Title 19 - DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 1—Controlled Substances

PROPOSED AMENDMENT

19 CSR 30-1.017 Registration Process. The Department of Health and Senior Services is amending sections (1), (3), (5), (6), (7) and (8).

PURPOSE: This amendment requires applicants to apply for registrations through an electronic online system and eliminates the paper application process.

- (1) Database and Survey Process.
- (A) Applicants may apply for and receive a registration that is effective for up to twelve (12) months.
- (B) Applicants [may] shall apply [with either a paper application or] through the department's electronic online system.
- (C) Simultaneously with completing an application for a controlled substances registration, practitioners may also complete an annual voluntary census to assist the department in determining practitioner shortages and underserved regions of the state. Required questions and fields for controlled substance registrations are marked with an asterisk (*) in the electronic online system [and on paper applications].

(3) Requirements for All Applicants.

- (A) Any person who is required to be registered and who is not so registered may apply **online** for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is processed and the registration is issued. All applications are for new registrations.
- (B) Applications for registration shall be made on **online** forms designated by the Department of Health and Senior Services. Application [forms may be requested from the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or may] for registration shall be completed online and submitted electronically via the Missouri Department of Health and Senior Services' website at [www.health.mo.gov] https://health.mo.gov/safety/bndd/ along with the required fee.
- (C) [A written] **An** application [in paper form] shall contain the **electronic** signature of the applicant and shall be provided to the Department of Health and Senior Services with any required fee. This is a nonrefundable processing fee.
- (D) An application which does not contain or is not accompanied by the required information or fee may be denied sixty (60) days after notifying the applicant of the deficiency.
- (E) An application may be withdrawn by making a written request to the Department of Health and Senior Services.
- (F) A person who is registered may conduct activities with controlled substances in Schedules II, III, IV, and V, as authorized by statute, unless a registration is restricted as to schedules or activities because of a settlement agreement, probation, or other disciplinary action taken by the Department of Health and Senior Services, the Drug Enforcement Administration,

or a professional licensing board. Authority to conduct activities with controlled substances in Schedule I requires a separate application and registration.

- (5) Applications for Individual Practitioner Registrations. Applications by physicians, veterinarians, optometrists, podiatrists, and researchers for Missouri Controlled Substance Registrations shall include:
- (A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III, gender, race, and ethnicity;
- (B) A listing of all addresses and practice locations where controlled substance activities will be taking place. The applicant's street addresses, cities, zip codes, counties, and state. The number of hours worked per week for each location shall be provided for performing direct patient care (non-hospital), administration, research, teaching, in-patient hospital care, and other. The applicant shall also identify his or her primary, principle practice location, where he or she spends the most time. This will be the principle practice address that appears on the controlled substances registration. A physical street address is required and post office box addresses shall not be accepted;
- (C) Whether the application is for a physician, veterinarian, optometrist, podiatrist, or researcher;
- (D) His or her anticipated drug activities such as administering, prescribing, or dispensing;
- (E) The required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs him or her;
- (F) His or her business telephone number, fax number, email address, federal controlled substances registration number, if applicable; professional degree, if applicable; and professional license number, if applicable. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;
- (G) Whether the applicant, or any officer of a corporate applicant, or individual employed by any applicant having access to controlled substances, has ever entered a plea of guilty, no contest, *nolo contendere*, or otherwise been convicted of any violation of any state or federal law related to the possession, manufacture, distribution, dispensing, or prescribing of controlled substances. If the answer is yes, the applicant shall provide an explanation;
- (H) If the applicant is an individual or a registrant that holds a professional license, whether he or she is currently licensed and registered to practice his or her profession under the laws of this state;
- (I) If the applicant is not an individual or registrant that holds a professional license, the applicant shall answer yes or no to whether the applicant is currently authorized to conduct business under the laws of this state;
- (J) Previous Discipline. If the applicant currently holds or has previously held a state or federal controlled substance registration or state professional license or registration, the applicant shall answer yes or no to whether the applicant's license, registration, or application or renewal thereof has ever been surrendered, revoked, suspended, denied, restricted, or placed on probation and if any such action is pending. If the answer is yes, the applicant shall provide an explanation;
- (K) Whether the applicant is abusing or has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing" or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

- (L) Copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (G) and (J) of this section, if the department does not already have them on file:
- (M) The [original] **electronic** signature of the individual applicant [, if the application is submitted on paper];
 - (N) His or her Social Security number and date of birth (MM/DD/YYYY);
 - (O) The date the application is signed;
 - (P) What drug schedules the applicant is requesting authority in; and
- (Q) A listing of mid-level practitioners by name and license number with whom applicant has agreements pursuant to Chapter 334, RSMo.
- (6) Applications for Pharmacies and Businesses. Applications for retail pharmacies and ambulance services, ambulatory surgery centers, analytical laboratories, correctional centers, distributors, exporters, hospices, hospitals, importers, manufacturers, narcotic treatment programs, long-term care facility E-kits, teaching institutions, researchers, or other applicants not listed in sections (5)–(8), shall include:
 - (A) The applicant's full legal name, and if applicable, d/b/a name;
 - (B) The applicant's tax ID number, if applicable;
- (C) The applicant's facility license number, if applicable, and federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate an application is pending;
 - (D) The applicant's email address;
- (E) The applicant's principle Missouri business street address, city, state, county, and zip code as it will appear on the controlled substances registration certificate. Post office box numbers shall not be accepted. A separate mailing address may also be provided;
 - (F) The applicant's business telephone number and fax number;
- (G) The applicant's type of business activity, licensure type, licensure agency, and license number;
 - (H) What controlled substance schedules the applicant is requesting authority in;
- (I) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the owner, CEO or administrator, corporate officer, medical director, pharmacist in charge, or any employee with access to controlled drugs has ever pled guilty, no contest, *nolo contendere*, or ever been convicted of any violation of state or federal law relating to controlled substances;
- (J) Whether there are any previous or pending disciplinary actions regarding the applicant's professional license or any controlled substance registration, whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;
- (K) The application shall be submitted **online** with the required fee and fee information. If claiming an exemption from a fee, the applicant must identify the name of the government agency;
- (L) Copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (I) and (J) of this section, if the department does not already have them on file;

- (M) If the applicant is a retail business, the applicant shall provide a letter from the Missouri Department of Revenue that documents that no Missouri taxes are due and the applicant is in good standing; and
- (N) The applicant shall **electronically** sign and date an application [submitted on paper and may use the electronic process if applying online]. An application may be signed by the owner, chief executive officer or administrator, corporate officer, medical director, or pharmacist in charge.
- (7) Applications for Dentists. Applications for dentists with the degrees of D.D.S. or D.M.D. shall include:
- (A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III;
 - (B) His or her Social Security number and date of birth (MM/DD/YYYY);
- (C) The applicant's federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;
 - (D) The applicant's gender, race, and ethnicity;
 - (E) The applicant's email address;
 - (F) The applicant's primary specialty and any board certification;
- (G) Whether the applicant is licensed to practice and conduct activities and the applicant's licensure type, license number, and name of licensing agency;
 - (H) What drug schedules the applicant is requesting to conduct activities in;
- (I) The applicant's anticipated drug activities such as administering, prescribing, or dispensing;
- (J) The applicant's street addresses, city, zip code, county, and state of their primary, principle practice location, where they spend the most time. This will be the address that appears on the controlled substances registration. Post office box numbers shall not be accepted. Applicants shall also provide any secondary practice locations and the number of chair-side work hours per week at each location. The number of hours worked per week for each location shall be provided for performing direct patient care (non-hospital), administration, research, teaching, inpatient hospital care, and other;
 - (K) The applicant's business phone number and fax number;
- (L) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the applicant or any employees with access to controlled drugs have ever pled guilty, no contest, *nolo contendere*, or ever been convicted of any violation of state or federal law relating to controlled substances;
- (M) Information regarding any previous or pending disciplinary actions regarding the applicant's professional license or any controlled substance registration, as to whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;
- (N) Whether the applicant is abusing or has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing" or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

- (O) The application shall be submitted with the required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs him or her;
- (P) The applicant shall provide copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (L) and (M) of this section, if the department does not already have them on file; and
- (Q) The applicant shall sign and date an application submitted [on paper and may use the electronic process if applying online] electronically.
- (8) Applications for Mid-Level Practitioners. Applications for mid-level practitioners as defined by 21 CFR 1300.01(b)(28) such as advanced practice nurses and physician assistants shall include:
- (A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III;
 - (B) The applicant's social security number and date of birth (MM/DD/YYYY);
- (C) The applicant's federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;
 - (D) The applicant's gender, race, and ethnicity;
 - (E) The applicant's email address;
- (F) Whether the applicant is licensed to practice and conduct activities and the applicant's licensure type, license number, and name of licensing agency;
- (G) What controlled substance schedules (III, IV, or V) the applicant is requesting to conduct activities in;
 - (H) Which physicians the applicant has collaborative or supervision agreements with;
- (I) A copy of the applicant's collaborative or supervision agreements with physicians, and a list of controlled substances from each physician that the mid-level practitioner is authorized to conduct activities with, in that agreement;
- (J) The applicant's street address, city, zip code, county, and state of the applicant's primary, principle practice location. This will be the principle address that appears on the controlled substances registration. Post office boxes shall not be accepted. Applicants shall also provide any secondary practice location addresses and the number of hours worked per week for each location for performing direct patient care (non-hospital), administration, research, teaching, in-patient hospital care, and other;
 - (K) The applicant's business phone number and fax number;
- (L) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the applicant or any employee with access to controlled drugs has ever pled guilty, no contest, *nolo contendere*, or ever been convicted of any violation of state or federal law relating to controlled substances;
- (M) Information regarding any previous or pending disciplinary actions regarding the applicant's professional license or any controlled substance registration, as to whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied:
- (N) Whether the applicant has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing"

or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

- (O) The application shall be submitted with the required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs the applicant;
- (P) The applicant shall provide copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (L) and (M) of this section, if the department does not already have them on file; and
- (Q) The applicant shall sign and date an application submitted [on paper and may use the electronic process if applying online] electronically.

AUTHORITY: section 195.195, RSMo 2000.* Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011. Amended: Filed **** 2022, effective ***2023. *Original authority: 195.195,RSMo 1957, amended 1971, 1989, 1993.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to this proposed amendment with Michael Boeger, Missouri Department of Health and Senior Services, Bureau of Narcotics and Dangerous Drugs, PO Box 570, Jefferson City, MO 65102 or via email at BNDD@health.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.