

PR Department of Health Issues Regulation for Clinical Laboratories, Blood Banks and Plasmapheresis Centers

ATTORNEYS

- Arturo J. García-Solá
- Lizzie M. Portela-Fernández
- Samuel T. Céspedes Jr.
- Roberto Prats-Palerm
- Marcos Rodríguez-Ema
- Adrián P. Goyco-Vera

PRACTICE AREAS

- Health Care

An McV Health Care Alert

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On October 2, 2023, the Puerto Rico Secretary of Health approved Regulation No. 9508 to Regulate the Establishment and Operations of Clinical Analysis Laboratories, Anatomic Pathology Laboratories, Blood Banks and Plasmapheresis Centers in Puerto Rico (“Regulation 9508”). As anticipated on our November 8, 2022 Alert, this Regulation repeals and replaces Regulation No. 120 of the Secretary of Health.

Regulation 9508 intends to bring the Department of Health's regulations in line with the statutory and regulatory provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and provide new rules applicable to source plasma donation activities. Among the most significant changes, Regulation 9508 (i) allows certain staff in hemodialysis facilities, ambulances and other facilities to perform CLIA waived tests upon obtaining a special authorization, (ii) imposes notice requirements for the temporary or permanent closure of a clinical laboratory; and (iii) includes provisions to regulate the establishment and operation of plasmapheresis centers.

Regulation 9508 becomes effective on **November 2, 2023**.

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