March 11, 2013

Teresa Camfield, Executive Director
KMESA
1303 US Hwy 127 S
Suite 402, #394
Frankfort, KY 40601

Dear Ms. Camfield:

Thank you for the questions for clarification on behalf of home medical equipment providers who provide orthotic devices across the commonwealth. Below you will find your questions and the Board’s response to those questions.

1. Our understanding is that if the patient purchases off the shelf orthotics; the supplier is only required to hold a certification for certified fitter, not an ABC or BOC license.
   a. Must have a KY state license as an orthotic fitter to supply off the shelf orthotics. There is no ABC or BOC certifications required once individual is licensed with state license.

2. If a DME provider only fits diabetic therapeutic shoes and they are certified to fit the diabetic shoes via CFTS/ABC; does the state require them to also be a licensed Orthotic fitter?
   a. No, shoe fitters are exempt, as long are they are providing non-custom.

3. If a DME provider or mass merchandise retailer (Dicks sporting Goods, Walmart, Walgreens, CVS) sell off the shelf orthotics (OTSO defined by CMS/HCPCS) are they required to be a certified orthotic fitter and obtain a state license or may they fit these type braces if they are certified by Allied or a manufacturer's certification program?
   a. No, Any purchases purchased over the counter, there is not a license required.

4. Are Heat molded devices considered off the shelf or custom? Are providers required to be certified and/or licensed to fit and dispense these type devices?
   a. If any modifications(heat molding) are performed to any device, that requires clinic knowledge therefore requires a license

5. If the HME supplier provides a tape measure to the customer/patient to measure their own wrist, arm, leg, calf, ankle, or etc. to obtain the correct size to purchase is this acceptable? In this above scenario; is the supplier required to be licensed to sell orthotic devices?
a. If you are solely there to cash person out to complete transaction purchase you will not need a license. Interactions that may require expertise or any clinical assessment will need a license.

6. Our understanding is that is the patient purchases off the shelf orthotics; the supplier is only required to hold a certification for certified fitter? The information about the product regarding sizing and indications is all on the box or in the box and does not require any special education or knowledge for the consumer to make a purchase decision. I would formulate the question more along that assumption.
    a. Same response as #6.

7. If the supplier fits or adjusts the orthotic then they are they required to be certified and/or licensed? Please clarify.
    a. Yes, a KY State license would be required

8. HME provider heard the O&P Board is considering letting pharmacy techs and/or staff also be exempt (not just the Pharmacists themselves as law states) and allowed to fit braces. Is this true? These people have NO training. How is this improving patient quality of service?
    a. Addressed with an agreement with Board and Pharmacy Board - exempts for pharmacist and certain education requirements for individuals working under pharmacist.

9. Case in Point: HME provider went to a chain pharmacy and played the dumb customer and asked for assistance in finding the right brace I needed. A customer service rep (not the pharmacist) came to help me and didn’t really know anything. Pharmacy providers currently do not comply with the law the way we understand it.
    a. Pharmacy 1st, if education requirements are not met it will come to POP Board.

10. If a DME provider only fits mastectomy forms and bras, do they have to be ABC/BOC certified or just certified by a Mastectomy manufacturer?
    a. Exempt from Board’s statutes

11. Are mail order companies allowed to ship custom sized or fitted braces to patients in Ky.? If so, this violates KRS Chapter 315, HB282, which requires state licensure and sources confirm out of state providers are shipping these devices into KY.
    a. Required to have a KY state license to provide care.

If you should have any questions please contact the Board Administrator, Robin Vick at 502.564.3296 x 246 or by email to robinf.vick@ky.gov.

Thank you,

Sienna G. Newman
Chair, Kentucky Board of Prosthetics, Orthotics and Pedorthics

SGN:rv