

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Health Care
(Amendment)

902 KAR 20:370. Operations and services; private duty nursing agencies.

RELATES TO: KRS 2.015, 216B.020, [~~216B.010, 216B.015, 216B.040, 216B.042, 216B.045-216B.055, 216B.075, 216B.105-216B.131, 216B.990, 311.560(4), 314.011(8),~~] 314.041, 314.051, 45 C.F.R. Parts 160, 164, 42 U.S.C. 1320d-2 - 1320d-8

STATUTORY AUTHORITY: KRS 216B.042(1)

NECESSITY, FUNCTION AND CONFORMITY: KRS 216B.042(1) requires the [Kentucky] Cabinet for Health and Family Services to promulgate administration regulations necessary for the proper administration of the licensure function and establish licensure standards to ensure safe, adequate, and efficient[regulate] health facilities and health services. This administrative regulation establishes minimum licensure requirements for the operation of[,] and[nursing] services provided by[,] private duty nursing agencies.

Section 1. Definitions. (1) ~~["Agency" means a private duty nursing agency.~~

~~(2) "Governing authority" or "licensee" means the individual, agency, partnership, or corporation, in which the ultimate responsibility and authority for the conduct of the institution is vested.~~

~~(3) "License" means an authorization issued by the cabinet for the purpose of operating a private duty nursing agency. (4) "Licensed practical nurse" or "LPN" means a person licensed pursuant to KRS 314.051.~~

~~(5) "Private duty nursing agency" means a public or private organization, including any partnership, corporation, or other legal entity, that provides or arranges for the provision of private duty nursing services.~~

(2) "Private duty nursing services" means the delivery of skilled nursing services as defined by subsection (3) of this section to a patient who has a medically predictable, recurring need for services on a continuous basis rather than part-time or short-term intermittent nursing care.

(3) "Skilled nursing services" means the delivery of nursing care to a patient of a private duty nursing agency that:

(a) Exceeds the level of routine health monitoring;

(b) Is clinically appropriate;

(c) Is subject to:

1. A nursing reassessment no less than every ninety (90) days; and

2. Frequent changes in the plan of treatment;

(d) Is based on the expectation that the service will improve, restore, or maintain function, or slow the patient's decline of the disease or functional ability; and

(e) Includes skilled interventions provided directly by a licensed nurse. Examples of skilled interventions may include:

1. Bowel and bladder care;

2. Administering medications or oxygen;

3. Treating decubitus ulcers or other types of wound care; or

4. Ventilation care.[an entity in the business of providing licensed nursing care to a patient in his or her home for a continuous block of time, in increments of at least four (4) hours, in which the private duty nursing agency supervises nursing care provided by agency personnel. It shall not include a registered nurse providing nursing services as an independent practitioner.

~~(6) "Registered nurse" or "RN" means a person licensed pursuant to KRS 314.041.]~~

Section 2. Scope. (1) Private duty nursing services shall be:

(a) Ordered and directed by the treating practitioner or specialist after a face-to-face evaluation of the patient;

(b) Provided by:

1. A registered nurse (RN) licensed in accordance with KRS 314.041; or

2. A licensed practical nurse (LPN) licensed in accordance with KRS 314.051; and

(c) Provided to a patient in his or her temporary or permanent place of residence or other community-based setting, including:

1. The patient's home; or

2. Outside of the patient's home, as necessitated by normal life activities.

(2) A private duty nursing agency shall not include:

(a) A registered nurse who provides nursing services as an independent practitioner; or

(b) An entity that seeks certification under Title XVIII of the Social Security Act.

Section 3. Administration. (1) The licensee shall be legally responsible for:

(a) The operation of the private duty nursing agency; and

(b) [Have legal responsibility for the service and for] Compliance with [relevant] federal, state, and local laws and administrative regulations pertaining to the operation of the agency.

(2) The licensee shall:

(a) [law;

(b)] Establish lines of authority;

(b) [and

(c)] Designate an administrator who shall be responsible for the daily operation of the agency;

(c) [-

(2) Policies. The licensee shall] Establish and implement [enforce] written administrative policies covering all aspects of operation, including:

1. [(a)] A description of the agency's organizational structure, staffing, and allocation of responsibility and accountability;

2. [(b) A description of linkages with inpatient facilities and other providers; (c)] Policies and procedures for the evaluation [guidance and control] of personnel performance;

3. [(d)] A narrative describing in detail:

a. [1.] The services offered by the agency; and

b. [2.] Methods and protocols for service delivery; and

3.] Qualifications of personnel involved in the delivery of services [the service];

(d) Establish [(e) A description of the administrative and patient care records and reports; (f)] procedures for [to be followed in] the handling and administration of drugs and biologicals; and

(e) Maintain policies regarding the delivery and supervision of [(g)] patient care that shall:

1. Be [policies] developed by [with the advice of] a group of professional health providers, including at least one (1) [or more] physician and one (1) [or more] registered nurse; and

2. [, and shall] Include the following:

a. [1.] A description of the services provided;

b. [2.] A requirement for a written [nursing care] plan of treatment for each [a] patient who receives private duty nursing services;

c. [3.] Guidelines to ensure coordination of treatment with other [licensed] health facilities and practitioners that deliver services to patients of the agency [care providers servicing a patient];

- d.[4.] Guidelines for the medical management of health problems, including [a. the] conditions that require[requiring] medical consultation or patient referral;
- e.[and b. Maintenance of health records; 5.] Procedures for the annual review and evaluation of the services provided;
- f.[6.] Guidelines for patient and environment assessment; and
- g.[7.] Guidelines to ensure that a patient is receiving adequate services for assistance with daily living activities.

Section 4. [(3)] Personnel. (1) Each private duty nursing agency [(a) Medical director. The agency] shall have:

(a) A medical director who is:[shall be:]

- 1. A Kentucky-licensed physician with specialized training and experience in medical services provided by the agency; and
- 2. Responsible for medical aspects of medical services provided by the agency; and[-]
- (b)[The agency shall provide] Adequate staffing to provide for effective patient care[;] in accordance with the terms and conditions of the contract with the patient.

(2) Each private duty nursing agency's[(c) The licensee shall provide] written personnel policies[, which] shall be:

- (a)[1.] Available to each employee;
- (b)[2.] Reviewed on an annual basis; and
- (c)[3.] Revised as necessary.

(3)[(d)] There shall be a written job description for each position that[, which] shall be reviewed and revised as necessary.

(4)[(e)] There shall be an employee health and infection control program, including tuberculosis screening and[with provisions for tuberculin] testing in accordance with 902 KAR 20:205[and titers necessary to the nursing service to be performed].

(5)[(f)] The private duty nursing agency[licensee] shall maintain a current personnel record for each employee, including:

(a)[- Data maintained shall include:

- 1. Name, address and Social Security number;
- 2.] Evidence of each employee's current registration, certification, or licensure, if applicable;

(b) Documentation of the employee's[3. Records of] training and experience;

(c) Evidence of an annual[4. Records of] performance evaluation;

(d) Documentation of compliance with the agency's health and infection control program;

(e) A[5. Current negative tuberculin skin test or chest x-ray for an employee having direct contact with a patient; and

6.] preemployment background check in which the agency shall not employ an individual in a position that involves providing direct services if the individual:

1. Is listed on the:

a. Nurse aide or home health aide abuse registry pursuant to 906 KAR 1:100; or

b. Caregiver misconduct registry pursuant to 922 KAR 5:120; or

2. Has a conviction of, or a plea of guilty, an Alford plea, or a plea of nolo contendere to:

a. A felony offence that is related to:

(i) Theft;

(ii) Abuse, possession, or sale of illegal drugs;

(iii) Abuse, neglect, or exploitation of a child or an adult; or

(iv) A sexual crime; or

b. A misdemeanor offense related to abuse, neglect, or exploitation of an adult; and

(f) Evidence of orientation and, if needed, on-the-job training related to the employee's job

~~responsibilities~~~~[criminal conviction information for private duty nursing agency personnel who provide nursing care to a patient in his or her home].~~

~~(6)~~~~(g)~~ An employee ~~with~~~~[of the program who has]~~ direct patient care responsibilities shall have current cardiopulmonary resuscitation (CPR) certification from~~[either]~~ the American Heart Association, ~~[or the]~~ American Red Cross, or equivalent.

Section 5. Patient Records. (1) Each private duty nursing agency shall maintain a clinical record for each patient that includes:

~~(a) Pertinent past and current~~~~(h) In-service training. An employee shall participate in ongoing in-service training programs relating to the employee's job activities.~~

~~(4) Medical records.~~

~~(a) The service shall maintain a medical record for each patient, to include the following:~~

~~1.] medical, nursing, and social history~~~~[relevant to the service provided], including information obtained~~~~[data obtainable] from other providers;~~

~~(b)~~~~[2.] Name of the referring physician, or other ordering practitioner, if any, acting within the statutory scope of practice;~~

~~(c)~~~~[3.] Orders of the referring physician, or other ordering practitioner, if any, acting within the statutory scope of practice;~~

~~(d)~~~~[4.] Description of each contact, including the:~~

~~1.~~~~[a.] Condition or reason necessitating contact;~~

~~2.~~~~[b.] Assessment;~~

~~3.~~~~[c.] Service provided;~~

~~4.~~~~[d.] Medication and treatment prescribed; and~~

~~5.~~~~[e.] Disposition made; and~~

~~(e)~~~~[5.] Documentation of referrals made, including:~~

~~1.~~~~[a.] Reason for referral;~~

~~2.~~~~[b.] To whom the patient was referred; and~~

~~3.~~~~[c.] Information obtained from a referral source.~~

~~(2) Ownership.~~

~~(a) Medical records shall be the property of the private duty nursing agency.~~

~~(b) The original medical record shall not be removed except by court order.~~

~~(c) Copies of medical records or portions thereof may be used and disclosed in accordance with the requirements established in this administrative regulation.~~

~~(3) Confidentiality and Security: Use and Disclosure.~~

~~(a) The agency shall maintain the confidentiality and security of patient records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, as amended, including the security requirements mandated by subparts A and C of 45 C.F.R. Part 164, or as provided by applicable federal or state law.~~

~~(b) The private duty nursing agency may use and disclose patient records. Use and disclosure shall be as established or required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, or as established in this administrative regulation.~~

~~(c) A private duty nursing agency may establish higher levels of confidentiality and security than those required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164.~~~~(b) Confidentiality of patient records shall be maintained at all times.~~

~~(c) Transfer of records. If the patient moves to another source of care, the agency shall:~~

~~1. Establish systematic procedures to assist in continuity of care; and~~

~~2. Transfer medical records if requested and upon the agency receiving a release signed by the patient or the patient's agent.]~~

(d) Retention of records.~~[4.] After a patient's~~~~[the]~~ death or discharge ~~[of an adult patient]~~, the completed medical record shall be placed in an inactive file and:

1. Retained for six (6)~~[five (5)]~~ years; or

2.~~[After the death or discharge of a minor patient, the record shall be placed in an inactive file and retained for five (5) years from the date of the event, or]~~ Three (3) years after the patient reaches the age of majority in accordance with KRS 2.015, whichever is longer.

~~(4)~~~~(e)~~ The agency shall:

(a) Designate a specific location for the maintenance and storage of the agency's medical records;

~~(b)~~~~(f)~~ ~~The agency shall]~~ Have provisions for storage of medical records in the event the agency ceases to operate; and

~~(c)~~~~(g)~~ ~~The licensee shall]~~ Safeguard the record and its content against loss, defacement, or tampering.

Section 6. Private Duty~~[3.] Nursing Services~~~~[Provided by Private Duty Nursing Agencies].~~

(1) A private duty nursing agency shall develop~~[Nursing services provided by a private duty nursing agency, if ordered by a physician or other ordering practitioner acting within the statutory scope of practice, shall be provided in accordance with]~~ a plan of treatment for each patient receiving private duty nursing services.

(2)~~(a)~~ The plan of treatment shall be developed in consultation with the:

(a) Prescribing practitioner;

(b)~~(c)~~ Agency personnel~~;~~] and

(c)~~(d)~~ Patient, patient's family~~]~~, family member, or patient's responsible party.

(3)~~(b)~~ The plan of treatment shall be reviewed:

(a) By the ordering practitioner in consultation with:

1. Agency personnel; and

2. The patient, patient's family member, or patient's responsible party; and~~(c)~~

(b) At~~(e)~~ intervals as the severity of the patient's illness requires~~(f)~~] or at least once every two (2) months.

(4) Services~~(2) Each private duty nursing agency service]~~ shall be nonabusive and provided in a manner that~~(which)~~ ensures the greatest amount of safety and security for the patient.

(5)~~(3)~~ Private duty nursing agency personnel shall ensure that medical waste generated as a result of a service shall be removed from a patient's home and disposed of properly.

Section 7. Licensure. Within ninety (90) days from the effective date of this administrative regulation, the cabinet shall:

(1) Convert any licensed home health agency that is not certified under Title XVIII of the Social Security Act to a licensed private duty nursing agency; and

(2) Not require approval of a new certificate of need to convert an existing home health agency license to a private duty nursing license.~~[Section 4. Licensing Procedures. (1) Initial licensure.~~

~~(a) A private duty nursing agency applying for a license to operate shall return a completed L&R 144 to the Office of Inspector General along with the initial licensing fee of \$134.~~

~~(a) The Office of the Inspector General shall conduct an initial licensing inspection pursuant to 902 KAR 20:008.~~

~~(2) Relicensure. Prior to the date that the license to operate expires, a private duty nursing agency shall send a completed L&R 144 to the Office of the Inspector General along with the annual relicensure fee of \$134.~~

Section 5. Incorporation by Reference. (1) "Form L&R 144, Application for a License to Op-

~~erate a Health Facility or Service, January 2001 edition" is incorporated by reference.~~

~~(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of the Inspector General 275 East Main Street, Fifth Floor East, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.]~~

STEVEN D. DAVIS, Inspector General

ADAM M. MEIER, Secretary

APPROVED BY AGENCY: July 2, 2019

FILED WITH LRC: July 11, 2019 at 2 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on August 26, 2019, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by August 19, 2019, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until August 31, 2019. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. In accordance with KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Chase Coffey, Executive Administrative Assistant, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; Phone: 502-564-6746; Fax: 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Stephanie Brammer-Barnes, email: stephanie.brammer@ky.gov., Phone: 502-564-2888; and Chase Coffey

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes minimum licensure requirements for the operation of and services provided by private duty nursing agencies.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with KRS 216B.042, which requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, including licensure standards and procedures to ensure safe, adequate, and efficient health services.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.042 by establishing standards for licensed private duty nursing agencies.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing standards for licensed private duty nursing agencies.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment

changes the existing administrative regulation as follows:

Updates the definition of "private duty nursing agency" and adds definitions for the terms "private duty nursing services" and "skilled nursing services";

Clarifies that a private duty nursing service is skilled nursing care to a patient who has a medically predictable, recurring need for services on a continuous basis rather than part-time or intermittent nursing care;

Removes the requirement for private duty nursing services to be provided to patients for no less than four (4) hours per visit;

Requires private duty nursing services to be ordered and directed by the treating practitioner or specialist after a face-to-face evaluation of the patient;

Clarifies that a private duty nursing agency must provide services to a patient only in community-based settings such as the patient's temporary or permanent place of residence, including the patient's home or outside the patient's home, as necessitated by normal life activities;

Clarifies that private nursing agencies cannot seek Medicare-certification;

Eliminates the requirement for a description of linkages with inpatient facilities and other providers;

Eliminates the requirement for a description of the agency's methods and protocols for service delivery because such is unnecessary as the Kentucky Board of Nursing establishes nursing guidelines;

Establishes a prohibition against employment if a prospective employee is found on the nurse aide or home health aide abuse registry or caregiver misconduct registry, or has certain criminal convictions;

Requires compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA);

Requires currently licensed home health agencies that are not Medicare-certified to convert to licensure as a private duty nursing agency within ninety (90) days of the effective date of this administrative regulation, thereby ensuring compliance with the definition of "home health agency" which is established by KRS 216.935(2) and requires licensed home health agencies to be Medicare-certified; and

Makes technical changes for compliance with KRS Chapter 13A to improve clarity and flow.

(b) The necessity of the amendment to this administrative regulation: Because home health agencies have historically been designed as a model of care for elderly Medicare beneficiaries and other patients who need only part-time or intermittent nursing care, the home health agency model is not well-suited for the kind of on-going care required by adults and children with disabilities or patients who otherwise have a medically predictable, recurring need for services on a continuous basis. This amendment is therefore necessary to ensure adequate access to skilled nursing services for patients who need these services to continue living at home. In addition to the delivery of skilled nursing care that is more than part-time or intermittent, private duty nursing agencies are distinguishable from home health agencies as follows:

Private duty nursing agencies are prohibited from obtaining Federal certification under Title XVIII of the Social Security Act while home health agencies are required by state law to be Medicare-certified pursuant to KRS 216.935(2); and

The delivery of skilled nursing services by private duty nursing agencies must be subject to nursing reassessments no less than every ninety (90) days as well as subject to frequent changes in the plan of treatment.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of KRS 216B.042 by establishing standards for licensed private duty nursing agencies.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will assist in the effective administration of the statutes by establishing standards for licensed private duty nursing agencies.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation impacts private duty nursing agencies. There are currently fourteen (14) licensed private duty nursing agencies in Kentucky.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Licensed private duty nursing agencies:

Will no longer be required to provide services for at least four (4) hours per visit;

Must ensure that the care delivered to patients is skilled nursing care as ordered and directed by the treating practitioner or specialist;

Must conduct a nursing reassessment no less than every ninety (90) days;

Must have an administrator responsible for the daily operation of the facility and have a physician medical director;

Must establish and implement written administrative policies covering all aspects of operation;

Must have adequate staffing to provide for effective patient care;

Must ensure that employees with direct patient care responsibilities have current cardiopulmonary resuscitation certification;

Must comply with the preemployment screening requirements;

Must maintain patient records as established by this administrative regulation; and

Must develop a plan of treatment for each patient in consultation with the prescribing practitioner, agency personnel, and patient or patient's responsible party.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No additional costs will be incurred to comply with this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The licensure of private duty nursing agencies helps ensure that there is adequate access to skilled nursing services provided to people who require more than part-time or intermittent nursing care, including people with disabilities or individuals who otherwise have a medically predictable, recurring need for skilled services on a continuous basis.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs to the cabinet for implementation of this administrative regulation.

(b) On a continuing basis: There are no additional costs to the cabinet for implementation of this administrative regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State general funds and agency monies are used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary to implement this amendment.

(8) State whether or not this administrative regulation established any fees or directly or indi-

rectly increased any fees: This amendment does not establish or increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts private duty nursing agencies and the Cabinet for Health and Family Services, Office of Inspector General.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.042(1)

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate any additional revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not general any additional revenue.

(c) How much will it cost to administer this program for the first year? This amendment imposes no additional costs on the administrative body.

(d) How much will it cost to administer this program for subsequent years? This amendment imposes no additional costs on the administrative body.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: