

*David A. Catania* 1  
Councilmember David A. Catania 2

A BILL 3

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IN THE COUNCIL OF THE DISTRICT OF COLUMBIA 5

\_\_\_\_\_ 6

Councilmember David A. Catania introduced the following bill which was referred to the 7  
Committee on \_\_\_\_\_ 8

To provide for licensing the manufacture of prescription drugs by the Department of Health 9  
following the Declaration by the Mayor that the public health and safety of District 10  
residents would be served by requiring the issuance of a license to manufacture a 11  
prescription drug for public use, and to provide for a hearing procedure for interested 12  
parties. 13

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this 14  
act may be cited as the "Prescription Drug Compulsory Manufacture License Act of 2005". 15

Sec. 2. Declaration of public health and intent to license. 16

(a) The Mayor may declare that the public health and safety of the residents of the District 17  
of Columbia would be served by requiring the issuance of a license by the Department of Health 18  
to manufacture a prescription drug for public use. 19

(b) The Declaration shall contain the following information: 20

(1) That the issuance of a license to manufacture the prescription drug shall serve 21  
the public health and safety of District residents; 22

(2) A list of the relevant patents, copyrights, trademarks, and any other relevant property to be licensed; and

(3) The proposed license, including the royalty rate, with a default rate of 4% of the District's acquisition price, if not otherwise specified.

(c) The Declaration shall be published in the District of Columbia Register.

(d) Notice of the Declaration, and a copy thereof, shall be sent to the registered agent in the state of incorporation of each company that may be affected by the licensing within 5 days of the Declaration being published in the District of Columbia Register.

(e) The licensure process shall be conducted by the Department of Health.

Sec. 3. Notice of intervention and hearing.

(a) Within 45 days after the date of publication of the Declaration in the District of Columbia Register, any company affected by the licensing may challenge the Department of Health licensure of any property listed in the Declaration by serving a Notice of Intervention on the Department of Health, which shall refer the matter to the Office of Administrative Hearings.

(b) Following the filing of a Notice of Intervention, a public hearing shall be held by the Office of Administrative Hearings pursuant to the Office of Administrative Hearings Establishment Act of 2001, effective March 6, 2002, (D.C. Law 14-76; D.C. Official Code § 2-1831.01 *et seq.*).

(c) No later than 180 days after the hearing an order shall be issued by the Office of Administrative Hearings addressing the legal rights, duties, and privileges of the interested parties.

Sec. 4. Issuance of license.

(a) Within 30 days following the 45-day Intervention period if no Notice of Intervention has been served or within 30 days following the issuance of an order in favor of the District the Department of Health shall issue the license for the manufacture of the prescription drug as described in the Declaration or upon the terms and conditions described in an order, which shall include a just compensation to the owner of the property being licensed.

(b) The Department of Health is authorized to assign the license to one or more prescription drug manufacturers solely for the manufacture of the prescription drug for use by the District and other states which have issued substantially similar licenses.

Sec. 5. Coordination with other states.

(a) If another state issues a license under a process similar to this act, the Department of Health is authorized to fully recognize the validity and effect of such license within the District.

(b) The Department of Health shall specifically recognize any such license by publication in the District of Columbia Register. Within 30 days of publication, the Department of Health shall issue a license to the out-of-state licensee on substantially similar terms and conditions.

(c) For purposes of this section, compliance with subsections (a) and (b) shall constitute compliance with this act.

(d) The Department of Health may enter into joint purchasing agreements with other states to maximize efficient manufacture of the licensed prescription drug for several states. The purchasing agreement shall be exempt from District procurement laws in order to enable a single prescription drug manufacturer to receive multiple licenses from multiple states for a single prescription drug.

Sec. 6. Fiscal impact statement.

The Council adopts the fiscal impact statement in the committee report as the fiscal  
impact statement required by section 602(c)(3) of the District of Columbia Home Rule Act,  
approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(3)).

Sec. 7. Effective date.

This act shall take effect following approval by the Mayor (or in the event of veto by the  
Mayor, action by the Council to override the veto), a 30-day period of Congressional review as  
provided in section 602(c)(1) of the District of Columbia Home Rule Act, approved December  
24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of  
Columbia Register.