

**TITLE 475. OKLAHOMA STATE BUREAU OF NARCOTICS AND DANGEROUS
DRUGS CONTROL
CHAPTER 10. REQUIREMENTS FOR REGISTRATION**

475:10-1-2. Time and method of payment of registration fees [AMENDED]

Registration and re-registration fees shall be paid at the time when the application for registration or re-registration is submitted for filing. ~~Payment should be made in the form of a personal, certified, or cashier's check or money order made payable to "Oklahoma State Bureau of Narcotics and Dangerous Drugs Control."~~

475:10-1-3. Exemption from registration or payment of fees [AMENDED]

(a) The Director may exempt from payment of a fee for registration or re-registration any agency of the United States, the State of Oklahoma, or any political subdivision or agency thereof, which is authorized to purchase controlled dangerous substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct research, instructional activities, or chemical analysis with such substances or any combination thereof, in the course of official duties (e.g., city, county, state or governmental institutions duly licensed by appropriate state agencies).

(b) The Director may exempt from registration the following persons:

(1) Any official, employee or officer of any agency of the United States, State of Oklahoma, or political subdivision or agency thereof, who is authorized to purchase controlled dangerous substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct research, instructional activities or chemical analysis with such substances, to possess such substances or any combination thereof, in the course of his/her official duties or employment.

(2) Such persons shall be deemed agents of their respective agencies, provided that their professional handling of controlled dangerous substances are confined to the agency of their specific place of official duties or employment [e.g., practitioners limited to practice with such official agency, pharmacies or drug departments limited to dispensing of controlled dangerous substances to inpatients only of their respective institutions, registered nurses, and others as defined in 63 Okl.St. Ann. § 2-302(€)].

[Source: Amended at 12 Ok Reg 2835, eff 7-15-95]

475:10-1-5. Exemptions of agents and employees [AMENDED]

The following persons shall not be required to register and may lawfully possess controlled dangerous substances in the performance of their official duties under the provisions of the Act:

(1) An agent, or employee thereof, of any registered manufacturer, distributor, dispenser or user for scientific purposes of any controlled dangerous substance if such agent is acting in the usual course of his/her business or employment.

(2) An individual physician who is a resident or staff physician or a registered or otherwise-

authorized hospital shall not be required to register in order to administer, prescribe or dispense controlled dangerous substances in the usual course of his/her professional practice, while acting within the scope of his/her employment in the hospital, provided that:

(A) Such resident or staff physician is authorized to carry on the respective activities under the laws of the State of Oklahoma by their appropriate State of Oklahoma licensing board.

(B) The hospital by whom he/she is employed has verified that the individual physician is so licensed by the appropriate State of Oklahoma licensing board.

(C) Such administering, prescribing or dispensing is confined solely to inpatients or outpatients of the hospital by which the individual physician is employed.

(D) All prescriptions and records relating to controlled dangerous substances administered, dispensed or prescribed to inpatients or outpatients shall reflect the designated specific internal hospital code number given to each resident or staff physician so authorized by the hospital pursuant to 475:25-1-18 and Title 21 Code of Federal Regulations, §1301.2422(C)(5) and (6).

(3) Interns of teaching hospitals shall not be required to register and may administer, dispense and prescribe controlled dangerous substances in accordance with paragraph (2) of this Section, provided that:

(A) All prescriptions issued by such interns for outpatients shall be countersigned by a physician licensed by the physician's appropriate State of Oklahoma licensing board and shall bear such physician's personal designated hospital code number.

(B) Such intern is so authorized by the hospital and is acting only within the scope of his/her employment within the teaching hospital.

(4) An individual physician, dentist, podiatrist or veterinarian, as defined in 63 Okl.St. Ann. §2-101(a), who is a resident or foreign-trained, whose practice is, for any reason, limited solely to federal, state or local government institutions, shall dispense, administer or prescribe controlled dangerous substances under the authority of the registration of the institutional hospital by whom he/she is employed in lieu of being registered himself/herself, provided that:

(A) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice.

(B) Such individual practitioner is authorized to carry on the respective activities under the laws of the State of Oklahoma by the appropriate State of Oklahoma licensing board.

(C) The hospital or other institution by which he/she is employed has verified that the individual practitioner is so permitted to dispense, administer or prescribe drugs within the jurisdiction.

(D) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution.

(E) Records relating to controlled dangerous substances that are prescribed by such residents, foreign-trained physicians, or physicians limited to federal, state or local government institutions, shall be kept pursuant to Title 21 Code of Federal Regulations §1301.24(C)(5)

1304.04 and 475:25-1-18

(5) An individual practitioner, as defined in (4) of this Section, who is limited solely to federal, state or local government institutional practice, may obtain individual fee-exempt registration in the event that such institution by which he/she is employed does not maintain a hospital as defined by the appropriate State of Oklahoma licensing agency and is not so registered with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

(A) Such limited practitioners shall be required to maintain records of all controlled dangerous substances administered, dispensed and distributed by such practitioner.

(B) Such limited practitioners shall be authorized to dispense, administer or prescribe controlled dangerous substances in the course of their professional practice only within such institution as designated by their appropriate Oklahoma state professional licensing boards.

(C) Such limited practitioners shall be required to report to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control each change of location of institutional employment.

(D) Such limited practitioners shall be held individually responsible for safeguards, record keeping, inventories, transferring and disposing of controlled dangerous substances in accordance with this Chapter.

475:10-1-9. Application for registration pursuant to Title 63 Okl.St. Ann. §2-302

[AMENDED]

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time unless otherwise provided in this Title. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Director to such person.

(b) After any person is first registered he/she shall thereafter be required to be registered no later than the first day of November of each year.

(c) Any person who fails to register shall be in violation of the Uniform Controlled Dangerous Substances Act and subject to penalties as provided therein.

(d) Applications for registration of new principal places of business and new personal registration requests received after July 1st of each year will, if accepted for registration, be registered for the forthcoming registration year and, therefore, will not be required to pay the registration fee for the remaining four (4) months of the registration year in which application is made.

475:10-1-10. Application forms notices for registration and re-registration [AMENDED]

(a) Any person required to be registered under Title 63 may obtain the appropriate registration application ~~form~~ notice by contacting the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

(b) Any person desiring to professionally handle controlled dangerous substances for the purpose of canine drug detector handling and or training, manufacturing, distributing, conducting scientific research, or performing analytical laboratory services by scientific analysis of

controlled dangerous substances listed in the Uniform Controlled Dangerous Substances Act, Schedules I through V, shall apply for registration as follows:

(1) Application for registration as a canine drug detector handler and or trainer, researcher or analytical laboratory shall be required with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control as an individual.

(2) Two (2) copies of the proposed operational protocol shall be attached to the application form notice.

(3) A detailed description, diagram, and/or photographs of all security measures proposed for the safe storage of all controlled dangerous substances shall be attached to the application form notice.

(c) Any place or person licensed by their appropriate State of Oklahoma licensing board who desires to professionally handle controlled dangerous substances in their practice of medicine, retail pharmacy, hospital, teaching institution, or institutional drug department shall apply for registration.

(d) ~~Registration forms~~ Renewal notices will be mailed as applicable to each registered person approximately ninety (90) days before the expiration date of October 31 of each year; if any registered person does not receive such form notice within thirty (30) days prior to the expiration date of his/her registration, he/she must give notice of such omission and request such form notice either by personal contact with, or in writing to, the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control. It shall be the registrant's responsibility to maintain a valid registration.

(e) Each application shall include all information called for in the form notice, unless the item is not applicable, in which case this fact shall be indicated, and the application form notice with comments shall be required to be returned to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control. The address of the registrant shall include the mailing address and physical directions to the registrant's location [if different from the mailing address.] A post office box will not be considered a sufficient mailing address.

(f) Each application, attachment or other document filed as a part of any application shall be signed by the applicant or by an officer or official of the applicant. Those applications with questions left unanswered or without proper signature will not be accepted.

[Source: Amended at 12 Ok Reg 2835, eff 7-15-95; Amended at 24 Ok Reg 2736, eff 8-11-07]

475:10-1-11. Operational protocols [AMENDED]

(a) An operational protocol to conduct scientific research, scientific analysis, institutional instructional activities or drug canine training with ~~controlled~~ controlled dangerous substances listed in Schedules I through V shall be in the following form and contain the following information where applicable:

(1) Scientific research, analytical laboratory, institutional instructional activities, or drug canine handlers.

(A) Name, business address, and Federal Drug Enforcement Administration registration

number.

(B) Institutional affiliation, if any.

(C) Qualifications, including an academic vita and an appropriate bibliography (listing publications).

(i) Applicants shall be required affirmatively to establish (by documentation or suitable references or other appropriate means) their good moral character and high ethical professional standing.

(ii) Applicants for scientific research shall possess at least an earned bachelor's degree in natural science, medicine or other appropriate field from institution(s) accredited by bodies recognized by the designated authority of the OU Health Sciences Center.

(iii) Applicants for scientific research proposing studies involving human subjects should minimally possess an earned doctorate in medicine or natural sciences or other appropriate field from accredited institution(s).

(iv) Applicants for scientific analysis (Analytical Laboratory Activities) who propose studies involving chemical analysis or other chemical, physical or biological scientific activities with Schedule I-V substances shall be required to have satisfactorily completed a minimum of thirty-two (32) semester hours, or their equivalent, of acceptable courses in chemistry, with one (1) or more accredited courses in analytical chemistry.

(v) Institutional instructional activities or institutions of higher learning requesting registration of an agent of such institution shall be an institution accredited by the Oklahoma State Regents for Higher Education, or such agent of an institution shall be required to have satisfactorily completed a minimum of thirty-two (32) semester hours, or their equivalent, of acceptable courses in chemistry from an institution(s) accredited by bodies recognized by the United States Office of Education or the United States Department of Health, Education and Welfare.

(vi) Except for drug canine handlers, all applicants shall further be required to document at least one (1) year of recent suitable, professional experience for the activities to be undertaken for a Schedule I registration. This may consist of formal participation in established and recognized analytical laboratory analysis of controlled dangerous substances, research programs, institutional instructional activities, or other evidence of appropriate background approved by the Director (post-doctoral training, applicable laboratory experience, etc.).

(2) Research project.

(A) Title of project.

(B) Statement of purpose.

(C) Name of controlled dangerous substance or substances involved and the amount of each substance intended for use.

(D) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.

(E) Location where the research will be conducted.

(F) Statement of the security provisions for storing the controlled dangerous substances and for dispensing the controlled dangerous substances in order to prevent diversion.

(G) If the researcher or investigator desires to manufacture any controlled dangerous substances listed in this part, a statement of the quantity to be manufactured and the sources of the chemicals to be used.

(3) Authority.

(A) Institutional approval.

(B) Approval of Human Research Committee for human studies.

(C) Indication of an approval for new Federal Drug Enforcement Administration registration number if additional registration is required by the D.E.A.

(D) Indication of an approved funded grant (number), if any.

(4) Adequate environment and facilities. All applicants shall be required to establish that they have access to and beneficial use of an institutional (or other) environment appropriate to the type of activities contemplated, and that they possess the necessary facilities (inclusive of proper laboratory facilities and equipment, etc.). This requirement shall be interpreted as requiring that overall environment, facilities and equipment meet generally recognized standards for the activities proposed.

(5) Confidentiality of research subjects.

(A) Any person registered under the Uniform Controlled Dangerous Substances Act who intends to maintain the confidentiality of those persons who are the subjects of such research shall, pursuant to Title 63 Okl.St. Ann. §2-106(G), upon registration or within a reasonable time thereafter, submit to the Director a separate request for each research project involving controlled dangerous substances, which shall contain the following:

(i) The researcher's registration number with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control and/or Federal Drug Enforcement Administration registration number(s) for that project.

(ii) The location of the research project.

(iii) A general description of the research or a copy of the research protocol as required in this Chapter.

(iv) A specific request to withhold the names and/or any other identifying characteristics of the research subjects.

(v) The reasons supporting the request.

(B) Within thirty (30) days from the receipt of the request, the Director shall issue a letter, either granting confidentiality, requesting additional information, or denying confidentiality, in which case the reasons for the denial shall be included. A grant of confidentiality shall be limited solely to the specific research project indicated in the request.

(b) Within thirty (30) days after the date of completion of the research project, the researcher shall so notify the Director.

475:10-1-15. Amendments to and withdrawal of applications [AMENDED]

(a) An application may be amended or withdrawn without permission of the Director at any time before the date on which the applicant receives an order to show cause why the registration should not be denied, revoked or suspended pursuant to Title 63 Okl.St. Ann. §2-305. An application may be amended with permission of the Director at any time where good cause is shown by the applicant or where the amendment is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application ~~when sent by registered or certified mail, return receipt requested,~~ shall be deemed to be a withdrawal of the application.

475:10-1-16. Inspection [AMENDED]

The Director, his or her agents, as well as specifically designated or assigned state, county and municipal officers whose duty it is to enforce the laws of this State relating to controlled dangerous substances may inspect, or cause to be inspected, the establishment of an applicant or registrant pursuant to Title 63 Okl.St. Ann. §2-502 this Title and the provisions of Title 63 of the Oklahoma Statutes.

475:10-1-20. Modification of registration [AMENDED]

Any registrant may apply to modify his/her registration to authorize the handling of additional controlled dangerous substances by submitting a letter of request to the Registration Division of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control. The letter shall contain the registrant's name, address, state and federal registration numbers as printed on the registrant's State of Oklahoma and Federal Certificates of Registration, and the substances and/or schedules to be added to his/her registration, and shall be signed by the registrant. If the registrant is seeking to handle additional controlled dangerous substances listed in Schedule I of the Uniform Controlled Dangerous Substances Act for the purpose of chemical analysis for scientific purposes, scientific research, or instructional activities, he/she shall attach two (2) copies of his/her protocol describing each anticipated activity involved with the additional substances or, in the event of instructional activities, a statement describing the nature, extent and duration of such instructional activity, as appropriate. No fee shall be required to be paid for the modification. ~~If the modification in registration is approved, the Director shall provide written notification to the registrant, who shall maintain the notification with the current Certification of Registration until expiration.~~

475:10-1-21. Change of business address [AMENDED]

The registrant shall notify the Registration Division of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control in writing, sent via U.S. certified mail, return receipt requested, or through the registrant's online account, within fourteen (14) calendar days of any

change of their business (mailing or physical) address.

475:10-1-22. Termination of registration [AMENDED]

The registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice including, but not limited to, full retirement. Any registrant who discontinues business or professional practice shall notify the Director ~~promptly~~ within fourteen (14) calendar days of such fact.

[Source: Amended at 12 Ok Reg 2835, eff 7-15-95]