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TITLE 856 INDIANA BOARD OF PHARMACY

Proposed Rule LSA Document #05-139

DIGEST

Adds 856 IAC 1-39 to implement rules based on Senate Enrolled Act 206 (P.L.122-2005) to establish the definitions, requirements for the licensure of home medical equipment services providers, license renewal requirements, fees including fees for the application, issuance, and renewal of license, and standards regarding the safety and quality of home medical equipment services. Effective 30 days after filing with the Secretary of State.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

Estimated Number of Small Businesses Subject to This Rule:

Industry Sector 532291 Home Health Equipment Rental

Industry Sector 621610 Home Health Care Services

The Indiana Board of Pharmacy ("Board") estimates that some small businesses will be directly affected by this rule. The Indiana Board of Pharmacy has the authority to promulgate rules in accordance with the requirements of SEA 206 (P.L.122-2005), including specifying which home medical equipment is to be regulated; setting standards for licensure of providers; specifying the governing safety and quality of home medical equipment services that are to be provided to customers; specifying the amount of insurance coverage; and setting reasonable fees for the application, issuance, and renewal of a license. The proposed rule is needed as a matter of consumer protection to assure that the citizens of Indiana are receiving Home Medical Equipment Services from qualified, established providers. The technological advances in HME services demands there be some method for the state to verify that providers of such service are competent and available for education, service, and repair. This will, also, provide another avenue for the government to control fraud and abuse. This proposed rule will have the following cost on the regulated entities:

- There are approximately 300 home medical equipment service providers \times \$150 issuance fee = \$45,000.
 - There are approximately 300 of home medical equipment service providers \times \$200 renewal = \$60,000.
 - The cost of insurance coverage home medical equipment service providers are required to obtain and maintain = \$300,000.
- However, this is a requirement for Medicare, not specifically for this rule. The Board is incorporating the Medicare requirements into our rule.

Estimated Average Annual Administrative Costs That Small Businesses Will Incur:

The Board estimates that there will be no annual reporting, record keeping, or administrative costs incurred by small businesses to comply with this rule.

Estimated Total Annual Economic Impact on Small Businesses:

The Board estimates that there will be an impact on small businesses as a result of compliance with this rule.

- Justification of Requirements or Costs on Small Businesses Where Rule Is Not Expressly Required by Law: There are compliance costs on small business because home medical equipment service providers will be required to obtain and maintain liability insurance. The requirements on small business is justified as a matter of consumer protection to assure that the citizens of Indiana are receiving home medical equipment services from qualified, established providers. The technological advances in home medical equipment services demands there be some method for the state to verify that providers of such service are competent and available for education, service, and repair. This will, also, provide another avenue for the government to control fraud and abuse.
- Supporting Data, Studies, or Analyses: The Board has relied on information provided by the Association of Indiana Home Medical Equipment Services.

Regulatory Flexibility Analysis of Alternative Methods:

The new proposed rule found in this proposed rule was mandated by P.L.122-2005 (SEA 206-2005); therefore, the Board has not analyzed alternatives to this proposed rule.

- Explanation of Preliminary Determination: The General Assembly required the Board to enact and establish these rules, and thus the Board did not explore alternative measures.
- Supporting Data, Studies, or Analyses: The Board did not rely on any studies in its decision not to employ alternatives to rulemaking.

856 IAC 1-39

SECTION 1. 856 IAC 1-39 IS ADDED TO READ AS FOLLOWS:

Rule 39. Home Medical Equipment Service Providers

856 IAC 1-39-1 “Board” defined

Authority: IC 25-26-21-7

Affected: IC 25-26-21-1

Sec. 1. As used in this rule, “board” has the meaning set forth in IC 25-26-21-1. *(Indiana Board of Pharmacy; 856 IAC 1-39-1)*

856 IAC 1-39-2 “DMEPOS” defined

Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 2. As used in this rule, “DMEPOS” means durable medical equipment, prosthetics, orthotics, and supplies. *(Indiana Board of Pharmacy; 856 IAC 1-39-2)*

856 IAC 1-39-3 “Home medical equipment” defined

Authority: IC 25-26-21-7

Affected: IC 25-26-21-2

Sec. 3. As used in this rule, “home medical equipment” has the meaning set forth in IC 25-26-21-2. The term also includes the following:

- (1) Continuous passive motion (CPM) machines.
- (2) Patient lift devices.
- (3) Defibrillators.
- (4) Manual wheelchairs.
- (5) Hospital bed accessories.
- (6) Electronically controlled or computerized wheel chairs and seating systems that are sold.

(Indiana Board of Pharmacy; 856 IAC 1-39-3)

856 IAC 1-39-4 “Home medical equipment services” defined

Authority: IC 25-26-21-7

Affected: IC 25-26-21-3

Sec. 4. As used in this rule, “home medical equipment services” has the meaning set forth in IC 25-26-21-3. *(Indiana Board of Pharmacy; 856 IAC 1-39-4)*

856 IAC 1-39-5 “Licensee” defined

Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 5. As used in this rule, “licensee” means the holder of a home medical equipment service provider license issued under IC 25-26-21 and this title. *(Indiana Board of Pharmacy; 856 IAC 1-39-5)*

856 IAC 1-39-6 “Provider” defined

Authority: IC 25-26-21-7

Affected: IC 25-26-21-4

Sec. 6. As used in this rule, “provider” has the meaning set forth in IC 25-26-21-4. *(Indiana Board of Pharmacy; 856 IAC 1-39-6)*

856 IAC 1-39-7 Fees

Authority: IC 25-1-8-2; IC 25-26-21-7

Affected: IC 25-26-21

Sec. 7. (a) The fee for an original licensure application shall be:

(1) one hundred fifty dollars (\$150); and

(2) paid at the time of filing the initial application.

(b) The fee for a biennial renewal shall be:

(1) two hundred dollars (\$200); and

(2) paid at the time of license renewal.

(Indiana Board of Pharmacy; 856 IAC 1-39-7)

856 IAC 1-39-8 Renewal

Authority: IC 25-1-8-2; IC 25-26-21-7

Affected: IC 25-26-21

Sec. 8. Home medical equipment service provider licenses shall expire on December 31 of each odd-numbered year. *(Indiana Board of Pharmacy; 856 IAC 1-39-8)*

856 IAC 1-39-9 Proof of insurance

Authority: IC 25-1-8-2; IC 25-26-21-7

Affected: IC 25-26-21

Sec. 9. Before being issued a license, each home medical equipment service provider shall obtain and maintain comprehensive business and liability insurance, consistent with minimum Medicare DMEPOS Supplier Standards. *(Indiana Board of Pharmacy; 856 IAC 1-39-9)*

856 IAC 1-39-10 Oxygen and related respiratory services

Authority: IC 25-26-21-7

Affected: IC 25-26-21; IC 25-34.5

Sec. 10. In order to provide oxygen and related respiratory services, each licensee shall employ or contract with:

(1) a respiratory care practitioner licensed under IC 25-34.5; or

(2) another duly licensed health professional with education and training in oxygen and related respiratory services.

(Indiana Board of Pharmacy; 856 IAC 1-39-10)

856 IAC 1-39-11 Training

Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 11. (a) Each licensee shall conduct and document training for each employee:

(1) at the time of hire; and

(2) annually.

(b) Documentation of training shall be readily available for inspection.

(c) Training programs:

(1) shall be conducted according to industry standards; and

(2) may be subject to board approval.

(Indiana Board of Pharmacy; 856 IAC 1-39-11)

856 IAC 1-39-12 Patient records

Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 12. Each licensee shall maintain patient records, relevant to services rendered, in accordance with state and federal guidelines. (Indiana Board of Pharmacy; 856 IAC 1-39-12)

856 IAC 1-39-13 Equipment maintenance

Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 13. Each licensee shall maintain documentation of the maintenance of equipment according to industry standards. (Indiana Board of Pharmacy; 856 IAC 1-39-13)

856 IAC 1-39-14 Personnel policies and procedures

Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 14. Each licensee shall maintain employee personnel records and policies consistent with the following:

(1) The scope of services provided.

(2) State and federal requirements.

(Indiana Board of Pharmacy; 856 IAC 1-39-14)

856 IAC 1-39-15 Safety and quality of home medical equipment services

Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 15. Each licensee shall:

(1) clean;

(2) repair;

(3) store;

(4) segregate; and

(5) identify;

all equipment in a manner that makes the equipment safe for use by the public according to industry standards. (Indiana Board of Pharmacy; 856 IAC 1-39-15)

856 IAC 1-39-16 Licenses

Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 16. Each licensee shall ensure that each employee is appropriately licensed or credentialed, or both, for the services provided. (Indiana Board of Pharmacy; 856 IAC 1-39-16)

856 IAC 1-39-17 Physical location

Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 17. Each licensee shall have a physical location from which home medical equipment services are provided. (Indiana Board of Pharmacy; 856 IAC 1-39-17)

856 IAC 1-39-18 Availability of licensee

Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 18. Each licensee shall provide twenty-four (24) hours a day, seven (7) days a week availability to their clients consistent with the nature of the services the licensee provides. (Indiana Board of Pharmacy; 856 IAC 1-39-18)

856 IAC 1-39-19 Medicare DMEPOS supplier standards

Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 19. The board hereby incorporates by reference the Medicare supplier standards titled Special Payment Rules for Items Furnished by DMEPOS Suppliers and Issuance of DMEPOS Supplier Billing Privileges found at 42 CFR 424.57(c), effective December 11, 2000. (Indiana Board of Pharmacy; 856 IAC 1-39-19)

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on November 14, 2005 at 9:45 a.m., at the Indiana Government Center-South, 402 West Washington Street, Room W064, Indianapolis, Indiana the Indiana Board of Pharmacy will hold a public hearing on a proposed new rule to implement rules based on Senate Enrolled Act 206 (P.L.122-2005) to establish the definitions, requirements for the licensure of home medical equipment services providers, license renewal requirements, fees including fees for the application, issuance, and renewal of license, and standards regarding the safety and quality of home medical equipment services.

The Indiana Board of Pharmacy has the authority to promulgate rules in accordance with the requirements of SEA 206 (P.L.122-2005), including specifying which home medical equipment is to be regulated; setting standards for licensure of providers; specifying the governing safety and quality of home medical equipment services that are to be provided to customers; specifying the amount of insurance coverage; and setting reasonable fees for the application, issuance, and renewal of a license. The proposed rule is needed as a matter of consumer protection to assure that the citizens of Indiana are receiving Home Medical Equipment Services from qualified, established providers. The technological advances in HME services demands there be some method for the state to verify that providers of such service are competent and available for education, service, and repair. This will, also, provide another avenue for the government to control fraud and abuse. This proposed rule will have the following cost on the regulated entities:

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Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W072 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Frances L. Kelly
Executive Director
Indiana Professional Licensing Agency