

To dispense DME/Device in Maryland before the June 1, 2014 effective date, DME/Device pharmacies must possess or apply for a pharmacy permit that will expire May 31, 2014.

FAQs for DME/Device Only Pharmacies BEFORE June 1, 2014

1. WHICH APPLICATION FORMS SHOULD A DME/DEVICE PROVIDER COMPLETE?

For DME/Device providers located in Maryland:

The APPLICATION FOR PHARMACY WAIVER PERMIT must be completed. Please write on the top of the application "DME or Device dispenser only." Providers of durable medical equipment and devices only are not required to have a pharmacist on staff.

For DME/Device providers located outside of Maryland:

The APPLICATION FOR NON-RESIDENT PHARMACY PERMIT must be completed. Please write on the top of the application "DME or Device dispenser only." Providers of durable medical equipment and devices only are not required to have a pharmacist on staff.

To access the forms go to the Board of Pharmacy website:

<http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx>

Click on the ESTABLISHMENTS tab at the top of the page

Click on "Click Here For Establishment Forms." Links to the forms will be on the next page.

(Health Occupations Article, 12-401 – 12-413, Annotated Code of Maryland.)

2. WHAT IS THE APPLICATION FEE?

The initial pharmacy fee is \$700.00 and the renewal fee is \$600.00. Checks must be made payable to the *Maryland Board of Pharmacy*. Please do not send cash.
(COMAR 10.34.09)

3. IS A POLICY & PROCEDURE MANUAL REQUIRED TO BE SUBMITTED WITH THE APPLICATION?

Yes. Applicants are encouraged to submit electronic versions, such as a CD, pdf, or jump drive, in lieu of hard copy manuals.

4. IS A FLOOR PLAN REQUIRED?

Yes, including floor plans for warehouses.

5. WILL A SECURITY SYSTEM BE REQUIRED?

Yes. Please see the Maryland Code of Regulations (COMAR) 10.34.05.

6. MOST OF THE QUESTIONS IN THE APPLICATION DO NOT APPLY TO A DME/DEVICE PROVIDER. HOW DO I RESPOND TO THOSE QUESTIONS?

Please respond to the best of your ability and indicate *N/A* (providing explanations) as appropriate.

7. AM I REQUIRED TO HAVE A COPY OF THE 2012 EDITION MARYLAND PHARMACY LAWS OR THE MOST CURRENT EDITION?

Yes. Please see COMAR 10.34.14.02.

8. IS AN OPENING INSPECTION REQUIRED BEFORE THE PERMIT IS ISSUED?

Following submission of a complete application and fee, an opening inspection by Board staff must be performed and passed by entities located in Maryland.

An APPLICATION FOR NON-RESIDENT PHARMACY PERMIT must include the most recent inspection date and the name of the agency that performed the inspection. If your State does not perform opening inspections please indicate this on the application or on a separate piece of paper.

9. WHO IS THE POINT OF CONTACT FOR FOLLOWING UP ON THE STATUS OF PERMITS?

Keisha.Wise@maryland.gov or you may call the main phone number for the Board of Pharmacy 410-764-4765

10. WILL PHYSICAL THERAPY PRACTICES BE REQUIRED TO OBTAIN A PHARMACY PERMIT FROM THE BOARD OF PHARMACY?

Yes. Any person that dispenses prescription DME/Devices into, out of, or within Maryland is required to be licensed by the Board. See Health Occupations Article, 12-401, Annotated Code of Maryland.

11. IF A COMPANY HAS A DISTRIBUTOR LICENSE, DO THEY STILL NEED TO GET A WAIVER LICENSE?

A wholesale distributor permit is for an entity that is "distributing" prescription devices to persons other than a consumer or patient. A pharmacy permit is for an entity that is "dispensing" prescription drugs or devices to a consumer or patient according to a prescription. An entity that distributes and dispenses would need both permits.