Document: Readopted Rules, **Register Page Number:** 25 IR 1342
Source: January 1, 2002, Indiana Register, Volume 25, Number 4
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TITLE 856 INDIANA BOARD OF PHARMACY

LSA Document #01-151(F)(2)

DIGEST

Readopts rules in anticipation of IC 4-22-2.5-2, providing that all rules of the Indiana administrative agencies in force on December 31, 1995, expire on January 1, 2002. Effective 30 days after filing with the secretary of state.

856 IAC 2-3-10	**856 IAC 2-3-24**
856 IAC 2-3-13	**856 IAC 2-6-2**
856 IAC 2-3-14	**856 IAC 2-6-11**
856 IAC 2-3-15	**856 IAC 2-6-12**

SECTION 1. UNDER IC 4-22-2.5-3, 856 IAC 2-3-13 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

856 IAC 2-3-13 Application forms; reregistration forms
Authority: IC 35-48-3-1
Affected: IC 35-48-3-5

Sec. 13. ~~Application forms; contents; signature.~~ (a) If any person is required to be registered, and is not so registered and is applying for registration, **the following apply:**

(1) To manufacture and perform other coincident activities (see ~~Section 3.12(b)(7)~~ **856 IAC 2-3-3(b)(7)** *[section 3(b)(7) of this rule]*) with controlled substances, he **or she** shall apply on Form CSR-1A.

(2) To dispense, or to conduct research (other than research described in ~~3.12(a)(6)~~ **856 IAC 2-3-3(a)(6)** *[section 3(a)(6) of this rule]*) with, or to conduct instructional activities with, controlled substances listed in Schedules II through V **under 856 IAC 2-2-3 through 856 IAC 2-2-6,** he **or she** shall apply on Form CSR-1.

(3) To conduct research with narcotic drugs listed in Schedules II through V **under 856 IAC 2-2-3 through 856 IAC 2-2-6,** as described in ~~3.12(a)(6)~~ **856 IAC 2-3-3(a)(6)** *[section 3(a)(6) of this rule]***,** he **or she** shall apply on Form CSR-1.

(4) To conduct research with controlled substances listed in Schedule I **under 856 IAC 2-2-2,** he **or she** shall apply on Form CSR-1 in accordance with an approved Schedule I **under 856 IAC 2-2-2** research protocol. Such protocol shall be subject to inspection by **the** Indiana board of pharmacy.

(5) To conduct instructional activities with controlled substances listed in Schedule I **under 856 IAC 2-2-2,** he **or she** shall apply as a researcher on Form CSR-1 with two **(2)** copies of a statement describing the nature, extent, and duration of such instructional activities attached to the form.

(6) To conduct chemical analysis with controlled substances listed in any schedule, he **or she** shall apply on Form CSR-1. ~~and~~

(7) To distribute controlled substances, he **or she** shall apply on Form CSR-1.

(b) If any person is registered and is applying for reregistration, **the following apply:**

(1) To manufacture and perform other coincident activities (see ~~Section 3.12(b)(7)~~ **856 IAC 2-3-3(b)(7)***[section 3(b)(7) of this rule]***),** with controlled substances, he **or she** shall apply on Form CSRII-A.

(2) To dispense, or to conduct research (other than research described in ~~3.22(a)(6)~~ **856 IAC 2-3-3(a)(6)***[section 3(a)(6) of this rule]***)** with, or to conduct instructional activities with, controlled substances listed in Schedules II through V **under 856 IAC 2-2-3 through 856 IAC 2-2-6,** he **or she** shall apply on Form CSR-II.

(3) To conduct research with narcotic drugs listed in Schedules II through V **under 856 IAC 2-2-3 through 856 IAC 2-2-6,** as described in ~~3.12(a)(6)~~ **856 IAC 2-3-3(a)(6)** *[section 3(a)(6) of this rule]***,** he **or she** shall apply on Form

CSR-II.

(4) To continue to conduct research with controlled substances listed in Schedule I **under 856 IAC 2-2-2** under one **(1)** or more approved research protocols, by the Drug Enforcement Administration, he **or she** shall apply on Form CSR-II.

(5) To continue to conduct instructional activities with controlled substances listed in Schedule I **under 856 IAC 2-2-2** under one **(1)** or more approved instructional statements, he **or she** shall apply as a researcher on Form CSR-II.

(6) To conduct chemical analysis with controlled substances listed in any schedule, he **or she** shall apply on Form CSR-II. ~~and~~

(7) To distribute controlled substances, he **or she** shall apply on Form CSR-II.

(c) Applications for registration may be obtained by writing to the controlled substance division **of the** Indiana ~~State~~ board of pharmacy. ~~315 State Office Building, Indianapolis, Indiana.~~ Applications for reregistration will be mailed, as applicable, to each registered person approximately **sixty** (60) days before the expiration date of his **or her** registration; if any registered person does not receive such forms within **forty-five** (45) days before the expiration date of his **or her** registration, he **or she** must promptly give notice of such fact and request such forms by writing to the controlled substance division **of the** Indiana board of pharmacy. ~~at the foregoing address.~~

(d) Each application for registration to handle any basic class of controlled substance listed in Schedule I **under 856 IAC 2-2-2** (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in Schedule II **under 856 IAC 2-2-3,** or to conduct research with any narcotic controlled substance listed in Schedule II **under 856 IAC 2-2-3,** shall include the controlled substances code number, as set forth in Part I *[856 IAC 2-1]*, for each basic class or substance to be covered by such registration.

(e) Each application shall include all information called for on the form unless the item is not applicable, in which case this fact shall be indicated.

(f) Each application, attachment, or other document filed as part of an application shall be signed by:

(1) the applicant, if an individual; ~~by~~

(2) a partner of the applicant, if a partnership; or ~~by~~

(3) an officer or authorized representative of the applicant, if a corporation, corporate division, association, trust, or other entity.

(Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.32; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1342)

SECTION 2. UNDER IC 4-22-2.5-3, 856 IAC 2-3-24 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

856 IAC 2-3-24 Evidentiary hearing

Authority: IC 35-48-3-1
Affected: IC 35-48-3-6

Sec. 24. ~~Purpose of hearing.~~ The **controlled substances** advisory committee shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration. *(Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.51; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1343)*

SECTION 3. UNDER IC 4-22-2.5-3, 856 IAC 2-6-2 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

856 IAC 2-6-2 Persons entitled to issue prescriptions

Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 2. ~~Persons entitled to issue prescriptions.~~ (a) A prescription for a controlled substance may be issued only by an

individual practitioner who is:

(1) authorized to prescribe controlled substances by the state; ~~of Indiana;~~ and

(2) either registered or exempted from registration pursuant to ~~sections 3.14(b)~~ **856 IAC 2-3-5(b)** or ~~3.15 of this part.~~ **856 IAC 2-3-6.**

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an ~~employee or agent of the~~ individual practitioner **or a practitioner's authorized agent.**

~~Note of Explanation.~~ **(c)** Controlled substances prescriptions issued by individual practitioners in adjoining states to Indiana or other states are considered valid prescriptions if the practitioner issuing the prescription has a current and valid Drug Enforcement Administration certificate registration number. It is the pharmacist's responsibility as with all controlled substances prescriptions, to be sure beyond reasonable doubt in his **or her** professional judgment that the practitioner is issuing the prescription in good faith and has a valid Drug Enforcement Administration certificate of registration. *(Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.02; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1343)*

SECTION 4. UNDER IC 4-22-2.5-3, 856 IAC 2-6-12 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

856 IAC 2-6-12 Schedules III and IV controlled substances

Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 12. ~~Requirement of prescription.~~ (a) A pharmacist may dispense a controlled substance listed in Schedule III or IV **under 856 IAC 2-2-4 or 856 IAC 2-2-5,** which is a prescription drug as determined under the federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a prescribing individual practitioner or an oral prescription made by a prescribing individual practitioner **or a practitioner's authorized agent** and promptly reduced to writing by the pharmacist containing all information required in ~~section 6.04,~~ **856 IAC 2-6-4** *[section 4 of this rule]***,** except for the signature of the prescribing individual practitioner.

(b) An individual practitioner may administer or dispense a controlled substance listed in Schedule III or IV **under 856 IAC 2-2-4 or 856 IAC 2-2-5** in the course of his **or her** professional practice without a prescription, subject to ~~section 6.06.~~ **856 IAC 2-6-6** *[section 6 of this rule]***.**

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III or IV **under 856 IAC 2-2-4 or 856 IAC 2-2-5** pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in ~~section 6.04~~ **856 IAC 2-6-4** *[section 4 of this rule]***,** except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner ~~which~~ **that** is dispensed for immediate administration to the ultimate user, subject to ~~section 6.06.~~ **856 IAC 2-6-6** *[section 6 of this rule]***.** *(Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.21; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1343)*

SECTION 5. UNDER IC 4-22-2.5-3, THE FOLLOWING ARE REPEALED: 856 IAC 2-3-10; 856 IAC 2-3-14; 856 IAC 2-3-15; 856 IAC 2-6-11.

LSA Document #01-151(F)
Intent to Readopt Rules Published: June 1, 2001; 24 IR 2859
Proposed Readopted Rules Published: September 1, 2001; 24 IR 4220
Hearing Held: October 9, 2001
Approved by Attorney General: November 14, 2001
Approved by Governor: November 29, 2001
Filed with Secretary of State: November 30, 2001, 11:00 a.m.