TITLE 856 INDIANA BOARD OF PHARMACY

Proposed Rule
LSA Document #12-619

DIGEST

Amends 856 IAC 1-1.1-3 to update the definition of "in personal attendance". Adds 856 IAC 1-1.1-4 to define "reasonable visual and vocal distance". Adds 856 IAC 1-1.1-5 to define "supervision". Adds 856 IAC 1-1.1-6 to define "pharmaceutical care". Adds 856 IAC 1-1.1-7 to define "real-time online database". Adds 856 IAC 1-1.1-8 to define "unlicensed person". Adds 856 IAC 1-1.1-9 to define "electronic database". Adds 856 IAC 1-1.1-10 to define "electronic record or image". Amends 856 IAC 1-29-1 concerning the approval of electronic data processing system. Amends 856 IAC 1-29-3 to update the hard copy of daily dispensing, verification and retention, and back-up capability requirements. Amends 856 IAC 1-29-6 to update data entry and supervision requirements. Amends 856 IAC 1-29-9 to update the applicability of 856 IAC 1-29. Amends 856 IAC 1-31-1 to update facsimile machines requirements. Amends 856 IAC 1-31-2 to update the requirements for the use of a facsimile machine to electronically transmit a prescription or drug order. Adds 856 IAC 1-31-3 concerning facsimile prescription or drug order maintenance. Amends 856 IAC 1-32-2 to update the requirements for noncontrolled and controlled substance prescription transfers. Amends 856 IAC 1-32-4 to update the responsibilities of pharmacists. Adds 856 IAC 1-32-5 concerning electronic transfers. Amends 856 IAC 1-34-2 to update security feature requirements. Amends 856 IAC 1-37-1 to update the requirements for central fill or processing, or both, of prescriptions and drug orders. Adds 856 IAC 1-37-1.1 regarding central fill or processing, or both, facilities. Adds 856 IAC 1-37-1.2 concerning central fill or processing, or both, supervision. Adds 856 IAC 1-37-1.3 concerning central fill or processing, or both, remote practice. Amends 856 IAC 1-37-2 updating the contracting for central fill or processing, or both, requirements. Adds 856 IAC 1-37-2.1 concerning contracting for central fill or processing, or both, policies and procedures. Amends 856 IAC 1-37-3 updating policy and procedures manual requirements. Amends 856 IAC 1-40-8 to update electronic data intermediary requirements. Adds 856 IAC 1-41 concerning cognitive services. Adds 856 IAC 1-42 concerning remote pharmacy practice. Amends 856 IAC 2-4-1 to update records and inventories requirements. Adds 856 IAC 2-6-1.5 concerning signature requirements. Amends 856 IAC 2-6-4 concerning issuance of prescriptions and information required. Amends 856 IAC 2-6-7 to update schedule II controlled substances, prescription required, and exception requirements. Amends 856 IAC 2-6-9 to update schedule II controlled substances partial filling of prescriptions requirements. Amends 856 IAC 2-6-10 to update schedule II controlled substances, label information, and exceptions requirements. Amends 856 IAC 2-6-12 to update schedules III and IV controlled substances requirements. Amends 856 IAC 2-6-13 to update schedules III, IV, and V controlled substances, refilling prescriptions, and retrievable information requirements. Amends 856 IAC 2-6-17 to update schedule V controlled substances, prescription requirements, refilling, and exceptions requirements. Amends 856 IAC 2-6-18 to update dispensing without a prescription and delivery of devices requirements. Repeals 856 IAC 1-35-2 and 856 IAC 1-35-3. Effective 30 days after filing with the Publisher.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

856 IAC 1-1.1-3; 856 IAC 1-1.1-4; 856 IAC 1-1.1-5; 856 IAC 1-1.1-6; 856 IAC 1-1.1-7; 856 IAC 1-1.1-8; 856 IAC 1-1.1-9; 856 IAC 1-1.1-10; 856 IAC 1-29-1; 856 IAC 1-29-3; 856 IAC 1-29-6; 856 IAC 1-29-9; 856 IAC 1-31-1; 856 IAC 1-31-2; 856 IAC 1-31-3; 856 IAC 1-32-2; 856 IAC 1-32-4; 856 IAC 1-32-5; 856 IAC 1-34-2; 856 IAC 1-35-2; 856 IAC 1-35-3; 856 IAC 1-37-1; 856 IAC 1-37-1.1; 856 IAC 1-37-1.2; 856 IAC 1-37-1.3; 856 IAC 1-37-2; 856 IAC 1-37-2.1; 856 IAC 1-37-3; 856 IAC 1-40-8; 856 IAC 1-41; 856 IAC 1-42; 856 IAC 2-4-1; 856 IAC 2-6-1.5; 856 IAC 2-6-4; 856 IAC 2-6-7; 856 IAC 2-6-9; 856 IAC 2-6-10; 856 IAC 2-6-12; 856 IAC 2-6-13; 856 IAC 2-6-17; 856 IAC 2-6-18

SECTION 1. 856 IAC 1-1.1-3 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-1.1-3 "In personal attendance" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-2; IC 25-26-13-18

Sec. 3. ~~The term~~ "In personal attendance", as the same is in IC 25-26-13-18(a) of the Pharmacy Practice Act, means being physically present in the area specified as the dimensions of the pharmacy in the relevant pharmacy permit application. **This section in no way restricts functions listed under the practice of pharmacy**

definition in IC 25-26-13-2 that are unrelated to the direct filling, dispensing, distribution, and storage of a legend drug product.

(Indiana Board of Pharmacy; 856 IAC 1-1.1-3; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; errata filed Jan 9, 2002, 4:20 p.m.: 25 IR 1645; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 2. 856 IAC 1-1.1-4 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-1.1-4 "Reasonable visual and vocal distance" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4. The standard for "reasonable visual and vocal distance", as found in IC 25-26-13-18(a)(4) of the Pharmacy Practice Act, can be met by a pharmacist being physically present within the licensed permitted area or by a means that provides for adequate supervision of technicians as individually approved by the board.

(Indiana Board of Pharmacy; 856 IAC 1-1.1-4)

SECTION 3. 856 IAC 1-1.1-5 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-1.1-5 "Supervision" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 5. For purposes of this article, "supervision" means the physical or real-time act of oversight and management by a managing pharmacist, pharmacist in charge, or qualifying pharmacist of another individual's work or work product. Unless otherwise stated in this article, individuals practicing pharmacy must be directly supervised either through a direct line of sight and hearing, or via technological means that allow a supervisor to adequately ensure quality of care and patient services. In accordance with other sections in this article, if a facility is using technology to allow indirect supervision, they must have documented policies and procedures and other adequate safeguards to protect against patient harm, diversion, and privacy incidents.

(Indiana Board of Pharmacy; 856 IAC 1-1.1-5)

SECTION 4. 856 IAC 1-1.1-6 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-1.1-6 "Pharmaceutical care" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 6. For purposes of this article, "pharmaceutical care" includes the spectrum of services and products provided by a board licensee to a patient or consumer in the normal course of practice. The term includes, but is not limited to, dispensing legend drug product and delivery of cognitive services.

(Indiana Board of Pharmacy; 856 IAC 1-1.1-6)

SECTION 5. 856 IAC 1-1.1-7 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-1.1-7 "Real-time online database" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 7. "Real-time online database" means a database that is continuously updated in real time and allows users to share and store patient information and interface with each other in a secure environment over the Internet or an intranet. Where appropriate, facilities or companies utilizing this type of database will comply with other applicable federal or state laws and regulations that govern e-commerce, privacy, access, or sharing of patient information, such as, but not limited to, U.S. Drug Enforcement Administration regulations that outline what information must be maintained and included in any electronic transfer transaction.

(Indiana Board of Pharmacy; 856 IAC 1-1.1-7)

SECTION 6. 856 IAC 1-1.1-8 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-1.1-8 "Unlicensed person" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 8. "Unlicensed person" means any individual that is not HIPAA trained and does not hold a valid license, certification, permit, or registration issued by the board. Unlicensed persons are prohibited from performing pharmacy dispensing functions related to legend drug product in the pharmacy dispensing environment. The pharmacy dispensing environment includes the secured area where legend drug product is stored, reviewed, bottled, and dispensed (this does not include palleted legend drug product not yet reviewed or received by the pharmacist staff and held in a separate or distinct storage area). This prohibition does not apply to the presence of supervised cleaning staff, delivery personnel, or individuals present on site to perform administrative or operational functions and directly supervised by the pharmacist.

(Indiana Board of Pharmacy; 856 IAC 1-1.1-8)

SECTION 7. 856 IAC 1-1.1-9 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-1.1-9 "Electronic database" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 9. "Electronic database" means a record of information stored electronically that can be accessed using applications designed to securely store, retrieve, and organize information required to be maintained according to applicable state and federal pharmacy laws and regulations.

(Indiana Board of Pharmacy; 856 IAC 1-1.1-9)

SECTION 8. 856 IAC 1-1.1-10 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-1.1-10 "Electronic record or image" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 10. "Electronic record or image" means a record or image capable of being copied, reproduced, or created via technology designed to capture information in one (1) form and reproduce it in an electronic medium presentable and usable to an end user. For example, an electronic image could be a scanned version of a written prescription. An electronic record or image must be capable of being securely stored and retrieved after the date of creation for subsequent use or evaluation, or both. Such a record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted.

(Indiana Board of Pharmacy; 856 IAC 1-1.1-10)

SECTION 9. 856 IAC 1-29-1 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-29-1 Approval of electronic data processing system

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. (a) No electronic data processing system may be used by a pharmacist pursuant to a ~~Type I, Type III, and Type VI~~ **category I or category III** pharmacy permit as an alternative to his or her recordation of prescription information unless that system has been approved by the ~~Indiana~~ board. ~~of pharmacy (board).~~

(b) No electronic data processing system may be used by a pharmacist as an alternative to his **or her** recordation of information directly on the original prescription ~~pursuant to~~ **under** IC 25-26-13-25(c), without the approval of the board, and such an electronic data processing system does not qualify for approval unless it satisfies at a minimum the requirements found in this rule. Any such system must be approved by the board before initial installation in Indiana. Any pharmacy installing such a system must make a written request to the board for approval. Approval is subject to withdrawal for cause so that the pharmacist must in such a case discontinue use of the system as an alternative.

(Indiana Board of Pharmacy; 856 IAC 1-29-1; filed Aug 16, 1984, 3:55 p.m.: 7 IR 2543; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 10. 856 IAC 1-29-3 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-29-3 Hard copy of daily dispensing; verification and retention; back-up capability

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 3. (a) A pharmacy using an electronic data processing system must provide a separate hard copy printout of prescription **or drug** order and refill data for each day's dispensing or other board approved uniformly maintained readily retrievable system. This hard copy printout or other board approved system shall include the following:

(1) Prescription number.
(2) Date of dispensing.
(3) Patient name.
(4) Drug and strength (if applicable).
(5) Quantity dispensed.
(6) Prescriber identification.
(7) Pharmacist identification.
(8) Refill status.
(9) Controlled drug schedule identification.

(b) The dispensing pharmacist must verify that the data is correct to the best of his **or her** knowledge and date and sign the document or log book in the same manner as he **or she** would sign a check or legal document.

(c) This documentation shall be maintained for a period of ~~five (5)~~ **two (2)** years from the dispensing date. The daily hard copy printout may be replaced with a monthly printout or other permanent documentation containing the same information.

(d) Each system must have the capability of informational backup and such documentation must be stored in a secure location.

(e) If the electronic data processing system can capture an unalterable and legible digital image of the prescription or drug order, the digital image may be considered the original prescription record.

(1) A prescription that is stored as a digital image must have any notes of clarification or alterations, or both, recorded as an electronic annotation on the digital image of the prescription.

(2) As used in this section, "digital image" means the electronic record produced through the process of imaging, whereby a hard copy prescription is scanned by a computer and converted from a human-readable format to a computer-readable, digital format that can be used in an electronic data processing system.

(3) As used in this section, "electronic annotation" means a means by which to mark up a digital image so as to allow notes or clarification, or both, to be added to the prescription record without altering the original digital image.

(f) The electronic data processing system must be capable of maintaining, printing, and providing, upon a request by the board or the board's compliance officers, all of the prescription information required by state law and regulations of the board within seventy-two (72) hours of the request.

(Indiana Board of Pharmacy; 856 IAC 1-29-3; filed Aug 16, 1984, 3:55 p.m.: 7 IR 2544; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 11. 856 IAC 1-29-6 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-29-6 Data entry; supervision

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 6. When electronic data processing equipment is utilized in any pharmacy, input of drug information shall be performed by a pharmacist or under the immediate and personal supervision of a pharmacist. The pharmacist must certify the accuracy of the information entered and verify the prescription **or drug** order.

(Indiana Board of Pharmacy; 856 IAC 1-29-6; filed Aug 16, 1984, 3:55 p.m.: 7 IR 2545; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 12. 856 IAC 1-29-9 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-29-9 Applicability of rule

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 9. This rule applies to pharmacies with ~~Type I, Type III, Type IV, and Type VI~~ **category I and category III** permits.

(Indiana Board of Pharmacy; 856 IAC 1-29-9; filed Aug 16, 1984, 3:55 p.m.: 7 IR 2545; filed Mar 8, 1989, 10:00 a.m.: 12 IR 1634; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; filed Sep 21, 1992, 9:00 a.m.: 16 IR 724; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 13. 856 IAC 1-31-1 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-31-1 "Facsimile machine" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-2

Sec. 1. As used in this rule, "facsimile machine" means a machine that electronically transmits exact images through connection with a ~~telephone~~ **telecommunications** network.

(Indiana Board of Pharmacy; 856 IAC 1-31-1; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1390; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 14. 856 IAC 1-31-2 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-31-2 Use of a facsimile machine to electronically transmit a prescription or drug order

Authority: IC 25-26-13-4
Affected: IC 25-1-9; IC 25-26-13-15

Sec. 2. Prescription or drug orders for legend drugs, **including schedules II through V substances,** may be transmitted by facsimile machine from an authorized prescribing practitioner **or an authorized employee or agent of the individual practitioner** to a pharmacy under the following restrictions:

~~(1) The original prescription or order transmitted by facsimile machine contains:~~
~~(A) all information required under IC 25-26-13-2;~~
~~(B) the name and address of the pharmacy to which the prescription or drug order is being transmitted; and~~
~~(C) the name of the person transmitting the prescription or drug order.~~

~~(2) A statement that the prescription is valid only if transmitted by facsimile machine is included on the face of the original prescription or drug order.~~

~~(3) Actual transmission is done by or under the direct supervision of the authorized prescribing practitioner or by an authorized agent.~~

~~(4)~~ **(1)** A prescription **or drug order** for a schedule II controlled substance may be transmitted ~~by the practitioner or the practitioner's authorized agent~~ to a pharmacy via facsimile equipment, provided the original written, signed prescription **or drug order** is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in subdivision ~~(5)~~ **(2)** or ~~(6).~~ **(3).**

~~(5)~~ **(2)** A prescription **or drug order** prepared in accordance with 856 IAC 2-6-4 written for a schedule II narcotic substance to be compounded for the direct administration to a patient in a private residence, long-term care facility, or hospice setting by means of:

(A) parenteral;
(B) intravenous;
(C) intramuscular;
(D) subcutaneous; or
(E) intraspinal;

infusion may be transmitted ~~by the practitioner or the practitioner's agent~~ by facsimile. ~~The facsimile serves as the original written prescription, and it shall be maintained in accordance with IC 25-26-13-25.~~

~~(6)~~ **(3)** A prescription **or drug order** prepared in accordance with 856 IAC 2-6-4 written for a schedule II substance for a resident of a long-term care facility licensed under 410 IAC 16.2-3.1 may be transmitted ~~by the practitioner or the practitioner's authorized agent~~ to the dispensing pharmacy by facsimile. ~~The facsimile serves as the original written prescription for the purpose of this subdivision, and it shall be maintained in accordance with IC 25-26-13-25.~~

~~(7)~~ **(4)** A prescription **or drug order** prepared in accordance with 856 IAC 2-6-4 written for a schedule II narcotic substance for a patient enrolled in a hospice program, inpatient or outpatient, certified by Medicare under Title XVIII or licensed by Indiana may be transmitted ~~by the practitioner or the practitioner's agent~~ to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription **or drug order** that the patient is a hospice patient. ~~The facsimile serves as the original written prescription for purposes of this subdivision and maintained in accordance with IC 25-26-13-25.~~

~~(8) A controlled substance prescription or drug order for a Schedule III, IV, or V controlled substance may be sent by facsimile machine and must be sent by the prescribing practitioner or an authorized agent.~~

~~(9) A facsimile machine transmitted copy of a prescription or drug order must produce a nonfading copy or be reduced to writing, either manually or via other processes, for example, photocopying, that produces a nonfading document. Proper notation on the file copy shall indicate that the prescription order was initially received via facsimile machine transmission.~~

~~(10)~~ **(5)** The receiving facsimile machine must be located in the ~~prescription department of the pharmacy or in another~~ nonpublic area of the **licensed** pharmacy to protect patient/pharmacist/authorizing prescribing practitioner confidentiality and security as required by IC 25-26-13-15.

~~(11)~~ **(6)** Using facsimile equipment to circumvent documentation, authenticity, verification, or other standards of the profession of pharmacy **as defined by IC 25-26-13 or this title** will be considered professional incompetence under IC 25-1-9.

(Indiana Board of Pharmacy; 856 IAC 1-31-2; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1390; filed Aug 17, 1995, 8:30 a.m.: 19 IR 39; filed May 26, 2000, 8:52 a.m.: 23 IR 2502; filed May 10, 2001, 9:22 a.m.: 24 IR 3067; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 15. 856 IAC 1-31-3 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-31-3 Facsimile prescription or drug order maintenance

Authority: IC 25-26-13-4
Affected: IC 25-1-9; IC 25-26-13-25

Sec. 3. The facsimile serves as the original written prescription or drug order, and it shall be maintained in accordance with IC 25-26-13-25.

(Indiana Board of Pharmacy; 856 IAC 1-31-3)

SECTION 16. 856 IAC 1-32-2 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-32-2 Noncontrolled and controlled substance prescription transfers

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 2. (a) Prescription information for legend drugs that are not controlled substances may be transferred at any time during the lifetime of the prescription up to one (1) year after the date ~~of the original filling,~~ **originally issued by the prescriber** or when the original number of authorized refills expires, whichever comes first.

(b) Except as limited by the requirement of subsection (a), prescriptions for legend drugs that are not controlled substances may be transferred any number of times.

(c) If any authorized refills remain, prescriptions for schedule III, schedule IV, and schedule V controlled substances may be transferred only once within six (6) months from the date the prescription was issued. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(d) Prescriptions for schedule II controlled substances may not be transferred.

(Indiana Board of Pharmacy; 856 IAC 1-32-2; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; filed May 26, 2000, 8:52 a.m.: 23 IR 2503; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

SECTION 17. 856 IAC 1-32-4 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-32-4 Pharmacists' responsibilities

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 4. Transfer of prescription information ~~under this rule~~ must **be communicated between a licensed pharmacist or pharmacists and/or a licensed pharmacist intern or interns in accordance with these rules and all applicable U.S. Drug Enforcement Administration regulations and must** meet the following requirements:

(1) The ~~transfer is communicated directly between two (2) licensed pharmacists or by suitable electronic device approved by the Indiana board of pharmacy, and the~~ **pharmacist or pharmacist intern** transferring ~~pharmacist records~~ **the prescription shall do** the following: ~~information:~~

(A) ~~Write the word "VOID" on the face of~~ **Indicate that** the ~~invalidated~~ prescription **is no longer active and has been transferred.**

(B) Record ~~on the reverse of the invalidated prescription,~~ the name, address, and **U.S.** Drug Enforcement Administration registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription.

(C) Record the date of the transfer and the name of the pharmacist transferring the information.

(2) The pharmacist **or pharmacist intern** receiving the transferred prescription shall ~~reduce to writing~~ **record** the following:

~~(A) Write the word "TRANSFER" on the face of the transferred prescription.~~

~~(B) Provide~~ **(A)** All information required to be on a prescription and include the following:

(i) Date of issuance of original prescription.

(ii) Original number of refills authorized on original prescriptions.

(iii) Date of original dispensing.

(iv) Number of valid refills remaining and date of last refill and, in the event the transfer is for the second or subsequent transfer of a substance that is a schedule III, schedule IV, or schedule V controlled substance, the date and location of the previous refill.

(v) Pharmacy's name, address, **U.S.** Drug Enforcement Administration registration number, and original prescription number from which the prescription information was transferred.

(vi) Name of the ~~transferor~~ pharmacist, **and pharmacist intern if applicable, transferring and receiving the transferred prescription.**

~~(C)~~ **(B)** Both the original and transferred prescription must be maintained as required under IC 25-26-13-25.

~~(3) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.~~

(Indiana Board of Pharmacy; 856 IAC 1-32-4; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; errata filed Jul 10, 1992, 9:00 a.m.: 15 IR 2465; filed May 26, 2000, 8:52 a.m.: 23 IR 2503; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

SECTION 18. 856 IAC 1-32-5 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-32-5 Electronic transfers

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 5. (a) Two (2) or more pharmacies may establish and use a common electronic file to maintain required information related to the practice of the profession of pharmacy.

(b) Pharmacies using such a common electronic file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file as described in section 4 of this rule provided the following:

(1) The pharmacies are under common ownership or a contractual agreement.

(2) Any such common file must contain complete and adequate records of such prescription or prescriptions and refill or refills dispensed according to IC 25-26-13-25.

(3) All pharmacies and pharmacists involved in the transactions pursuant to the practice of the profession of pharmacy are properly licensed, permitted, or registered within the United States.

(4) A policy and procedures manual that governs all participating pharmacies and pharmacists:

(A) is available to the board upon request; and

(B) includes the procedure for maintaining appropriate records for regulatory oversight for tracking a prescription during each stage of the practice of the profession of pharmacy.

(5) The pharmacists involved in the practice of the profession of pharmacy are identified. A pharmacist shall be accountable for the specific tasks performed.

(Indiana Board of Pharmacy; 856 IAC 1-32-5)

SECTION 19. 856 IAC 1-34-2 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-34-2 Security feature requirements

Authority: IC 35-48-7-8

Affected: IC 16-42-19-5

Sec. 2. (a) All controlled substance prescriptions written by licensed Indiana practitioners, as defined by IC 16-42-19-5, must contain the following security features:

(1) A latent, repetitive "void" pattern screened at five percent (5%) in reflex blue must appear across the entire face of the document when the prescription is photocopied.

(2) There shall be a custom artificial watermark printed on the back side of the base paper so that it may only be seen at a forty-five (45) degree angle. The watermark shall consist of the words "Indiana Security Prescription", appearing horizontally in a step-and-repeated format in five (5) lines on the back of the document using 12-point Helvetica bold type style.

(3) An opaque RX symbol must appear in the upper right-hand corner, one-eighth (1/8) of an inch from the top of the pad and five-sixteenths (5/16) of an inch from the right side of the pad. The symbol must:

(A) be three-fourths (3/4) inch in size; and ~~must~~

(B) disappear if the prescription copy is lightened.

(4) Six (6) quantity check-off boxes must be printed on the form and the following quantities must appear and the appropriate box be checked off for the prescription to be valid:

(A) 1–24.

(B) 25–49.

(C) 50–74.

(D) 75–100.

(E) 101–150.

(F) 151 and over.

(5) No advertisements may appear on the front or back of the prescription blank.

(6) Logos, defined as a symbol utilized by an individual, professional practice, professional association, or hospital, may appear on the prescription blank. The upper left one (1) inch square of the prescription blank is reserved for the purpose of logos. Only logos, as defined by this subdivision, may appear on the prescription blank.

(7) Only one (1) prescription may be written per prescription blank. The following statement must be printed on the bottom of the pad: "Prescription is void if more than one (1) prescription is written per blank.".

(8) Refill options that can be circled by the prescriber must appear below any logos and above the signature lines on the left side of the prescription blank in the following order:

Refill NR 1 2 3 4 5 Void after_____.

(9) Practitioner name and state issued professional license number must be preprinted, stamped, or manually printed on the prescription.

(10) All prescription blanks printed under this rule shall be four and one-fourth (4 1/4) inches high and five and one-half (5 1/2) inches wide.

(b) Nothing in this rule shall prevent licensed Indiana practitioners from utilizing **the following:**

(1) Security paper prescriptions for the prescribing of any legend drug.

(2) Electronic prescribing in accordance with this title and applicable U.S. Drug Enforcement Administration rules and regulations.

(Indiana Board of Pharmacy; 856 IAC 1-34-2; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2782, eff Jan 1, 1996; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 20. 856 IAC 1-37-1 IS AMENDED TO READ AS FOLLOWS:

Rule 37. Central Fill or Processing, or Both, of Prescriptions and Drug Orders

856 IAC 1-37-1 "Central fill or processing, or both, of prescriptions and drug orders" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. ~~"Centralized prescription~~ **"Central fill or processing, or both, of prescriptions and** drug ~~order processing"~~ **orders"** means, **to** the **extent permissible by law, the filling or** processing by a pharmacy of a request from another pharmacy, **provider, payor, pharmacy benefit manager, or patient** to do the following

according to IC 25-26-13:

(1) Fill or ~~refill~~ **dispense, or both,** a **new or refillable** prescription **or** drug order.

(2) Perform processing **or professional, or both,** functions, including **any of** the following:

~~(A) Dispensing.~~

~~(B)~~ **(A)** Drug utilization review.

(B) Data entry and evaluation.

(C) Claims adjudication.

(D) Refill authorizations.

(E) Therapeutic interventions.

(F) Counseling.

(G) Any other cognitive services as defined under 856 IAC 1-41.

(H) Other functions as determined or approved by the board on an individual basis that do not adversely impact positive patient outcomes or patient safety.

(Indiana Board of Pharmacy; 856 IAC 1-37-1; filed Oct 14, 2005, 1:00 p.m.: 29 IR 815; readopted filed Nov 22, 2011, 12:16 p.m.: 20111221-IR-856110370RFA)

SECTION 21. 856 IAC 1-37-1.1 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-37-1.1 Central fill or processing, or both, facilities

Authority: IC 25-26-13-4
Affected: IC 25-26

Sec. 1.1. A pharmacy that performs centralized functions may perform:

(1) either processing or filling functions; and

(2) both functions out of the same facility in accordance with this article and the documented policies and procedures manual discussed below.

(Indiana Board of Pharmacy; 856 IAC 1-37-1.1)

SECTION 22. 856 IAC 1-37-1.2 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-37-1.2 Central fill or processing, or both, supervision

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1.2. Central fill or processing, or both, activities must occur in a permitted pharmacy environment under the supervision of a qualifying pharmacist as defined in IC 25-26-13.

(Indiana Board of Pharmacy; 856 IAC 1-37-1.2)

SECTION 23. 856 IAC 1-37-1.3 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-37-1.3 Central fill or processing, or both, remote practice

Authority: IC 25-26-13-4
Affected: IC 25-26

Sec. 1.3. Permitted central fill or central processing pharmacies may engage in remote practice and supervision, but only to the extent that it relates to the processing functions discussed in this rule or the delivery of cognitive services defined in 856 IAC 1-41, or both. Those facilities that choose to engage in remote practice shall comply with the following:

(1) 856 IAC 1-42-4.

(2) 856 IAC 1-42-5.

(3) 856 IAC 1-42-6.

(4) 856 IAC 1-42-7.

Those facilities that utilize remote practice pharmacy are also required to keep an active record of transactions and individuals that perform remote work that is available for inspection or review.

(Indiana Board of Pharmacy; 856 IAC 1-37-1.3)

SECTION 24. 856 IAC 1-37-2 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-37-2 Contracting for central fill or processing, or both

Authority: IC 25-26-13-4
Affected: IC 25-26

Sec. 2. A **permitted** pharmacy ~~licensed or registered by the board,~~ may ~~perform or~~ outsource ~~centralized prescription processing services~~ **and contract for central fill or processing, or both, functions** provided the **involved** parties have:

(1) the same owner or **are employed by the same organization; or**

(2) a written contract outlining the:

(A) services to be provided; and

(B) responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations **and the provisions discussed in section 1 of this rule;**

and share a common electronic ~~file~~ **database** or have appropriate technology to allow access to sufficient information necessary or required to **process,** fill, or refill a prescription **or** drug order **or provide cognitive services, or both.**

(Indiana Board of Pharmacy; 856 IAC 1-37-2; filed Oct 14, 2005, 1:00 p.m.: 29 IR 816; readopted filed Nov 22, 2011, 12:16 p.m.: 20111221-IR-856110370RFA)

SECTION 25. 856 IAC 1-37-2.1 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-37-2.1 Contracting for central fill or processing, or both, policies and procedures

Authority: IC 25-26-13-4
Affected: IC 25-26

Sec. 2.1. The pharmacy shall maintain as part of its documented policies and procedures a section addressing its contractual relationship and any outsources or contractually provided services that are performed by another entity.

(Indiana Board of Pharmacy; 856 IAC 1-37-2.1)

SECTION 26. 856 IAC 1-37-3 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-37-3 Policy and procedures manual

Authority: IC 25-26-13-4
Affected: IC 25-26

Sec. 3. The parties performing or contracting for ~~centralized prescription~~ **central fill or** processing, **or both,** services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review, upon request, and that includes, but it is not limited to, the following:

(1) A description of how the parties will comply with federal and state laws and regulations.

(2) The maintenance of the following:

(A) Appropriate records to identify the responsible pharmacist or pharmacists in the dispensing and counseling processes.

(B) A mechanism for tracking the prescription **or** drug order during each step in the **processing or** dispensing, **or both,** process.

(C) A mechanism to identify ~~on the prescription label~~ all pharmacies **or licensed persons, or both** involved

in: ~~dispensing the prescription drug order.~~
(i) processing;
(ii) filling and dispensing; or
(iii) providing cognitive services.
(3) The provision of adequate security to:
(A) protect the product integrity; and
(B) prevent the illegal use or disclosure of protected health information.
(4) The maintenance of a continuous quality improvement program for ~~centralized prescription~~ **central fill or** processing, ~~pharmacy~~ **or both,** services.

(Indiana Board of Pharmacy; 856 IAC 1-37-3; filed Oct 14, 2005, 1:00 p.m.: 29 IR 816; readopted filed Nov 22, 2011, 12:16 p.m.: 20111221-IR-856110370RFA)

SECTION 27. 856 IAC 1-40-8 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-40-8 Electronic data intermediary requirements

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 8. An applicant for approval as an electronic data intermediary shall do the following:
(1) File an application provided by the board.
(2) Provide proof of certification under applicable U.S. Drug Enforcement Administration regulations for electronic transmission of controlled substances.
~~(2)~~ **(3)** Submit information regarding how the EDI shall do the following:
(A) Guarantee the security of the following:
(i) The prescription.
(ii) The practitioner's identity and privacy.
(iii) The patient's identity, privacy, and confidentiality.
(B) Validate the authorized practitioner's licensure status.
~~(3)~~ **(4)** Appear before the board, if requested.

(Indiana Board of Pharmacy; 856 IAC 1-40-8; filed Jan 23, 2006, 8:35 a.m.: 29 IR 1931; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA)

SECTION 28. 856 IAC 1-41 IS ADDED TO READ AS FOLLOWS:

Rule 41. Cognitive Services

856 IAC 1-41-1 "Cognitive services" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. (a) As used in this rule, "cognitive services" means those services provided by a licensed pharmacist (or registered pharmacist intern under the supervision of a licensed pharmacist) that involve the delivery of patient care, counseling, and/or professional advice that may facilitate pharmaceutical care. The term includes, but is not limited to, the following functions:
(1) Medication therapy management.
(2) Prospective drug review.
(3) Drug utilization review.
(4) Drug interaction review.
(5) Collaborative practice with eligible prescribers.
(6) Pharmacist prescribing where permissible under collaborative practice.
(7) Patient counseling (whether in person or via technology that allows the pharmacist to have real-time access to patient data and real-time visual or vocal contact with the patient).
(8) Patient education and outreach designed to improve patient outcomes.
(9) Facilitating patient medication compliance and adherence.

(10) Facilitating preventative health or disease state management programs.
(11) Reducing medication errors.
(12) Review and analysis of records of continuous quality improvement programs or protocols.

(b) The term does not include the following activities:
(1) Administrative or clerical functions.
(2) Third party claims.
(3) Sales calls.
(4) Record keeping not required to be performed by a pharmacist.
(5) Reporting not required to be performed by a pharmacist.
(6) Provision of customer service not related to patient counseling on a prescription or drug order review.
(7) Duties related to preparation and dispensing of a prescription or drug order that will result in ultimate review by a licensed pharmacist.

(Indiana Board of Pharmacy; 856 IAC 1-41-1)

856 IAC 1-41-2 Delivery of cognitive services

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 2. The delivery of cognitive services occurs between a licensed pharmacist (or a registered pharmacist intern under the supervision of a licensed pharmacist) and a patient, group of patients, another pharmacist or pharmacists, prescriber or prescribers, or other eligible health care provider regarding the provision of pharmaceutical care as defined in this article.

(Indiana Board of Pharmacy; 856 IAC 1-41-2)

856 IAC 1-41-3 Licensure requirement

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. In order to provide or deliver cognitive services, an individual must have an active license in good standing in a state that has the same minimum standards for licensure as the state of Indiana including, but not limited to, passage of the North American Pharmacist Licensure Examination (NAPLEX).

(Indiana Board of Pharmacy; 856 IAC 1-41-3)

SECTION 29. 856 IAC 1-42 IS ADDED TO READ AS FOLLOWS:

Rule 42. Remote Pharmacy Practice

856 IAC 1-42-1 "Remote pharmacy practice" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. "Remote pharmacy practice" means the provision of pharmaceutical services not related to physically handling or dispensing pharmaceutical drugs or devices. This rule is intended to govern the practice of licensed pharmacists acting as independent contractors whether or not directly employed or affiliated with an entity that is licensed by the board to practice pharmacy into or out of the state of Indiana. This service also does not include the provision of pharmaceutical care that is conducted within the physical confines or premises of a permitted in-state pharmacy or a registered nonresident pharmacy.

This rule is not intended to overrule or supersede the provisions, practices, and requirements listed in 856 IAC 1-37.

(Indiana Board of Pharmacy; 856 IAC 1-42-1)

856 IAC 1-42-2 Permissible activities

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 2. The following are permissible activities covered by the remote practice pharmacy:
(1) Perform processing functions.
(2) Consulting services by contract with a dispensing pharmacy.
(3) Claims adjudication.
(4) Remote order/entry.
(5) Remote order review and approval.
(6) Other cognitive services as defined in 856 IAC 1-41.

(Indiana Board of Pharmacy; 856 IAC 1-42-2)

856 IAC 1-42-3 Requirements for licensure

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. Individuals who wish to engage in the remote practice of pharmacy in or into the state of Indiana as provided in this rule must satisfy the following licensure requirements:
(1) Have an active Indiana pharmacist license.
(2) Provide evidence, upon board request, of continuing education and any other relevant training for services provided.
(3) Have a license in good standing with no current or pending discipline (that is, ongoing probation) in this state or any other state in which the individual is licensed, unless otherwise approved by the board following a personal appearance.

(Indiana Board of Pharmacy; 856 IAC 1-42-3)

856 IAC 1-42-4 System, access, security, and privacy requirements

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 4. Pharmacists that provide or engage in remote practice of pharmacy services must employ security and privacy standards and protocols that adequately protect patient privacy and health. Accordingly, a pharmacist must satisfy the following requirements:
(1) Utilize a system that is capable of the following:
(A) Real-time access and exchange of live patient data.
(B) Secure and encrypted mediums of exchange.
(C) Limited access portals with rigorous authentication and identification protocols.
(D) Providing back-up or disaster recovery capability in the event of failure or loss of service.
(2) Utilize a system or program that at a minimum is capable of maintaining the following information on each transaction, service, prescription, or drug order reviewed, entered, or provided by the pharmacist performing the service:
(A) An electronic record that can be reproduced in electronic or manual format for inspection or review at any point within the scope of the appropriate record retention requirement as stipulated by either state or federal law.
(B) Track the identity of the individual pharmacist that took an action and the date and time at which this action took place.

(3) Utilize a system capable of maintaining compliance with HIPAA and other state or federal, or both, laws and regulations that relate to patient privacy.
(4) Utilize a system approved and reviewed by the board or board staff following a personal appearance or petition to the board.

(Indiana Board of Pharmacy; 856 IAC 1-42-4)

856 IAC 1-42-5 Record keeping requirements and notice

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 5. Pharmacists that engage in remote practice of pharmacy services are required to:
(1) maintain appropriate records; and
(2) make the records available for inspection and review upon board request.
Retention requirements should be documented in a pharmacist's policies and procedures and also made available for review by the board. Length of retention stipulated in the policy should reflect any applicable state or federal, or both, requirements.

(Indiana Board of Pharmacy; 856 IAC 1-42-5)

856 IAC 1-42-6 Work environment for remote practice of pharmacy

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 6. Remote pharmacy practice shall be conducted in a work environment that is conducive to providing quality patient treatment decisions, private counseling, or other health care related activities permissible under 856 IAC 1-41 but that do not include dispensing. Individuals that practice remotely are prohibited from practicing in a space that serves as their primary living, household, or family space. For example, if working out of a home environment, the individual should perform this work in a dedicated office space that is not actively used as a bedroom, living room, or other miscellaneous family space. This space should be open and accessible for an inspection by board staff if required. Work product or equipment in this space should be capable of being properly secured to protect patient privacy.

(Indiana Board of Pharmacy; 856 IAC 1-42-6)

856 IAC 1-42-7 Policies and procedures

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 7. A pharmacist that is providing remote practice of pharmacy services shall develop, implement, review, revise, and comply with policies and procedures for the services they provide. These policies and procedures should reflect the nature and extent of the services they perform. In the event a pharmacist is performing services via a contract with another service provider, dispensing pharmacy, or other institution, their contract shall stipulate or designate, or both, whose policies and procedures control for the services being performed. At a minimum, the policies and procedures shall include the following:
(1) A policy or statement concerning the services being provided or performed.
(2) A policy outlining the responsibilities of each of the parties involved.
(3) A policy or list that documents the names, addresses, telephone numbers, and all license and permit numbers of the parties involved in the services to be performed.
(4) A policy that documents the protection, confidentiality, and integrity of patient information.
(5) A policy that addresses record maintenance as stipulated above.
(6) A policy that addresses any necessary additional mechanisms or controls for compliance with other federal and state laws.
(7) A policy for operating and maintaining a continuous quality improvement program for remote practice of pharmacy services, designed to objectively and systematically monitor and evaluate the

quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(Indiana Board of Pharmacy; 856 IAC 1-42-7)

SECTION 30. 856 IAC 2-4-1 IS AMENDED TO READ AS FOLLOWS:

856 IAC 2-4-1 Records and inventories

Authority: IC 35-48-3-1
Affected: IC 35-48-3-7

Sec. 1. (a) Every registrant shall keep records and maintain inventories in conformance with the record keeping and inventorying requirements of federal law and regulation.

(b) For purposes of this section, "readily retrievable" means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, red-lined, or in some manner visually identifiable apart from other items appearing on the records. Manufacturers, distributors, and research records or electronic data processing printouts shall be made available within five (5) working days after a request by the Indiana board of pharmacy for such records or information on controlled substances transactions.

(c) Each registered pharmacy shall maintain, for a period of two (2) years, its prescriptions of controlled substances by maintaining any of the following:

(1) Three (3) separate files as follows:
  (A) A file for schedule II drugs dispensed.
  (B) A file for schedules III, IV, and V drugs dispensed.
  (C) A file for prescriptions for all other drugs dispensed.

(2) Two (2) separate files as follows:
  (A) A file for all noncontrolled drugs dispensed.
  (B) Another file for all controlled drugs dispensed in schedules II, III, IV, and V. If this method is used, the prescriptions in the file for schedules III, IV, and V must be stamped with the letter "C" in red ink, not less than one (1) inch high, in the lower right-hand corner.

(3) Two (2) separate files as follows:
  (A) A file for schedule II drugs dispensed.
  (B) Another file for schedules III, IV, and V drugs, including all other noncontrolled drugs dispensed. If this method is used, the prescriptions in the file of schedules III, IV, and V drugs must be stamped with the letter "C" in red ink, not less than one (1) inch high, in the lower right-hand corner.

However, if a pharmacy employs an automated data processing system or other electronic record keeping system for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" under subdivisions (2) and (3) is waived.

(d) Electronically transmitted prescriptions must be maintained in accordance with applicable federal regulations.

(Indiana Board of Pharmacy; Reg 28, Ch IV, Sec 4.01; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 26, 2000, 8:52 a.m.: 23 IR 2504; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 31. 856 IAC 2-6-1.5 IS ADDED TO READ AS FOLLOWS:

856 IAC 2-6-1.5 Signature requirements

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

Sec. 1.5. All references to "signed" in this section shall include either:
(1) manually written in pen or indelible pencil; or
(2) electronically signed in accordance with applicable federal regulations.

(Indiana Board of Pharmacy; 856 IAC 2-6-1.5)

SECTION 32. 856 IAC 2-6-4 IS AMENDED TO READ AS FOLLOWS:

856 IAC 2-6-4 Issuance of prescriptions; information required

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

Sec. 4. ~~Manner of issuance of prescriptions.~~ (a) All prescriptions for controlled substances shall be dated as of, and signed, ~~on,~~ the day when issued and shall bear the full name and address of the patient, and the name, address, and federal controlled substance registration number of the practitioner. A practitioner may sign a prescription ~~in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith).~~ **either in writing or electronically in accordance with applicable federal regulations.** Where an oral order is not permitted, prescriptions shall be:

(1) written with ink, ~~or~~ indelible pencil, **computer printer,** or typewriter and ~~shall be~~ manually signed by the practitioner; **or**

(2) electronically written, signed, and transmitted in accordance with applicable federal regulations.

~~The~~ **(b) Nonelectronically prescribed** prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations, **or applicable federal regulations.**

~~(b)~~ **(c)** An intern, resident, or foreign-trained physician exempted from registration under ~~section 3.14(c),~~ **856 IAC 2-3-5(c)** shall include on all prescriptions issued by him **or her** the federal controlled substance registration number of the hospital or other institution and the special internal code number assigned to him **or her** by the hospital or other institution as provided in ~~section 3.14(c),~~ **856 IAC 2-3-5(c)** in lieu of the registration number of the practitioner required by this section. Each prescription shall have the name of the intern, resident, or foreign-trained physician stamped or printed on it, as well as the signature of the physician.

~~(c)~~ **(d)** An official exempted from registration under ~~section 3.15~~ **856 IAC 2-3-6** shall include on all prescriptions issued by him **or her,** his **or her** branch of service or agency ~~(e.g.,~~ **(for example,** "U.S. Army" or "Public Health Service") and his **or her** service identification number in lieu of the federal controlled substance registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his **or her** Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or hand-printed on it, as well as the signature of the officer.

(e) A prescription issued electronically by a practitioner exempted under subsections (c) and (d) shall conform to applicable federal regulations.

(Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.04; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 33. 856 IAC 2-6-7 IS AMENDED TO READ AS FOLLOWS:

856 IAC 2-6-7 Schedule II controlled substances; prescription required; exceptions

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

Sec. 7. (a) A pharmacist may dispense directly a controlled substance listed in schedule II, which is a

prescription drug as determined under the federal Food, Drug, and Cosmetic Act, only pursuant to a ~~written~~ prescription signed by the prescribing individual practitioner, except as provided in subsection (d).

(b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule II in the course of his or her professional practice without a prescription subject to section 6 of this rule.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule II only pursuant to a ~~written~~ prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined ~~by~~ **in** subsection (e), a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a prescribing individual practitioner provided the following:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner.

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in section 4 of this rule, except for the signature of the prescribing individual practitioner.

(3) If the prescribing individual practitioner is not known to the pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his or her phone number as listed in the telephone directory and/or other good faith efforts to assure his or her identity.

(4) Within seven (7) days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of section 4 of this rule, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven (7) day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription ~~which~~ **that** had earlier been reduced to writing. The pharmacist shall notify the Indiana board of pharmacy if the prescribing individual fails to deliver a written prescription to him or her, failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing individual practitioner.

(e) For the purpose of authorizing an oral prescription of a controlled substance listed in schedule II of IC 35-48 as amended, "emergency situation" means those situations in which the prescribing practitioner determines the following:

(1) ~~That~~ Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.

(2) ~~That~~ No appropriate alternative treatment is available, including administration of a drug that is not a controlled substance under schedule II of IC 35-48 as amended.

(3) ~~That~~ It is not reasonably possible for the prescribing practitioner to provide a written prescription ~~to be presented~~ **or electronically transmitted prescription** to the person dispensing the substance, prior to the dispensing.

(Indiana Board of Pharmacy; Reg 28, Ch VI,Sec 6.11; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 26, 2000, 8:52 a.m.: 23 IR 2505; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 34. 856 IAC 2-6-9 IS AMENDED TO READ AS FOLLOWS:

856 IAC 2-6-9 Schedule II controlled substances; partial filling of prescriptions

Authority: IC 35-48-3-1
Affected: IC 35-48-2-6; IC 35-48-3-9

Sec. 9. (a) The partial filling of a prescription for a controlled substance listed in schedule II under IC 35-48-2-6, as amended, is permissible if the pharmacist is unable to supply the full quantity called for in a

prescription written **either manually or electronically in accordance with applicable federal regulations,** or emergency oral prescription and makes a notation of the quantity supplied on the face of the written prescription, ~~(or~~ **on the** written record of the emergency oral prescription **or electronically recorded if electronically transmitted.** The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling. However, if the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

(b) A prescription **prescribed, either in writing or electronically in accordance with applicable federal regulations,** for a schedule II controlled substance ~~written~~ for patients in long-term care facilities may be filled in partial quantities to include individual dosage units. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the:

(1) date of the partial filling;
(2) quantity dispensed;
(3) remaining quantity authorized to be dispensed; and ~~the~~
(4) identification of the dispensing pharmacist.

The total quantity of a schedule II controlled substance dispensed in all partial fillings must not exceed the total quantity prescribed. A schedule II prescription, for a patient in a long-term care facility, shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by the discontinuance of medication.

(c) A prescription for a schedule II controlled substance ~~written~~ **prescribed, either in writing or electronically in accordance with applicable federal regulations,** for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. The pharmacist has a responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription the patient is "terminally ill". A prescription that is partially filled and does not contain the notation "terminally ill" shall be deemed to have been filled in violation of this section. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained and readily retrievable) the:

(1) date of the partial filling;
(2) quantity dispensed;
(3) remaining quantity authorized to be dispensed; and ~~the~~
(4) identification of the dispensing pharmacist.

Prior to any subsequent partial filling, the pharmacist is to determine that the additional partial filling is necessary. The total quantity of a schedule II controlled substance dispensed in all partial fillings must not exceed the total quantity prescribed. A schedule II prescription for a patient with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by the discontinuance of medication.

(Indiana Board of Pharmacy; Reg 28, Ch VI, Sec 6.13; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 8, 1986, 9:55 a.m.: 9 IR 2205; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1391; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 35. 856 IAC 2-6-10 IS AMENDED TO READ AS FOLLOWS:

856 IAC 2-6-10 Schedule II controlled substances; label information; exceptions

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

Sec. 10. ~~Labeling of substances.~~ (a) The pharmacist filling a written **prescription, an electronically transmitted prescription,** or **an** emergency oral prescription for a controlled substance listed in **856 IAC 2-2-3,** Schedule II, shall affix to the package a label showing **the following:**

(1) The date of filling.
(2) The pharmacy name and address.
(3) The serial number of the prescription.
(4) The name of the patient.

(5) The name of the prescribing practitioner. ~~and~~
(6) Directions for use. ~~and~~
(7) The cautionary statement, "Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed".
(8) Any others if any, contained in ~~such~~ **the** prescription or required by law.

(b) The requirements of ~~paragraph~~ **subsection** (a) ~~of this section~~ do not apply when a controlled substance listed in **856 IAC 2-2-3,** Schedule II, is prescribed for administration to an ultimate user who is institutionalized, provided ~~that:~~ **the following:**
(1) Not more than **a seven** (7) day supply of the controlled substance listed in **856 IAC 2-2-3,** Schedule II, is dispensed at one **(1)** time.
(2) The controlled substance listed in **856 IAC 2-2-3,** Schedule II, is not in the possession of the ultimate user prior to the administration. ~~and~~
(3) The institution maintains appropriate safeguards and records regarding the proper:
(A) administration;
(B) control;
(C) dispensing; and
(D) storage;
of the controlled substance listed in **856 IAC 2-2-3,** Schedule II. ~~and~~
(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.14; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 36. 856 IAC 2-6-12 IS 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. (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 ~~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 ~~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 ~~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 that is dispensed for immediate administration to the ultimate user, subject to ~~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; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 37. 856 IAC 2-6-13 IS AMENDED TO READ AS FOLLOWS:

856 IAC 2-6-13 Schedules III, IV, and V controlled substances; refilling prescriptions; retrievable

information

Authority: IC 35-48-3-1
Affected: IC 35-48-2; IC 35-48-3-9

Sec. 13. (a) No prescription for a controlled substance listed in schedule III (IC 35-48-2-8), schedule IV (IC 35-48-2-10), or schedule V (IC 35-48-2-12) shall be filled or refilled more than six (6) months after the date on which such prescription was issued, and no such prescription shall be authorized to be refilled more than five (5) times.

(b) Each refill of a prescription shall be recorded by one (1) of the following methods:
(1) On the back of the original prescription, ~~and, if used,~~ **an electronically transmitted record in accordance with applicable federal regulations, or** a uniformly maintained, readily retrievable record. ~~such as a medication record or patient profile.~~
(2) In the storage memory of an electronic data processing system if such board approved system is used in the pharmacy.

(c) The following prescription information shall be retrievable by using or entering the serial number of the prescription:
(1) The name (and strength, if applicable) and dosage form of the controlled substance.
(2) The date on which the prescription was written, **electronically transmitted,** or ~~phoned~~ **orally transmitted** and reduced to writing by the pharmacist.
(3) The date of original filling and the date or dates of all refills.
(4) A notation or notations for the original filling and each and every subsequent refilling sufficient to identify the dispensing pharmacist.
(5) The total number of refills originally authorized and remaining for each individual prescription.
If the pharmacist does nothing more than date and initial the prescription to indicate a refill has been dispensed, the pharmacist shall be deemed to have dispensed a refill for the full face amount (that is the originally prescribed amount) of the prescription.

(d) Additional refills for prescriptions for controlled substances listed in schedule III (IC 35-48-2-8), schedule IV (IC 35-48-2-10), or schedule V (IC 35-48-2-12) may be added to the original prescription ~~on~~ **pursuant to** an ~~oral~~ authorization transmitted to the pharmacist by the original prescribing practitioner providing the following conditions are met:
(1) The total quantity authorized does not exceed the original face amount of the prescription and five (5) total refills, and none of the refills is for more dose units or a larger quantity than the original face amount of the prescription.
(2) No dispensing takes place pursuant to the original prescription more than six (6) months after the date of the original issue of the prescription.
(3) The pharmacist receiving the ~~oral~~ authorization records that authorization on the reverse of the original prescription, or in a readily retrievable record, and the following information:
(A) The date of the authorization.
(B) The number of the dose units or quantity authorized.
(C) The number of additional refills authorized.
(D) The initials of the pharmacist receiving the ~~oral~~ authorization.

(e) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five (5) refill, six (6) month limitation.

(Indiana Board of Pharmacy; Reg 28, Ch VI, Sec 6.22; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 20, 1988, 9:30 a.m.: 11 IR 3564; filed Jul 5, 1995, 10:00 a.m.: 18 IR 2783; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 38. 856 IAC 2-6-17 IS AMENDED TO READ AS FOLLOWS:

856 IAC 2-6-17 Schedule V controlled substances; prescription requirements; refilling; exceptions

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

Sec. 17. ~~Requirement of prescription.~~ (a) A pharmacist may dispense a controlled substance listed in **856 IAC 2-2-6,** Schedule V, pursuant to a prescription as required for controlled substances listed in **856 IAC 2-2-4 and 856 IAC 2-2-5,** Schedules III and IV, in section ~~6.21~~ **12 of this rule.** A prescription for a controlled substance listed in **856 IAC 2-2-6,** Schedule V, may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription. If no such authorization is given, the prescription may not be refilled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with section ~~6.24~~ **15 of this rule** and file the prescription in accordance with section ~~6.25.~~ **16 of this rule.**

(b) An individual practitioner may administer or dispense a controlled substance listed in **856 IAC 2-2-6,** Schedule V, in the course of his **or her** professional practice without a prescription, subject to section ~~6.24.~~ **15 of this rule.**

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in **856 IAC 2-2-6,** Schedule V, only pursuant to a ~~written~~ prescription signed by the 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~~ **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 ~~6.24.~~ **15 of this rule.**

(Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.31; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 39. 856 IAC 2-6-18 IS AMENDED TO READ AS FOLLOWS:

856 IAC 2-6-18 Dispensing without prescription; delivery of devices

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

Sec. 18. (a) A controlled substance listed in schedule V in the Controlled Substance Act, IC 35-48, ~~which~~ **that** does not require a prescription under federal, state, or local law or a device known as a hypodermic syringe ~~and/or~~ **or** needle, **or both,** for human use may be dispensed **only** by a pharmacist **or a pharmacist intern under the direct supervision of a pharmacist** without a prescription to a purchaser at retail, provided ~~that:~~ **the following:**

~~(1) such dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the direct supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in his [sic.] section, the actual cash, credit transaction, or delivery may be completed by a non-pharmacist),~~

~~(2) no~~ **(1) Not** more than:

~~(i)~~ **(A) two hundred forty** (240) **cubic centimeters** (cc) **(eight** (8) ounces) or **forty-eight** (48) dosage units of any substance containing opium;

~~(ii)~~ **(B) one hundred twenty** (120) cc **(four** (4) ounces) or **twenty-four** (24) dosage units of any other substance nor more than **forty-eight** (48) dosage units may be dispensed at retail to the same purchaser in any given **forty-eight** (48) hour period;

~~(3)~~ **(2)** The purchaser is at least eighteen (18) years of age. However, if the item being purchased is a device known as a hypodermic syringe ~~and/or~~ **or** needle, **or both,** for human use, the age restriction shall not apply.

~~(4)~~ **(3)** The pharmacist **or pharmacist intern** requires every purchaser of a controlled substance or device as described in ~~856 IAC 2-6-18(a)~~ **subsection (a)** not known to the pharmacist to furnish suitable identification (including proof of age where appropriate). ~~and~~

~~(5)~~ **(4)** Separate bound record books for dispensing of:

~~(i)~~ **(A)** controlled substances; and

(ii) **(B)** devices under this section;

are maintained by the pharmacist. These books shall contain the name and address of the purchaser, the name and quantity of controlled substance or devices purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance or devices to the purchaser ~~these books~~ **and** shall be maintained in accordance with the record keeping requirements of 856 IAC 2-4-1.

(b) Delivery of devices, as described above, to inpatients of institutions is exempt from this section.

(c) The delivery of a device known as a hypodermic syringe-needle other than by a pharmacist **or pharmacist intern** in a licensed pharmacy or a licensed practitioner in his **or her** lawful place of practice is prohibited.

(Indiana Board of Pharmacy; Reg 28, Ch VI, Sec 6.32; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 20, 1988, 9:30 a.m.: 11 IR 3565; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

SECTION 40. THE FOLLOWING ARE REPEALED: 856 IAC 1-35-2; 856 IAC 1-35-3.

Notice of Public Hearing

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