/Carey

May 2025

NEW LAW ON RARE, INFREQUENT OR ORPHAN DISEASES PUBLISHED

On May 8, 2025, Law No. 21,743 was published in the Official Gazette, establishing a regulatory framework for the planning, development, and implementation of public policies, programs, and actions related to rare, infrequent, or orphan diseases—those with a prevalence of less than one case per two thousand inhabitants.

Key aspects of the law:

• **Guiding principles** : Public-private cooperation, protection of personal data, civil society participation, and humanization of treatment.
• **Technical Advisory Commission** : Will advise the Ministry of Health. Its composition and operation will be defined by ministerial decree.
• **List of rare diseases** : To be issued by the Ministry with a renewable validity of two years.
• **National registry:** Will include people diagnosed with these conditions for statistical and research purposes, in compliance with data protection regulations (Law No. 19,628).
• **Effective date:** The law will enter into force on July 7, 2025, except for the national registry, which will be effective once the relevant technical standard is published.

The Ministry of Health **must issue the decree and technical standard within six months of the law's effective date.**

Authors: Ignacio Gillmore

This news alert is provided by Carey y Cía. Ltda. for educational and informational purposes only and is not intended and should not be construed as legal advice.

Carey y Cía. Ltda.
Isidora Goyenechea 2800, 43rd Floor.
Las Condes, Santiago, Chile.
www.carey.cl