

§13800. Access to distributed drugs

A manufacturer or wholesaler licensed under section 13758 shall make a drug distributed in this State available for sale in this State to an eligible product developer for purposes of conducting testing required to support an application for approval of a drug under the Federal Food, Drug, and Cosmetic Act, Section 505(b) or 505(j) or the licensing of a biological product under the federal Public Health Service Act, Section 351. [PL 2017, c. 434, §5 (NEW).]

The manufacturer or wholesaler licensed under section 13758 shall make the drug available for sale at a price no greater than the wholesale acquisition cost and without any restriction that would block or delay the eligible product developer's application in a manner inconsistent with Section 505-1(f)(8) of the Federal Food, Drug, and Cosmetic Act, 21 United States Code, Section 355-1(f)(8) (2016). [PL 2017, c. 434, §5 (NEW).]

An eligible product developer that receives a drug at a price no greater than the wholesale acquisition cost for that drug pursuant to this section shall charge consumers in this State the same price or less for the drug manufactured by that eligible product developer. [PL 2017, c. 434, §5 (NEW).]

As used in this section, "wholesale acquisition cost" means the manufacturer's list price for a brand-name drug or a generic drug per person per year or course of treatment when sold to wholesalers or direct purchasers in the United States, not including discounts or rebates, for the most recent month for which information is available. [PL 2017, c. 434, §5 (NEW).]

SECTION HISTORY

PL 2017, c. 434, §5 (NEW).

The State of Maine claims a copyright in its codified statutes. If you intend to republish this material, we require that you include the following disclaimer in your publication:

All copyrights and other rights to statutory text are reserved by the State of Maine. The text included in this publication reflects changes made through the Second Regular Session of the 131st Maine Legislature and is current through January 1, 2025. The text is subject to change without notice. It is a version that has not been officially certified by the Secretary of State. Refer to the Maine Revised Statutes Annotated and supplements for certified text.

The Office of the Revisor of Statutes also requests that you send us one copy of any statutory publication you may produce. Our goal is not to restrict publishing activity, but to keep track of who is publishing what, to identify any needless duplication and to preserve the State's copyright rights.

PLEASE NOTE: The Revisor's Office cannot perform research for or provide legal advice or interpretation of Maine law to the public. If you need legal assistance, please contact a qualified attorney.