(DRAFT FOR FINAL APPROVAL BY THE HOUSE)
(JUNE 24, 2017)

GOVERNMENT OF PUERTO RICO

18th Legislative Assembly | 1st Ordinary Session

HOUSE OF REPRESENTATIVES

H.B. 1034

MAY 8, 2017

Presented by Representative *Méndez Núñez*

Concerning the Health Committee

ACT

To amend Sections 5.01, 5.08, and 5.15 of Act 247-2004, as amended, known as the "Puerto Rico Pharmacy Act", to expedite the import and lower the cost of drugs in Puerto Rico; to provide for the electronic notification by manufacturers and distributors; to increase the payment of the corresponding fees; and for other purposes.

EXPLANATORY MEMORANDUM

It is a well-known fact that health treatment costs continue to rise. One of the costs that has the greatest impact on the Puerto Rican pocketbook is that of drugs. New-generation drugs are constantly emerging that can result in benefits not only for the health, but also for the expenditure of our limited health budget. However, despite the fact that sometimes cheaper drugs approved by the Federal Food and Drug Administration (FDA) already exist, they cannot be distributed in Puerto Rico until they are registered and approved by the Department of Health.

Although we have consistently recognized the Department of Health's duty to implement public health measures aimed at promoting and preserving everyone's health,[1] the Legislative Assembly has repeatedly attempted to address the problem

[1] Act 247-2004, as amended, known as the "Puerto Rico Pharmacy Act", imposes on it the duty to ensure the flow of drug products within the jurisdiction of the Commonwealth of Puerto Rico.

caused by the anachronistic drug registration process on the island. As recently as 2013 and 2014,[2] we passed legislation to transform the drug register from being a process of presenting physical and useless folders to be stored by the Department of Health to a modern and agile electronic register; however, unfortunately, the problem persists. The Department does not have the staff to review the registrations that are constantly presented, resulting in months of delay in the administrative processes, which prevents medications which benefit citizens from entering our market and that could lower health costs both for citizens and the government itself, and from being distributed in Puerto Rico. This cannot continue to be an impediment for Puerto Rican citizens to have access to medications for their benefit, as soon as they are approved by the federal authorities concerned.

The Government of Puerto Rico has assumed an obligation to the people to ensure that technology is used and maximized to transform government processes, making them more efficient and transparent. For this reason, this Legislative Assembly in its ministerial duty to ensure health and the provision of adequate services to the entire population, recognizes that it is imperative to update the register through an agile procedure that guarantees the availability to the people of Puerto Rico of drugs and medications that have already been approved by the Food and Drug Administration (FDA). Regarding natural products, this legislative assembly recognizes that Federal Laws regulate this entire market, among them, DSHEA 1994 (Dietary Supplements Health and Education Act), FFDCA (Federal Food Drug and Cosmetic Act), DSNDCPA (Dietary Supplement and Nonprescription Drug Consumer Protection Act), CGMPs (Dietary Supplement Current Good Manufacturing Practices) and Dietary Supplements Labeling Guide. In addition to this, there are federal agencies that oversee the manufacture of natural products, including the US Food and Drug Administration, Center of Food Center and Applied Nutrition, Office of Dietary Supplements Program and the Health Departments of each state where manufacturing plants are located, among others.

THE LEGISLATIVE ASSEMBLY OF PUERTO RICO HEREBY RESOLVES:

Section 1.- Section 5.01 of Chapter V of Act 247-2004, as amended, is hereby amended to read as follows:

[2] Act 133-2013 and Act 119-2014, amending Act 247, supra.

"CHAPTER V

MANUFACTURE, DISTRIBUTION AND DISPENSATION OF DRUGS

Section 5.01.—Drugs Register

No person in Puerto Rico may display, offer for sale, distribute, sell, deliver, store, give away or donate, or make any advertisement whatsoever for drug products, with or without prescription, natural products or homeopathic products to be used by human beings or other animals unless such drug products, natural products or homeopathic products have been entered in the registry kept by the Department for those purposes. With respect to natural products, as long as they are manufactured in FDA-certified laboratories in the United States, they shall not require registration, as they meet all federal requirements for sale, promotion and distribution.

The Secretary shall set forth two (2) procedures for the electronic registration of drugs, be they prescription or non-prescription drugs:

(1) Initial Registry of Medications approved by the FDA - Every drug manufacturer and distributor shall submit, within the first thirty (30) days after this Act has been enacted, an electronic notice to the Department, by e-mail or using a compact disc (CD), along with the payment of the appropriate fees, as provided by law or the regulations. It is provided that the notice, which shall not require further action or approval by the Department, shall contain an electronic file, in a spreadsheet format, containing all the drugs that the manufacturer or distributor intends to

display, offer for sale, distribute, sell, deliver, store, give away, donate, or promote in Puerto Rico, with only one item from the following information:

(a) Name and address of the entity that prepares, manufactures or repackages the medication.

(b) Name and address of the distributor in Puerto Rico.

(c) Shape, size, and strength of the drug issued (specifying whether its form is solid or liquid), as well as the dosing available.

(d) Direct link to the drug reference information in the DailyMeds Internet database of the U.S. Department of Health and Human Services Institutes of Health.

(e) Approval by the Federal Food and Drug Administration (FDA).

(f) National Drug Code (NDC) Number

(g) Name of who the representative agent shall be, with his contact information.

(h) Number of the valid license, issued in accordance with the provisions of this Act.

(2) Update of the Register of FDA-Approved Drugs - Every manufacturer and distributor of drugs shall submit an update to his initial register at least five (5) days before a new drug is to be introduced, there is a change in the dosage form of a previously notified drug, or there is a change in the representative agent; within such five (5) day period, the

corresponding fees shall be paid. For the update, the same spreadsheet shall be used, identifying in yellow the change or changes that have arisen.

It is further provided that the Secretary of the Department of Health shall establish by regulation a register for homeopathic products in digital or electronic format that the Department shall make available for such purposes when such products are governed by the standards and controlled by the Federal Food and Drug Administration (FDA). The Secretary of the Department of Health may, if he considers it advisable and necessary for the proper enforcement of the public policy to be implemented, establish by regulation registrations for other natural products not manufactured in FDA-certified laboratories in the United States and homeopathic products in digital or electronic format available to the Department for such purposes.

The Department of Health shall ensure direct and continuous access to the Department of Consumer Affairs (DACO), the Register of Drug Products, the Register of Natural Products, and the Register of Homeopathic Products in order to strengthen the effective performance of the DACO's oversight function with respect to the sale of these products."

Section 2.- Section 5.08 of Chapter V of Act 247-2004, as amended, is hereby amended to read as follows:

"CHAPTER V

MANUFACTURE, DISTRIBUTION AND DISPENSATION OF DRUGS

Section 5.08.—Representative Agent

Any drug manufacturer or distributor who is not engaged in their storage or distribution in Puerto Rico, shall notify the Secretary, together with its Register of Drug Products, the name and address of the person who shall act as representative agent for such manufacturer or distributor. He/she shall be the person authorized to and responsible for starting and/or keeping the register of the drug products the manufacturer or distributor markets and distributes in Puerto Rico."

Section 3.- Section 5.15 of Chapter V of Act 247-2004, as amended, is hereby amended to read as follows:

"CHAPTER V

MANUFACTURE, DISTRIBUTION AND DISPENSATION OF DRUGS

Section 5.15.—License, Certificate and Authorization Fees and Effectiveness

(a) The licenses required under this Chapter, unless related to the Register of Drug Products, shall be in effect for two (2) years from the date of issue and shall be renewed in staggered intervals, after having met the requirements and complied with the procedures to be established by regulation, and after having paid the corresponding fees; except for the certificates of registration of drug products and/or biological products for medical, dental and podiatric offices, and for clinical trials in higher education institutions or medical offices, which shall be three (3) years in force, and shall be obtained by filing the registration according to the date

of renewal of the professional license of the physician, dentist or podiatrist, when applicable. In addition, it shall be the Department of Health's duty, as far as possible and as fiscal resources permit, to establish the procedures to be able to file and issue through its governmental Web Page (Internet) the application to obtain the licenses required in this Chapter or the Certificate of Triennial Registration of Drug Products and/or Biological Products in a Medical Office, and Certificate of Triennial Registration of Drug Products and/or Biological Products for Clinical Trials in a Higher Education Institution.

(b) ...

(c) ...

(d) ...

(f) The licenses, certificates and authorizations listed below shall be payable at the following fees, which shall be in effect from the date of adoption of this Act, until the Secretary establishes other fees by regulation:

1. Initial drug product register - $500.00, plus $25.00 for each drug product (not for each dose)
2. Pharmaceutical industry license - $500.00
3. Wholesale medication distributor license - $350.00
4. Wholesaler drugstore license - $350.00
5. Drug Registration Update - $250.00, plus $25.00 for each new drug, for each change in the dosage form of a previously notified drug, or

for the change of representative agent

6. Wholesale non-prescription drug distributor license - $100.00

7. Retail non-prescription drug distributor license - $50.00

8. Wholesale veterinary non-prescription drug distributor license - $100.00

9. Wholesale veterinary prescription drug distributor license - $100.00

10. Retail veterinary non-prescription drug distributor license- $75.00

11. Veterinary facility license - $100.00

12. Pharmacy license - $100.00

13. Authorization to distribute and dispense radioactive drugs, biological products, or sterile parenteral drugs - $25.00

14. First aid kit license - $50.00

15. License to distribute and dispense biological products - $75.00

16. Triennial Drug Registration Certificate - $75.00

17. Triennial Registration Certificate for Drug Products and Biological Products - $200.00

(g) License fees shall be paid by money order or check payable to the order of the Secretary of the Treasury or by wire transfer, credit or debit card, following the rules and procedures set forth by the Secretary of the Treasury concerning the means of payment.

(h) The revenues collected from such fees shall be deposited into the Health Fund created under the provisions of Section 11-A of Act 26 dated

November 13, 1975, as amended, to be used exclusively by the Pharmacy Division in overseeing compliance with the provisions under Chapter V of this Act."

Section 4.-Power to Regulate

The Secretary of Health is empowered to temper, in a term of one hundred and twenty (120) days, the regulation necessary to implement the changes accepted through the approval of this Act. It is further provided that any regulation that contravenes the provisions of the Register of Drug Products and its processes shall automatically cease to have effect.

Section 5.- Severability Clause

If any sentence, word, letter, article, section or part of this Act were held to be null or unconstitutional, the ruling, veredict, or judgment to such effect shall not affect, impair, or invalidate the remainder of this Act. The effect of said judgment shall be limited to the sentence, word, letter, article, section of this Act thus held to be null or unconstitutional. If the application to a person or a circumstance of any sentence, word, letter, article of this Act were held to be null or unconstitutional, the ruling, veredict, or judgment to such effect shall not affect or invalidate the application of the remainder of this Act to such persons or circumstances where it may be validly applied. It is the explicit and unequivocal will of this Legislative Assembly that the courts enforce the provisions and application thereof to the greatest extent possible, even if it renders ineffective, invalidates, or holds to be unconstitutional any part thereof, or even if it renders ineffective, nullifies, invalidates, impairs, or holds to be unconstitutional the

application thereof to any person or circumstance. This Legislative Assembly would have approved this Act regardless of any determination of severability that the Court may make.

Section 6.-Effectiveness

This Act shall take effect immediately after its approval, but its effectiveness is subject to the approval of the regulations established through Section 4 hereof.