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In reply, please refer to file:

STATE OF HAWAII
DEPARTMENT OF HEALTH
OFFICE OF HEALTH CARE ASSURANCE
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STATE LICENSING OF DURABLE MEDICAL EQUIPMENT (DME) SUPPLIERS DOING BUSINESS IN HAWAII

Policy and Procedure
November 1, 2016

The Hawaii Department of Health, Office of Health Care Assurance (OHCA) is the state agency responsible to conduct state licensing activities to determine compliance with state regulations on the licensure of durable medical equipment (DME) suppliers doing business in Hawaii. This includes in-state and out-of-state suppliers who sell, dispense, deliver, or service durable medical equipment in Hawaii.

Purpose

The purpose of this policy and procedure (P&P) is to state the procedures for licensing DME suppliers and the basis for the term of the license.

Background

Effective January 1, 2017, Durable Medical Equipment (DME) suppliers who conduct business in Hawaii are required to be licensed pursuant to Act 137 SLH 2016 (formerly Senate Bill 2076) which was enacted on June 30, 2016. This licensing program is aimed to help patients in Hawaii get access to critical, life-sustaining medical supplies by setting standards of service for DME suppliers.

Under Act 137, durable medical equipment is defined as:

- Equipment that is considered a selected product under the Centers for Medicare and Medicaid Services durable medical equipment, prosthetics, orthotics, and supplies competitive bidding program that can stand repeated use;
- Is primarily and customarily used to serve a medical purpose;
- Is generally not useful to a person in the absence of an illness or injury;
- Is appropriate for use in the home;
- Does not contain any prescription drug; and
- Is not considered to be a specialty item, equipment, or service.

Act 137 also defines a DME supplier as a person who sells, dispenses, delivers, or services durable medical equipment.

Act 137 mandates that for any person to operate as a DME supplier in the state, the supplier shall first obtain a Hawaii license. A DME supplier who applies for a state license shall attest and provide corroborating documentation to the department that the supplier:

- Is in compliance with the business registration laws of the State and has all required tax identification numbers;

- Is licensed and in good standing in the state in which its dispensing facilities are primarily located, if applicable and complies with all applicable state and federal laws, rules, and standards;

- Has designated a responsible agent or agents either in or out of Hawaii who shall be responsible for providing timely and satisfactory services to consumers in Hawaii; provided that:
    1. The responsible agent or agents must be available to consumers in Hawaii by phone during standard business hours in Hawaii to answer inquiries or resolve issues; and

    2. If the responsible agent or agents are not immediately available, then the supplier shall have a system capable of accepting and recording incoming phone inquiries; provided that the supplier shall respond no later than one business day after the inquiry is received;

- Has implemented and maintains written procedures at each location for handling complaints and problems from all consumers, which includes a complaint file documenting complaints or problems and resolution of the complaints or problems; and

- Will agree to notify consumers within two business days if the supplier cannot or will not provide the equipment, item, or service ordered; provided that suppliers may be exempt from this requirement if selling, dispensing, delivering, or servicing specialty equipment or items.

Policy

1. No person may operate as a DME supplier unless the supplier is licensed by OHCA pursuant to Act 137 and this policy.

2. All DME suppliers shall be licensed pursuant to Act 137 and this policy and meet all requirements for licensure under state law prior to selling, dispensing, delivering, or servicing durable medical equipment in Hawaii.

3. To obtain an initial license or to renew a license, a DME supplier shall submit to OHCA a DME supplier license application form that requests specific information on the applicant. Attachment 1 is a copy of the application form and instructions for completing the application.

4. All documentation listed on the application form and instructions must be submitted with the application form, along with the license fee of $350.00, for the application to be considered complete.

5. The completed application shall be reviewed to determine whether the information included in the application meets the requirements for licensure.

6. Desk reviews of the application shall be the primary method to determine the accuracy of the application. The OHCA may test the accuracy of the application by calling the

applicant or licensee to verify components of the application such as the applicant's hours of operation, the ability to reach the applicant's representative in-person, or to leave a voice message and to receive a call back from the representative. OHCA retains the right to conduct on-site inspections of the supplier's Hawaii-based location to further verify the accuracy of the information contained in the application.

7. The review of the application shall be completed within sixty (60) days of receipt, consistent with the review of applications of other health care facilities, agencies, or organizations.

8. The term of the DME supplier license shall be for three (3) years, consistent with the term of other licenses where the primary method of application review is desk review.

9. The effective date of the DME supplier license shall be the date the review of the application was completed and shall continue for three (3) years. The license shall expire of the last day of the month of the effective date unless revoked or suspended.

10. A license may be revoked or suspended if the DME supplier fails to meet the requirements of licensure and fails to take corrective action to comply with the requirements. OHCA shall notify the DME supplier in writing of the license revocation or suspension. Corrective action means action achieved by the DME Supplier to correct the failure of meeting licensure requirements and to return to compliance with Act 137 and this policy. Corrective action must be demonstrated within ten (10) days of receipt of written notice by OHCA.

This Policy and Procedure is effective beginning November 1, 2016, and is approved by:

Nov 22, 2016

Keith R. Ridley
Chief, Office of Health Care Assurance

Signature Date