

ARTICLE 5. STANDARDS OF PROFESSIONAL CONDUCT AND COMPETENT PRACTICE OF MEDICINE

Rule 1. General Provisions

844 IAC 5-1-1 Definitions

Authority: IC 25-22.5-2-7

Affected: IC 16-18-2-199; IC 16-42-19-5; IC 25-1-9; IC 25-10; IC 25-13; IC 25-14; IC 25-20; IC 25-23; IC 25-23.5; IC 25-23.6; IC 25-24; IC 25-26-13-17; IC 25-27; IC 25-27.5; IC 25-29; IC 25-33; IC 25-34.5; IC 25-35.6; IC 35-48-1-9; IC 35-48-2

Sec. 1. For purposes of this article and IC 25-1-9, the following definitions apply:

- (1) "Addict" means a person who is physiologically and/or psychologically dependent upon a drug that is classified as a narcotic, controlled substance, or dangerous drug.
- (2) "Classified as a narcotic" means any substance that is designated as a controlled substance under IC 35-48-1 or IC 35-48-2, or so classified in any subsequent amendment or revision of said statutes.
- (3) "Controlled substance" has the same meaning set forth in IC 35-48-1-9.
- (4) "Dangerous drug" means any substance that is designated as a controlled substance under IC 35-48-1 or IC 35-48-2, or so classified in any subsequent amendment or revision of said statute.
- (5) "General health information site" means a noninteractive Internet site that is accessible by anyone with access to the Internet and intended to provide general, user nonspecific information or advice about maintaining health or the treatment of an acute or chronic illness, health condition, or disease state.
- (6) "Habitue" means a person who:
 - (A) is physiologically and/or psychologically dependent upon any narcotic drug classified as a narcotic, dangerous drug, or controlled substance under Indiana law; or
 - (B) consumes, on a regular basis and without any medically justifiable purpose, a narcotic drug classified as a narcotic, dangerous drug, or controlled substance under Indiana law, whether or not such person has developed a physiological or psychological dependence upon such substance.
- (7) "Institutional setting" means any health care facility whose primary purpose is to provide a physical environment for patients to obtain health care services, except those places where practitioners, as defined by IC 16-42-19-5, who are duly licensed, engage in private practice and pharmacies licensed under IC 25-26-13-17.
- (8) "Internet medical practice site" means a patient-specific Internet site, access to which is limited to licensed physicians, associated medical personnel, and patients.
- (9) "Internet site" means an electronic source of health information content, commerce, connectivity, and/or service delivery.
- (10) "Legend drug" has the meaning set forth in IC 16-18-2-199.
- (11) "Passive tracking mechanism" means a persistent electronic file used to track Internet site navigation, which allows the Internet site to record and retain user-specific navigation information whenever the user accesses the Internet site. Examples include:
 - (A) cookies;
 - (B) clear.gifs; or
 - (C) Web bugs.
- (12) "Personal health information" means any information, whether oral or recorded in any form or medium, that:
 - (A) is created or received by a physician or other health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
 - (B) relates to the:
 - (i) past, present, or future physical or mental health or condition of an individual;
 - (ii) provision of health care to an individual; or
 - (iii) past, present, or future payment for the provision of health care to an individual.
- (13) "Physician-patient e-mail" means computer-based communication between physicians or associated medical personnel and patients within a professional relationship in which the physician has taken on an explicit measure of responsibility for

the patient's care.

(14) "Practitioner" means a person who holds an unlimited license to practice medicine or osteopathic medicine in Indiana or a limited license or permit as may be issued by the board.

(15) "Professional incompetence" may include, but is not limited to, a pattern or course of repeated conduct by a practitioner demonstrating a failure to exercise such reasonable care and diligence as is ordinarily exercised by practitioners in the same or similar circumstances in the same or similar locality.

(16) "Specific professional health care provider" means any person who holds a specific license to practice in an area of health care in Indiana, including, but not limited to, the following persons:

- (A) Any chiropractor licensed under IC 25-10.
- (B) Any dental hygienist licensed under IC 25-13.
- (C) Any dentist licensed under IC 25-14.
- (D) Any hearing aid dealer licensed under IC 25-20.
- (E) Any nurse licensed under IC 25-23.
- (F) Any optometrist licensed under IC 25-24.
- (G) Any pharmacist licensed under IC 25-26.
- (H) Any physical therapist licensed under IC 25-27.
- (I) Any podiatrist licensed under IC 25-29.
- (J) Any psychologist licensed under IC 25-33.
- (K) Any speech pathologist or audiologist licensed under IC 25-35.6.
- (L) Any respiratory care practitioner certified under IC 25-34.5.
- (M) Any occupational therapist certified under IC 25-23.5.
- (N) Any clinical social worker, marriage and family therapist, or mental health counselor licensed under IC 25-23.6.
- (O) Any physician assistant certified under IC 25-27.5.
- (P) Any hypnotist certified under IC 25-20.5-1-7 [IC 25-20.5-1 was repealed by P.L.84-2010, SECTION 102, effective July 1, 2010.].

(Medical Licensing Board of Indiana; 844 IAC 5-1-1; filed Apr 12, 1984, 8:28 a.m.: 7 IR 1522; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; filed Oct 1, 2003, 9:32 a.m.: 27 IR 521; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA)

844 IAC 5-1-2 Standards of professional conduct (Repealed)

Sec. 2. *(Repealed by Medical Licensing Board of Indiana; filed Nov 30, 1990, 4:15 p.m.: 14 IR 755)*

844 IAC 5-1-3 Disciplinary action

Authority: IC 25-22.5-2-7
Affected: IC 25-1-9

Sec. 3. Failure to comply with this article may result in disciplinary proceedings against the offending practitioners. Further, all practitioners licensed in Indiana shall be responsible for having knowledge of the standards of conduct and practice established by statute and rule pursuant to IC 25-22.5-2-7. *(Medical Licensing Board of Indiana; 844 IAC 5-1-3; filed Apr 12, 1984, 8:28 a.m.: 7 IR 1526; filed Nov 30, 1990, 4:15 p.m.: 14 IR 750; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; filed Oct 1, 2003, 9:32 a.m.: 27 IR 522; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA)*

Rule 2. Standards of Professional Conduct

844 IAC 5-2-1 Applicability

Authority: IC 25-22.5-2-7
Affected: IC 25-1-9; IC 25-22.5-1

Sec. 1. A practitioner in the conduct of his/her practice of medicine or osteopathic medicine shall abide by, and comply with, the standards of professional conduct in this rule. (*Medical Licensing Board of Indiana; 844 IAC 5-2-1; filed Nov 30, 1990, 4:15 p.m.: 14 IR 750; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-2 Confidentiality

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 2. A practitioner shall maintain the confidentiality of all knowledge and information regarding a patient, including, but not limited to, the patient's diagnosis, treatment, and prognosis, and of all records relating thereto, about which the practitioner may learn or otherwise be informed during the course of, or as a result of, the patient-practitioner relationship. Information about a patient shall be disclosed by a practitioner when required by law, including, but not limited to, the requirements of IC 34-4-12.6-1 [*IC 34-4 was repealed by P.L.1-1998, SECTION 221, effective July 1, 1998.*] and of IC 16-4-8-1, and any amendments thereto, or when authorized by the patient or those responsible for the patient's care. (*Medical Licensing Board of Indiana; 844 IAC 5-2-2; filed Nov 30, 1990, 4:15 p.m.: 14 IR 750; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-3 Information to patient

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 3. A practitioner shall give a truthful, candid, and reasonably complete account of the patient's condition to the patient or to those responsible for the patient's care, except where a practitioner reasonably determines that the information is or would be detrimental to the physical or mental health of the patient, or in the case of a minor or incompetent person, except where a practitioner reasonably determines that the information is or would be detrimental to the physical or mental health of those persons responsible for the patient's care. (*Medical Licensing Board of Indiana; 844 IAC 5-2-3; filed Nov 30, 1990, 4:15 p.m.: 14 IR 750; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-4 Case withdrawal

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 4. (a) The practitioner shall give reasonable written notice to a patient or to those responsible for the patient's care when the practitioner withdraws from a case so that another practitioner may be employed by the patient or by those responsible for the patient's care. A practitioner shall not abandon a patient.

(b) A practitioner who withdraws from a case, except in emergency circumstances, shall, upon written request and in conformity with the provisions of IC 16-4-8-1 through IC 16-4-8-11 and of any subsequent amendment or revision thereof, make available to his/her patient or to those responsible for the patient's care, and to any other practitioner or specific professional health care provider employed by the patient, or by those responsible for the patient's care, all records, test results, histories, x-rays, radiographic studies, diagnoses, files, and information relating to said patient which are in the practitioner's custody, possession, or control, or copies of such documents hereinbefore described. (*Medical Licensing Board of Indiana; 844 IAC 5-2-4; filed Nov 30, 1990, 4:15 p.m.: 14 IR 751; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-5 Reasonable care

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 5. A practitioner shall exercise reasonable care and diligence in the treatment of patients based upon generally accepted scientific principles, methods, treatments, and current professional theory and practice. (*Medical Licensing Board of Indiana; 844 IAC 5-2-5; filed Nov 30, 1990, 4:15 p.m.: 14 IR 751; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-6 Degree basis for licensing

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 6. A practitioner shall not represent, advertise, state, or indicate the possession of any degree recognized as the basis for licensure to practice medicine or osteopathic medicine unless the practitioner is actually licensed on the basis of such degree in the state(s) in which he/she practices. (*Medical Licensing Board of Indiana; 844 IAC 5-2-6; filed Nov 30, 1990, 4:15 p.m.: 14 IR 751; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-7 Consultations; referrals

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 7. A practitioner shall make reasonable efforts to obtain consultation whenever requested to do so by a patient or by those responsible for a patient's care. Further, the practitioner shall refer a patient to another practitioner in any case where the referring practitioner does not consider himself/herself qualified to treat the patient, and may refer the patient to another practitioner where the referring practitioner is unable to diagnose the illness or disease of the patient. (*Medical Licensing Board of Indiana; 844 IAC 5-2-7; filed Nov 30, 1990, 4:15 p.m.: 14 IR 751; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-8 Peer reviews

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 8. (a) A practitioner who has personal knowledge based upon a reasonable belief that another practitioner holding the same licenses has engaged in illegal, unlawful, incompetent, or fraudulent conduct in the practice of medicine or osteopathic medicine shall promptly report such conduct to a peer review or similar body, as defined in IC 34-4-12.6-1(c) [*IC 34-4 was repealed by P.L.1-1998, SECTION 221, effective July 1, 1998.*], having jurisdiction over the offending practitioner and the matter. This provision does not prohibit a practitioner from promptly reporting said conduct directly to the medical licensing board. Further, a practitioner who has personal knowledge of any person engaged in, or attempting to engage in, the unauthorized practice of medicine or osteopathic medicine shall promptly report such conduct to the medical licensing board.

(b) A practitioner who voluntarily submits himself/herself to, or is otherwise undergoing a course of, treatment for addiction, severe dependency upon alcohol or other drugs or controlled substances, or for psychiatric impairment, where such treatment is sponsored or supervised by an impaired physicians' committee of a state, regional, or local organization of professional health care providers, or where such treatment is sponsored or supervised by an impaired physicians' committee of a hospital, shall be exempt from reporting to a peer review committee as set forth in subsection (a) or to the medical licensing board for so long as:

(1) the practitioner is complying with the course of treatment; and

(2) the practitioner is making satisfactory progress.

(c) If the practitioner fails to comply with, or is not benefitted by, the course of treatment, the practitioner-chief administrative officer, his designee, or any member of the impaired physicians' committee shall promptly report such facts and circumstances to the medical licensing board. This section shall not, in any manner whatsoever, directly or indirectly, be deemed or construed to prohibit, restrict, limit, or otherwise preclude the medical licensing board from taking such action as it deems appropriate or as may otherwise be provided by law. (*Medical Licensing Board of Indiana; 844 IAC 5-2-8; filed Nov 30, 1990, 4:15*

p.m.: 14 IR 751; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA)

844 IAC 5-2-9 Fees

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 9. (a) Fees charged by a practitioner for his/her professional services shall be reasonable and shall reasonably compensate the practitioner only for services actually rendered.

(b) A practitioner shall not enter into agreement for, charge, or collect an illegal or clearly excessive fee.

(c) Factors to be considered in determining the reasonableness of a fee include, but are not limited to, the following:

(1) The difficulty and/or uniqueness of the services performed and the time, skill, and experience required.

(2) The fee customarily charged in the locality for similar practitioner services.

(3) The amount of the charges involved.

(4) The quality of performance.

(5) The nature and length of the professional relationship with the patient.

(6) The experience, reputation, and ability of the practitioner in performing the kind of services involved.

(Medical Licensing Board of Indiana; 844 IAC 5-2-9; filed Nov 30, 1990, 4:15 p.m.: 14 IR 752; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA)

844 IAC 5-2-10 Fee division

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 10. A practitioner shall not divide a fee for professional services with another practitioner who is not a partner, employee, or shareholder in a professional corporation, unless:

(1) the patient consents to the employment of the other practitioner after a full disclosure that a division of fees will be made; and

(2) the division of fees is made in proportion to actual services performed and responsibility assumed by each practitioner.

(Medical Licensing Board of Indiana; 844 IAC 5-2-10; filed Nov 30, 1990, 4:15 p.m.: 14 IR 752; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA)

844 IAC 5-2-11 Referral fees

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 11. A practitioner shall not pay, demand, or receive compensation for referral of a patient, except for a patient referral program operated by a medical society or association which is approved by the medical licensing board. *(Medical Licensing Board of Indiana; 844 IAC 5-2-11; filed Nov 30, 1990, 4:15 p.m.: 14 IR 752; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA)*

844 IAC 5-2-12 Employees

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 12. A practitioner shall be responsible for the conduct of each and every person employed by the practitioner (whether

such employee is a physician, nurse, physician's assistant, or other specific professional health care provider employed by the practitioner) for every action or failure to act by said employee or employees in the course of said employee's employment relationship with said practitioner, provided, however, that a practitioner shall not be responsible for the actions of persons he/she may employ whose employment by the practitioner does not relate directly to the practitioner's practice of medicine or of osteopathic medicine. (*Medical Licensing Board of Indiana; 844 IAC 5-2-12; filed Nov 30, 1990, 4:15 p.m.: 14 IR 752; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-13 Advertising

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 13. (a) A practitioner shall not, on behalf of himself/herself, a partner, associate, shareholder in a professional corporation, or any other practitioner or specific health care provider affiliated with the practitioner, use, or participate in the use of, any form of public communication containing a false, fraudulent, misleading, deceptive, or unfair statement or claim.

(b) Subject to the requirements of subsection (a), and in order to facilitate the process of informed selection of a practitioner by the public, a practitioner may advertise services through the public media including, but not limited to, a telephone directory, physicians' or osteopaths' directory, newspaper or other periodical, radio or television, or through written communication not involving personal contact, provided that the advertisement is dignified and confines itself to the existence, scope, nature, and field of practice of the practitioner.

(c) If the advertisement is communicated to the public by radio, cable, or television, it shall be prerecorded, approved for broadcast by the practitioner, and a recording and transcript of the actual transmission shall be retained by the practitioner for a period of five (5) years from the last date of broadcast.

(d) If a practitioner advertises a fee for a service, treatment, consultation, examination, radiographic study, or other procedure, the practitioner must render that service or procedure for no more than the fee advertised.

(e) Unless otherwise specified in the advertisement, if a practitioner publishes or communicates any fee information in a publication that is published more frequently than one (1) time per month, the practitioner shall be bound by any representation made therein for a period of thirty (30) days after the publication date. If a practitioner publishes or communicates any fee information in a publication that is published once a month or less frequently, the practitioner shall be bound by any representation made therein until the publication of the succeeding issue. If a practitioner publishes or communicates any fee information in a publication which has no fixed date for publication of a succeeding issue, the practitioner shall be bound by any representation made therein for one (1) year.

(f) Unless otherwise specified, if a practitioner broadcasts any fee information by radio, cable, or television, the practitioner shall be bound by any representation made therein for a period of ninety (90) days after such broadcast.

(g) Except as otherwise specified in this article, a practitioner shall not contact or solicit individual members of the public personally or through an agent in order to offer services to such person or persons unless that individual initiated contact with the practitioner for the purpose of engaging that practitioner's professional services. (*Medical Licensing Board of Indiana; 844 IAC 5-2-13; filed Nov 30, 1990, 4:15 p.m.: 14 IR 752; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-14 Referrals

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 14. A practitioner may, whenever the practitioner believes it to be beneficial to the patient, send or refer a patient to a qualified specific professional health care provider for treatment or health care which falls within the specific professional health care provider's scope of practice. Prior to any such referral, however, the practitioner shall examine, and/or consult with, the patient to ensure that a condition exists in the patient which would be within the scope of practice of the specific professional health care provider to whom the patient is referred or sent. (*Medical Licensing Board of Indiana; 844 IAC 5-2-14; filed Nov 30, 1990, 4:15*

p.m.: 14 IR 753; errata filed Feb 18, 1991, 3:55 p.m.: 14 IR 1457; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA)

844 IAC 5-2-15 Admitting patients

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 15. A practitioner shall not charge a separate and distinct fee for the incidental, administrative, nonmedical service of securing admission of a patient to a hospital or other medical or health care facility. *(Medical Licensing Board of Indiana; 844 IAC 5-2-15; filed Nov 30, 1990, 4:15 p.m.: 14 IR 753; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA)*

844 IAC 5-2-16 Discontinuance of practice

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 16. (a) A practitioner, upon his/her retirement, or upon discontinuation of the practice of medicine or osteopathic medicine, or upon leaving or moving from a community, shall not sell, convey, or transfer for valuable consideration, remuneration, or for anything of value, patient records of that practitioner to any other practitioner.

(b) A practitioner, upon his/her retirement, or upon discontinuation of the practice of medicine or osteopathic medicine, or upon leaving or moving from a community, shall notify all of his/her active patients in writing, or by publication once a week for three (3) consecutive weeks in a newspaper of general circulation in the community, that he/she intends to discontinue his/her practice of medicine or osteopathic medicine in the community, and shall encourage his/her patients to seek the services of another practitioner, provided, however, that this section shall not apply to practitioners solely engaged in internship, residency, preceptorship, fellowship, teaching, or other postgraduate medical education or training programs. The practitioner discontinuing his/her practice shall make reasonable arrangements with his/her active patients for the transfer of his/her records, or copies thereof, to the succeeding practitioner, or to a program conducted by a medical society or association approved by the medical licensing board.

(c) As used herein, "active patient" applies and refers to a person whom the practitioner has examined, treated, cared for, or otherwise consulted with during the two (2) year period prior to retirement, discontinuation of the practice of medicine or osteopathic medicine, or leaving or moving from a community.

(d) Nothing herein provided shall preclude, prohibit, or prevent a practitioner from conveying or transferring the practitioner's patient records to another practitioner, holding an unlimited license to practice medicine or osteopathic medicine, who is assuming a practice, provided that written notice is furnished to all patients as hereinbefore specified. *(Medical Licensing Board of Indiana; 844 IAC 5-2-16; filed Nov 30, 1990, 4:15 p.m.: 14 IR 753; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA)*

844 IAC 5-2-17 Contingency fees prohibited

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 17. A practitioner shall not base his fee upon the uncertain outcome of a contingency, whether such contingency be the outcome of litigation or any other occurrence or condition which may or may not develop, occur, or happen. *(Medical Licensing Board of Indiana; 844 IAC 5-2-17; filed Nov 30, 1990, 4:15 p.m.: 14 IR 754; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA)*

844 IAC 5-2-18 Liability to patients

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 18. A practitioner shall not attempt to exonerate himself from or limit his liability to a patient for his/her personal malpractice except that a practitioner may enter into agreements which contain informed, voluntary releases and/or waivers of liability in settlement of a claim made by a patient or by those responsible for a patient's care. (*Medical Licensing Board of Indiana; 844 IAC 5-2-18; filed Nov 30, 1990, 4:15 p.m.: 14 IR 754; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-19 Patient complaints

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 19. A practitioner shall not attempt to preclude, prohibit, or otherwise prevent the filing of a complaint against him/her by a patient or other practitioner for any alleged violation of this title or of any alleged violation of IC 25-22.5-1, or any other law. (*Medical Licensing Board of Indiana; 844 IAC 5-2-19; filed Nov 30, 1990, 4:15 p.m.: 14 IR 754; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-20 Schedule II controlled substances

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1; IC 35-48-2-6

Sec. 20. A physician shall not utilize, prescribe, order, dispense, administer, supply, sell, or give any amphetamine, sympathomimetic amine drug or compound designated as a Schedule II controlled substance pursuant to the provisions of IC 35-48-2-6 to any person for purposes of weight reduction or for control in the treatment of obesity. (*Medical Licensing Board of Indiana; 844 IAC 5-2-20; filed Nov 30, 1990, 4:15 p.m.: 14 IR 754; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

844 IAC 5-2-21 Schedule III or IV controlled substances (Voided)

Sec. 21. (*Voided by P.L.177-1997, SECTION 14, effective July 1, 1997.*)

844 IAC 5-2-22 Use of term, "board certified"

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1

Sec. 22. A practitioner shall not represent in any manner that he or she is "board certified" or use any similar words or phrase calculated to convey the same unless the practitioner states by which board he/she is certified and the specific field or area of certification. (*Medical Licensing Board of Indiana; 844 IAC 5-2-22; filed Nov 30, 1990, 4:15 p.m.: 14 IR 755; readopted filed Nov 9, 2001, 3:16 p.m.: 25 IR 1325; readopted filed Oct 4, 2007, 3:36 p.m.: 20071031-IR-844070050RFA; readopted filed Nov 25, 2013, 9:24 a.m.: 20131225-IR-844130307RFA*)

Rule 3. Appropriate Use of the Internet in Medical Practice

844 IAC 5-3-1 General provisions

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5

Sec. 1. A practitioner shall comply with this article when utilizing the Internet in the delivery of patient care. (*Medical Licensing Board of Indiana; 844 IAC 5-3-1; filed Oct 1, 2003, 9:32 a.m.: 27 IR 522; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA*)

844 IAC 5-3-2 Evaluation of the patient

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5

Sec. 2. A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions or contraindications to the treatment recommended or provided, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise. (*Medical Licensing Board of Indiana; 844 IAC 5-3-2; filed Oct 1, 2003, 9:32 a.m.: 27 IR 523; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA*)

844 IAC 5-3-3 Treatment

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5

Sec. 3. Treatment, including issuing a prescription, based solely on an on-line questionnaire or consultation is prohibited. (*Medical Licensing Board of Indiana; 844 IAC 5-3-3; filed Oct 1, 2003, 9:32 a.m.: 27 IR 523; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA*)

844 IAC 5-3-4 Electronic communications

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5

Sec. 4. (a) Written policies and procedures must be maintained by the physician for the use of patient-physician electronic mail. Such policies and procedures must address the following:

- (1) Privacy.
- (2) Health care personnel (in addition to the physician addressee) who will process messages.
- (3) Hours of operation.
- (4) Types of transactions that will be permitted electronically.
- (5) Required patient information to be included in the communication, such as patient name, identification number, and type of transaction.
- (6) Archival and retrieval of patient medical data.
- (7) Quality oversight mechanisms.
- (8) Protocol to be followed in emergency situations.

(b) Policies and procedures must be periodically evaluated for currency and maintained in an accessible and readily available manner for review.

(c) Sufficient security measures must be in place and documented to assure confidentiality and integrity of patient-identifiable information. Transmissions, including patient e-mail, prescriptions, and laboratory results must be secure within existing technology, that is, password protected, encrypted electronic prescriptions, or other reliable authentication techniques.

(d) Patient-physician e-mail pertinent to the ongoing care of the patient, as well as other patient-related electronic communications, must be maintained as part of, and integrated into, the patient's medical record, whether that record is paper or electronic.

(e) Turnaround time shall be established for patient-physician e-mail and medical practice sites must clearly indicate alternative form or forms of communication for urgent matters.

(f) E-mail systems must be configured to include an automatic reply to acknowledge message delivery and that messages have been read. Patients must be encouraged to confirm that they have received and read messages. (*Medical Licensing Board of*

Indiana; 844 IAC 5-3-4; filed Oct 1, 2003, 9:32 a.m.: 27 IR 523; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA)

844 IAC 5-3-5 Informed consent

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5

Sec. 5. A written agreement must be employed documenting patient informed consent for the use of patient-physician e-mail. The agreement must be discussed with and signed by the patient and included in the medical record. The agreement must include the following terms:

- (1) Types of transmissions that will be permitted, such as:
 - (A) prescription refills;
 - (B) appointment scheduling; and
 - (C) patient education.
- (2) Fees, if any, that will be assessed for on-line consultations or other electronic communication.
- (3) Under what circumstances alternate forms of communication or office visits must be utilized.
- (4) A statement that physician-patient e-mail is not to be used in emergency situations.
- (5) Instructions on what steps the patient should take in an emergency situation.
- (6) Security measures, such as encrypting data, password protected screen savers and data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy.
- (7) Hold harmless clause for information lost due to technical failures.
- (8) Requirement for express patient consent to forward patient-identifiable information to a third party.
- (9) Patient's failure to comply with the agreement may result in physician terminating the e-mail relationship.

(Medical Licensing Board of Indiana; 844 IAC 5-3-5; filed Oct 1, 2003, 9:32 a.m.: 27 IR 523; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA)

844 IAC 5-3-6 Medical records

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5

Sec. 6. (a) The medical record must include written or electronic copies of all patient-related electronic communications, including the following:

- (1) Patient-physician e-mail.
- (2) Prescriptions.
- (3) Laboratory and test results.
- (4) Evaluations and consultations.
- (5) Records of past care.
- (6) Instructions.

Informed consent agreements related to the use of e-mail shall also be filed in the medical record.

(b) Patient medical records must remain current and accessible for review and be maintained in compliance with applicable state and federal requirements. (Medical Licensing Board of Indiana; 844 IAC 5-3-6; filed Oct 1, 2003, 9:32 a.m.: 27 IR 523; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA)

844 IAC 5-3-7 Disclosure

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5

Sec. 7. (a) An interactive Internet medical practice site is a practice location and requires a defined physician-patient

relationship.

(b) Internet medical practice sites must clearly disclose the following:

- (1) The owner of the site.
- (2) The specific services provided.
- (3) The office address and contact information for the medical practice.
- (4) Licensure and qualifications of the physician or physicians and associated health care providers.
- (5) Fees for on-line consultation and services and how payment is to be made.
- (6) Financial interests in any information, products, or services.
- (7) Appropriate uses and limitations of the site, including providing health advice and emergency health situations.
- (8) Uses and response times for e-mails, electronic messages, and other communications transmitted via the site.
- (9) To whom patient health information may be disclosed and for what purpose.
- (10) Rights of patients with respect to patient health information.
- (11) Information collected and any passive tracking mechanisms utilized.

(Medical Licensing Board of Indiana; 844 IAC 5-3-7; filed Oct 1, 2003, 9:32 a.m.: 27 IR 524; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA)

844 IAC 5-3-8 Accountability

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5

Sec. 8. Medical practice sites must provide patients a clear mechanism to do the following:

- (1) Access, supplement, and amend patient-provided personal health information.
- (2) Provide feedback regarding the site and the quality of information and services.
- (3) Register complaints, including information regarding filing a complaint with the consumer protection division of the office of the attorney general.

(Medical Licensing Board of Indiana; 844 IAC 5-3-8; filed Oct 1, 2003, 9:32 a.m.: 27 IR 524; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA)

844 IAC 5-3-9 Advertising or promotion of goods or products

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5

Sec. 9. Advertising or promotion of goods or products from which the physician receives direct remuneration, benefits, or incentives is prohibited unless the physician discloses that the physician receives direct remuneration, benefits, or incentives from the sale of the goods or products. *(Medical Licensing Board of Indiana; 844 IAC 5-3-9; filed Oct 1, 2003, 9:32 a.m.: 27 IR 524; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA)*

844 IAC 5-3-10 Links

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5

Sec. 10. Practitioner Internet sites may provide links to general health information sites to enhance patient education; however, the physician shall not receive direct remuneration, benefits, or incentives from providing such links or from the services or products marketed by such links unless the physician discloses that the physician receives direct remuneration, benefits, or incentives from providing such links or from the services or products marketed by such links. *(Medical Licensing Board of Indiana; 844 IAC 5-3-10; filed Oct 1, 2003, 9:32 a.m.: 27 IR 524; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA)*

Rule 4. Prescribing to Persons Not Seen by the Physician

844 IAC 5-4-1 General provisions

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9; IC 25-22.5-1-2; IC 25-23-1-19.4

Sec. 1. (a) Except in institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority practicing in accordance with standard care arrangements, as described in subsection (d), a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.

(b) Except in institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority practicing in accordance with the requirements of IC 25-23-1-19.4 and 848 IAC 5, as described in subsection (d), a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any legend drug that is not a controlled substance to a person who the physician has never personally physically examined and diagnosed unless the physician is providing care in consultation with another physician who has an ongoing professional relationship with the patient, and who has agreed to supervise the patient's use of the drug or drugs to be provided.

(c) A physician shall not advertise or offer, or permit the physician's name or certificate to be used in an advertisement or offer, to provide any legend drug in a manner that would violate subsection (a) or (b).

(d) Subsections (a) and (b) do not apply to or prohibit the following:

(1) The provision of drugs to a person who is admitted as an inpatient to or is a resident of an institutional facility.

(2) The provision of controlled substances or legend drugs by a physician to a person who is a patient of a colleague of the physician, if the drugs are provided pursuant to an on-call or cross-coverage arrangement between the physicians.

(3) The provision of controlled substances or legend drugs by emergency medical squad personnel, nurses, or other appropriately trained and licensed individuals as permitted by IC 25-22.5-1-2.

(4) The provision of controlled substances or drugs by an advanced practice nurse with prescriptive authority practicing in accordance with a standard care arrangement that meets the requirements of IC 25-23-1-19.4 and 848 IAC 5.

(Medical Licensing Board of Indiana; 844 IAC 5-4-1; filed Oct 1, 2003, 9:32 a.m.: 27 IR 524; errata filed Oct 8, 2003, 1:45 p.m.: 27 IR 538; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA)

844 IAC 5-4-2 Expedited partner therapy

Authority: IC 25-22.5-2-7

Affected: IC 25-1-9

Sec. 2. Section 1 of this rule does not apply if the physician is prescribing or dispensing medications for the treatment of *Chlamydia trachomatis* or *Neisseria gonorrhoeae* to sex partner(s) of the physician's diagnosed patient without requiring examination of the sex partner(s). Medications must be in accordance with current professional theory or practice for the treatment of these infections. The current Centers for Disease Control and Prevention of Sexually Transmitted Diseases Treatment Guidelines shall be considered an authoritative source of such current professional theory or practice. Partner management of patients with gonorrhea or chlamydia shall include providing the following items:

(1) Notification to the infected patient that all partners should be evaluated and treated;

(2) Written materials for the infected patient to give partners that state that a clinical evaluation is desirable; lists common medication side effects and the appropriate response to them; fact sheets regarding sexually transmitted diseases; and emergency contact information;

(3) Prescriptions or dispensed medications and accompanying written materials shall be given to the physician's patient for distribution to named partners; and

(4) The physician shall maintain appropriate documentation of partner management. Documentation shall include the names of partners, if available, and a record of treatment provided. If the partner's name is not available, documentation shall be kept within patient's file.

(Medical Licensing Board of Indiana; 844 IAC 5-4-2; filed Sep 28, 2011, 11:06 a.m.: 20111026-IR-844110044FRA)

Rule 5. Standards for Procedures Performed in Office-Based Settings That Require Moderate Sedation/Analgesia, Deep Sedation/Analgesia, General Anesthesia, or Regional Anesthesia

844 IAC 5-5-1 Purpose

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 1. This rule establishes standards for procedures performed in office-based settings that require:

- (1) moderate sedation/analgesia;
- (2) deep sedation/analgesia;
- (3) general anesthesia; or
- (4) regional anesthesia.

(Medical Licensing Board of Indiana; 844 IAC 5-5-1; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-2 Application of rule

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 2. Except as provided in section 15 of this rule, this rule does not apply to:

- (1) local anesthesia;
- (2) topical anesthesia;
- (3) superficial nerve blocks; or
- (4) minimal sedation/anxiolysis.

(Medical Licensing Board of Indiana; 844 IAC 5-5-2; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-3 "Accreditation agency" defined

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 3. As used in this rule, "accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to office-based settings by the board under this rule. *(Medical Licensing Board of Indiana; 844 IAC 5-5-3; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)*

844 IAC 5-5-4 "American Society of Anesthesiologists (ASA) Physical Status Classification System" defined

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 4. As used in this rule, "American Society of Anesthesiologists (ASA) Physical Status Classification System" refers to the following classifications:

- (1) P1 - A normal healthy patient.
- (2) P2 - A patient with mild systemic disease.
- (3) P3 - A patient with severe systemic disease.
- (4) P4 - A patient with severe systemic disease that is a constant threat to life.
- (5) P5 - A moribund patient who is not expected to survive without the operation.
- (6) P6 - A declared brain-dead patient whose organs are being removed for donor purposes.

(Medical Licensing Board of Indiana; 844 IAC 5-5-4; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-5 "Anesthesia" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 5. As used in this rule, "anesthesia" includes the following:

- (1) Moderate sedation/analgesia.
- (2) Deep sedation/analgesia.
- (3) General anesthesia.
- (4) Regional anesthesia.

(Medical Licensing Board of Indiana; 844 IAC 5-5-5; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-6 "Deep sedation/analgesia" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 6. (a) As used in this rule, "deep sedation/analgesia" means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. For purposes of this rule, reflex withdrawal from a painful stimulus is not considered a purposeful response.

(b) The following are conditions that a patient under deep sedation/analgesia may experience:

- (1) The ability to independently maintain ventilatory function may be impaired.
- (2) Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.
- (3) Cardiovascular function is usually maintained.

(Medical Licensing Board of Indiana; 844 IAC 5-5-6; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-7 "General anesthesia" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 7. (a) As used in this rule, "general anesthesia" means a drug-induced loss of consciousness during which patients are not arousable, even by pain stimulation.

(b) The following are conditions that a patient under general anesthesia may experience:

- (1) The ability to independently maintain ventilatory function is often impaired.
- (2) Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function.
- (3) Cardiovascular function may be impaired.

(Medical Licensing Board of Indiana; 844 IAC 5-5-7; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-8 "Health care provider" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 8. As used in this rule, "health care provider" means an individual licensed or legally authorized by this state to provide health care services. *(Medical Licensing Board of Indiana; 844 IAC 5-5-8; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-*

844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-9 "Immediate presence" defined

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 9. As used in this rule, "immediate presence" means, at a minimum, that the directing practitioner must be:

- (1) physically located within the office-based setting;
- (2) prepared to immediately conduct hands-on intervention if needed; and
- (3) not engaged in activities that could prevent the practitioner from being able to immediately intervene and conduct hands-on interventions if needed.

(Medical Licensing Board of Indiana; 844 IAC 5-5-9; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-10 "Local anesthesia" defined

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 10. As used in this rule, "local anesthesia" means a transient and reversible loss of sensation in a circumscribed portion of the body produced by:

- (1) a local anesthetic agent; or
- (2) cooling a circumscribed area of the skin.

The term includes subcutaneous infiltration of an agent. *(Medical Licensing Board of Indiana; 844 IAC 5-5-10; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)*

844 IAC 5-5-11 "Minimal sedation/anxiolysis" defined

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 11. As used in this rule, "minimal sedation/anxiolysis" means a drug-induced state during which a patient responds normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are usually not affected. *(Medical Licensing Board of Indiana; 844 IAC 5-5-11; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)*

844 IAC 5-5-12 "Moderate sedation/analgesia" defined

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 12. (a) As used in this rule, "moderate sedation/analgesia" (also sometimes called "conscious sedation") means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

- (b) The following are conditions that a patient under moderate sedation/analgesia may experience:
- (1) No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate.
 - (2) Cardiovascular function is usually maintained.

(Medical Licensing Board of Indiana; 844 IAC 5-5-12; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-13 "Office-based setting" defined

Authority: IC 25-22.5-2-7

Affected: IC 16-21-2; IC 25-22.5

Sec. 13. As used in this rule, "office-based setting" means any:

- (1) facility;
- (2) clinic;
- (3) center;
- (4) office; or
- (5) other setting;

where procedures are performed that require moderate sedation/analgesia, deep sedation/analgesia, general anesthesia, or regional anesthesia. The term does not include a hospital operated by the federal government or a setting licensed under IC 16-21-2 as a hospital, ambulatory surgical center, abortion clinic, or birthing center. (*Medical Licensing Board of Indiana; 844 IAC 5-5-13; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA*)

844 IAC 5-5-14 "Practitioner" defined

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 14. As used in this rule, "practitioner" has the meaning set forth in 844 IAC 5-1-1(14). (*Medical Licensing Board of Indiana; 844 IAC 5-5-14; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA*)

844 IAC 5-5-15 "Regional anesthesia" defined

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 15. (a) As used in this rule, "regional anesthesia" means the administration of anesthetic agents to a patient to interrupt nerve impulses without the loss of consciousness and includes the following:

- (1) Major conduction blocks, such as:
 - (A) epidural;
 - (B) spinal; and
 - (C) caudal;

blocks.

- (2) Peripheral nerve blocks, such as:
 - (A) brachial;
 - (B) lumbar plexus;
 - (C) peribulbar; and
 - (D) retrobulbar;

blocks.

- (3) Intravenous regional anesthesia, such as Bier blocks.

(b) Notwithstanding section 2 of this rule, a superficial nerve block or application of a local anesthetic agent in which the total dosage administered exceeds the recommended maximum dosage per body weight described in the manufacturer's package insert shall be considered regional anesthesia for purposes of this rule. (*Medical Licensing Board of Indiana; 844 IAC 5-5-15; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA*)

844 IAC 5-5-16 "Rescue" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 16. As used in this rule, "rescue" means an intervention by a practitioner proficient in airway management and advanced life support. In rescuing a patient, the practitioner must:

- (1) correct adverse physiologic consequences of the deeper-than-intended level of sedation, such as:
 - (A) hypoventilation;
 - (B) hypoxia; and
 - (C) hypotension; and
- (2) return the patient to the originally intended level of sedation.

(Medical Licensing Board of Indiana; 844 IAC 5-5-16; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-17 "Superficial nerve block" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 17. As used in this rule, "superficial nerve block" means an agent placed in the proximity of any nerve or group of nerves outside of the vertebral canal to produce a loss of sensation in an anatomic or circumscribed area. For purposes of this rule, the term is limited to:

- (1) ankle;
- (2) metacarpal;
- (3) digit; and
- (4) paracervical;

blocks. *(Medical Licensing Board of Indiana; 844 IAC 5-5-17; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)*

844 IAC 5-5-18 "Topical anesthesia" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 18. As used in this rule, "topical anesthesia" means a transient and reversible loss of sensation to a circumscribed area produced by an anesthetic agent applied directly or by spray to the skin or mucous membranes. *(Medical Licensing Board of Indiana; 844 IAC 5-5-18; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)*

844 IAC 5-5-19 Standards for procedures performed in office-based settings

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 19. (a) Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Practitioners intending to produce a given level of sedation must be able to rescue a patient whose level of sedation becomes deeper than initially intended. Practitioners administering deep sedation/analgesia in an office-based setting, or directing or supervising the administration of deep sedation/analgesia in an office-based setting, must be able to rescue patients who enter a state of general anesthesia. Practitioners administering moderate sedation/analgesia in an office-based setting, or directing or supervising the administration of moderate sedation/analgesia in an office-based setting, must be able to rescue patients who enter a state of deep sedation/analgesia.

- (b) Practitioners administering regional anesthesia, or supervising or directing the administration of regional anesthesia,

must be knowledgeable about the risks of regional anesthesia and the interventions required to correct any adverse physiological consequences that may occur in the administration of regional anesthesia.

(c) A health care provider may not administer or monitor an anesthetic agent containing alkylphenols in an office-based setting unless the health care provider is:

- (1) trained in the administration of general anesthesia; and
- (2) not involved in the conduct of the procedure.

(Medical Licensing Board of Indiana; 844 IAC 5-5-19; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-20 Accreditation required

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 20. After January 1, 2010, a practitioner may not perform or supervise a procedure that requires anesthesia in an office-based setting unless the office-based setting is accredited by an accreditation agency approved by the board under this rule. *(Medical Licensing Board of Indiana; 844 IAC 5-5-20; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)*

844 IAC 5-5-21 Approval of accreditation agencies; requirements

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5-1-2

Sec. 21. In approving accreditation agencies to perform accreditation of office-based settings, the board shall ensure that the certification program, at a minimum, includes standards for the following aspects of an office-based setting's operations:

(1) Anesthesia, as follows:

(A) The level of anesthesia administered shall be appropriate for the:

- (i) patient;
- (ii) procedure;
- (iii) clinical setting;
- (iv) education and training of the personnel; and
- (v) equipment available.

Practitioners shall select patients for procedures in office-based settings using anesthesia by criteria, including the American Society of Anesthesiologists (ASA) Physical Status Classification System, and so document.

(B) The choice of specific anesthetic agents and techniques shall focus on providing anesthesia that will:

- (i) be safe, effective, and appropriate; and
- (ii) respond to the specific needs of patients while also ensuring rapid recovery to normal function with appropriate efforts to control postoperative pain, nausea, or other side effects.

(C) A health care provider administering anesthesia shall be licensed, qualified, and working within the provider's scope of practice. In those cases in which a nonphysician provider administers the anesthesia, the provider must be:

- (i) under the direction and supervision of a practitioner as required by IC 25-22.5-1-2(a)(20); or
- (ii) under the direction of and in the immediate presence of a practitioner as required by IC 25-22.5-1-2(a)(13), if the provider is a certified registered nurse anesthetist.

(D) A:

- (i) health care provider who administers anesthesia; and
- (ii) practitioner who:
 - (AA) performs a procedure that requires anesthesia; or
 - (BB) directs or supervises the administration of anesthesia;

in an office-based setting shall maintain current training in advanced resuscitation techniques, such as advanced cardiac life support (ACLS) or pediatric advanced life support (PALS), as applicable. At least one (1) person with

ACLS or PALS training should be immediately available until the patient is discharged.

(E) In addition to the health care provider performing the procedure, sufficient numbers of qualified health care providers, each working within the individual provider's scope of practice, must be present to:

- (i) evaluate the patient;
- (ii) assist with the procedure;
- (iii) administer and monitor the anesthesia; and
- (iv) recover the patient.

Other health care providers involved in the delivery of procedures in an office-based setting that require anesthesia, at a minimum, shall maintain training in basic cardiopulmonary resuscitation.

(F) Patients who have preexisting medical or other conditions who may be at particular risk for complications shall be referred to:

- (i) a hospital;
- (ii) an ambulatory surgical center; or
- (iii) another office-based setting appropriate for the procedure and the administration of anesthesia.

(G) The practitioner administering the anesthesia, or supervising or directing the administration of anesthesia as required by clause (C), shall do the following:

- (i) Perform a preanesthetic examination and evaluation or ensure that it has been appropriately performed by a qualified health care provider.
- (ii) Develop the anesthesia plan or personally review and concur with the anesthesia plan if the plan has been developed by a certified registered nurse anesthetist (CRNA).
- (iii) Remain physically present during the operative period and be immediately available until the patient is discharged from anesthesia care for diagnosis, treatment, and management of complications or emergencies.
- (iv) Assure provision of appropriate postanesthesia care.

(H) Patient assessment shall occur throughout the preprocedure, periprocedure, and postprocedure phases. The assessment shall:

- (i) address not only physical and functional status, but also physiological and cognitive status; and
- (ii) be documented in the medical record.

The procedure and anesthesia shall be properly documented in the medical record.

(I) Physiologic monitoring of patients shall be appropriate for the type of anesthesia and individual patient needs, including continuous monitoring or assessment of the following:

- (i) Ventilation.
- (ii) Cardiovascular status.
- (iii) Body temperature.
- (iv) Neuromuscular function and status.
- (v) Patient positioning.
- (vi) Oxygenation using a quantitative technique such as pulse oximetry.

When general anesthesia is used, equipment to assess exhaled carbon dioxide must also be available.

(J) Provisions shall be made for a reliable source of the following:

- (i) Oxygen.
- (ii) Suction.
- (iii) Resuscitation equipment.
- (iv) Emergency drugs.

(2) Procedures, as follows:

(A) Procedures shall be provided by qualified health care providers in an environment that promotes patient safety.

(B) Procedures to be undertaken shall be within the:

- (i) scope of practice, training, and expertise of the health care providers; and
- (ii) capabilities of the facilities.

(C) The procedure shall be of a duration and degree of complexity that will permit patients to recover and be discharged from the office-based setting in less than twenty-four (24) hours.

(D) Provisions shall be made for appropriate ancillary services on site or in another predetermined location. Ancillary services shall be provided in a safe and effective manner in accordance with accepted ethical professional practice and statutory requirements. These services include, but are not limited to:

- (i) pharmacy;
- (ii) laboratory;
- (iii) pathology;
- (iv) radiology;
- (v) occupational health; and
- (vi) other associated;

services.

(3) Facilities and equipment, as follows:

(A) The office-based setting shall:

- (i) be clean and properly maintained and have adequate lighting and ventilation;
- (ii) be equipped with the appropriate medical equipment, supplies, and pharmacological agents that are required in order to provide:

- (AA) anesthesia;
- (BB) recovery services;
- (CC) cardiopulmonary resuscitation; and
- (DD) other emergency services;

(iii) have:

- (AA) appropriate firefighting equipment;
- (BB) signage;
- (CC) emergency power capabilities and lighting; and
- (DD) an evacuation plan;

(iv) have the necessary:

- (AA) personnel;
- (BB) equipment; and
- (CC) procedures;

to handle medical and other emergencies that may arise in connection with services provided; and

(v) comply with:

- (AA) applicable federal, state, and local laws and codes and regulations, and provisions must be made to accommodate disabled individuals in compliance with the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.); and
- (BB) federal and state laws and regulations regarding protection of the health and safety of employees.

(B) The space allocated for a particular function or service shall be adequate for the activities performed.

(C) In locations where anesthesia is administered, there shall be appropriate anesthesia apparatus and equipment to allow appropriate monitoring of patients. All equipment shall be maintained, tested, and inspected according to the manufacturer's specifications. Backup power sufficient to ensure patient protection in the event of an emergency shall be available. There shall be sufficient space to:

- (i) accommodate all necessary equipment and personnel; and
- (ii) allow for expeditious access to patients and all monitoring equipment.

(D) When anesthesia services are provided to infants and children, the required:

- (i) equipment;
- (ii) medications; and
- (iii) resuscitative capabilities;

shall be appropriately sized for children.

(E) All equipment used in patient care, testing, or emergency situations shall be inspected, maintained, and tested:

- (i) on a regular basis; and
- (ii) according to manufacturers' specifications.

- (F) Appropriate emergency equipment and supplies shall be readily accessible to all patient service areas.
- (G) Efforts shall be made to eliminate hazards that might lead to:
 - (i) slipping;
 - (ii) falling;
 - (iii) electrical shock;
 - (iv) burns;
 - (v) poisoning; or
 - (vi) other trauma.
- (H) Procedures shall be implemented to:
 - (i) minimize the sources and transmission of infections; and
 - (ii) maintain a sanitary environment.
- (I) A system shall be in place to:
 - (i) identify;
 - (ii) manage;
 - (iii) handle;
 - (iv) transport;
 - (v) treat; and
 - (vi) dispose of;hazardous materials and wastes, whether solid, liquid, or gas.
- (J) Smoking must be prohibited in all patient care areas.

(Medical Licensing Board of Indiana; 844 IAC 5-5-21; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)

844 IAC 5-5-22 Practitioners requirements

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 22. (a) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who directs or supervises the administration of anesthesia in an office-based setting, must have:

- (1) admitting privileges at a nearby hospital;
- (2) a transfer agreement with another practitioner who has admitting privileges at a nearby hospital; or
- (3) an emergency transfer agreement with a nearby hospital.

(b) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who directs or supervises the administration of anesthesia in an office-based setting, shall ensure that a patient's informed consent for the nature and objectives of the anesthesia planned and procedure to be performed is obtained in writing before the procedure is performed. The informed consent shall be:

- (1) obtained after a discussion of the risks, benefits, and alternatives; and
- (2) documented in the patient's medical record.

(c) Written procedures for credible peer review to determine the appropriateness of the following shall be established and reviewed at least annually:

- (1) Clinical decision making.
- (2) Overall quality of care.

(d) Agreements with local emergency medical service (EMS) shall be in place for purposes of transfer of patients to the hospital in case of an emergency. EMS agreements shall be re-signed at least annually.

(e) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who directs or supervises the administration of anesthesia in an office-based setting, shall show competency by maintaining privileges at an accredited or licensed hospital or ambulatory surgical center, for the procedures they perform in the office-based setting. Alternatively, the governing body of the office-based setting is responsible for a peer review process for privileging practitioners based on nationally recognized credentialing standards.

(f) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who directs or supervises the administration of anesthesia in an office-based setting, shall have appropriate education and training. *(Medical Licensing Board of Indiana; 844 IAC 5-5-22; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA; readopted filed Dec 2, 2014, 10:09 a.m.: 20141231-IR-844140391RFA)*

Rule 6. Opioid Prescribing Requirements

844 IAC 5-6-1 Scope

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2
Affected: IC 25-1-9; IC 25-22.5

Sec. 1. This rule establishes standards and protocols for physicians in the prescribing of opioid controlled substances for pain management treatment. *(Medical Licensing Board of Indiana; 844 IAC 5-6-1; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.]*

844 IAC 5-6-2 Definitions

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2
Affected: IC 25-1-9; IC 25-22.5; IC 35-48-1-9

Sec. 2. (a) The definitions in this section apply throughout this rule.

(b) "Chronic pain" means a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

(c) "Controlled substances" has the meaning set forth in IC 35-48-1-9.

(d) "Morphine equivalent dose" means a conversion of various opioids to a standardized dose of morphine by the use of accepted conversion tables.

(e) "Opioid" means any of various narcotics containing opium or one (1) or more of its natural or synthetic derivatives. However, if such a narcotic is not a controlled substance, it shall not be an opioid for the purposes of this rule.

(f) "Outset of an opioid treatment plan" means that a patient has been prescribed opioids as described in section 3(c) of this rule, and, therefore, the provisions stated in section 3(a) of this rule become applicable to that patient.

(g) "Terminal" means a condition caused by injury, disease, or illness from which, to a reasonable degree of medical certainty:

(1) there can be no recovery; and

(2) progression to death can be anticipated as an eventual consequence of that condition.

(Medical Licensing Board of Indiana; 844 IAC 5-6-2; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.]

844 IAC 5-6-3 Triggers for imposition of requirements; exemptions

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2
Affected: IC 16-21; IC 16-25; IC 16-28; IC 25-1-9; IC 25-22.5

Sec. 3. (a) This section and sections 4 through 10 of this rule establish requirements concerning the use of opioids for chronic pain management for patients.

(b) Notwithstanding subsection (a), this section and sections 4 through 10 of this rule shall not apply to the use of opioids for chronic pain management for the following:

(1) Patients with a terminal condition.

(2) Residents of a health facility licensed under IC 16-28.

(3) Patients enrolled in a hospice program licensed under IC 16-25.

(4) Patients enrolled in an inpatient or outpatient palliative care program of a hospital licensed under IC 16-21 or a hospice licensed under IC 16-25.

However, a period of time that a patient who was, but is no longer, a resident or patient as described in subdivisions (2) through (4) shall be included in the calculations under subsection (c).

(c) The requirements in the sections identified in subsection (a) only apply if a patient has been prescribed:

(1) more than sixty (60) opioid-containing pills a month for more than three (3) consecutive months;

(2) a morphine equivalent dose of more than fifteen (15) milligrams per day; for more than three (3) consecutive months;

(3) a transdermal opioid patch for more than three (3) consecutive months;

(4) at any time it is classified as a controlled substance under Indiana law, tramadol, but only if the patient's tramadol dose reaches a morphine equivalent dose of more than sixty (60) milligrams per day for more than three (3) consecutive months;

or

(5) a hydrocodone-only extended release medication that is not in an abuse deterrent form.

Subsections (c)(1) and (c)(2) [subdivisions (1) and (2)] do not apply to the controlled substances addressed by subsections (c)(3) through (c)(5) [subdivisions (3) through (5)].

(d) Because the requirements in the sections identified in subsection (a) do not apply until the time stated in subsection (c), the initial evaluation of the patient for the purposes of sections 4, 7(a) [sic], and 8(a) of this rule shall not be required to take place until that time.

(e) Notwithstanding subsection (d), the physician may undertake those actions earlier than required if the physician deems it medically appropriate and, if those actions meet the requirements, a further initial evaluation is not required. If the physician conducts actions earlier than required under this subsection, any subsequent requirements are determined by when the initial evaluation would have been required and not at the earlier date it actually was conducted. (*Medical Licensing Board of Indiana; 844 IAC 5-6-3; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.]*)

844 IAC 5-6-4 Evaluation and risk stratification by physician

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2

Affected: IC 25-1-9; IC 25-22.5

Sec. 4. (a) The physician shall do the physician's own evaluation and risk stratification of the patient by doing the following in the initial evaluation of the patient:

(1) Performing an appropriately focused history and physical exam and obtain or order appropriate tests, as indicated.

(2) Making a diligent effort to obtain and review records from previous health care providers to supplement the physician's understanding of the patient's chronic pain problem, including past treatments, and documenting this effort.

(3) Asking the patient to complete an objective pain assessment tool to document and better understand the patient's specific pain concerns.

(4) Assessing both the patient's mental health status and risk for substance abuse using available validated screening tools.

(5) After completing the initial evaluation, establishing a working diagnosis and tailoring a treatment plan to meaningful and functional goals with the patient reviewing them from time to time.

(b) Where medically appropriate, the physician shall utilize nonopioid options instead of or in addition to prescribing opioids. (*Medical Licensing Board of Indiana; 844 IAC 5-6-4; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.]*)

844 IAC 5-6-5 Physician discussion with patient; treatment agreement

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2

Affected: IC 25-1-9; IC 25-22.5

Sec. 5. The physician shall discuss with the patient the potential risks and benefits of opioid treatment for chronic pain, as

well as expectations related to prescription requests and proper medication use. In doing so, the physician shall:

- (1) Where alternative modalities to opioids for managing pain exist for a patient, discuss them with the patient.
- (2) Provide a simple and clear explanation to help patients understand the key elements of their treatment plan.
- (3) Counsel women between fourteen (14) and fifty-five (55) years of age with child bearing potential about the risks to the fetus when the mother has been taking opioids while pregnant. Such described risks shall include fetal opioid dependency and neonatal abstinence syndrome (NAS).
- (4) Discuss with the patient risks of dependency and addiction.
- (5) Discuss with the patient safe storage practices for prescribed opioids.
- (6) Provide a written warning to the patient disclosing the risks associated with taking extended release medications that are not in an abuse deterrent form, if the physician prescribes for the patient a hydrocodone-only extended release medication that is not in an abuse deterrent form.
- (7) Together with the patient, review and sign a "Treatment Agreement", which shall include at least the following:
 - (A) The goals of the treatment.
 - (B) The patient's consent to drug monitoring testing in circumstances where the physician determines that drug monitoring testing is medically necessary.
 - (C) The physician's prescribing policies, which must include at least a:
 - (i) requirement that the patient take the medication as prescribed; and
 - (ii) prohibition of sharing medication with other individuals.
 - (D) A requirement that the patient inform the physician:
 - (i) about any other controlled substances prescribed or taken by the patient; and
 - (ii) if the patient drinks alcohol while taking opioids.
 - (E) The granting of permission to the physician to conduct random pill counts.
 - (F) Reasons the opioid therapy may be changed or discontinued by the physician.

A copy of the treatment agreement shall be retained in the patient's chart.

(Medical Licensing Board of Indiana; 844 IAC 5-6-5; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.]

844 IAC 5-6-6 Patient visits to physician

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2

Affected: IC 25-1-9; IC 25-22.5

Sec. 6. (a) Physicians shall not prescribe opioids for patients without periodic scheduled visits. Visits for patients with a stable medication regimen and treatment plan shall occur face to face at least once every four (4) months. More frequent visits may be appropriate for patients working with the physician to achieve optimal management. For patients requiring changes to the medication and treatment plan, if changes are prescribed by the physician, the visits required by this subsection shall be scheduled at least once every two (2) months until the medication and treatment has been stabilized.

(b) During the visits required by subsection (a), the physician shall evaluate patient progress and compliance with the patient's treatment plan regularly and set clear expectations along the way, such as attending physical therapy, counseling, or other treatment options. *(Medical Licensing Board of Indiana; 844 IAC 5-6-6; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.]*

844 IAC 5-6-7 INSPECT report

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2

Affected: IC 25-1-9; IC 25-22.5; IC 35-48-7-11.1

Sec. 7. At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing opioids for a patient shall run an INSPECT report on that patient under IC 35-48-7-11.1(d)(4) and document in the patient's chart whether the

INSPECT report is consistent with the physician's knowledge of the patient's controlled substance use history. (*Medical Licensing Board of Indiana; 844 IAC 5-6-7; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.]*)

844 IAC 5-6-8 Drug monitoring testing

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2

Affected: IC 25-1-9; IC 25-22.5

Sec. 8. (a) After December 31, 2014, at any time the physician determines that it is medically necessary, whether at the outset of an opioid treatment plan, or any time thereafter, a physician prescribing opioids for a patient shall perform or order a drug monitoring test, which must include a confirmatory test using a method selective enough to differentiate individual drugs within a drug class, on the patient.

(b) In determining whether a drug monitoring test under subsection (a) is medically necessary, the physician shall consider, subject to the provisions of subsection (c), each of the following factors where applicable and reasonably feasible:

- (1) Whether there is reason to believe a patient is not taking the prescribed opioids or is diverting the opioids.
- (2) Whether there has been no appreciable impact on the patient's chronic pain despite being prescribed opioids for a period of time that would generally have an impact.
- (3) Whether there is reason to believe the patient is taking or using controlled substances other than opioids or other drugs or medications including illicit street drugs that might produce significant polypharmacological effects or have other detrimental interaction effects.
- (4) Whether there is reason to believe the patient is taking or using opioids in addition to the opioids being prescribed by the physician and any other treating physicians.
- (5) Attempts by the patient to obtain early refills of opioid containing prescriptions.
- (6) The number of instances in which the patient alleges that their opioid containing prescription has been lost or stolen.
- (7) When the patient's INSPECT report provides irregular or inconsistent information.
- (8) When a previous drug monitoring test conducted on the patient raised concerns about the patient's usage of opioids.
- (9) Necessity of verifying that the patient no longer has substances in the patient's system that are not appropriate under the patient's treatment plan.
- (10) When the patient engages in apparent aberrant behaviors or shows apparent intoxication.
- (11) When the patient's opioid usage shows an unauthorized dose escalation.
- (12) When the patient is reluctant to change medications or is demanding certain medications.
- (13) When the patient refuses to participate in or cooperate with a full diagnostic workup or examination.
- (14) Whether a patient has a history of substance abuse.
- (15) When the patient has a health status change (for example, pregnancy).
- (16) Co-morbid psychiatric diagnoses.
- (17) Other evidence of chronic opioid use, controlled substance abuse or misuse, illegal drug use or addiction, or medication noncompliance.
- (18) Any other factor the physician believes is relevant to making an informed professional judgment about the medical necessity of a prescription.

(c) It shall not be considered a violation of this section for a physician to fail to conduct a review of all eighteen (18) factors listed in subsection (b) if the physician reasonably determines following a review of less than all of the factors listed in subsection [sic] (b) that a drug monitoring test is medically necessary.

(d) Nothing about subsection (b) shall be construed to prohibit the physician from performing or ordering a drug monitoring test at any other time the physician considers appropriate.

(e) If a test performed under subsection (a), or conducted under subsection (d), reveals inconsistent medication use patterns or the presence of illicit substances, a review of the current treatment plan shall be required. Documentation of the revised treatment plan and discussion with the patient must be recorded in the patient's chart. (*Medical Licensing Board of Indiana; 844 IAC 5-6-8; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule*

document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.]

844 IAC 5-6-9 Morphine equivalent doses above 60; revising of assessments and treatment plans

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2

Affected: IC 25-1-9; IC 25-22.5

Sec. 9. When a patient's opioid dose reaches a morphine equivalent dose of more than sixty (60) milligrams per day, a face-to-face review of the treatment plan and patient evaluation must be scheduled, including consideration of referral to a specialist. If the physician elects to continue providing opioid therapy at a morphine equivalent dose of more than sixty (60) milligrams per day, the physician must develop a revised assessment and treatment plan for ongoing treatment. The revised assessment and treatment plan must be documented in the patient's chart, including an assessment of increased risk for adverse outcomes, including death, if the physician elects to provide ongoing opioid treatment. *(Medical Licensing Board of Indiana; 844 IAC 5-6-9; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.]*

844 IAC 5-6-10 Physician assistants and advanced practice nurses

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2

Affected: IC 25-1-9; IC 25-22.5; IC 25-23-1; IC 25-27.5-5; IC 25-27.5-6

Sec. 10. (a) IC 25-27.5-5 addresses the scope of practice of physician assistants in their dependent practice under supervising physicians including limiting the duties and responsibilities of physician assistants to those that are delegated by the supervising physician and that are within the supervising physician's scope of practice. IC 25-27.5-6 addresses supervisory responsibilities of the supervising physician, or when applicable, a physician designee. The prescribing of opioids for chronic pain management as regulated by this rule falls within the requirements on supervising physicians, or when applicable, on physician designees, under IC 25-27.5-5 and IC 25-27.5-6 including appropriate delegating of duties and responsibilities to physician assistants and appropriate supervision of physician assistants.

(b) IC 25-23-1-19.4 through IC 25-23-1-19.8 and 848 IAC 5 address the practice of advanced practice nurses with prescriptive authority in collaboration with a physician. The prescribing of opioids for chronic pain management as regulated by this rule falls within the requirements on collaborating physicians regarding the prescriptive authority for advanced practice nurses under IC 25-23-1-19.4 through IC 25-23-1-19.8 and 848 IAC 5. *(Medical Licensing Board of Indiana; 844 IAC 5-6-10; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.]*

Rule 7. (Reserved)

Rule 8. Telehealth Services Pilot Program

844 IAC 5-8-1 Scope

Authority: IC 25-22.5-2-7; IC 25-22.5-14-1

Affected: IC 25-22.5-14

Sec. 1. This rule establishes standards and procedures to implement a telehealth services pilot program utilizing telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, treatment, supervision, and information across a distance. *(Medical Licensing Board of Indiana; 844 IAC 5-8-1; filed Apr 8, 2015, 12:37 p.m.: 20150506-IR-844140442FRA)*

844 IAC 5-8-2 Definitions

Authority: IC 25-22.5-2-7; IC 25-22.5-14-1

Affected: IC 25-22.5-2-1; IC 25-22.5-14

Sec. 2. (a) The definitions in this section apply throughout this rule.

(b) "Board" refers to the medical licensing board of Indiana established by IC 25-22.5-2-1.

(c) "Participant" means a physician who holds an active, unrestricted license to practice medicine in the state of Indiana. A participant may choose to organize under an entity or entities for authorized purposes.

(d) "Pilot program" means a pilot program established by the board to provide telehealth services to patients in Indiana without the requirement of an in-person, patient-physician relationship. The board may authorize more than one (1) participant to provide telehealth services under the pilot program.

(e) "Telehealth" means the practice of health care delivery, diagnosis, consultation, treatment, transfer of medical data, or exchange of medical education information by means of real-time video or secure chat or secure e-mail or integrated telephony while the patient is at any location and the health care provider is at any other location.

(f) "Telehealth services" means the use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, treatment, supervision, and information across a distance.

(g) "Valid prescription" refers to a prescription that is issued by a licensed physician for a legitimate medical purpose in the usual course of professional practice and issued by the licensed physician who has first obtained a medical history and conducted an evaluation of the patient adequate to establish a diagnosis.

(h) "Visit" includes a single, independent encounter not to include follow-up visits by the same patient for that initial encounter. A visit by an established patient for a new encounter of treatment would be considered a new visit for purposes of the pilot. (*Medical Licensing Board of Indiana; 844 IAC 5-8-2; filed Apr 8, 2015, 12:37 p.m.: 20150506-IR-844140442FRA*)

844 IAC 5-8-3 Pilot program requirements

Authority: IC 25-22.5-2-7; IC 25-22.5-14-1

Affected: IC 16-18-2-168; IC 25-22.5-14

Sec. 3. The pilot program must include the following requirements:

(1) All telehealth services must be provided by a physician licensed in good standing under IC 25-22.5 who has an established physical practice in Indiana.

(2) Each patient's medical record shall be considered a health record as defined at IC 16-18-2-168 and be subject to all confidentiality requirements associated with a health record.

(3) All technology must be secure and comply with the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1938 (1996) and 45 CFR Parts 160 and 164).

(4) Prescriptions may not be issued for a controlled substance or an abortifacient.

(5) Services provided under the pilot program shall include primary, urgent, and nonemergent care and may not include emergency care.

(6) The geographic area that will be served under the pilot program shall be limited to the state of Indiana.

(7) Telehealth shall not include any encounter in which the patient is assured that any outcome, including the issuance of a prescription, will be issued as a quid pro quo for the payment of the provider's consultation fee or solely on the basis of an online questionnaire.

(8) The pilot program shall consist of at least two (2) months of actively treating patients and must include:

(A) a minimum of two hundred (200) visits; or

(B) no less than one hundred (100) visits that include the issuance of a prescription.

(*Medical Licensing Board of Indiana; 844 IAC 5-8-3; filed Apr 8, 2015, 12:37 p.m.: 20150506-IR-844140442FRA*)

844 IAC 5-8-4 Telehealth consultation requirements

Authority: IC 25-22.5-2-7; IC 25-22.5-14-1

Affected: IC 25-22.5-14

Sec. 4. Telehealth consultations shall at least do the following:

(1) Encourage the availability of patient medical information.

(2) Include a documented patient evaluation including history and discussion adequate to establish a diagnosis and identify

underlying conditions or contraindications to the treatment recommended.

(3) Allow each patient upon conclusion of the encounter the ability to forward documentation to selected care providers to uphold patient's continuity of care.

(4) Not be based exclusively on the basis of an online questionnaire.

(5) Require participants to address what, if any, tools or peripherals are available to assist in the initial history and physician examination of the patient.

(Medical Licensing Board of Indiana; 844 IAC 5-8-4; filed Apr 8, 2015, 12:37 p.m.: 20150506-IR-844140442FRA)

844 IAC 5-8-5 Pilot program evaluation; surveys

Authority: IC 25-22.5-2-7; IC 25-22.5-14-1

Affected: IC 25-22.5-14

Sec. 5. (a) The participants shall establish a survey tool that, at a minimum, evaluates the:

(1) satisfaction of participating patients and participating physicians; and

(2) efficacy of a visit and determine whether additional follow-up was needed.

(b) At a minimum, these surveys shall be distributed to each participating:

(1) patient no sooner than forty-eight (48) hours and no later than six (6) weeks following a visit; and

(2) physician on a monthly basis.

(c) Complete survey results shall be made available to the board at the conclusion of the pilot program or as requested by the board. *(Medical Licensing Board of Indiana; 844 IAC 5-8-5; filed Apr 8, 2015, 12:37 p.m.: 20150506-IR-844140442FRA)*

844 IAC 5-8-6 Pilot program reporting

Authority: IC 25-22.5-2-7; IC 25-22.5-14-1

Affected: IC 5-14-6; IC 25-22.5-14

Sec. 6. Before the earlier of six (6) months after the completion of the pilot program, February 1, 2015, or an alternative deadline that may be established by the general assembly, the board shall report to the general assembly in an electronic format under IC 5-14-6 concerning the outcomes of the pilot program, including the following:

(1) The number of patients served.

(2) The number of prescriptions issued.

(3) The number of in-person follow-up visits required. This requirement shall be satisfied by written documentation in each patient's medical record indicating that follow-up care was recommended.

(4) Overall physician and patient satisfaction.

(Medical Licensing Board of Indiana; 844 IAC 5-8-6; filed Apr 8, 2015, 12:37 p.m.: 20150506-IR-844140442FRA)

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