

Document: Proposed Rule, **Register Page Number:** 26 IR 164

Source: October 1, 2002, Indiana Register, Volume 26, Number 1

Disclaimer: This document was created from the files used to produce the official Indiana Register. However, this document is unofficial.

**TITLE 410 INDIANA STATE DEPARTMENT OF
HEALTH**

Proposed Rule
LSA Document #02-43

DIGEST

Amends 410 IAC 15-1.5-4 and 410 IAC 15-1.5-5 to remove the 48 hour requirement for authentication of entries in medical records and add requirements regarding appropriate authentication of entries in medical records. Effective 30 days after filing with the secretary of state.

410 IAC 15-1.5-4

410 IAC 15-1.5-5

SECTION 1. 410 IAC 15-1.5-4 IS AMENDED TO READ AS FOLLOWS:

410 IAC 15-1.5-4 Medical record services

Authority: IC 16-21-1-7

Affected: IC 16-21-1

Sec. 4. (a) The medical record service has administrative responsibility for the medical records that shall be maintained for every individual evaluated or treated within those services that come under the hospital's license.

(b) The organization of the medical record service shall be appropriate to the scope and complexity of the services provided as follows:

- (1) The service shall be directed by a registered record administrator (RRA) or an accredited record technician (ART). If a full-time or part-time RRA or ART is not employed, then a consultant RRA or ART shall be provided to assist the person in charge. Documentation of the findings and recommendations of the consultant shall be maintained.
- (2) The medical record service shall be provided with the necessary direction, staffing, and facilities to perform all required functions in order to ensure prompt completion, filing, and retrieval of records.

(c) An adequate medical record shall be maintained with documentation of service rendered for each individual who is evaluated or treated as follows:

- (1) Medical records are documented accurately and in a timely manner, are readily accessible, and permit prompt retrieval of information.
- (2) A unit record system of filing should be utilized. When this is not possible, a system shall be established by the hospital to retrieve when necessary all divergently located record components.
- (3) The hospital shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. Each entry shall be authenticated **promptly** in accordance with the hospital and medical staff policies.
- (4) Medical records shall be retained in their original or legally reproduced form as required by federal and state law.
- (5) Plain paper facsimile orders, reports, and documents are acceptable for inclusion in the medical record if allowed by the hospital policies.
- (6) The hospital shall have a system of coding and indexing medical records which allows for timely retrieval of records by diagnosis and procedure in order to support continuous quality assessment and improvement activities.
- (7) The hospital shall ensure the confidentiality of patient records which includes, but is not limited to, the following:
 - (A) A procedure for releasing information from or copies of records only to authorized individuals in accordance with federal and state laws.

(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.

(d) The medical record shall contain sufficient information to:

- (1) identify the patient;
- (2) support the diagnosis;
- (3) justify the treatment; and
- (4) document accurately the course of treatment and results.

(e) All entries in the medical record shall be:

- (1) legible and complete;
- (2) made only by individuals given this right as specified in hospital and medical staff policies; and
- (3) authenticated and dated promptly ~~within forty-eight (48) hours~~ in accordance with subsection (c)(3).

(f) All inpatient records, except those in subsection (g), shall document and contain, but not be limited to, the following:

- (1) Identification data.
- (2) The medical history and physical examination of the patient done within the time frames as prescribed by the medical staff rules and section 5(b)(3)(M) of this rule.
- (3) A statement of the diagnosis or impressions drawn from the admission history and physical examination.
- (4) Diagnostic and therapeutic orders.
- (5) Evidence of appropriate informed consent for procedures and treatments for which it is required as specified by the informed consent policy developed by the medical staff and governing board, and consistent with federal and state law.
- (6) Clinical observations, including results of therapy, documented in a timely manner.
- (7) Progress notes.
- (8) Operative note in accordance with 410 IAC 15-1.6-9(c)(7).
- (9) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.
- (10) Nursing notes, nursing plan of care, and entries by other health care providers that contain pertinent, meaningful observations and information.
- (11) Reports of pathology and clinical laboratory examinations, radiology and nuclear medicine examinations or treatment, anesthesia records, and any other diagnostic or therapeutic procedures and their results.
- (12) Documentation of complications and unfavorable reactions to drugs and anesthesia.
- (13) A discharge summary authenticated by the physician. A final progress note may be substituted for the discharge summary in the case of a normal newborn infant and uncomplicated obstetric delivery. The final progress note should include any instruction given to the patient and family.
- (14) Final diagnosis.

(g) A short stay record form used for inpatients hospitalized for less than forty-eight (48) hours, observation patients, ambulatory care patients, and ambulatory surgery patients shall document and contain, but not be limited to, the following:

- (1) Identification data.
- (2) Medical history and description of the patient's condition and pertinent physical findings.
- (3) Diagnostic and therapeutic orders.
- (4) Care based on identified standard of care and standard of practice.
- (5) Data necessary to support the diagnosis and the treatment given, with reports of procedures and tests, and their results, clinical observations, including the results of therapy, and anesthesia given, if applicable.
- (6) Operative note in accordance with 410 IAC 15-1.6-9(c)(7), if applicable.
- (7) Final progress note, including instructions to the patient and family with dismissal diagnosis and disposition of patient.
- (8) Authentication by the physician and other responsible personnel in attendance.

(h) Outpatient records shall document and contain, but not be limited to, the following:

- (1) Identification data.

- (2) Diagnostic and therapeutic orders.
- (3) Description of treatment given, procedures performed, and documentation of patient response to intervention, if applicable.
- (4) Results of diagnostic tests and examinations done, if applicable.

(i) Emergency service records shall document and contain, but not be limited to, the following:

- (1) Identification data.
- (2) Time of arrival, means of arrival, time treatment is initiated, and time examined by the physician, if applicable.
- (3) Pertinent history of illness or injury, description of the illness or injury, and examination, including vital signs.
- (4) Diagnostic and therapeutic orders.
- (5) Description of treatment given or prescribed, clinical observations, including the results of treatment, and the reports of procedures and test results, if applicable.
- (6) Authentication by the practitioner or licensed health professional who rendered treatment or prescribed for the patient in accordance with hospital policy.
- (7) Instruction given to patient on release, prescribed follow-up care, signature of patient or responsible other, and name of person giving instructions.
- (8) Diagnostic impression and condition on discharge documented by the practitioner, and disposition of the patient and time of dismissal.
- (9) Copy of transfer form, if patient is referred to the inpatient service of another hospital. If care is not furnished to a patient or if the patient is referred elsewhere, the reasons for such action shall be recorded.

(Indiana State Department of Health; 410 IAC 15-1.5-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1269; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

SECTION 2. 410 IAC 15-1.5-5 IS AMENDED TO READ AS FOLLOWS:

410 IAC 15-1.5-5 Medical staff

Authority: IC 16-21-1-7

Affected: IC 16-21-1; IC 25-22.5

Sec. 5. (a) The hospital shall have an organized medical staff that operates under bylaws approved by the governing board and is responsible to the governing board for the quality of medical care provided to patients. The medical staff shall be composed of two (2) or more physicians and other practitioners as appointed by the governing board and do the following:

- (1) Conduct outcome oriented performance evaluations of its members at least biennially.
- (2) Examine credentials of candidates for appointment and reappointment to the medical staff by using sources in accordance with hospital policy and applicable state and federal law.
- (3) Make recommendations to the governing board on the appointment or reappointment of the applicant for a period not to exceed two (2) years.
- (4) Maintain a file for each member of the medical staff which includes, but is not limited to, the following:
 - (A) A completed, signed application.
 - (B) The date and year of completion of all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable.
 - (C) A copy of their current Indiana license showing date of licensure and current number or an available certified list provided by the health professions bureau. A copy of practice restrictions, if any, shall be attached to the license issued by the health professions bureau through the medical licensing board.
 - (D) A copy of their current Indiana controlled substance registration showing number, as applicable.
 - (E) A copy of their current Drug Enforcement Agency registration showing number, as applicable.
 - (F) Documentation of experience in the practice of medicine.
 - (G) Documentation of specialty board certification, as applicable.
 - (H) Category of medical staff appointment and delineation of privileges approved.
 - (I) A signed statement to abide by the rules of the hospital.
 - (J) Documentation of current health status as established by hospital and medical staff policy and procedure and federal and state requirements.
 - (K) Other items specified by the hospital and medical staff.

(b) The medical staff shall adopt and enforce bylaws and rules to carry out its responsibilities. These bylaws and rules shall:

- (1) be approved by the governing board;
- (2) be reviewed at least triennially; **and**
- (3) include, but not be limited to, the following:
 - (A) A description of the medical staff organizational structure. If the organization calls for an executive committee, a majority of the members shall be physicians on the active medical staff.
 - (B) Meeting requirements of the staff.
 - (C) A provision for maintaining records of all meetings of the medical staff and its committees.
 - (D) A procedure for designating an individual physician with current privileges as chief, president, or chairperson of the staff.
 - (E) A statement of duties and privileges for each category of the medical staff.
 - (F) A description of the medical staff applicant qualifications.
 - (G) Criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.
 - (H) A process for review of applications for staff membership, delineation of privileges in accordance with the competence of each practitioner, and recommendations on appointments to the governing board.
 - (I) A process for appeals of decisions regarding medical staff membership and privileges.
 - (J) A process for medical staff performance evaluations based on clinical performances indicated in part by the results of quality assessment and improvement activities.
 - (K) A process for reporting practitioners who fail to comply with state professional licensing law requirements as found in IC 25-22.5, and for documenting appropriate enforcement actions against practitioners who fail to comply with the hospital and medical staff bylaws and rules.
 - (L) A provision for physician coverage of emergency care ~~which that~~ addresses at least:
 - (i) a definition of emergency care to include, but not be limited to:
 - (AA) inpatient emergencies; **and**
 - (BB) emergency services emergencies; and
 - (ii) a timely response.
 - (M) A requirement that a complete physical examination and medical history be performed:
 - (i) on each patient admitted by a practitioner who has been granted such privileges by the medical staff;
 - (ii) within seven (7) days prior to date of admission and documented in the record with a durable, legible copy of the report and changes noted in the record on admission; or
 - (iii) within forty-eight (48) hours after an admission.
 - (N) A requirement that all physician orders shall be in writing or acceptable computerized form and shall be authenticated ~~within forty-eight (48) hours~~ by the responsible individual **in accordance with hospital and medical staff policies.**
 - (O) A requirement that all verbal orders must be repeated and verified and that the repetition and verification be documented in the patient's medical record signed and dated by the authorized health care professional that took the order. If there is no repetition and verification of the verbal order the prescribing physician/practitioner shall authenticate and date the verbal order within forty-eight (48) hours.**
 - ~~(P)~~ **(P)** A requirement that the final diagnosis be documented along with completion of the medical record within thirty (30) days following discharge.

(c) The medical staff should attempt to secure autopsies in all cases of unusual deaths and educational interest. There shall be the following:

- (1) A mechanism for documenting in writing the following:
 - (A) That permission to perform an autopsy was obtained.
 - (B) The source of the permission.
- (2) A system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

(Indiana State Department of Health; 410 IAC 15-1.5-5; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1271; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on October 22, 2002 at 2:00 p.m., at the Indiana State Department of Health, 2 North Meridian Street, Rice Auditorium, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on proposed amendments to remove the 48 hour requirement for authentication of entries in medical records and add requirements regarding appropriate authentication of entries in medical records. Copies of these rules are now on file at the Health Care Regulatory Services Commission, Indiana State Department of Health, 2 North Meridian Street, 5th Floor and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Gregory A. Wilson, M.D.
State Health Commissioner
Indiana State Department of Health