



# GOBIERNO DE PUERTO RICO

Departamento de Salud

## PUBLIC NOTICE REGULATION AMENDMENT AND PUBLIC HEARINGS

**TO ADOPT A SECOND AMENDMENT OF THE SECRETARY OF HEALTH REGULATION NO. 156 FOR THE OPERATION OF ESTABLISHMENTS THAT MANUFACTURE, DISTRIBUTE AND DISPATCH MEDICATIONS IN PUERTO RICO, REGULATION NO. 8703 FROM FEBRUARY 18, 2016, AS REGISTERED IN THE PUERTO RICO DEPARTMENT OF STATE, AND AS AMENDED BY THE SECRETARY OF HEALTH REGULATION NO. 156A, REGULATION NO. 8806 FROM SEPTEMBER 8, 2016 AS REGISTERED IN THE PUERTO RICO DEPARTMENT OF STATE.**

By virtue of the powers and faculties granted by Puerto Rico Act No. 81 from March 14, 1912, as amended, also known as the "Health Department Act", Puerto Rico Act No. 247 from September 3, 2004, as amended, also known as the "Puerto Rico Pharmacy Act" (**Act 247-2004**), and the Government of Puerto Rico Administrative Procedures Act, Act No. 38 from June 30, 2017, as amended, The Secretary of Health hereby gives notice of his intent to adopt a second amendment of the *Secretary of Health Regulation No. 156 for the Operation of Establishments that Manufacture, Distribute And Dispatch Medications in Puerto Rico*, Regulation No. 8703 from February 18, 2016, as registered in the Puerto Rico Department of State, and as amended by *The Secretary of Health Regulation No. 156A*, Regulation No. 8806 from September 8, 2016, as Registered in the Puerto Rico Department of State. The purpose of the proposed amendment is to update regulatory provisions with recent amendments to Act 247-2004, particularly with respect to the process for drug registration, drug donations and state of emergency protocols, among other matters.

**Public hearings on the proposed amendment will be held on Thursday, October 22, 2020 from 1:00 pm to 4:30 pm and Friday, October 23, 2020 from 9:00 am to 12:00pm.** In light of the social distancing measures implemented because of the COVID-19 pandemic, the hearings will be held remotely through the technological mechanisms established by SARAFS.

The general public is invited to present their comments and suggestions, within thirty (30) days from the publication date of this notice, in person or by mail to the following address: Office of the Auxiliary Secretary for the Regulation and Accreditation of Healthcare Facilities (SARAFS, as per its Spanish acronym), 1090 Marginal Ruiz Soler, Bayamón, PR 00961-7329. In addition, comments can be submitted by email to the following addresses: [nilda.ortiz@salud.pr.gov](mailto:nilda.ortiz@salud.pr.gov), [veronica.nunez@salud.pr.gov](mailto:veronica.nunez@salud.pr.gov), and/or [myriam.diaz@salud.pr.gov](mailto:myriam.diaz@salud.pr.gov).

A copy of the proposed amendment, as well as a copy of this notice are available through the SARAFS section of the Department of Health's internet page. For additional information, please contact Veronica I. Nuñez Marrero, Esq., Auxiliary Secretary, at (787) 765-2929, ext. 4701.

In San Juan, Puerto Rico, October 6, 2020.

**VERÓNICA I. NUÑEZ MARRERO, ESQ.**  
**AUXILIARY SECRETARY**

**SUBMITTED TO THE OFFICE OF THE ELECTORAL CONTROLLER: OCE-SA-2020-1347**