S T A T E O F T E N N E S S E E
OFFICE OF THE
ATTORNEY GENERAL
PO BOX 20207
NASHVILLE, TENNESSEE 37202

December 19, 2013

Opinion No. 13-105

Sale of Diabetic Shoes

QUESTIONS

1. Do the provisions of Title 63 or Title 68, Tennessee Code Annotated, or any other provisions of Tennessee law permit or authorize appropriately trained pharmacy personnel or home medical equipment providers to provide fitting and patient management services for off-the-shelf therapeutic diabetic shoes and inserts?

2. Do the provisions of Title 63 or Title 68, Tennessee Code Annotated, or any other provisions of Tennessee law permit or authorize appropriately trained pharmacy personnel or home medical equipment providers to measure, fit, or adjust any device utilizing a "crush box" impression system, scanning or non-custom fabricated and fitted devices?

3. Do the training criteria described in Tenn. Code Ann. § 63-3-208(a) constitute sufficient appropriate training to permit or authorize either pharmacy personnel or home medical equipment providers to provide such services?

OPINIONS

1. Yes. Both Tenn. Code Ann. § 63-3-208 and Tenn. Comp. R. & Regs. 1155-04-.20(1) regarding "Pharmacists, Home Medical Equipment Providers, and Orthosis Manufacturers" provide that nothing in such section or rules, respectively, shall be interpreted as limiting or restricting individuals acting under the supervision and control of a pharmacist or pharmacy licensed under Title 63, or home medical equipment provider licensed under Title 68, from measuring, fitting or adjusting any non-custom fabricated and fitted device, including but not limited to over-the-counter devices or off-the-shelf devices, so long as such individual does not create a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical condition and so long as such individual meets one of the criteria for such device as is articulated in Tenn. Code Ann. § 63-3-208(a)(1)-(3), or Tenn. Comp. R. & Regs. 1155-04-.20(1)(a)-(c). "Patient management services," which is not defined in either the above statute or rule, would appear to fall within the above statutory and regulatory provisions only if such services involve the "measuring, fitting or adjusting" any non-custom fabricated and fitted device, as described above.

2. No. The above regulation prohibits such individuals from "creat[ing] a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical condition." Tenn. Comp. R. & Regs. 1155-04-.20(1). Furthermore, Tenn. Comp. R. & Regs. 1155-04-.20(2) permits such individuals to measure, fit or adjust "any *non-custom* fabricated and fitted pedorthic devices, including but not limited to diabetic shoes," provided such individual meets the criteria of either subparagraph (1)(b) or (1)(c) and "*so long as the individual does not create a cast, mold or scan of a part of the human body* for the purpose of constructing a medical device to treat a patient's medical problem." (Emphasis added). Further, Tenn. Code Ann. § 63-3-207(b) prohibits any person from selling or dispensing such "crush box" impression systems without a written prescription from a health care practitioner authorized by law to write such prescription, while Tenn. Comp. R. & Regs. 1155-04-.21 requires certain actions with respect to therapeutic footwear to be performed by a licensed health care practitioner.

3. By enacting Tenn. Code Ann. § 63-3-208(a), the Legislature has deemed the training criteria described in that section to constitute sufficient appropriate training to permit or authorize pharmacy personnel or home medical equipment providers to provide such services.

ANALYSIS

1. Diabetic shoes, which are sometimes referred to as therapeutic shoes, include depth or custom-molded shoes along with inserts for individuals with diabetes.[1] Tenn. Code Ann. § 63-3-208, which is contained in the "Tennessee Orthotics, Prosthetics, and Pedorthics Practice Act of 2005," Tenn. Code Ann. §§ 63-3-201 to -213, provides:

> (a) Nothing in this part or in the rules adopted by the board pursuant to this part shall be interpreted to limit or restrict a health care practitioner licensed under this title from engaging in the full scope of practice of such person's profession, training or services. Nothing in this part or in the rules adopted by the board pursuant to this part shall be interpreted or permitted to limit or restrict individuals acting under the supervision and control of a pharmacist or pharmacy licensed under this title or home medical equipment provider licensed under title 68 from measuring, fitting or adjusting any non-custom-fabricated and fitted device, including, but not limited to, over-the-counter or off-the-shelf devices, so long as such individual does not create a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical condition and so long as such individual meets one (1) of the following criteria for such device:

[1] *See* http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DMEPOS_Qual_Stand_Booklet_ICN905709.pdf. The question posed refers to "off-the-shelf" therapeutic diabetic shoes and inserts. An "off-the-shelf device" is defined in Tenn. Code Ann. § 63-3-201(12) and Tenn. Comp. R. & Regs. 1155-04-.17(2).

> (1) Documented training from a manufacturer or training from a licensed or certified orthotist, prosthetist or pedorthist;
>
> (2) Certification or registration as a fitter of orthotic, prosthetic or pedorthic devices from a nationally recognized board or association such as the Board for Orthotist/Prosthetist Certification (BOC), the Board of Certification for Pedorthists, the National Community Pharmacists Association (NCPA) or the American Board for Certification in Orthotics and Prosthetics (ABC); or
>
> (3) Direct supervision by a trained and experienced, or certified or registered, fitter of orthotic, prosthetic or pedorthic devices.
>
> (b) Nothing in this part or in the rules adopted by the board pursuant to this part shall be interpreted or permitted to limit or restrict individuals acting under the supervision and control of a pharmacist or pharmacy licensed under this title or home medical equipment provider licensed under title 68 from measuring, fitting or adjusting any non-custom-fabricated and fitted pedorthic devices, including, but not limited to, diabetic shoes, so long as such individual meets the criteria of either subdivision (a)(2) or (a)(3) and so long as the individual does not create a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical problem.

Further, Tenn. Code Ann. § 63-3-209(3) also provides that nothing in the above part shall be construed to restrict the measuring, fitting or adjusting of an orthotic device by an employee or authorized representative of an orthosis manufacturer registered with the federal food and drug administration, "when such employee or representative is supervised by a licensed health care professional authorized by law to prescribe, measure or fit such device, and the measuring, fitting or adjusting of such device occurs in the office of such licensed health care professional or in a health care facility." In turn, Tenn. Comp. R. & Regs. 1155-04-.20, regarding "Pharmacists, Home Medical Equipment Providers, and Orthosis Manufacturers" provides:

> (1) Nothing in these rules shall be interpreted as limiting or restricting individuals acting under the supervision and control of a pharmacist or pharmacy licensed under Title 63, or home medical equipment provider licensed under Title 68, from measuring, fitting or adjusting any non-custom fabricated and fitted device, including but not limited to over-the-counter devices or off-the-shelf devices, so long as such individual does not create a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical condition and so long as such individual meets one of the following criteria for such device:
>
> > (a) Documented training from a manufacturer; or training from a licensed or certified orthotist, prosthetist, or pedorthist; or

> (b) Certification or registration as a fitter of orthotics, prosthetics, or pedorthics, from a nationally recognized board or association such as the Board for Orthotist/Prosthetist Certification (BOC), the Board of Certification for Pedorthists, the National Community Pharmacists Association (NCPA), or the American Board for Certification in Orthotics and Prosthetics (ABC); or
>
> (c) Direct supervision by a trained and experienced, or certified, or registered, fitter of orthotic, prosthetic, or pedorthic devices.

(2) Nothing in these rules shall be interpreted as limiting or restricting individuals acting under the supervision and control of a pharmacist or pharmacy licensed under Title 63, or home medical equipment provider licensed under Title 68, from measuring, fitting or adjusting any non-custom fabricated and fitted pedorthic devices, including but not limited to diabetic shoes, provided such individual meets the criteria of either subparagraph (1) (b) or (1) (c) and so long as the individual does not create a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical problem.

(3) Nothing in these rules shall be interpreted as limiting or restricting the measuring, fitting or adjusting of an orthotic device by an employee or authorized representative of an orthosis manufacturer registered with the federal Food and Drug Administration, provided:

> (a) Such employee or representative is supervised by a licensed health care professional authorized by law to prescribe, measure or fit such device, and who examines the patient to ensure that the device has been properly measured, fitted or adjusted by the employee or representative; and
>
> (b) The measuring, fitting or adjusting of such device occurs in the office of such licensed health care professional or in a health care facility.

Thus, the above statutes and regulation provide that nothing therein shall be interpreted as limiting or restricting individuals acting under the supervision and control of a pharmacist or pharmacy licensed under Title 63, or home medical equipment provider licensed under Title 68, from measuring, fitting or adjusting any non-custom fabricated and fitted device, including but not limited to over-the-counter devices or off-the-shelf devices, so long as such individual does not create a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical condition and so long as such individual meets one of the criteria for such device as is articulated in Tenn. Code Ann. § 63-3-208(a)(1)-(3) or Tenn. Comp. R. & Regs. 1155-04-.20(1)(a)-(c), respectively.

Moreover, the above rules also provide that nothing in the rules shall be interpreted as limiting or restricting individuals acting under the supervision and control of a pharmacist or pharmacy licensed under Title 63, or home medical equipment provider licensed under Title 68,

from measuring, fitting or adjusting any non-custom fabricated and fitted pedorthic devices, including but not limited to diabetic shoes, provided such individual meets the above criteria and so long as the individual does not create a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical problem. Tenn. Comp. R. & Regs. 1155-04-.20(2) and (3).

Last, nothing in the above statute shall be construed to restrict the measuring, fitting or adjusting of an orthotic device by an employee or authorized representative of an orthosis manufacturer registered with the federal Food and Drug Administration, when such employee or representative is supervised by a licensed health care professional authorized by law to prescribe, measure or fit such device, and the measuring, fitting or adjusting of such device occurs in the office of such licensed health care professional or in a health care facility. Tenn. Code Ann. § 63-3-209.

"Patient management services," (which is a term that is not defined in either the above statute or rule) would appear to fall within the above statutory and regulatory provisions only to the extent that such "patient management services" involve the "measuring, fitting or adjusting" any non-custom fabricated and fitted device, as described above, or involve activities covered by Tenn. Comp. R. & Regs. 1155-04-.20(3)(a), which permits an employee or authorized representative of an orthosis manufacturer registered with the FDA to examine the patient "to ensure that the device has been properly measured, fitted or adjusted by the employee or representative."

Therefore, both Tenn. Code Ann. §§ 63-3-208 and -209 and Tenn. Comp. R. & Regs. 1155-04-.20(1), regarding "Pharmacists, Home Medical Equipment Providers, and Orthosis Manufacturers," provide that nothing in such statutes or rules, respectively, shall be interpreted as limiting or restricting individuals acting under the supervision and control of a pharmacist or pharmacy licensed under Title 63, or home medical equipment provider licensed under Title 68, from measuring, fitting or adjusting any non-custom fabricated and fitted device, including but not limited to over-the-counter devices or off-the-shelf devices, so long as such individual does not create a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical condition and so long as such individual meets one of the criteria for such device as is articulated in Tenn. Code Ann. § 63-3-208(a)(1)-(3), or Tenn. Comp. R. & Regs. 1155-04-.20(1)(a)-(c).

2. Tenn. Code Ann. § 63-3-207(b) provides:

> No person shall dispense or sell an over-the-counter or off-the-shelf device based upon an image of the customer's limb captured by the person through a mold, cast, scanning device, digital appliance, or pressure sensitive device, unless the customer has first presented to that person a written prescription for that device from a health care practitioner authorized by law to write such a prescription.[2]

[2] The Centers for Medicare and Medicaid Services also provide a "Documentation Checklist" concerning therapeutic shoes for persons with diabetes. *See* https://www.cgsmedicare.com/jc/mr/PDF/Thera_Shoes_DC_int.pdf.

Furthermore, Tenn. Comp. R. & Regs. 1155-04-.20(1) prohibits individuals described in such rule from "creat[ing] a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical condition,"[3] while Tenn. Comp. R. & Regs. 1155-04-.20(2) permits such individuals to measure, fit or adjust "any *non-custom* fabricated and fitted pedorthic devices, including but not limited to diabetic shoes," provided such individual meets the criteria of either subparagraph (1)(b) or (1)(c) and "*so long as the individual does not create a cast, mold or scan of a part of the human body* for the purpose of constructing a medical device to treat a patient's medical problem." (Emphasis added).[4]

3. By enacting Tenn. Code Ann. § 63-3-208(a)(1)-(3), the Legislature has deemed the training criteria described in that section to constitute sufficient appropriate training to permit or authorize pharmacy personnel or home medical equipment providers to provide such services.

ROBERT E. COOPER, JR.
Attorney General and Reporter

BARRY TURNER
Deputy Attorney General

SARA E. SEDGWICK
Senior Counsel

Requested by:

The Honorable Ferrell Haile, D.Ph.
State Senator
10A Legislative Plaza
Nashville, Tennessee 37243

[3] Tenn. Comp. R. & Regs. 1155-04-.21 also requires certain specified actions with respect to therapeutic footwear and medical devices for the foot and ankle to be performed by a health care practitioner licensed under Title 63 acting within his or her lawful scope of practice.

[4] "Custom fabricated and fitted device" is defined in Tenn. Code Ann. § 63-3-201(3) and Tenn. Comp. R & Regs. 1155-04-.18.