

# Title 10

## MARYLAND DEPARTMENT OF HEALTH

### Subtitle 34 BOARD OF PHARMACY

#### 10.34.17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties.

Authority: Health Occupations Article, §12-403, Annotated Code of Maryland

##### **.01 Definitions.**

- A. In this chapter, the following terms have the meanings indicated.
- B. Terms Defined.
  - (1) “Board” means the State Board of Pharmacy.
  - (2) “Comprehensive care facility” means a facility which admits patients suffering from disease, disabilities, or advanced age, requiring medical service and nursing service rendered by or under the supervision of a registered nurse.
  - (3) “Continuing care in a retirement community” means providing shelter and providing either medical and nursing or other health related services or making the services readily accessible through the provider or an affiliate of the provider, whether or not the services are specifically offered in the written agreement for shelter:
    - a) To an individual who is 60 years old or older and not related by blood or marriage to the provider;
    - b) For the life of the individual or for a period exceeding 1 year; and
    - c) Under one or more written agreements that require a transfer of assets or an entrance fee notwithstanding periodic charges.
  - (4) “Full service pharmacy” means a pharmacy that provides complete pharmaceutical services to the general public and does not restrict or limit its services to any group of individuals.
  - (5) Pharmaceutical Specialty.
    - a) “Pharmaceutical specialty” means a limited pharmaceutical service provided by a pharmacy that:
      - i. Is in or makes use of a specialized setting by virtue of certain equipment, systems, location, or physical structure; and
      - ii. Restricts or limits its services to a group or groups of individuals requiring such specialty services.
    - b) “Pharmaceutical specialty” includes the following services:
      - i. Assisted living facilities;
      - ii. Comprehensive care facilities;
      - iii. Developmental disabilities facilities;
      - iv. Home infusion;
      - v. Inpatient hospital;
      - vi. Nonsterile compounding;
      - vii. Nuclear pharmaceutical;
      - viii. Research
      - ix. Sterile compounding;
      - x. Veterinary care;
      - xi. Provision of pharmaceutical services across all settings of care within a continuing care in a retirement community; and
      - xii. Other services approved by the Board.
  - (6) “Waiver pharmacy” means a pharmacy that has been issued a waiver permit by the Board.

## **.02 Pharmaceutical Specialty.**

- A. The Board may recognize as a pharmaceutical specialty not listed under Regulation .01B(4) of this chapter, upon written application and supporting documentation to the Board by an applicant for a waiver permit.
- B. When evaluating an application for a waiver pharmacy, the Board shall consider whether:
  - (1) The pharmaceutical specialty service is necessary to meet a specific therapeutic need;
  - (2) The location is accessible without endangering public health and safety;
  - (3) The pharmacy is properly equipped to perform the pharmaceutical specialty;
  - (4) The applicant has provided a full and detailed description of the pharmaceutical specialty that clearly substantiates the basis for the request of a waiver permit; and
  - (5) A policy and procedure manual is included with the application which sets forth a detailed description of the pharmacy operation.
- C. No one criterion or combination of criteria listed in §B of this regulation shall be binding upon the Board.
- D. The Board's determination of whether a limited practice or setting constitutes a pharmaceutical specialty is final.

## **.03 Requirements of a Waiver Pharmacy.**

- A. The Board shall issue a waiver permit to an applicant that:
  - (1) Meets the requirements of this chapter; and
  - (2) Performs pharmaceutical specialty services;
    - a) Listed in Regulation .01B(4) of this chapter; or
    - b) Approved by the Board.
- B. The applicant shall:
  - (1) Submit an application form approved by the Board;
  - (2) Pay a fee as set forth in COMAR 10.34.09;
  - (3) Submit any other documentation as required by the Board;
  - (4) Employ at least one pharmacist at the applicant's proposed facility who has received education or training in the pharmaceutical specialty in addition to that required for licensure; and
  - (5) Notify the Board in writing within 30 days of any change in the information given on the initial or renewal waiver pharmacy application.

## **.04 Restricted Practice.**

- A. A waiver pharmacy is restricted to the pharmaceutical specialty services approved by the Board in the waiver permit.
- B. A waiver pharmacy may not perform functions of a full service pharmacy.
- C. A full service pharmacy may perform pharmaceutical specialty services as long as the full service pharmacy is able to demonstrate competency in performing pharmaceutical specialty.
- D. A full service pharmacy and a waiver pharmacy may operate on the same premises provided that the full service pharmacy and the waiver pharmacy:
  - (1) Obtain separate permits from the Board;
  - (2) Are supervised by separate licensed pharmacists who are responsible for the operations of their respective pharmacies at all times the pharmacies are in operation; and
  - (3) Maintain separate inventory and record keeping for each pharmacy permit.