

> 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:

- 1 Guiding principles:** Public-private cooperation, protection of personal data, civil society participation, and humanization of treatment.
- 2 Technical Advisory Commission:** Will advise the Ministry of Health. Its composition and operation will be defined by ministerial decree.
- 3 List of rare diseases:** To be issued by the Ministry with a renewable validity of two years.
- 4 National registry:** Will include people diagnosed with these conditions for statistical and research purposes, in compliance with data protection regulations (Law No. 19,628).
- 5 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.**

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