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**TITLE 844 MEDICAL LICENSING BOARD OF
INDIANA**

Proposed Rule
LSA Document #02-268

DIGEST

Amends 844 IAC 5-1-1 concerning definitions. Amends 844 IAC 5-1-3 concerning disciplinary action. Adds 844 IAC 5-3 concerning appropriate use of the Internet in medical practice. Adds 844 IAC 5-4 prescribing to persons not seen by the physician. Effective 30 days after filing with the secretary of state.

844 IAC 5-1-1
844 IAC 5-1-3

844 IAC 5-3
844 IAC 5-4

SECTION 1. 844 IAC 5-1-1 IS AMENDED TO READ AS FOLLOWS:

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 25-20.5-1-7; IC 25-22.5-6-2.1; 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 the standards of professional conduct and competent practice of medicine, this article and IC 25-1-9, the following definitions apply:

(a) "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.

(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.

~~(b)~~ (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.

~~(c)~~ (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:

- ~~(1)~~ (A) Any chiropractor licensed under IC 25-10.
- ~~(2)~~ (B) Any dental hygienist licensed under IC 25-13.
- ~~(3)~~ (C) Any dentist licensed under IC 25-14.
- ~~(4)~~ (D) Any hearing aid dealer licensed under IC 25-20.
- ~~(5)~~ (E) Any nurse licensed under IC 25-23.
- ~~(6)~~ (F) Any optometrist licensed under IC 25-24.
- ~~(7)~~ (G) Any pharmacist licensed under IC 25-26.
- ~~(8)~~ (H) Any physical therapist licensed under IC 25-27.
- ~~(9)~~ (I) Any podiatrist licensed under IC 25-29.
- ~~(10)~~ (J) Any psychologist licensed under IC 25-33.
- ~~(11)~~ (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.

(d) For purposes of clarifying the terminology used in IC 25-22.5-6-2.1(b)(7), and for purposes of the standards of professional conduct and competent practice of medicine, the following definitions apply:

- (1) “Addict” means a person who is physiologically and/or psychologically dependent upon a drug which is classified as a narcotic, controlled substance or dangerous drug.
- (2) “Habitue” means a person who is physiologically and/or psychologically dependent upon any narcotic, drug classified as a narcotic, dangerous drug or controlled substance under Indiana law; or a person who 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.
- (3) “Classified as a narcotic” means any substance which 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.

(4) "Dangerous drug" means any substance which 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.

(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)

SECTION 2. 844 IAC 5-1-3 IS AMENDED TO READ AS FOLLOWS:

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 ~~section 1 of this rule, and 844 IAC 5-2 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 ~~regulation 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)*

SECTION 3. 844 IAC 5-3 IS ADDED TO READ AS FOLLOWS:

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)*

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)*

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)*

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)*

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)

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)*

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)

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)

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)*

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)

SECTION 4. 844 IAC 5-4 IS ADDED TO READ AS FOLLOWS:

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 subsections (d) and (e), 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 this article, as described in subsections (d) and (e), 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 this article.**

(Medical Licensing Board of Indiana; 844 IAC 5-4-1)

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on March 27, 2003 at 9:45 a.m., at the Indiana Government Center-South, 402 West Washington Street, Conference Center Room C, Indianapolis, Indiana the Medical Licensing Board of Indiana will hold a public hearing on proposed amendments concerning definitions, appropriate use of the Internet in medical practice, and prescribing to persons not seen by the physician. Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W041 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Lisa R. Hayes
Executive Director
Health Professions Bureau