental registration number. The laboratory registration number shall appear on all invoices or other correspondence of the laboratory.

Section 5. ~~[Section 6.]~~ A dentist shall use only those services of a commercial dental laboratory that is duly registered with the board as required by this administrative regulation. A dentist shall include the registration number of the dental laboratory on the dentist's work order.

Section 6. [Section 7.] Initial Registration.

(1) The owner or operator of a commercial dental laboratory desiring to obtain a registration shall:

(a) Submit an Application for Registration of Dental Laboratories; and

(b) Pay the fee required by 201 KAR 8:520.

(2) ~~[Each commercial dental laboratory operating, doing business, or intending to operate or do business within the state shall submit an Application for Registration of Dental Laboratory or Renewal of Registration of Dental Laboratory to the board on a form~~

~~provided by the board accompanied with the registration or renewal fee required.]~~ The application shall include:

- ~~(a) [(1)]~~ The name, mailing address, phone number, and e-mail address of the laboratory;
- ~~(b) [(2)]~~ The physical address of the laboratory if different from the mailing address;
- ~~(c) [(3)]~~ The name and CDT number of the supervising CDT or the name and license number of the supervising dentist who is licensed in this state; and
- ~~(d) An acknowledgement by the supervising CDT or dentist who is licensed in this state that the laboratory:~~
 - ~~1. [(4)] [A statement that the laboratory]~~ Meets the infectious disease control requirements under Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control and Prevention (CDC) of the United States Public Health Service;
 - ~~2. [(5)] [An acknowledgement by the supervising CDT or dentist who is licensed in this state that the laboratory]~~ Will provide material disclosure to the prescribing dentist that contains the U.S. Food and Drug Administration registration number of all patient contact materials contained in the prescribed restoration in order that the dentist may include those numbers in the patient's record; and
 - ~~3. [(6)] [An acknowledgement by the supervising CDT or dentist who is licensed in this state that he or she]~~ Will disclose to the prescribing dentist the point of origin of the manufacture of the prescribed restoration. If the restoration was partially or entirely manufactured by a third-party provider, the point of origin disclosure shall identify the portion manufactured by a third-party provider and the city, state, and country of the provider.

Section 7. Registration Renewal.

- (1) Commercial dental lab registrations shall expire on July 31 of each year and must be renewed to continue operating or doing business in Kentucky.
- (2) To renew a registration, the owner or operator shall:
 - (a) Submit a Renewal Application for Registration of Dental Laboratories on or before July 31; and
 - (b) Pay the fee required by 201 KAR 8:520.
- (3) The renewal application shall include the information required in Section 6(2)(a-d) of this administrative regulation.

~~[Section 8.] [Each commercial dental laboratory registered with the board shall be required to renew its registration before July 31 each year by completing and submitting a Renewal of Registration of Dental Laboratory form and paying a fee of \$150.]~~

Section 8. [Section 9.] Incorporation by Reference.

- (1) The following material is incorporated by reference:
 - (a) "Application for Registration of Dental Laboratories", November 2022~~[June 2014]~~;
 - and
 - (b) "Renewal Application for Registration of Dental Laboratories", November 2022~~[March 2014]~~.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222, Monday through Friday, 8 a.m. through 4:30 p.m. This material is also available on the board's Web site at <http://dentistry.ky.gov>.

JEFF ALLEN, Executive Director

APPROVED BY AGENCY: November 14, 2022

FILED WITH LRC: November 15, 2022 at 11:50 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this Amendment shall be held on January 25, 2023 at 4:00pm, Eastern Time at the Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed Amendment. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed Amendment. Written comments shall be accepted through January 31, 2023. Send written notification of intent to be heard at the public hearing, or written comments on the proposed Amendment to the contact person below.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Jeff Allen

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This regulation establishes requirements for registering dental laboratories that do business in Kentucky.

(b) The necessity of this administrative regulation:

KRS 313.021(1)(a) requires the board to exercise the administrative functions of the Commonwealth in the regulation of dental laboratories.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

This administrative regulation establishes requirements for registering dental laboratories that do business in Kentucky.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation establishes requirements for registering dental laboratories in conformity with its authorizing statute.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

This amendment includes minor clarifications of the existing requirements for dental laboratory registration.

(b) The necessity of the amendment to this administrative regulation:

This amendment is necessary in order to clarify some registration requirements and to update Materials Incorporated by Reference in the existing regulation.

(c) How the amendment conforms to the content of the authorizing statutes:

This administrative regulation updates the requirements for registering dental laboratories that do business in Kentucky in conformity with its authorizing statute.

(d) How the amendment will assist in the effective administration of the statutes:

The amendment clarifies the requirements to register dental laboratories and updates the registration form, thereby reducing non-compliance and improving public safety.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

This regulation will primarily affect the approximately 250 dental laboratories doing business in Kentucky. (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

Each entity will still register in accordance with applicable law and administrative regulations. No additional actions are required as a result of this amendment.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

No additional costs will be accrued as a result of this amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

The amendment will result in a healthier patient population and the avoidance of potentially costly violations of applicable law and administrative regulations.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

No cost.

(b) On a continuing basis:

No cost.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

? Not applicable.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

No increase is needed.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This amendment maintains existing fees and does not increase them, even indirectly.

(9) TIERING: Is tiering applied?

No; this amendment impacts all similarly situated entities equally.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

None.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 313.021.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

None.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

None.

(c) How much will it cost to administer this program for the first year?

No cost.

(d) How much will it cost to administer this program for subsequent years?

No cost. Note: If specific dollar amounts cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

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Revenues (+/-):None.

Expenditures (+/-):None.

Other Explanation:

Not applicable.

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

None

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

None

(c) How much will it cost the regulated entities for the first year?

\$150 or less.

(d) How much will it cost the regulated entities for subsequent years?

\$150 or less.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]. This amendment will not have a major economic impact.