

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 shall register with the board.

(2) A dental laboratory shall be considered operating or doing business in Kentucky 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. 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. 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. 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) The application shall include:

(a) The name, mailing address, phone number, and e-mail address of the laboratory;

(b) The physical address of the laboratory if different from the mailing address;

(c) 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. 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. 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. 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. Incorporation by Reference.

- (1) The following material is incorporated by reference:
 - (a) "Application for Registration of Dental Laboratories", November 2022; and
 - (b) "Renewal Application for Registration of Dental Laboratories", November 2022.
- (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.