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**TITLE 410 INDIANA STATE DEPARTMENT OF
HEALTH**

Proposed Rule
LSA Document #01-159

DIGEST

Adds 410 IAC 17-9, 410 IAC 17-10, 410 IAC 17-11, 410 IAC 17-12, 410 IAC 17-13, 410 IAC 17-14, 410 IAC 17-15, and 410 IAC 17-16 to protect the health, safety, and welfare of patients, govern the qualifications of applicants for licenses, govern the operating policies, supervision, and maintenance of service records of home health agencies, and govern the procedure for issuing, renewing, denying, or revoking a license to a home health agency. Effective 30 days after filing with the secretary of state.

410 IAC 17-1.1	410 IAC 17-9
410 IAC 17-2	410 IAC 17-10
410 IAC 17-3	410 IAC 17-11
410 IAC 17-4	410 IAC 17-12
410 IAC 17-5	410 IAC 17-13
410 IAC 17-6	410 IAC 17-14
410 IAC 17-7	410 IAC 17-15
410 IAC 17-8	410 IAC 17-16

SECTION 1. 410 IAC 17-9 IS ADDED TO READ AS FOLLOWS:

Rule 9. Definitions

410 IAC 17-9-1 Applicability

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 1. The definitions in this rule apply throughout this article. (*Indiana State Department of Health; 410 IAC 17-9-1*)

410 IAC 17-9-2 “Administrator” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 2. “Administrator” means any health care professional who has at least one (1) year of supervisory or administrative experience in health service, or any other individual who has at least one (1) year of experience in health service administration or health service finance. (*Indiana State Department of Health; 410 IAC 17-9-2*)

410 IAC 17-9-3 “Advance directive” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 3. “Advance directive” means a written instruction, such as a living will or durable power of attorney for health care, recognized under state law and relating to the provision of such care when the individual is incapacitated. (*Indiana State Department of Health; 410 IAC 17-9-3*)

410 IAC 17-9-4 “Attendant care services” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 4. “Attendant care services” means those services that could be performed by an impaired individual for whom the services are provided if the individual were not impaired, that enable the impaired individual to live in the individual’s home and community, rather than in an institution, and to carry out functions of daily living, self care, and mobility. The term includes the following:

- (1) Assistance in getting in and out of beds, wheelchairs, and motor vehicles.**
- (2) Assistance with routine bodily functions, including the following:**
 - (A) Bathing and personal hygiene.**
 - (B) Using the toilet.**
 - (C) Dressing and grooming.**
 - (D) Feeding, including preparation and cleanup.**
- (3) The provision of assistance as follows:**
 - (A) Through providing reminders or cues to take medication, the opening of pre-set medication containers, and providing assistance in the handling or ingesting of noncontrolled substance medications, including eye drops, herbs, supplements, and over-the-counter medications.**
 - (B) To an individual who is unable to accomplish the task due to an impairment and who is:**
 - (i) competent and has directed the services; or**
 - (ii) incompetent and has the services directed by a competent individual who may consent to health care for the impaired individual.**

(Indiana State Department of Health; 410 IAC 17-9-4)

410 IAC 17-9-5 “Branch office” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 5. “Branch office” means a location or site from which a home health agency provides services for a portion of the total geographic area served by the parent home health agency. To be a branch office, the office must be part of the parent agency and share administration, supervision, and services with the parent agency. The parent agency and the branch office must be capable of sharing emergency functions, including services, on a daily basis. A branch office must be located within one hundred twenty (120) minutes driving time of the parent agency. *(Indiana State Department of Health; 410 IAC 17-9-5)*

410 IAC 17-9-6 “Bylaws” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 6. “Bylaws” means a written set of rules adopted by a home health agency for governing the agency’s operation. *(Indiana State Department of Health; 410 IAC 17-9-6)*

410 IAC 17-9-7 “Clinical note” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 7. “Clinical note” means a notation written and dated by a member of the health team regarding his or her contact with a patient who is being treated under a medical plan of care. *(Indiana State Department of Health; 410 IAC 17-9-7)*

410 IAC 17-9-8 “Closed files” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 8. “Closed files” means those files which concern services provided prior to a patient’s discharge. *(Indiana State Department of Health; 410 IAC 17-9-8)*

410 IAC 17-9-9 “Continuing education program” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 9. “Continuing education program means one (1) or more in-service training classes offered to home health aides for the purpose of satisfying the continuing education requirement. (Indiana State Department of Health; 410 IAC 17-9-9)

410 IAC 17-9-10 “Current service files” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 10. “Current service files” means those files concerning a patient who is currently receiving services from the home health agency. (Indiana State Department of Health; 410 IAC 17-9-10)

410 IAC 17-9-11 “Department” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 11. “Department” means the Indiana state department of health. (Indiana State Department of Health; 410 IAC 17-9-11)

410 IAC 17-9-12 “Encounter” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 12. “Encounter” means a direct personal contact between a patient and the person authorized by the home health agency to furnish services to the patient. (Indiana State Department of Health; 410 IAC 17-9-12)

410 IAC 17-9-13 “Frequency of visits” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 13. “Frequency of visits” means the number of encounters in a given period between a patient and the person authorized by the home health agency to furnish services to the patient. The term may be expressed as a number or a range. The number of encounters must be at least one (1). (Indiana State Department of Health; 410 IAC 17-9-13)

410 IAC 17-9-14 “Governing body” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 14. “Governing body” means person or group of persons who have the legal and financial responsibility for the home health agency’s overall operation. (Indiana State Department of Health; 410 IAC 17-9-14)

410 IAC 17-9-15 “Health care professional” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1; IC 25-10-1; IC 25-14; IC 25-22.5; IC 25-23-1; IC 25-23.5; IC 25-23.6-2-1; IC 25-24; IC 25-26-13; IC 25-27; IC 25-29; IC 25-35.6-1-2; IC 25-35.6-3

Sec. 15. “Health care professional” means any of the following:

- (1) A licensed physician.**
- (2) A licensed dentist.**
- (3) A licensed chiropractor.**
- (4) A licensed podiatrist.**
- (5) An licensed optometrist.**
- (6) A nurse licensed under IC 25-23-1.**

- (7) A physical therapist licensed under IC 25-27 or a physical therapy assistant certified under IC 25-27.
- (8) A speech-language pathologist or an audiologist licensed under IC 25-35.6-3.
- (9) A speech-language pathology aide or an audiology aide (as defined in IC 25-35.6-1-2).
- (10) An occupational therapist or an occupational therapist assistant certified under IC 25-23.5.
- (11) A social worker licensed under IC 25-23.6-2-1 or a social work assistant.
- (12) A pharmacist licensed under IC 25-26-13.

(Indiana State Department of Health; 410 IAC 17-9-15)

410 IAC 17-9-16 “Home health aide” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 16. “Home health aide” means an individual who provides home health aide services. The term does not include the following:

- (1) A health care professional.
- (2) A volunteer who provides home health aide services without compensation.
- (3) An immediate member of the patient’s family.

(Indiana State Department of Health; 410 IAC 17-9-16)

410 IAC 17-9-17 “Home health aide services” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 17. “Home health aide services” means only those home health services that may be performed by a home health aide. *(Indiana State Department of Health; 410 IAC 17-9-17)*

410 IAC 17-9-18 “Home health services” defined

Authority: IC 16-27-1-7

Affected: IC 12-10-17; IC 16-27-1-10; IC 25-22.5

Sec. 18. (a) “Home health services” means services that are:

- (1) provided to a patient by:
 - (A) a home health agency; or
 - (B) another person under an arrangement with a home health agency;in the temporary or permanent residence of the patient; and
- (2) ordered by a licensed physician, a licensed dentist, a licensed chiropractor, a licensed podiatrist, or a licensed optometrist.

(b) The term includes the following:

- (1) Nursing treatment and procedures.
- (2) Physical therapy.
- (3) Occupational therapy.
- (4) Speech therapy.
- (5) Medical social services.
- (6) Home health aide services.
- (7) Other therapeutic services.

(c) The term does not apply to the following:

- (1) Services provided by a physician licensed under IC 25-22.5.
- (2) Incidental services provided by a licensed health facility to patients of the licensed health facility.
- (3) Services provided by employers or membership organizations using health care professionals for their employees, members, and families of the employees or members if the health or home care services are not the predominant purpose of the employer or a membership organization’s business.
- (4) Nonmedical nursing care given in accordance with the tenets and practice of a recognized church or religious denomination to a patient who depends upon healing by prayer and spiritual means alone in

accordance with the tenets and practices of the patient's church or religious denomination.

(5) Services that are allowed to be performed by an attendant under IC 16-27-1-10.

(6) Authorized services provided by a personal services attendant under IC 12-10-17.

(Indiana State Department of Health; 410 IAC 17-9-18)

410 IAC 17-9-19 "Medical plan of care" defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 19. "Medical plan of care" means written instructions signed by the physician, dentist, chiropractor, podiatrist, or optometrist for the provision of care or treatment to be given by a registered or practical nurse, physical or occupational therapist, speech-language pathologist, social worker, or home health aide to a patient in the patient's place of residence. *(Indiana State Department of Health; 410 IAC 17-9-19)*

410 IAC 17-9-20 "Medication assistance" defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 20. "Medication assistance" means the provision of assistance:

(1) through providing reminders or cues to take medication, the opening of pre-set medication containers, and providing assistance in the handling or ingesting of noncontrolled substance medications, including eye drops, herbs, supplements, and over-the-counter medications; and

(2) to an individual who is unable to accomplish the task due to an impairment and who is:

(A) competent and has directed the services; or

(B) incompetent and has the services directed by a competent individual who may consent to health care for the impaired individual.

(Indiana State Department of Health; 410 IAC 17-9-20)

410 IAC 17-9-21 "Member of the health team" defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 21. "Member of the health team" means a health care professional or a home health aide. *(Indiana State Department of Health; 410 IAC 17-9-21)*

410 IAC 17-9-22 "Parent home health agency" or "parent agency" defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 22. "Parent home health agency" or "parent agency" means the home health agency that develops and maintains administrative and fiscal control over branch offices. *(Indiana State Department of Health; 410 IAC 17-9-22)*

410 IAC 17-9-23 "Licensed practical nurse" defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1; IC 25-23

Sec. 23. "Licensed practical nurse" means a person who is licensed as a practical nurse pursuant to IC 25-23. *(Indiana State Department of Health; 410 IAC 17-9-23)*

410 IAC 17-9-24 "Registered nurse" defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1; IC 25-23

Sec. 24. "Registered nurse" means a nurse who is licensed as a registered nurse pursuant to IC 25-23. *(Indiana State Department of Health; 410 IAC 17-9-24)*

410 IAC 17-9-25 “Social work assistant” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 25. “Social work assistant” means an individual who has a baccalaureate degree in psychology, sociology, or other field related to social work, and has had at least one (1) year of social work experience in a health care setting and is supervised by a social worker. (Indiana State Department of Health; 410 IAC 17-9-25)

410 IAC 17-9-26 “Social worker” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1; IC 25-23

Sec. 26. “Social worker” means a person who has a master’s degree from a school of social work accredited by the Council on Social Work Education, and who has one (1) year of social work experience in a health care setting. (Indiana State Department of Health; 410 IAC 17-9-26)

410 IAC 17-9-27 “Speech language pathologist” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1; IC 25-35.6

Sec. 27. “Speech language pathologist” means an individual who is licensed to practice speech language pathology pursuant to IC 25-35.6. (Indiana State Department of Health; 410 IAC 17-9-27)

410 IAC 17-9-28 “Summary report” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 28. “Summary report” means a clinical synopsis of the pertinent factors from the clinical notes regarding a patient requiring a medical plan of care, which is submitted as a report to the physician. (Indiana State Department of Health; 410 IAC 17-9-28)

410 IAC 17-9-29 “Supervision” defined

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 29. “Supervision” means guidance to a subordinate by a qualified health care professional for the accomplishment of a function or activity. Supervision shall be evidenced by documentation that demonstrates consistent, meaningful interaction and guidance between the qualified health care professional and his or her subordinate. (Indiana State Department of Health; 410 IAC 17-9-29)

SECTION 2. 410 IAC 17-10 IS ADDED TO READ AS FOLLOWS:

Rule 10. Home Health Licensure

410 IAC 17-10-1 Licensure

Authority: IC 16-27-1-7

Affected: IC 5-2-5; IC 16-20; IC 16-22-8; IC 16-27-1; IC 25-22.5

Sec. 1. (a) No home health agency shall be opened, operated, managed, maintained, or otherwise conduct business without a license issued by the department.

(b) A license is required for any home health agency providing care in Indiana where the parent agency is located in a state other than Indiana. The home health agency must be authorized by the secretary of state to conduct business in Indiana and have a branch office located in Indiana.

(c) Application for a license to operate a home health agency shall be made on a form provided by the

department and shall be accompanied by a nonrefundable fee of one hundred dollars (\$100).

(d) Disclosure of ownership and management information must be made to the department at the time of the home health agency's initial request for licensure, for each survey, and at the time of any change in ownership or management. The disclosure must include the following:

- (1) The name and address of all persons having at least five percent (5%) ownership or controlling interest in the home health agency.
- (2) The name and address of each person who is an officer, a director, a managing agent, or a managing employee of the home health agency.
- (3) The name and address of the corporation, association, or other company that is responsible for the management of the home health agency, and the name and address of the chief executive officer and the chairman or equivalent position of the governing body of that corporation, association, or other legal entity responsible for the management of the home health agency.

(e) After receiving a completed application, the nonrefundable fee required by subsection (c), and disclosure of ownership and management information, the department may issue a letter of approval for operating a home health agency for a period of up to ninety (90) days pending an on-site inspection. In determining whether to issue the letter of approval, the department shall consider the following factors:

- (1) Whether the department has filed an action against an agency owned or operated by the applicant that resulted in:
 - (A) the revocation of a license;
 - (B) the denial or renewal of a license;
 - (C) the issuance or renewal of a probationary license; or
 - (D) the payment of a civil penalty.
- (2) Whether the department has issued an order against an agency owned or operated by the applicant.
- (3) Whether an agency owned or operated by the applicant has surrendered its license to the department.
- (4) Whether any injunction has been issued against an agency owned or operated by the applicant.
- (5) Whether an agency owned or operated by the applicant has operated in substantial violation of this rule or any other law governing home health agencies at any time within two (2) years immediately preceding the date that the applicant applied for a license.

(f) The department may extend this ninety (90) day period for a total of one hundred twenty (120) days in fifteen (15) day increments. Such decision to grant an extension shall take into consideration the health, safety, and welfare of the citizens the home health agency serves and the individual circumstances warranting the need for the extension. The home health agency must provide the service or services that have been specified on the application prior to the inspection and must have a minimum of three (3) patients for record review. Record review may consist of both open and closed patient files.

(g) In determining whether to issue the initial license to operate a home health agency, the department may consider the factors described under subsection (e) and the results of the initial survey.

(h) The license shall relate back to and reflect the date of the first day of the ninety (90) day letter issued by the department.

(i) In determining whether to renew a license to operate a home health agency, the department may consider the factors described under subsection (e) of this rule and any actions pending against the home health agency.

(j) In conducting a survey, a surveyor shall receive copies of any and all documents necessary to make a determination of compliance. The surveyor may make copies with permission of the home health agency, or supervise any copying process to ensure that photocopies are true and accurate. At the sole discretion of the department and for good cause shown, the home health agency may be granted up to twenty-four (24) hours to produce documents requested by the surveyor.

(k) A home health agency may apply to provide a service that was not listed in its application or renewal

application by notifying the department in writing of the new service, the date the service is intended to be offered and all supporting documentation that shows the home health agency is qualified to provide the additional service. Such documentation includes, but is not limited to, the following:

- (1) Personnel qualifications and licensing.
- (2) Limited criminal history from the Indiana central repository established by IC 5-2-5.
- (3) Procedures for the supervision of personnel.
- (4) Contracts between the home health agency and any person offering the new service.
- (5) Records of physical exams showing that personnel are free of communicable disease. In the event the initial information submitted is not sufficient for the department to determine the home health agency's compliance regarding the new service, the department will inform the home health agency of the additional documents required. A home health agency may not offer additional services until it has received approval from the department to do so.

(l) The following are not required to be licensed as a home health agency:

- (1) A physician licensed under IC 25-22.5.
- (2) An individual whose permanent residence is in the patient's residence or who is a member of the patient's immediate family.
- (3) Incidental services provided by licensed health facilities to their patients.
- (4) An employee of a person holding a license under IC 16-27-1 who provides home health services only as an employee of the licensed person.
- (5) A local health department established under IC 16-20.
- (6) A health care professional who provides one health service through a contract with a person licensed under IC 16-27-1.
- (7) A durable medical equipment supply company that furnishes equipment but provides no home health services to persons in their homes.
- (8) A drugstore or wholesale medical supply company that furnishes no home health services to persons in their home.
- (9) A volunteer who provides home health aide services without compensation.
- (10) An individual health care professional who provides professional services to a patient in the temporary or permanent residence of the patient.

(m) Except as provided in 410 IAC 17-11-5, each license shall be for a term of one (1) year and shall expire one (1) year from the date of issuance. The licensee shall notify the department in writing thirty (30) days in advance of closing or selling the home health agency.

(n) Each license shall be issued only for the home health agency named in the application and shall not be transferred or assigned. Upon sale, assignment, lease, or other transfer, voluntary or involuntary, including those transfers that qualify as changes of ownership, a new owner or person in interest shall obtain a license from the department prior to maintaining, operating, or conducting a home health agency.

(o) The licensee shall submit an annual activity report to the department on a form provided by the department.

(p) Surveys may be, but are not limited to, the following:

- (1) Unannounced surveys conducted annually for compliance.
- (2) Post survey revisits conducted based on a home health agency's plan of correction and for the purpose of determining compliance.
- (3) Patient care complaints.

(Indiana State Department of Health; 410 IAC 17-10-1)

SECTION 3. 410 IAC 17-11 IS ADDED TO READ AS FOLLOWS:

Rule 11. State Administrative Actions

410 IAC 17-11-1 Actions by the commissioner

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 1. The commissioner of the department may take one (1) or more of the following actions on any ground listed in section 2 of this rule:

- (1) Issue a letter of correction.
- (2) Issue a probationary license.
- (3) Conduct a resurvey.
- (4) Deny a license or renewal of a license.
- (5) Revoke a license.
- (6) Impose a civil penalty in an amount not to exceed ten thousand dollars (\$10,000).

(Indiana State Department of Health; 410 IAC 17-11-1)

410 IAC 17-11-2 Grounds for actions by the commissioner

Authority: IC 16-27-1-7

Affected: IC 4-21.5; IC 16-27-1

Sec. 2. The commissioner may take action under section 1 of this rule on any of the following grounds:

- (1) Violation of any of the provisions of IC 16-27 or this article.
- (2) Permitting, aiding, or abetting the commission of an illegal act in a home health agency.
- (3) Conduct or practice found by the department to be detrimental to the welfare of the patients of the home health agency.

(Indiana State Department of Health; 410 IAC 17-11-2)

410 IAC 17-11-3 Renewal of home health licensure

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 3. An application for renewal of license shall be filed with the department at least sixty (60) days prior, but not sooner than ninety (90) days before, the expiration date of the current license. *(Indiana State Department of Health; 410 IAC 17-11-3)*

410 IAC 17-11-4 Civil penalties

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 4. (a) The commissioner may commence an action under IC 16-27-1 to levy civil penalties against a person who:

- (1) fails to comply with IC 16-27 or this article; or
- (2) interferes with or obstructs the department or its designated agent in the performance of duties pursuant to IC 16-27-1.

(b) A monetary civil penalty may be sought for each documented violation of IC 16-27-1 or this article. Monetary civil penalties issued may not exceed ten thousand dollars (\$10,000) per violation.

(c) In determining the seriousness of the violation and the specific amount of the civil penalty to be sought for each violation, the commissioner may consider, but is not limited to, the following:

- (1) The potential for harm or imminent threat to the patient's health.
- (2) The extent of deviation from statutory or regulatory requirements.
- (3) The degree of willfulness or negligence.
- (4) The history of noncompliance.

(d) The absence of direct harm will not necessarily result in assessment of a lower penalty for a violation. *(Indiana State Department of Health; 410 IAC 17-11-4)*

410 IAC 17-11-5 Probationary license

Authority: IC 16-27-1-7

Affected: IC 16-27-1-12

Sec. 5. A probationary license may be issued pursuant to IC 16-27-1-12 for three (3) months. The probationary license may be reissued but not more than three (3) probationary licenses may be issued during a twelve (12) month period. The issuance of a probationary license results in the automatic expiration of any other license held under this article. (Indiana State Department of Health; 410 IAC 17-11-5)

SECTION 4. 410 IAC 17-12 IS ADDED TO READ AS FOLLOWS:

Rule 12. Home Health Administration and Management

410 IAC 17-12-1 Home health agency administration and management

Authority: IC 16-27-1-7

Affected: IC 16-27-1; IC 16-27-2

Sec. 1. (a) Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level shall be clearly set forth in writing and be readily identifiable. Administrative and supervisory responsibilities shall not be delegated to another agency or organization, and all services not furnished directly, including services provided through a branch office, shall be monitored and controlled by the parent agency.

(b) A governing body, or designated person or persons so functioning, shall assume full legal authority and responsibility for the operation of the home health agency. The governing body shall appoint a qualified administrator, adopt and periodically review written bylaws or an acceptable equivalent, and oversee the management and fiscal affairs of the home health agency.

(c) An individual need not be a home health agency employee or be present full time at the home health agency in order to qualify as its administrator. The administrator, who may also be the supervising physician or registered nurse required by subsection (d), shall do the following:

- (1) Organize and direct the home health agency's ongoing functions.**
- (2) Maintain ongoing liaison among the governing body and the staff.**
- (3) Employ qualified personnel and ensure adequate staff education and evaluations.**
- (4) Ensure the accuracy of public information materials and activities.**
- (5) Implement a budgeting and accounting system.**
- (6) Ensure that the home health agency meets all rules and regulations for licensure.**
- (7) Upon request, make available to the commissioner or his designated agent all:
 - (A) reports;**
 - (B) records;**
 - (C) minutes;**
 - (D) documentation;**
 - (E) information; and**
 - (F) files;****

required to determine compliance within seventy-two (72) hours of such request or, in the event such a request is made in conjunction with a survey, by the time the surveyor exits the home health agency, whichever is sooner.

- (8) Ensure that a qualified person is authorized in writing to act in the administrator's absence.**

(d) A physician or a registered nurse who has two (2) years of nursing experience, with at least one (1) year of supervisory or administrative experience, shall supervise and direct nursing and other therapeutic services. Such person or similarly qualified alternate shall be on the premises or capable of being reached immediately by phone, pager, or other means. In addition, the person must be able to respond to an emergency, provide guidance to staff, answer questions, and resolve issues within a reasonable amount of time, given the emergency or issue that has been raised.

(e) The administrator shall be responsible for an ongoing quality assurance program designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, resolve identified problems, and improve patient care.

(f) Personnel practices for employees shall be supported by written policies. All employees caring for patients in Indiana shall be subject to Indiana licensure, certification, or registration required to perform the respective service. Personnel records of employees who deliver home health services shall be kept current and shall include documentation of orientation to the job, including the following:

- (1) Receipt of job description.
- (2) Qualifications.
- (3) A copy of limited criminal history pursuant to IC 16-27-2.
- (4) A copy of current license, certification or registration.
- (5) Annual performance evaluations.

(g) Personnel records of the supervising nurse, appointed pursuant to subsection (d), shall be kept current and shall include a copy of the following:

- (1) Limited criminal history pursuant to IC 16-27-2.
- (2) Nursing license.
- (3) Annual performance evaluations.
- (4) Documentation of orientation to the job.

Performance evaluations required by this subsection must be performed every nine (9) to fifteen (15) months of active employment.

(h) Each employee who will have direct patient contact shall have a physical examination by a physician or nurse practitioner no more than one hundred eighty (180) days before the date that the employee has direct patient contact. The physical examination shall be of sufficient scope to ensure that the employee will not spread infectious or communicable diseases to patients.

(i) The home health agency shall require all employees who will have direct patient contact to complete a PPD (mantoux) skin test for tuberculosis no more than thirty (30) days before the date that the employee has direct patient contact and annually thereafter for negative findings. Positive findings shall require appropriate clinical follow-up before the employee has direct patient contact, but no repeat skin test. A physician shall advise and approve policies regarding positive outcomes. The home health agency shall follow the Centers for Disease Control and Prevention guidelines for administering the tuberculin skin test. These guidelines are the "Core Curriculum on Tuberculosis", Chapter IV(B), Fourth Edition (2000).

(j) The information obtained from the physical examinations required by subsection (h) and PPD (mantoux) skin tests and clinical follow-ups required by subsection (i) must be maintained in separate medical files and treated as confidential medical records, except as provided in subsection (k):

(k) The following records shall be made available, on request, to the department for review:

- (1) Personnel records and policies that document the home health agency's compliance with subsection (f).
- (2) Records of physical examinations that document the agency's compliance with subsection (h).
- (3) Records of PPD (mantoux) skin tests, the results of the skin tests, appropriate clinical follow-up for positive findings, and any other records that document the home health agency's compliance with subsection (i).

(l) The department shall treat the information described in subsection (k) as confidential medical records and use it only for the purposes for which it was obtained.

(m) Policies and procedures shall be written and implemented for the control of communicable disease in compliance with applicable federal and state laws. (*Indiana State Department of Health; 410 IAC 17-12-1*)

410 IAC 17-12-2 Quality assessment and performance improvement

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 2. (a) The home health agency must develop, implement, maintain, and evaluate a quality assessment and performance improvement program. The program must reflect the complexity of the home health organization and services (including those services provided directly or under arrangement). The home health agency must take actions that result in improvements in the home health agencies performance across the spectrum of care. The home health agency's quality assessment and performance improvement program must use objective measures.

(b) The home health agency shall provide at least one (1) of the following services:

- (1) Nursing treatment and procedure.**
- (2) Home health aide services.**
- (3) Physical therapy.**
- (4) Speech-language pathology.**
- (5) Occupational therapy.**
- (6) Social services.**

(c) In all cases involving the provision of home health aide services, the home health agency shall provide case management by a health care professional acting within the scope of his or her practice. Such case management shall include an initial home visit for assessment of a patient's needs to determine the type, appropriateness, and adequacy of requested service, and the development of the patient care plan.

(d) If personnel under contracts are used by the home health agency, there shall be a written contract between those personnel and the home health agency that specifies the following:

- (1) That patients are accepted for care only by the primary home health agency.**
- (2) The services to be furnished.**
- (3) The necessity to conform to all applicable home health agency policies including personnel qualifications.**
- (4) The responsibility for participating in developing plans of care.**
- (5) The manner in which services will be controlled, coordinated, and evaluated by the primary home health agency.**
- (6) The procedures for submitting clinical notes, scheduling of visits, and conducting periodic patient evaluation.**
- (7) The procedures for payment for services furnished under the contract.**

(e) Services furnished under arrangements are subject to a written contract conforming with the requirements specified in subsection (d).

(f) When contracting temporary services from another licensed home health agency, organization, or independent contractor, the personnel records shall be maintained at the office of the employer and shall be available to the home health agency upon two (2) hours' notice.

(g) All personnel providing services shall maintain effective communications to assure that their efforts appropriately complement one another and support the objectives of the patient's care. The means of communication and the results shall be documented in the clinical record or minutes of case conferences.

(h) The home health agency shall coordinate its services with other health or social service providers serving the patient.

(i) A home health agency must develop and implement a policy requiring a notice of discharge of service to the patient, the patient's legal representative, or other individual responsible for the patient's care at least five (5) calendar days before the services are stopped.

(j) The five (5) day period described in subsection (i) does not apply in any of the following circumstances:

- (1) The health, safety, and/or welfare of the home health agency's employees would be at immediate and significant risk if the home health agency continued to provide services to the patient.**

- (2) The patient refuses the home health agency's services.
- (3) The patient's services are no longer reimbursable based on applicable reimbursement requirements and the home health agency informs the patient of community resources to assist the patient following discharge.
- (4) The patient no longer meets applicable regulatory criteria, such as lack of physician's order, and the home health agency informs the patient of community resources to assist the patient following discharge.

(k) A home health agency must continue, in good faith, to attempt to provide services during the five (5) day period described in subsection (i). If the home health agency cannot provide such services during that period, its continuing attempts to provide the services must be documented. (*Indiana State Department of Health; 410 IAC 17-12-2*)

410 IAC 17-12-3 Patient rights

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 3. (a) The patient or the patient's legal representative has the right to be informed of the patient's rights through effective means of communication. The home health agency must protect and promote the exercise of these rights as follows:

- (1) The home health agency shall provide the patient with a written notice of the patient's right in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.
- (2) The home health agency shall maintain documentation showing that it has complied with the requirements of this section.

(b) The patient has the right to exercise his or her rights as a patient of the home health agency as follows:

- (1) The patient's family or legal representative may exercise the patient's rights as permitted by law.
- (2) The patient has the right to have his or her property treated with respect.
- (3) The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the home health agency and must not be subjected to discrimination or reprisal for doing so.
- (4) The patient has the right to place a complaint with the department regarding treatment or care furnished by a home health agency.
- (5) The patient has the right to be informed about the care to be furnished, and of any changes in the care to be furnished as follows:
 - (A) The home health agency shall advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.
 - (B) The patient has the right to participate in the planning of the care. The home health agency shall advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.
 - (C) The home health agency shall advise the patient of any change in the plan of care, including reasonable discharge notice.
- (6) The patient has the right to confidentiality of the clinical records maintained by the home health agency. The home health agency shall advise the patient of the agency's policies and procedures regarding disclosure of clinical records.
- (7) The patient or patient's legal representative have the right under Indiana law to access the patient's clinical records unless certain exceptions apply. The home health agency shall advise the patient or the patient's legal representative of its policies and procedures regarding the accessibility of clinical records.
- (8) The patient has the right to be free from verbal, physical, and psychological abuse and to be treated with dignity.

(c) The home health agency shall investigate complaints made by a patient or the patient's family or legal representative regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the home health agency, and shall document both the existence of the complaint and the resolution of the complaint.

(d) The home health agency shall make available to the patient upon request, a written notice in advance of

furnishing care to the patient or during the initial evaluation visit before the initiation of treatment, a listing of all individuals or other legal entities who have an ownership or control interest in the agency as defined in 42 CFR 420.201, 42 CFR 420.202, and 42 CFR 420.206.

(e) The home health agency must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable state law. The home health agency may furnish advanced directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided. (*Indiana State Department of Health; 410 IAC 17-12-3*)

SECTION 5. 410 IAC 17-13 IS ADDED TO READ AS FOLLOWS:

Rule 13. Home Health Patient Care

410 IAC 17-13-1 Patient care

Authority: IC 16-27-1-7

Affected: IC 16-27-1; IC 25

Sec. 1. (a) Patients shall be accepted for care on the basis of a reasonable expectation that the patient's health needs can be adequately met by the home health agency in the patient's place of residence. Medical care shall follow a written medical plan of care established and periodically reviewed by the physician, dentist, chiropractor, optometrist, or podiatrist as follows:

(1) The medical plan of care shall be developed in consultation with the home health agency staff and shall cover all pertinent diagnoses and include the following:

- (A) Mental status.**
- (B) Types of services and equipment required.**
- (C) Frequency and duration of visits.**
- (D) Prognosis.**
- (E) Rehabilitation potential.**
- (F) Functional limitations.**
- (G) Activities permitted.**
- (H) Nutritional requirements.**
- (I) Medications and treatments.**
- (J) Any safety measures to protect against injury.**
- (K) Instructions for timely discharge or referral.**
- (L) Therapy modalities specifying length of treatment.**
- (M) Any other appropriate items.**

(2) The total medical plan of care shall be reviewed by the attending physician, dentist, chiropractor, optometrist, or podiatrist, and home health agency personnel as often as the severity of the patient's condition requires, but at least once every two (2) months. The health care professional staff of the home health agency shall promptly alert the person responsible for the medical component of the patient's care to any changes that suggest a need to alter the medical plan of care. A written summary report for each patient shall be sent to the physician, dentist, chiropractor, optometrist, or podiatrist at least every two (2) months.

(b) A home health agency may accept written orders for home health services from a physician, a dentist, a chiropractor, a podiatrist, or an optometrist licensed in Indiana or in any other state. If the home health agency receives an order from a physician, dentist, chiropractor, podiatrist, or optometrist who is licensed in another state, the home health agency shall take reasonable immediate steps to determine that the:

- (1) order complies with the laws of the state where the order originated; and**
- (2) individual who issued the order examined the patient and is licensed to practice in that state.**

(c) All orders issued by a physician, a dentist, a chiropractor, a podiatrist, or an optometrist for home health services must meet the same requirements whether the order originates in Indiana or another state. Orders issued from another state may not exceed the authority allowed under orders from the same profession in Indiana under IC 25.

(d) Home health agency personnel shall promptly notify a patient's physician or other appropriate licensed professional staff and legal representative, if any, of any significant physical or mental changes observed or reported by the patient. In the case of a medical emergency, the home health agency must know in advance which emergency system to contact. (*Indiana State Department of Health; 410 IAC 17-13-1*)

SECTION 6. 410 IAC 17-14 IS ADDED AS FOLLOWS:

Rule 14. Home Health Care Services

410 IAC 17-14-1 Scope of services

Authority: IC 16-27-1-7

Affected: IC 16-27-1; IC 25-23-1; IC 25-35.6; IC 27-1-5

Sec. 1. (a) The home health agency shall provide nursing services by a registered nurse or a licensed practical nurse in accordance with the medical plan of care as follows:

(1) The registered nurse shall perform nursing duties in accordance with the Indiana nurse practice act (IC 25-23). Except where services are limited to therapy only, for purposes of practice in the home health setting, the registered nurse shall do the following:

- (A) Make the initial evaluation visit.**
- (B) Regularly reevaluate the patient's nursing needs.**
- (C) Initiate the plan of care and necessary revisions.**
- (D) Initiate appropriate preventive and rehabilitative nursing procedures.**
- (E) Prepare clinical notes.**
- (F) Coordinate services.**
- (G) Inform the physician and other appropriate medical personnel of changes in the patient's condition and needs, counsel the patient and family in meeting nursing and related needs, participate in in-service programs, and supervise and teach other nursing personnel.**
- (H) Accept and carry out physician, chiropractor, podiatrist, dentist, and optometrist orders (oral and written).**
- (I) Assist the physician, chiropractor, podiatrist, dentist, or optometrist in evaluating level of function.**
- (J) Direct the activities of the licensed practical nurse.**
- (K) Delegate duties and tasks to licensed practical nurses and other individuals as appropriate.**

(2) The licensed practical nurse shall perform duties in accordance with the Indiana Nurse Practice Act (IC 25-23). For purposes of practice in the home health setting, the licensed practical nurse shall do the following:

- (A) Provide services in accordance with agency policies.**
- (B) Prepare clinical notes.**
- (C) Assist the physician and/or registered nurse in performing specialized procedures.**
- (D) Prepare equipment and materials for treatments observing aseptic technique as required.**
- (E) Assist the patient in learning appropriate self-care techniques.**
- (F) Accept and carry out physician, dentist, chiropractor, podiatrist, or optometrist orders (oral and written).**
- (G) Inform the physician, dentist, chiropractor, podiatrist, or optometrist of changes in the patient's condition and needs after consulting with the supervising registered nurse.**

(b) Any therapy services furnished by the home health agency shall be provided by the following:

- (1) A physical therapist or physical therapist assistant supervised by a licensed physical therapist in accordance with IC 27-1-5.**
- (2) An occupational therapist or occupational therapist assistant supervised by an occupation therapist in accordance with IC 25-23.5.**
- (3) A speech-language pathologist or audiologist in accordance with IC 25-35.6.**

(c) The appropriate therapist listed in subsection (b) shall do the following:

- (1) Make an initial evaluation visit to the patient for whom only therapy services are required.**
- (2) Review the plan of care as often as the severity of the patient's condition requires, but at least every two (2) months.**

- (3) Assist the physician, chiropractor, podiatrist, dentist, or optometrist in evaluating level of function.
- (4) Help develop the plan of care (revising as necessary).
- (5) Prepare clinical notes.
- (6) Advise and consult with the family and other home health agency personnel.
- (7) Participate in in-service programs.

(d) In carrying out the responsibilities identified in subsection (c), the therapist may:

- (1) direct the activities of any therapy assistant; or
- (2) delegate duties and tasks to other individuals as appropriate.

(e) Any social services furnished by the home health agency, shall be provided by a social worker, or a social work assistant under the supervision of a social worker, and in accordance with the medical plan of care. The social worker shall do the following:

- (1) Assist the physician and other team members in understanding the significant social and emotional factors related to the health problems.
- (2) Participate in the development of the plan of care.
- (3) Prepare clinical and progress notes.
- (4) Work with the family.
- (5) Use appropriate community resources.
- (6) Participate in discharge planning and in-service programs.
- (7) Act as a consultant to other home health agency personnel.
- (8) Accept and carry out physician orders for social work services.

(f) This rule does not prohibit the provision of:

- (1) homemaker services, including shopping, laundry, cleaning, and seasonal chores;
- (2) companion type services, including transportation, letter writing, mail reading, and escort services;
- (3) assistance with cognitive tasks, including managing finances, planning activities, and making decisions;
- (4) attendant care services; or
- (5) any other services for which an individual license, certification, registration, or permit is not required under state law.

(g) Home health aides shall be supervised by a health care professional to ensure competent provision of care. Supervision of services must be within the scope of practice of the health care professional providing the supervision.

(h) Home health aides must receive continuing education. Such continuing education shall total at least twelve (12) hours from January 1 through December 31, inclusive, with a minimum of eight (8) hours in any eight (8) of the following subject areas:

- (1) Communications skills, including the ability to read, write, and make brief and accurate oral presentations to patients, caregivers, and other home health agency staff.
- (2) Observing, reporting, and documenting patient status and the care or service furnished.
- (3) Reading and recording temperature, pulse, and respiration.
- (4) Basic infection control procedures and universal precautions.
- (5) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.
- (6) Maintaining a clean, safe, and healthy environment.
- (7) Recognizing emergencies and knowledge of emergency procedures.
- (8) The physical, emotional, and developmental needs of and ways to work with the populations served by the home health agency, including the need for respect for the patient, the patient's privacy, and the patient's property.
- (9) Appropriate and safe techniques in personal hygiene and grooming that include the following:
 - (A) Bed bath.
 - (B) Bath, sponge, tub, or shower.
 - (C) Shampoo, sink, tub, or bed.

- (D) Nail and skin care.
- (E) Oral hygiene.
- (F) Toileting and elimination.
- (10) Safe transfer techniques and ambulation.
- (11) Normal range of motion and positioning.
- (12) Adequate nutrition and fluid intake.
- (13) Medication assistance.
- (14) Any other task that the home health agency may choose to have the home health aide perform.

(i) During a home health aide's first year on the state's home health aide registry, the number of hours of training for that aide shall be a prorated portion of the usual twelve (12) and eight (8) hours.

(j) A home health aide continuing education program may be offered by any organization except a home health agency that has a probationary home health agency license.

(k) The training of home health aides pursuant to a continuing education program must be performed by or under the general supervision of a registered nurse. The home health agency shall maintain sufficient documentation to demonstrate that the continuing education requirements are met.

(l) The home health agency shall be responsible for ensuring that, prior to patient contact, the individuals who furnish home health aide services on its behalf meet the requirements of this section as follows:

(1) The home health aide shall:

(A) have successfully completed a competency evaluation program that addresses each of the subjects listed in subsection (h); and

(B) be entered on and be in good standing on the state aide registry.

(2) The home health agency shall maintain documentation, which demonstrates that the requirements of this subsection and subsection (h) were met.

(3) If the home health agency issuing the proof of the aide's achievement of successful completion of a competency evaluation program is not the employing agency, the employing agency shall keep a copy of the competency evaluation documentation in the home health aide's employment file.

(m) The home health aide shall be assigned to a particular patient by a registered nurse (or therapist in therapy only cases). The home health aide may not be assigned to perform additional tasks not included in the original competency evaluation until he or she has successfully been evaluated as competent in that task. The home health aide must report any changes observed in the patient's conditions and needs to the supervisory nurse or therapist.

(n) A registered nurse, or therapist in therapy only cases, shall make the initial visit to the patient's residence and make a supervisory visit at least every thirty (30) days, either when the home health aide is present or absent, to observe the care, to assess relationships, and to determine whether goals are being met. (*Indiana State Department of Health; 410 IAC 17-14-1*)

SECTION 7. 410 IAC 17-15 IS ADDED TO READ AS FOLLOWS:

Rule 15. Home Health Clinical Records

410 IAC 17-15-1 Clinical records

Authority: IC 16-27-1-7

Affected: IC 16-27-1; IC 16-39-7-1

Sec. 1. (a) Clinical records containing pertinent past and current findings in accordance with accepted professional standards shall be maintained for every patient as follows:

(1) The medical plan of care and appropriate identifying information.

(2) Name of the physician, dentist, chiropractor, podiatrist, or optometrist.

(3) Drug, dietary, treatment, and activity orders.

(4) Signed and dated clinical notes contributed to by all assigned personnel. Clinical notes shall be written the day service is rendered and incorporated within fourteen (14) days.

(5) Copies of summary reports sent to the person responsible for the medical component of the patient's care.

(6) A discharge summary.

(7) All entries must be legible, clear, complete, and appropriately authenticated and dated. Authentication must include signatures or a secured computer entry.

(b) Original clinical records shall be retained for the length of time as required by IC 16-39-7 after home health services are terminated by the home health agency. Policies shall provide for retention even if the home health agency discontinues operations.

(c) Clinical record information shall be safeguarded against loss or unauthorized use. Written procedures shall govern use and removal of records and conditions for release of information. Patient's written consent shall be required for release of information not authorized by law. Current service files shall be maintained at the parent or branch office from which the services are provided until the patient is discharged from service. Closed files may be stored away from the parent or branch office provided they can be returned to the office within seventy-two (72) hours. Closed files do not become current service files if the patient is readmitted to service. (*Indiana State Department of Health; 410 IAC 17-15-1*)

SECTION 8. 410 IAC 17-16 IS ADDED TO READ AS FOLLOWS:

Rule 16. Incorporation by Reference

410 IAC 17-16-1 Incorporation by reference

Authority: IC 16-27-1-7

Affected: IC 16-27-1

Sec. 1. Chapter IV(B) of "Core Curriculum on Tuberculosis, Fourth Edition, (2000)" is hereby incorporated by reference. Copies of this publication may be obtained by writing to Technical Information Services, Centers for Prevention Services, Centers for Disease Control, Mail Stop E06, Atlanta, Georgia 30333. Copies may also be obtained from the Indiana State Department of Health, 2 North Meridian Street, Indianapolis, Indiana 46202-3006. (*Indiana State Department of Health; 410 IAC 17-16-1*)

SECTION 9. THE FOLLOWING ARE REPEALED: 410 IAC 17-1.1; 410 IAC 17-2; 410 IAC 17-3; 410 IAC 17-4; 410 IAC 17-5; 410 IAC 17-6; 410 IAC 17-7; 410 IAC 17-8.

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on October 26, 2001 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 new rules to protect the health, safety, and welfare of patients, govern the qualifications of applicants for licenses, govern the operating policies, supervision, and maintenance of service records of home health agencies, and govern the procedure for issuing, renewing, denying, or revoking a license to a home health agency. Repeals 410 IAC 17-1.1, 410 IAC 17-2, 410 IAC 17-3, 410 IAC 17-4, 410 IAC 17-5, 410 IAC 17-6, 410 IAC 17-7, and 410 IAC 17-8. Copies of these rules are now on file at the Health Care Regulatory Services Commission, Indiana State Department of Health, 2 North Meridian Street, Fifth 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