

Article – Health Occupations

12-601.

(a) In this section, “manufacturing permit” means a permit issued by the Board under this section to manufacture or package drugs, medicines, devices, cosmetics, dentifrices, or toilet articles.

(b) This section does not affect the operation of a pharmacy as otherwise allowed under this title.

(c) (1) A person shall hold a manufacturing permit issued by the Board before the person may manufacture or package drugs, medicines, devices, cosmetics, dentifrices, or toilet articles in this State.

(2) A separate manufacturing permit is required for each place of operation.

(d) To qualify for a manufacturing permit, an applicant shall satisfy the Board that the applicant will conduct the manufacturing or packaging for which the permit is sought in compliance with the restrictions specified in subsection (e) of this section.

(e) A person may manufacture or package drugs, medicines, devices, cosmetics, dentifrices, and toilet articles in this State only if the operation is conducted:

(1) Under the personal and immediate supervision of:

(i) A licensed pharmacist; or

(ii) An individual approved by the Board, after investigation, as qualified by scientific or technical training or experience to perform the supervisory duties that are necessary to protect the public health and safety; and

(2) In compliance with the rules or regulations adopted under this section.

(f) (1) To apply for a manufacturing permit, an applicant shall:

(i) Submit an application to the Board on the form that the Board provides; and

(ii) Pay to the Board an application fee set by the Board.

(2) An applicant shall submit a separate application and pay a separate application fee for each manufacturing permit for which the applicant applies.

(g) The Board shall issue a manufacturing permit to any applicant who meets the requirements of this section.

(h) A manufacturing permit issued under this section authorizes the manufacturing permit holder to manufacture or package cosmetics, dentifrices, drugs, medicines, or toilet articles while the manufacturing permit is effective.