S T A T E O F T E N N E S S E E
OFFICE OF THE
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Opinion No. 01-150

Licensing of Home Medical Equipment Providers

QUESTION

Do the state statutes and rules which require licensure and regulation of free-standing home care organizations providing home medical equipment apply to Tennessee pharmacies which deliver a small amount of durable medical equipment?

OPINION

Yes, to the extent that a pharmacy's activities fall within the terms of the statutory definitions. A pharmacy which holds itself out to the public as providing home medical equipment services as defined at Tenn. Code Ann. §§ 68-11-201(16)(A) and (18), contracts or agrees to deliver such services, accepts physician orders for such services, or accepts responsibility for the delivery of such services, must be licensed as a home care organization providing home medical equipment services. The only exception would occur in instances where a pharmacy limits its provision of durable medical equipment services to upper and lower extremity prosthetics and related orthotics; canes, crutches, walkers, and bathtub grab bars; equipment used to administer drugs or medicine that can be dispensed only by a pharmacist; or to enteral and parenteral equipment.

ANALYSIS

Title 68, Chapter 11, Part 2 of the Tennessee Code, entitled "Regulation of Health and Related Facilities," provides for state licensure and regulation of the health-care related facilities, activities and services specified therein. Home care organizations which provide home medical equipment services are included within Part 2. No person, partnership, association, or corporation may establish, conduct, operate or maintain in the state any home care organization without having a license. Tenn. Code Ann. § 68-11-204(a)(1).

The above statutes provide that an entity is a "home care organization" if it holds itself out to the public as providing home medical equipment services; contracts or agrees to deliver such services; accepts, in the organization's name, physician orders for such services; or accepts responsibility for the delivery of such services. Tenn. Code Ann. § 68-11-201(12)(A). "Home medical equipment services" are defined

at Tenn. Code Ann. § 68-11-201(18) as:

> a service provided by any person who sells or rents home medical equipment for delivery to the consumer's place of residence in this state, regardless of the location of the home medical equipment provider.

"Home medical equipment" is defined at Tenn. Code Ann. § 68-11-201(16)(A) as:

> medical equipment intended for use by the consumer including, but not limited to, the following:
>
> (i) A device, instrument, apparatus, machine, or other similar article whose label bears the statement: "Caution: Federal law requires dispensing by or on the order of a physician.";
> (ii) Ambulating assistance equipment;
> (iii) Mobility equipment;
> (iv) Rehabilitation seating;
> (v) Oxygen care equipment and oxygen delivery systems;
> (vi) Respiratory care equipment and respiratory disease management devices;
> (vii) Rehabilitation environmental control equipment;
> (viii) Ventilators;
> (ix) Apnea monitors;
> (x) Diagnostic equipment;
> (xi) Feeding pumps;
> (xii) A bed prescribed by a physician to treat or alleviate a medical condition;
> (xiii) Transcutaneous electrical nerve stimulator;
> (xiv) Sequential compression devices; and
> (xv) Neonatal home phototherapy devices.

However, Tenn. Code Ann. § 68-11-201(16)(B) provides that "home medical equipment" does not include:

> (i) Medical equipment used or dispensed in the normal course of treating patients by hospitals and nursing facilities as defined in this part, other than medical equipment delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical equipment to an individual's residence;
> (ii) Upper and lower extremity prosthetics and related orthotics;

(iii) Canes, crutches, walkers, and bathtub grab bars;
(iv) Medical equipment provided through a physician's office incident to a physician's service;
(v) Equipment provided by a pharmacist which is used to administer drugs or medicine that can be dispensed only by a pharmacist; or
(vi) Enteral and parenteral equipment provided by a pharmacist.

The statutes require the Board for Licensing Health Care Facilities to establish by rules and regulations standards by which a home care organization providing home medical equipment services/home medical equipment provider shall be qualified and licensed. Tenn. Code Ann. §§ 68-11-201(12)(D); 68-11-226(a). These rules and regulations, entitled "Standards for Home Care Organizations Providing Home Medical Equipment," are found at Tenn. Comp. Adm. R. & Regs. Chapter 1200-8-29. They set out licensing procedures, standards and guidelines for home medical equipment and other regulatory requirements. *See, e.g.*, Tenn. Comp. Adm. R. & Regs. 1200-8-29-.02; 1200-8-29-.06.

We believe that the above statutes clearly require licensure and regulation as home care organizations providing home medical equipment services of all persons and entities, including Tennessee pharmacies, which fall within the terms of the statutory definitions. We thus conclude that a pharmacy which holds itself out to the public as providing home medical equipment services as defined at Tenn. Code Ann. §§ 68-11-201(16)(A) and (18), contracts or agrees to deliver such services, accepts physician orders for such services, or accepts responsibility for the delivery of such services, must be licensed as a home care organization providing home medical equipment services. The only exception would occur in instances where a pharmacy limits its provision of durable medical equipment services to upper and lower extremity prosthetics and related orthotics; canes, crutches, walkers, and bathtub grab bars; equipment used to administer drugs or medicine that can be dispensed only by a pharmacist; or to enteral and parenteral equipment.

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