

Important Amendments to Regulation No. 156 Approved for Establishments that Manufacture, Distribute and Dispense Medications and Medical Devices in Puerto Rico

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PRACTICE AREAS

- Health Care

An McV Health Care Alert

March 24, 2022

On March 8, 2022, the Puerto Rico Department of Health approved Regulation Number 156B (“Regulation No. 156B”) to amend certain provisions of Regulation Number 156 for the Operation of Establishments that Manufacture, Distribute, and Dispense Medications in Puerto Rico.

Below is a summary of the most significant amendments introduced by Regulation No. 156B:

- An increase in the fees charged for certain licenses and authorizations issued by the Pharmacy Division of the Office of the Assistant Secretary for the Regulation and Accreditation of Healthcare Facilities (SARAFS).
- An increase in the fee charged for the registration of a drug product with the Department of Health.
- Requirement that homeopathic drugs, FDA approved veterinary products and non-FDA approved medical devices be registered with the Department of Health.
- The implementation of changes to the to the registration process for drug products and medical devices:
 - Drug products will need to be registered by manufacturers registered with the FDA or distributors licensed by the Department of Health, or an administrative agent designated by such manufacturer or distributor.
 - Non-FDA approved medical devices will need to be registered by manufacturers or distributors registered with the FDA and/or licensed by the Department of Health, or an administrative agent designated by such manufacturer or distributor.
 - The manufacturer, distributor or administrative agent will be required to obtain an authorization from the Department of Health to register drug products or medical devices with the agency.

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- The availability of a new special permit for the use of temporary or mobile drugstores during a state of emergency declared by the Governor.
- Sets forth requirements and obligations related to the transmission of patients' medical or pharmacy records when the relationship between a health information system provider and the health care facility or health care provider terminates.
- Includes a new chapter on the management of drug donations during a state of emergency declared by the Governor.

The amendments introduced by Regulation No. 156B will be effective **April 9, 2022**. You may access the regulation **here**.

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