

PR Department of Health Revokes Special Authorization Requirement for Virtual Manufacturers, Virtual Distributors, and Non-Resident Distributors of Pharmaceutical Products

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On June 17, 2025, the Secretary of Health of Puerto Rico issued Administrative Order No. 612, revoking Administrative Order No. 564, which had been in effect since March 6, 2024. Administrative Order 564 required virtual manufacturers and virtual distributors of pharmaceutical products to obtain a Special Authorization from the Department of Health to be able to conduct business in Puerto Rico.

Relatedly, through letter dated June 17, 2025, the Secretary of Health also rescinded the notice issued on June 29, 2022, which had imposed a similar Special Authorization requirement on non-resident distributors intending to engage in the wholesale distribution of prescription drugs, over-the-counter drugs, homeopathic products, natural products, nutritional supplements, and medical devices in Puerto Rico.

As a result of Administrative Order No. 612 and the June 17, 2025 letter, both with immediate effectiveness, virtual manufacturers, virtual distributors, and non-resident U.S. distributors are no longer required to obtain a Special Authorization from the Department of Health to conduct business or distribute products in Puerto Rico.

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