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TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Proposed Rule LSA Document #05-260

DIGEST

Amends 410 IAC 17-10-1, 410 IAC 17-12-1, 410 IAC 17-12-3, 410 IAC 17-13-1, and 410 IAC 17-16-1 and adds 410 IAC 17-13-2 and 410 IAC 17-13-3 to revise the requirements and procedures for home health agencies, add requirements for home health aide registration upon change in employment, increase the annual license fee, and make changes for compliance with P.L.212-2005. Effective 30 days after filing with the Secretary of State.

Description of Rule

The Indiana State Department of Health (ISDH) has statutory responsibility for the licensing and surveying of home health agencies. HEA 1098 (2005) made changes to statutory definitions for home health services and attendant care services. The proposed rule amends the current rule to ensure consistency between the rules and state statute.

HEA 1098 (2005) also required the ISDH to license personal services agencies. The statute mandated an annual license fee of \$250 for personal services agencies and increased the maximum licensing fee for home health agencies from an annual \$200 to an annual \$250. This incremental increase was targeted at offsetting the cost of administering the personal services agency statute in which home health agencies may participate without an additional license. The proposed rule increases the home health agency licensing fee from \$100 to \$250. Because the personal services agency licensing system creates a service plan of care distinct from a nursing plan of care, the proposed home health rule distinguishes between the medical, nursing, and service plans of care.

Economic Impact on Small Businesses

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

IC 4-22-2.1-4 defines a small business as any person, firm, corporation, limited liability company, partnership, or association that:

- (1) is actively engaged in business in Indiana and maintains its principal place of business in Indiana;
- (2) is independently owned and operated;
- (3) employs one hundred (100) or fewer full-time employees; and
- (4) has gross annual receipts of five million dollars (\$5,000,000) or less.

The ISDH licenses 249 home health agencies. The North American Industry Classification System classifies these agencies as Home Health Care Services (NAICS 621610). The ISDH estimates that most of these home health agencies are small businesses as defined by IC 4-22-2.1-4.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

Each agency will incur a statutorily mandated licensing fee increase of \$150 from \$100 to \$250 per annum.

Each agency will incur a cost for the development of a template for new documentation requirements associated with a nurse directed plan of care. The ISDH estimates these costs at eight hours of staff time at \$15/hour amounting to a one-time cost of \$120. This cost could be eliminated if agencies using a home health aide plan of care convert the form to a nurse-directed plan of care. The requirements for a nurse-directed plan are significantly less than those of a medical plan of care.

Agencies currently providing services utilizing only home health aide services must obtain a physician's authorization and complete a full medical plan of care. The form is mailed to physicians for signature (without compensation) and returned to the agency. Many agencies find it necessary to complete this process several times if physicians fail to respond in a timely manner. The implementation of a nurse-directed care plan for these nonskilled services, home health aide only, eliminates the need for the complete medical plan of care and therefore eliminates the process of mailing the plan to a physician and awaiting return mail. Agencies will realize cost reductions proportionate to the number of clients receiving these services. Additionally, physicians will no longer be required to review and sign such plans, thereby reducing demands on their time. As noted, the nurse-directed plan of care carries significantly fewer requirements than the current medical plan of care.

The remaining rule requirements reflect those activities in which agencies are routinely engaged as part of their normal business operations. These areas do not add additional operational expense above the current rule requirements.

The average additional compliance cost beyond the current rule incurred by providers in year one is estimated at \$270 (\$150

increase in license fee and \$120 in one-time costs). The average additional compliance cost beyond the current rule incurred by providers in subsequent years is estimated at the license fee increase of \$150. These costs could be offset in part as described above.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

Based on these above assumptions, cost to the provider industry after year one is approximately \$37,350 annually, which is the increase in the licensure fee.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

Home health agencies provide services to three basic client groups utilizing three categories of personnel as follows:

Clients	Personnel
Skilled services	Physician ordered services provided by a licensed health practitioner and home health aide services under the supervision of the practitioner.
Nonskilled, home health aide services only	No physician oversight. Allowable medical services provided by a qualified home health aide.
Nonskilled, personal services	Services not of a medical nature performed by agency-trained personnel.

In the absence of a nurse directed plan of care, as required by the revised rule, home health aides would be performing medically related services without direction or supervision by a licensed health care practitioner (e.g., nurse-delegated care). The ISDH's mission, in part, is to protect the public health of Indiana residents. The ISDH believes that unsupervised provision of certain medical services is not congruent with the mission and are services beyond the scope of the average layperson. The rule therefore implements a nurse directed plan of care that provides the necessary oversight for personnel performing medical services that have a potential for harm but do not rise to the requirement that a licensed individual, subsequent to a physician's order, perform the services. This process benefits both the agency and referring physicians as noted in section 2, item C, and reduces economic impact.

5. Regulatory Flexibility Analysis

Other factors considered:

A. Establishment of less stringent compliance or reporting requirements for small businesses.

1. Nurse-directed plan of care: As previously stated, the nurse-directed plan of care reduces the burden on both the agency and the physician due to the less stringent requirements than those imposed by the medical plan of care.

2. Tuberculosis testing: The rule reduces the burden on agencies in regards to tuberculosis testing while maintaining patient and personnel safety. The rule permits agencies to accept proof of previous (within the preceding 12 months) TB testing. Prior to the revised rule, agencies were required to test each new employee upon hire regardless of the time interval from a previous test. In line with the Centers for Disease Control and Prevention (CDC) guidelines, which require annual testing for medium risk groups, the ISDH has reduced the testing burden. This change reduces costs to agencies for TB testing.

3. The revised rule permits the department to issue a 90-day provisional license with a possible extension of an additional 90 days. Previously, agencies had a 90-day window in which to demonstrate compliance. The window could be extended in 15-day increments. The 15-day increment schedule increased the burden on agencies to make conforming changes within 10 working days. The 90-day extension provides the agency additional days in which to make the necessary changes.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The rule provides for the use of an acceptable accreditation survey by a recognized accrediting body in lieu of a state survey. Therefore, accredited agencies with acceptable accreditation surveys are not subject to a duplicative state survey.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

See section B.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

The cause under consideration is amendments to existing rules. The implementation of performance standards is at the discretion of the Home Health Services and Hospices Services Council which includes representation from the regulated industry.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

In order to protect all clients utilizing home health care services and provide the noted benefits to each agency, it is necessary that the requirements, as amended, apply to all providers within this industry sector.

Conclusion

The proposed changes, with the exception of the statutorily mandated fee increase, provide the industry with a reduction in costs and lighten the burden necessary for compliance while protecting the health and safety of Indiana residents.

410 IAC 17-10-1

410 IAC 17-12-1

410 IAC 17-12-3

410 IAC 17-13-1
410 IAC 17-13-2
410 IAC 17-13-3
410 IAC 17-16-1

SECTION 1. 410 IAC 17-10-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 17-10-1 Licensure

Authority: IC 16-27-1-7

Affected: IC 12-17-15-3; IC 16-20; IC 16-22-8; IC 25-22.5

Sec. 1. (a) No home health agency shall:

- (1) be opened;
 - (2) **be** operated;
 - (3) **be** managed;
 - (4) **be** maintained; or
 - (5) 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:

- (1) be authorized by the secretary of state to conduct business in Indiana; and
- (2) have a branch office located in Indiana.

(c) Application for a license to operate a home health agency shall be:

- (1) made on a form provided by the department; and ~~shall be~~
- (2) accompanied by a nonrefundable fee of ~~one~~ **two** hundred **fifty** dollars (~~\$100~~): (**\$250**).

(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 names and addresses of** 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:
 - (A) an officer;
 - (B) a director;
 - (C) a managing agent; or
 - (D) a managing employee;

of the home health agency **and evidence supporting the qualifications required by this article.**

(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~~

(4) 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), ~~of this rule~~, and disclosure of ownership and management information, the department may issue a ~~letter of approval for operating a home health agency~~ **provisional license** for a period of ~~up to~~ **ninety (90)** days pending an on-site inspection. In determining whether to issue the ~~letter of approval~~, **provisional license**, 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 **any of the following**:
 - (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. ~~and~~
- (5) Whether an agency owned or operated by the applicant has operated in substantial violation of:

- (A) this rule; or

- (B) 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) **After:**

- (1) the opening of the agency; and**

- (2) before the expiration of the provisional license;**

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(s) 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. **conduct a licensing survey or additional documentation will be requested prior to the end of the provisional period to ensure compliance with this article.**

(g) If the agency is found to be in compliance with this article, the department will issue a full license to operate a home health agency. If the agency is not found to be in compliance with this article, the department may extend the provisional license for ninety (90) days. If the provisional license is extended, a revisit survey may be conducted or additional documentation will be requested before the end of the provisional period to ensure compliance with this article. If the agency is found to be in compliance with this article, the department will issue a full license to operate a home health agency. If the agency is not found to be in compliance with this article after the extended provisional period, the department may do any of the following:

- (1) Request additional information concerning the application.**

- (2) Conduct a further investigation to determine whether a provisional license should be granted.**

- (3) Deny the application.**

~~(g)~~ **(h) In determining whether to issue the initial license to operate a home health agency, the department may consider the following:**

- ~~(1) The factors described under subsection (e). of this rule and~~

- ~~(2) The results of the initial survey.~~

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

~~(i)~~ **(j) In determining whether to renew a license to operate a home health agency, the department may consider the following:**

- ~~(1) The factors described under subsection (e). of this rule and~~

- ~~(2) Any actions pending against the home health agency.~~

~~(j)~~ **(k) In conducting a survey, a surveyor shall receive copies of any and all documents necessary to make a determination of compliance. The surveyor may do either of the following:**

- ~~(1) Make copies with the permission of the home health agency. or~~

- ~~(2) 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)~~ **(l) 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 This 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 [IC 5-2-5 was repealed by P.L.2-2003, SECTION 102, effective July 1, 2003].**

- (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.

~~(h)~~ **(m)** 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:

(A) whose permanent residence is in the patient's residence; or

(B) 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 **(1)** 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.

(11) An entity does not need a home health license to provide early intervention services (as defined in IC 12-17-15-3) to a child pursuant to a state program funded by the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

~~(m)~~ **(n)** Except as provided in 410 IAC 17-11-5, each license shall:

(1) be for a term of one (1) year; and ~~shall~~

(2) 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)~~ **(o)** Each license shall:

(1) be issued only for the home health agency named in the application; and ~~shall~~

(2) 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 before** maintaining, operating, or conducting a home health agency.

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

~~(p)~~ **Surveys (q)** The department may ~~be~~ **conduct**, but ~~are~~ **is** not limited to, the following:

(1) Unannounced **licensing** surveys conducted annually for compliance.

(2) Post survey revisits conducted:

(A) based on a home health agency's plan of correction; and

(B) for the purpose of determining compliance.

(3) Patient care ~~complaints~~ **complaint surveys**.

(r) In the years that a home health agency has an accreditation survey by a body recognized as a home health accrediting agency, the home health agency may submit the accreditation survey report to the department for review and action as follows:

(1) If the department determines that the agency was found to substantially comply with the accreditation standards, the department will accept the report instead of a licensing survey.

(2) If the department determines that the agency failed to significantly comply with the accreditation standards, the department may conduct a licensing survey.

(Indiana State Department of Health; 410 IAC 17-10-1; filed Mar 18, 2002, 3:40 p.m.; 25 IR 2481)

SECTION 2. 410 IAC 17-12-1 IS AMENDED TO READ AS FOLLOWS:

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

Authority: IC 16-27-1-7

Affected: 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:

- (1) clearly set forth in writing; and ~~be~~
- (2) 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 **do the following:**

- (1) Appoint a qualified administrator.
- (2) Adopt and periodically review written bylaws or an acceptable equivalent. ~~and~~
- (3) 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), ~~of this rule~~, 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 **or her** 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 the~~ request or, in the event ~~such a the~~ 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 The~~ 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:

- (1) respond to an emergency;
- (2) provide guidance to staff;
- (3) answer questions; and
- (4) 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 **do the following:**

- (1) Objectively and systematically monitor and evaluate the quality and appropriateness of patient care.
- (2) Resolve identified problems. ~~and~~
- (3) 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 under IC 16-27-2.
- (4) A copy of current license, certification, or registration.
- (5) Annual performance evaluations.

(g) As follows, personnel records of the supervising nurse, appointed pursuant to under subsection (d), of this rule, shall:

(1) Be kept current. and shall

(2) Include a copy of the following:

- (1) (A) Limited criminal history pursuant to under IC 16-27-2.
- (2) (B) Nursing license.
- (3) (C) Annual performance evaluations.
- (4) (D) 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~~ not 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) ensure that all employees, staff members, persons providing care on behalf of the agency, and contractors having direct patient contact are evaluated for tuberculosis and documentation as follows:

(1) Any person with a negative history of tuberculosis or a negative test result must have a baseline two-step tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual has documentation that a tuberculin skin test has been applied at any time during the previous twelve (12) months and the result was negative.

(2) The second step of a two-step tuberculin skin test using the Mantoux method must be administered one (1) to three (3) weeks after the first tuberculin skin test was administered.

(3) Any person with:

(A) a documented:

- (i) history of tuberculosis;
- (ii) previously positive test result for tuberculosis; or
- (iii) completion of treatment for tuberculosis; or

(B) newly positive results to the tuberculin skin test;

must have one (1) chest radiograph to exclude a diagnosis of tuberculosis.

(4) After baseline testing, tuberculosis screening must:

(A) be completed annually; and

(B) include, at a minimum, a tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual was subject to subdivision (3).

(5) Any person having a positive finding on a tuberculosis evaluation may not:

- (A) work in the home health agency; or
- (B) provide direct patient contact;

unless approved by a physician to work.

(6) The home health agency must maintain documentation of tuberculosis evaluations showing that any person:

- (A) working for the home health agency; or
- (B) having direct patient contact;

has had a negative finding on a tuberculosis examination within the previous twelve (12) months.

(j) The information obtained from the:
(1) physical examinations required by subsection (h); ~~of this rule~~ and ~~PPD (mantoux) skin tests~~
(2) **tuberculosis evaluations** and clinical follow-ups required by subsection (i); ~~of this rule~~
must be maintained in separate medical files and treated as confidential medical records, except as provided in subsection (k). ~~of this rule.~~

(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). ~~of this rule.~~
(2) Records of physical examinations that document the agency's compliance with subsection (h). ~~of this rule.~~
(3) Records of ~~PPD (mantoux) skin tests~~; **the results of the skin tests following:**
(A) **Tuberculosis evaluations.**
(B) Appropriate clinical follow-up for positive findings. ~~and~~
(C) Any other records that document the home health agency's compliance with subsection (i). ~~of this rule.~~

(l) The department shall:
(1) treat the information described in subsection (k) ~~of this rule~~ as confidential medical records; and
(2) 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; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2483*)

SECTION 3. 410 IAC 17-12-3 IS AMENDED TO READ AS FOLLOWS:

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:~~ **and shall do the following:**

(1) ~~The home health agency shall~~ Provide the patient with a written notice of the patient's right:
(A) in advance of furnishing care to the patient; or
(B) 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 **the following:**
(A) Have his or her property treated with respect.
(~~3~~) ~~The patient has the right to~~ (B) 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~~ (C) Place a complaint with the department regarding treatment or care furnished by a home health agency.
(~~5~~) ~~The patient has the right to~~ (D) Be informed about the care to be furnished and of any changes in the care to be furnished as follows:

(~~A~~) (i) The home health agency shall advise the patient in advance of the:
(AA) disciplines that will furnish care; and ~~the~~
(BB) frequency of visits proposed to be furnished.
(~~B~~) (ii) 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 following:**
(AA) The care or treatment. ~~and in planning~~
(BB) Changes in the care or treatment.
(~~C~~) (iii) 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~~ **(E) 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) (3)~~ The patient or patient's legal representative ~~have~~ **has** 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) (4)~~ The patient has the right to be **as follows:**

~~(A)~~ Free from verbal, physical, and psychological abuse. ~~and to be~~

~~(B)~~ Treated with dignity.

(c) The home health agency shall **do the following:**

(1) Investigate complaints made by a patient or the patient's family or legal representative regarding **either of the following:**

(A) Treatment or care that is (or fails to be) furnished. ~~or regarding~~

(B) The lack of respect for the patient's property by anyone furnishing services on behalf of the home health agency. ~~and shall~~

(2) 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, **in effect on July 1, 2005.**

(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; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2486)*

SECTION 4. 410 IAC 17-13-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 17-13-1 Medical plan of care

Authority: IC 16-27-1-7

Affected: 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) As follows, the medical plan of care shall:

~~(A)~~ Be developed in consultation with the home health agency staff. ~~and shall~~

(B) Include all services to be provided if a skilled service is being provided.

~~(C)~~ Cover all pertinent diagnoses. ~~and~~

~~(D)~~ Include the following:

~~(A)~~ **(i)** Mental status.

~~(B)~~ **(ii)** Types of services and equipment required.

~~(C)~~ **(iii)** Frequency and duration of visits.

~~(D)~~ **(iv)** Prognosis.

~~(E)~~ **(v)** Rehabilitation potential.

~~(F)~~ **(vi)** Functional limitations.

~~(G)~~ **(vii)** Activities permitted.

~~(H)~~ **(viii)** Nutritional requirements.

~~(I)~~ **(ix)** Medications and treatments.

~~(J)~~ **(x)** Any safety measures to protect against injury.

~~(K)~~ **(xi)** Instructions for timely discharge or referral.

~~(L)~~ **(xii)** Therapy modalities specifying length of treatment.

~~(M)~~ **(xiii)** 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:

- (A) physician;
- (B) dentist;
- (C) chiropractor;
- (D) optometrist; or
- (E) 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 following:**

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

(c) All orders issued by:

- (1) a physician;
- (2) a dentist;
- (3) a chiropractor;
- (4) a podiatrist; or
- (5) 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; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2486)*

SECTION 5. 410 IAC 17-13-2 IS ADDED TO READ AS FOLLOWS:

410 IAC 17-13-2 Nurse directed plan of care

Authority: IC 16-27-1-7

Affected: IC 25

Sec. 2. (a) A nurse directed plan of care must be developed by a registered nurse for the purpose of delegating nursing directed patient care provided through the home health agency for patients receiving only home health aide services in the absence of a skilled service.

(b) The nurse directed plan of care must contain the following:

- (1) A plan of care and appropriate patient identifying information.**
- (2) The name of the patient's physician.**
- (3) Services to be provided.**
- (4) The frequency and duration of visits.**
- (5) Medications, diet, and activities.**
- (6) Signed and dated clinical notes from all personnel providing services.**
- (7) Supervisory visits.**
- (8) Sixty (60) day summaries.**
- (9) The discharge note.**
- (10) The signature of the registered nurse who developed the plan.**

(Indiana State Department of Health; 410 IAC 17-13-2)

SECTION 6. 410 IAC 17-13-3 IS ADDED TO READ AS FOLLOWS:

410 IAC 17-13-3 Service plan

Authority: IC 16-27-1-7

Affected: IC 16-27-4; IC 25

Sec. 3. (a) This section shall apply to services that are performed by a personal services agency under IC 16-27-4 that is operated under a home health agency license, which include, but are not limited to, any of the following:

(1) Homemaker services, including the following:

- (A) Shopping.**
- (B) Laundry.**
- (C) Cleaning.**
- (D) Seasonal chores.**

(2) Companion type services, including the following:

- (A) Transportation.**
- (B) Letter writing.**
- (C) Mail reading.**
- (D) Escort services.**

(3) Assistance with cognitive tasks, including the following:

- (A) Managing finances.**
- (B) Planning activities.**
- (C) Making decisions.**

(4) Attendant care services.

(5) Any other services for which an individual:

- (A) license;**
- (B) certification;**
- (C) registration; or**
- (D) permit;**

is not required under state law.

(b) The personal services agency's manager or the manager's designee shall prepare a service plan for a client before providing personal services for the client. A permanent change to the service plan requires a written change to the service plan. The service plan must:

- (1) be in writing, dated, and signed by the individual who prepared it;**
- (2) list the types and schedule of services to be provided; and**
- (3) state that the services to be provided to the client are subject to the client's right to:**

- (A) temporarily suspend;**
- (B) permanently terminate;**
- (C) temporarily add; or**
- (D) permanently add;**

the provision of any service.

(c) All permanent changes require a change in the written service plan. The service plan must be signed and dated by the client not later than fourteen (14) days after:

- (1) services begin for the client; and**
- (2) any permanent change to the service plan.**

(d) Personal care services provided by a personal services agency operated under a home health agency license must meet the requirements of IC 16-27-4. (Indiana State Department of Health; 410 IAC 17-13-3)

SECTION 7. 410 IAC 17-16-1 IS AMENDED TO READ AS FOLLOWS:

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 (a) **When used in this article, references to the following publication shall mean the version of that publication listed and are hereby incorporated by reference:**

- (1) 42 CFR 420.201 (July 1, 2005 edition).
- (2) 42 CFR 420.202 (July 1, 2005 edition).
- (3) 42 CFR 420.206 (July 1, 2005 edition).

(b) **Federal rules that have been 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 do not include any later amendments than those specified in the incorporated citation. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. All incorporated material is available for public review at the department of Health, 2 North Meridian Street, Indianapolis, Indiana 46202-3006. (Indiana State Department of Health; 410 IAC 17-16-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2489)

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on May 3, 2006 at 1:30 p.m., at the Indiana State Department of Health, 2 North Meridian Street, Yoho Board Room, Third Floor, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on a proposed amendment to 410 IAC 17 to revise the requirements and procedures for home health agencies, add requirements for home health aide registration upon change in employment, increase the annual license fee, and make changes for compliance with P.L.212-2005.

These rules are designed to comply with the changes made by P.L.212-2005.

Copies of these rules are now on file at the Health Care Regulatory Commission at the Indiana State Department of Health, 2 North Meridian Street and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Sue Uhl
Deputy State Health Commissioner
Indiana State Department of Health