

IC 35-48-3

Chapter 3. Registration and Control

IC 35-48-3-1

Rules

Sec. 1. Rules. The board may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances within this state.

As added by Acts 1976, P.L.148, SEC.7.

IC 35-48-3-2

Limited permits for entities operating animal shelters

Sec. 2. (a) Any humane society, animal control agency, or governmental entity operating an animal shelter or other animal impounding facility is entitled to receive a limited permit only for the purpose of buying, possessing, and using:

- (1) sodium pentobarbital to euthanize injured, sick, homeless, or unwanted domestic pets and animals;
- (2) ketamine and ketamine products to anesthetize or immobilize fractious domestic pets and animals; and
- (3) a combination product containing tiletamine and zolazepam as an agent for the remote chemical capture of domestic pets or animals that otherwise cannot be restrained or captured.

(b) A humane society, animal control agency, or governmental entity entitled to receive a permit under this chapter must:

- (1) apply to the board according to the rules established by the board;
- (2) pay annually to the board a fee set by the board for the limited permit; and
- (3) submit proof, as determined by the board, that the employees of an applicant who will handle a controlled substance are sufficiently trained to use and administer the controlled substance.

(c) All fees collected by the board under this section shall be credited to the state board of pharmacy account.

(d) Storage, handling, and use of controlled substances obtained according to this section are subject to the rules adopted by the board.

(e) Before issuing a permit under this section, the board may consult with the board of veterinary medical examiners.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.193-1987, SEC.16; P.L.136-2001, SEC.1; P.L.84-2010, SEC.93.

IC 35-48-3-3

Registration requirements

Sec. 3. (a) Every person who manufactures or distributes any controlled substance within this state or who proposes to engage in the manufacture or distribution of any controlled substance within this state, must obtain biennially a registration issued by the board in

accordance with its rules.

(b) Every person who dispenses or proposes to dispense any controlled substance within Indiana must have a registration issued by the board in accordance with its rules. A registration issued to a dispenser under this subsection expires whenever the dispenser's license as a practitioner expires. The board shall renew a dispenser's registration under this subsection concurrently with any state license authorizing the dispenser to act as a practitioner.

(c) Persons registered by the board under this article to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this chapter.

(d) The following persons need not register and may lawfully possess controlled substances under this article:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if he is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment.

(3) An ultimate user or a person in possession of any controlled substance under a lawful order of a practitioner or in lawful possession of a schedule V substance.

(e) The board may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.

(f) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, dispenses, or possesses controlled substances.

(g) The board may inspect the establishment of a registrant or applicant for registration in accordance with the board's rules.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.156-1986, SEC.6.

IC 35-48-3-3.1

Expiration of controlled substance registration; renewal fees; notification of registrant of fees; evidence of extended registration

Sec. 3.1. (a) A registration to manufacture, distribute, or dispense a controlled substance that is:

(1) issued by the Indiana state board of pharmacy under this chapter, as effective April 30, 1986; and

(2) in effect on April 30, 1986;

does not expire until the date specified for renewal of the registration under section 3 of this chapter, as amended by P.L.156-1986. However, the registrant is liable for a prorated renewal fee proportionate to the fraction of the renewal period specified under section 3 of this chapter, as amended by P.L.156-1986, that the extended registration is in effect.

(b) The health professions bureau shall:

- (1) notify a registrant described under subsection (a) in writing of; and
- (2) collect;

the amount of the prorated fee applicable to the registrant's extended registration.

(c) The health professions bureau shall issue to a registrant described under subsection (a) such evidence of the registrant's extended registration as the state board of pharmacy requires.

As added by P.L.220-2011, SEC.629.

IC 35-48-3-4

Registration

Sec. 4. (a) The board shall register an applicant to manufacture or distribute controlled substances unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the board shall consider:

- (1) maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;
- (2) compliance with applicable state and local law;
- (3) any convictions of the applicant under any federal and state laws relating to any controlled substance;
- (4) past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;
- (5) furnishing by the applicant of false or fraudulent material in any application filed under this article;
- (6) suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and
- (7) any other factors relevant to and consistent with the public health and safety.

(b) Registration under subsection (a) of this section does not entitle a registrant to manufacture and distribute controlled substances in schedules I or II other than those specified in the registration.

(c) Practitioners must be registered to dispense any controlled substances or to conduct research with controlled substances in schedules II through V if they are authorized to dispense or conduct research under the law of this state. The board need not require separate registration under this chapter for practitioners engaging in research with nonnarcotic controlled substances in schedules II through V where the registrant is already registered under this chapter in another capacity, to the extent authorized by his registration in that other capacity.

(d) Registration to conduct research or instructional activities with controlled substances in schedules I through V does not entitle a registrant to conduct research or instructional activities with controlled substances other than those approved by the board in

accordance with the registration.

(e) The board may consult with the board of veterinary medical examiners before issuing a registration to a person:

- (1) who seeks to conduct research or instructional activities with controlled substances in schedules I through IV; and
- (2) whose activities constitute the practice of veterinary medicine (as defined by IC 25-38.1-1-12).

(f) Compliance by manufacturers and distributors with the provisions of the federal law respecting registration (excluding fees) entitles them to be registered under this article.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1981, P.L.170, SEC.7; P.L.84-2010, SEC.94.

IC 35-48-3-5

Denial, revocation, and suspension of registration; reinstatement

Sec. 5. (a) An application for registration or reregistration submitted pursuant to and a registration issued under section 3 of this chapter to manufacture, distribute, or dispense a controlled substance may be denied, suspended, or revoked by the board upon a finding that the applicant or registrant:

- (1) has furnished false or fraudulent material information in any application filed under this article;
- (2) has violated any state or federal law relating to any controlled substance;
- (3) has had the applicant's or registrant's federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances; or
- (4) has failed to maintain reasonable controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.

(b) The board may limit revocation or suspension of a registration or the denial of an application for registration or reregistration to the particular controlled substance with respect to which grounds for revocation, suspension, or denial exist.

(c) If the board suspends or revokes a registration or denies an application for reregistration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation or denial order may be placed under seal. The board may require the removal of such substances from the premises. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation or denial order becoming final, all controlled substances may be forfeited to the state.

(d) The board shall promptly notify the drug enforcement administration of all orders suspending or revoking registration, all orders denying any application for registration or reregistration, and all forfeitures of controlled substances.

(e) If the Drug Enforcement Administration terminates, denies,

suspends, or revokes a federal registration for the manufacture, distribution, or dispensing of controlled substances, a registration issued by the board under this chapter is automatically suspended.

(f) The board may reinstate a registration that has been suspended under subsection (e), after a hearing, if the board is satisfied that the applicant is able to manufacture, distribute, or dispense controlled substances with reasonable skill and safety to the public. As a condition of reinstatement, the board may impose disciplinary or corrective measures authorized under IC 25-1-9-9 or this article.

(g) A registration issued under this chapter is automatically revoked if any state license authorizing a dispenser to act as a practitioner is revoked.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1981, P.L.170, SEC.8; P.L.197-2007, SEC.93; P.L.84-2010, SEC.95.

IC 35-48-3-6

Order to show cause

Sec. 6. (a) Before recommending a denial, suspension, or revocation of a registration, or before refusing a renewal of registration, the board shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended, or why the renewal should not be denied. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the board at a time and place not less than thirty (30) days after the date of service of the order, but in the case of a denial or renewal of registration the show cause order shall be served not later than thirty (30) days before the expiration of the registration. These proceedings shall be conducted in accordance with IC 4-21.5 without regard to any criminal prosecution or other proceeding. Proceedings to refuse renewal of registration shall not abate the existing registration, which shall remain in effect pending the outcome of the administrative hearing.

(b) The board may suspend, without an order to show cause, any registration simultaneously with the institution of proceedings under section 4 of this chapter, or where renewal of registration is refused, if it finds that there is an imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the board or dissolved by a court of competent jurisdiction.

(c) If an applicant for reregistration (who is doing business under a registration previously granted and not revoked nor suspended) has applied for reregistration at least forty-five (45) days before the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the board so issues its order. The board may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least forty-five (45) days before

expiration of the existing registration, with or without request by the registrant, if the board finds that such extension is not inconsistent with the public health and safety.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.7-1987, SEC.166; P.L.84-2010, SEC.96.

IC 35-48-3-7

Records of registrants

Sec. 7. Records of Registrants. Persons registered to manufacture, distribute, or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the board issues.

As added by Acts 1976, P.L.148, SEC.7.

IC 35-48-3-8

Order forms

Sec. 8. Order Forms. Controlled substances in schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms is deemed compliance with this section.

As added by Acts 1976, P.L.148, SEC.7.

IC 35-48-3-9

Prescriptions

Sec. 9. (a) Except for dosages medically required for a period of not more than forty-eight (48) hours that are dispensed by or on the direction of a practitioner or medication dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in schedule II may be dispensed without the written or electronic prescription of a practitioner.

(b) In emergency situations, as defined by rule of the board, schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of section 7 of this chapter. No prescription for a schedule II substance may be refilled.

(c) Except for dosages medically required for a period of not more than forty-eight (48) hours that are dispensed by or on the direction of a practitioner, or medication dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in schedule III or IV, which is a prescription drug as determined under IC 16-42-19, shall not be dispensed without a written, electronic, or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six (6) months after the date thereof or be refilled more than five (5) times, unless renewed by the practitioner. Prescriptions for schedule III, IV, and V controlled substances may be transmitted by facsimile from the practitioner or the agent of the practitioner to a pharmacy. The facsimile prescription is equivalent to an original prescription to the

extent permitted under federal law.

(d) A controlled substance included in schedule V shall not be distributed or dispensed other than for a medical purpose.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.2-1993, SEC.192; P.L.163-1994, SEC.4; P.L.204-2005, SEC.21; P.L.174-2011, SEC.5.

IC 35-48-3-10

Repealed

(Repealed by P.L.157-1999, SEC.2.)

IC 35-48-3-11

Treatment for weight reduction or to control obesity

Sec. 11. (a) Only a physician licensed under IC 25-22.5 may treat a patient with a Schedule III or Schedule IV controlled substance for the purpose of weight reduction or to control obesity.

(b) A physician licensed under IC 25-22.5 may not prescribe, dispense, administer, supply, sell, or give any amphetamine, sympathomimetic amine drug, or compound designated as a Schedule III or Schedule IV controlled substance under IC 35-48-2-8 and IC 35-48-2-10 for a patient for purposes of weight reduction or to control obesity, unless the physician does the following:

(1) Determines:

(A) through review of:

(i) the physician's records of prior treatment of the patient;
or

(ii) the records of prior treatment of the patient provided by a previous treating physician or weight loss program; that the physician's patient has made a reasonable effort to lose weight in a treatment program using a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise without using controlled substances; and

(B) that the treatment described in clause (A) has been ineffective for the physician's patient.

(2) Obtains a thorough history and performs a thorough physical examination of the physician's patient before initiating a treatment plan using a Schedule III or Schedule IV controlled substance for purposes of weight reduction or to control obesity.

(c) A physician licensed under IC 25-22.5 may not begin and shall discontinue using a Schedule III or Schedule IV controlled substance for purposes of weight reduction or to control obesity after the physician determines in the physician's professional judgment that:

(1) the physician's patient has failed to lose weight using a treatment plan involving the controlled substance;

(2) the controlled substance has provided a decreasing contribution toward further weight loss for the patient unless continuing to take the controlled substance is medically necessary or appropriate for maintenance therapy;

(3) the physician's patient:

(A) has a history of; or

(B) shows a propensity for;
alcohol or drug abuse; or

(4) the physician's patient has consumed or disposed of a
controlled substance in a manner that does not strictly comply
with a treating physician's direction.

As added by P.L.157-1999, SEC.1. Amended by P.L.37-2001, SEC.1.