

TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Final Rule
LSA Document #17-483(F)

DIGEST

Amends 410 IAC 17-10-1 and 410 IAC 17-12-1 pursuant to P.L.51-2016, which changed the criminal history background check requirements for home health agencies. Effective 30 days after filing with the Publisher.

410 IAC 17-10-1; 410 IAC 17-12-1

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 10-13-3; IC 16-20; IC 16-22-8; IC 16-27-1; IC 25-22.5; IC 27-8-27-1

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
- (2) accompanied by a nonrefundable fee of two hundred fifty dollars (\$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) All persons having at least five percent (5%) ownership or controlling interest in the home health agency.
- (2) 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 corporation, association, or other company that is responsible for the management of the home health agency.

(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), and disclosure of ownership and management information, the department may issue a provisional license for a period of ninety (90) days pending an on-site inspection. In determining whether to issue the 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.
- (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:

- (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 the opening of the agency and before the expiration of the provisional license the department may 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.

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

(i) The full license shall relate back to and reflect the date of the first day of the first provisional license issued by the department.

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

(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.
- (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.

(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. This documentation includes, but is not limited to, the following:

- (1) Personnel qualifications and licensing.
- (2) ~~Limited Employee's national criminal history from the Indiana central repository established by IC-10-13-3.~~ **background check or expanded criminal history check.**
- (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.

(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 27-8-27-1) to a child pursuant to a state program funded by the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

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

- (1) be for a term of one (1) year; and
- (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.

- (o) Each license shall:
 - (1) be issued only for the home health agency named in the application; and
 - (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 before maintaining, operating, or conducting a home health agency.

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

- (q) The department may conduct, but 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 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; filed Sep 26, 2006, 9:56 a.m.: 20061025-IR-410050260FRA; errata filed Nov 8, 2006, 1:55 p.m.: 20061122-IR-410050260ACA; readopted filed Jul 14, 2008, 2:14 p.m.: 20080806-IR-410080322RFA; readopted filed Sep 10, 2014, 2:08 p.m.: 20141008-IR-410140299RFA)

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
- (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.
- (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), 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 the request or, in the event 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. 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.
- (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 under IC 16-27-2.~~ **an employee's national criminal history**

background check or expanded criminal history check.

- (4) A copy of current license, certification, or registration.
- (5) Annual performance evaluations.

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

- (1) Be kept current.
- (2) Include a copy of the following:
 - (A) ~~Limited criminal history under IC 16-27-2.~~ **National criminal history background check or expanded criminal history check.**
 - (B) Nursing license.
 - (C) Annual performance evaluations.
 - (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 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 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); and

(2) tuberculosis evaluations 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 the following:

(A) Tuberculosis evaluations.

(B) Appropriate clinical follow-up for positive findings.

(C) Any other records that document the home health agency's compliance with subsection (i).

(l) The department shall:

(1) treat the information described in subsection (k) 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; filed Sep 26, 2006, 9:56 a.m.: 20061025-IR-410050260FRA; errata filed Nov 8, 2006, 1:55 p.m.: 20061122-IR-410050260ACA; readopted filed Jul 14, 2008, 2:14 p.m.: 20080806-IR-410080322RFA; readopted filed Sep 10, 2014, 2:08 p.m.: 20141008-IR-410140299RFA*)