

Health Data Governance

Legislative and Regulatory
Landscape Review



CHILE

COUNTRY REPORT

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Transform Health is a global coalition of organisations that work to harness the potential of digital technology and the use of data to achieve universal health coverage (UHC) by 2030. To learn more about Transform Health visit: www.transformhealthcoalition.org.

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1. Introduction

This report analyses the legislative and regulatory landscape of Chile to understand how and to what extent the governance of health data is addressed. The Health Data Governance Principles (HDG Principles¹) served as a framework for this analysis to explore and document how the principles manifest in the existing legal and regulatory environment. This review entailed a content analysis of relevant legal texts against the eight HDG Principles.

This report identifies best practices for Chile’s health data governance, including recommendations on how to strengthen the health data governance landscape. Chile’s health data governance framework demonstrates a commitment to ethical data management and public health improvement. However, gaps were identified which highlight the need for a more comprehensive, cohesive, and future-focused approach. This report recommends aligning national laws with international standards, modernising regulations to address technological advancements and cross-border data flows and establishing a centralised supervisory authority to ensure compliance and to address data breaches. Implementing the recommendations outlined in this report will enhance Chile’s regulatory framework, fostering innovation while safeguarding individual rights and promoting public health equity.

Health Data Governance Principles

Protect People



Protect individuals & communities



Build trust in data systems



Ensure data security

Promote health value



Enhance health systems & services



Promote data sharing & interoperability



Enhance health systems & services

Prioritise equity



Establish data rights & ownership



Promote equitable benefit from health data

¹ View the Health Data Governance Principles: <https://healthdatapinciples.org>

2. National Legislative and Regulatory Overview

The following sources were used for the purpose of analysing the legislative and regulatory system of Chile:

-  Constitución Política de la República de Chile [C.P.]
-  Ley No. 20584, Regula los Derechos y Deberes que Tienen las Personas en Relación con Acciones Vinculadas a su Atención en Salud, Abril 24, 2012, Biblioteca del Congreso Nacional de Chile [BCN]
-  Suelen Carlos de Oliveira et al., *Health Policies in Chile (2000-2018): Trajectory and Conditioning Factors*, 36(11) Cad. Saude Publica e00002120 (2020)
-  Ley No. 19.628, sobre Protección de la Vida Privada (1999).
-  A Patricio Fabián Oliva Mella & Carmen Gloria Narváez, *Analysis of the Chilean Health System and Its Structure in Social Participation*, 46 Saúde em Debate (special issue) e407i (2022)
-  Gobierno de Chile, Política Nacional de Ciberseguridad (2017)
-  Derechos Digitales, Privacy in the Chilean Legal System, Policy Paper No. 08 (2013)
-  Dominguez-Cancino, Karen A., Palmieri, Patrick A., and Martinez-Gutierrez, Maria Soledad. *National Health Policy Reform for Primary Care in Chile: A Qualitative Analysis of the Health Program Documents*. J Prim Care Community Health (2020)
-  World Health Organization, *Towards Universal Health Coverage: The Chilean Experience*, World Health Report Background Paper, No. 4 (2010)

3. Analysis of the National Legislative and Regulatory Environment

The currently enacted or most recently published legislative and regulatory instruments in Chile relating to the HDG Principles are discussed under the sub-heading of each respective principle.

3.1. Protecting Individuals and Communities

Chile's legal framework safeguards the privacy, autonomy, and rights of individuals and communities concerning their health and personal data through constitutional protections, statutory laws, and policies. Article 19 of the Constitution guarantees the right to life, equality before the law, and the protection of personal data, alongside the right to privacy, which includes the treatment of sensitive information such as health data.

The Patients' Rights and Duties Law (Law No. 20,584) protects patients' rights, including confidentiality of personal health information, and mandates secure and responsible handling of clinical records. The Protection of Private Life Law (Law No. 19,628) regulates the treatment of personal data, including health-related information. It sets standards for informed consent, outlines the obligations of data controllers, and imposes requirements for maintaining data quality and security.

Additionally, the National Cybersecurity Policy (2023–2028) addresses individual and community rights in cyberspace. It emphasises the protection of personal data through robust security measures, equal access to digital resources, and cross-sectoral collaboration. These instruments collectively establish a framework aimed at protecting individuals and communities in the context of health data governance.

3.2. Building Trust in Data Systems

Chile's regulatory framework fosters trust in data systems by prioritising transparency, accountability, and data security. Article 19 of the Constitution underscores the protection of personal data and private life. The Protection of Private Life Law (Law No. 19,628) reinforces these principles, outlining requirements for consent, data quality, and the secure handling of sensitive information.

The Patients' Rights and Duties Law complements these measures by obliging healthcare providers to maintain the confidentiality of medical records and ensure their secure storage. These laws work in tandem with the National Cybersecurity Policy, which advocates for institutional collaboration to strengthen data systems and protect against cyber risks.

Together, these provisions ensure that personal data is managed responsibly, thereby fostering public confidence in Chile's health data systems.

3.3. Ensuring Data Security

Chile's approach to data security is embedded in its legal framework, particularly through Law No. 19,628. This law mandates data controllers to implement technical and organisational measures to ensure the security of personal data. It also obliges entities to maintain confidentiality and prevent unauthorised access or breaches.

The Patients' Rights and Duties Law reinforces these principles in the healthcare sector by requiring the secure handling of clinical records. The National Cybersecurity Policy supplements these efforts by focusing on safeguarding critical information infrastructure and promoting best practices in cybersecurity. These measures collectively create a robust framework for ensuring the security of health and personal data.

3.4. Enhancing Health Services and Systems

Chile's health governance framework aims to enhance the quality, accessibility, and efficiency of healthcare services through regulatory and policy initiatives. Law No. 20,584 mandates the confidentiality of clinical records and ensures that patients have access to their medical information, empowering them to make informed decisions about their care.

The Constitution obligates the State to ensure equal access to healthcare services, allowing citizens to choose between public and private systems. Health reforms have emphasised expanding coverage, modernising infrastructure, and integrating indigenous practices into mainstream healthcare to address cultural and regional disparities.

Digital transformation initiatives, including the introduction of electronic health records (EHRs), aim to improve the coordination and efficiency of healthcare delivery. These reforms are part of a broader strategy to ensure that healthcare systems meet the needs of Chile's diverse population.

3.5. Promoting Data Sharing and Interoperability

Chile's commitment to data sharing and interoperability is evident in its legislative and policy frameworks. Law No. 19,628 sets the foundation for secure data sharing by regulating data transfers and ensuring that sensitive information is protected.

The Patients' Rights and Duties Law complements this by requiring healthcare providers to maintain records in a manner that facilitates secure and efficient information sharing. The National Cybersecurity Policy further supports these objectives by promoting collaboration across institutions and enhancing digital infrastructure. These measures aim to create a cohesive health data ecosystem that supports interoperability while safeguarding privacy.



3.6. Facilitating Innovation Using Health Data

Chile's legal framework indirectly supports innovation in healthcare by providing a secure environment for data usage. Law No. 19,628 regulates the processing of personal data, including health information, ensuring compliance with ethical and legal standards. This enables the responsible use of data for research and technological development.

The Patients' Rights and Duties Law ensures that data used in healthcare innovation respects patient confidentiality and informed consent. The National Cybersecurity Policy strengthens this framework by advocating for encryption and secure data management practices, essential for fostering innovation while maintaining data integrity.

3.7. Promoting Equitable Benefits from Health Data

Chile's regulatory framework supports the equitable use of health data through broader legal and policy measures. The Constitution guarantees universal access to healthcare services, which is reinforced by health policies that prioritise equitable resource allocation and improved public health outcomes.

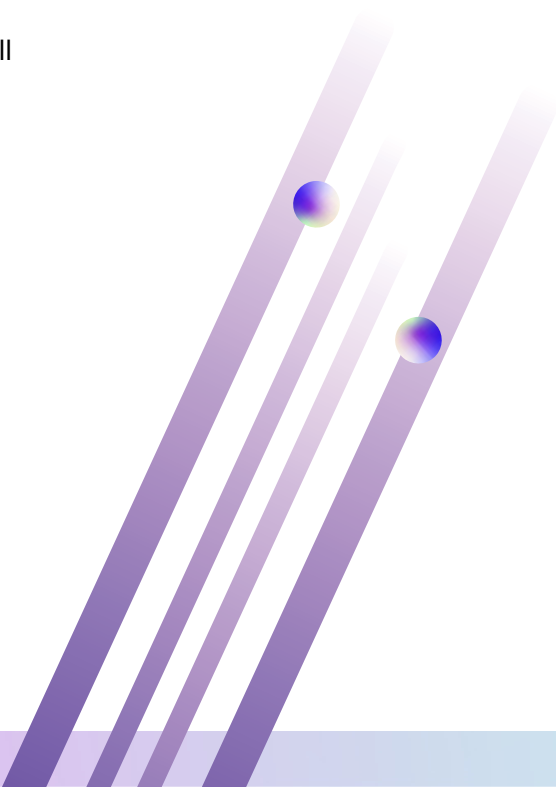
The Patients' Rights and Duties Law ensures transparency in healthcare delivery and empowers patients to access their health information, contributing to equity. National policies on digital health also emphasise bridging digital divides to ensure that technological advancements benefit all citizens, including marginalised populations.

3.8. Establishing Data Rights and Ownership

Chile's regulatory framework for data rights and ownership is defined primarily by Law No. 19,628. This law grants individuals the right to access, modify, and request the deletion of their personal data. It also requires explicit consent for data processing, ensuring that individuals retain control over their information.

The Patients' Rights and Duties Law reinforces these principles in the healthcare sector by mandating the confidentiality of clinical records and ensuring that patients can access their medical data. The National Cybersecurity Policy complements these measures by addressing the secure management of personal data in digital environments.

Together, these regulations establish a comprehensive framework for data rights and ownership, empowering individuals while ensuring compliance with data protection standards.



4. Best practices

Chile's health data regulatory framework incorporates best practices that emphasise data security, privacy, and efficiency, reflecting the country's commitment to robust health data governance.

- **Protection of Personal Data:** Chile ensures freedom in processing personal data within strict legal boundaries. The Protection of Private Life Law (Law No. 19,628) mandates informed consent for data processing, secure handling of sensitive health data, and the implementation of robust technical measures to prevent breaches.
- **Secure Handling of Health Records:** The Patients' Rights and Duties Law (Law No. 20,584) guarantees confidentiality and secure management of clinical records, aligning with best practices for data security and patient autonomy.
- **National Cybersecurity Policy Integration:** Chile's National Cybersecurity Policy promotes secure infrastructure and best practices in protecting critical information systems, addressing the evolving risks associated with digital health technologies.
- **Transparency in Healthcare Services:** The Constitution and related laws guarantee patients access to their medical records and clear, comprehensible information about available services. This transparency fosters trust in healthcare systems.
- **Cultural Relevance in Health Services:** Indigenous populations are supported through culturally relevant healthcare initiatives, integrating traditional medicine and linguistic diversity into service delivery.
- **Expanding Digital Transformation:** Chile's regulatory framework promotes the adoption of electronic health records (EHRs) and supports interoperability, ensuring healthcare systems can effectively share and utilise data.

These best practices highlight Chile's strategic focus on patient-centred care, secure data handling, and leveraging digital technologies to enhance healthcare delivery.

5. Gaps

While Chile's health data governance framework demonstrates significant strengths, several gaps hinder its full potential:

- **Lack of Comprehensive Oversight:** The absence of a dedicated regulatory authority with robust enforcement powers creates inconsistencies in data protection implementation and compliance.
- **Gaps in Definitions and Regulations:** Key terms, such as "sensitive data" and "public access sources," lack precise definitions, which leads to ambiguity in legal interpretations and enforcement.
- **Overuse of Consent Exceptions:** Excessive exceptions to consent requirements undermine the principle of individual control over personal data.
- **Fragmentation in Governance:** Dispersion across various regulations creates challenges in applying and harmonising data protection laws, reducing efficiency in governance.
- **Insufficient Cybersecurity Preparedness:** While the National Cybersecurity Policy lays the groundwork, its implementation needs strengthening to address vulnerabilities in health data systems.
- **Challenges in Data Sharing and Interoperability:** The fragmented health information system limits efficient data sharing and integration, affecting the quality and timeliness of healthcare services.
- **Limited Equity in Digital Health:** Digital transformation efforts face barriers in addressing the needs of marginalised populations, particularly in remote or under-resourced areas.

Addressing these gaps is critical to ensuring a unified, efficient, and secure health data governance framework in Chile.

6. Recommendations

To address the identified gaps and enhance health data governance in Chile, the following recommendations are proposed:

- **Establish a Centralised Regulatory Authority:** Create a dedicated body to oversee compliance, enforce data protection standards, and address breaches effectively.
- **Harmonise Legal Frameworks:** Introduce comprehensive legislation that consolidates fragmented rules and clarifies key definitions, ensuring consistency across health data governance.
- **Strengthen Cybersecurity Measures:** Expand the National Cybersecurity Policy to include specific guidelines for health data protection and critical infrastructure resilience.
- **Promote Equity in Digital Health:** Invest in infrastructure and training to improve access to digital health services in underserved regions, ensuring inclusivity in healthcare advancements.
- **Enhance Interoperability Standards:** Adopt unified technical standards for electronic health records and other digital health tools, promoting seamless data sharing across institutions.
- **Revise Consent Mechanisms:** Limit exceptions to consent requirements and establish more robust mechanisms for obtaining and managing informed consent.
- **Foster Public Awareness:** Launch educational campaigns to inform citizens about their rights under data protection laws and the importance of data security.
- **Encourage Innovation Safeguards:** Support innovation in health data usage while embedding security and ethical considerations into research and technological development.

These recommendations aim to address structural, technological, and operational challenges while fostering trust and equity in health data governance.

7. Conclusion

Chile's health data governance framework demonstrates a strong foundation in protecting personal health information and promoting transparency. However, gaps in regulatory oversight, legal clarity, and cybersecurity preparedness hinder the framework's full effectiveness. This report's recommendations call for comprehensive reforms, including establishing a centralised regulatory authority, enhancing equity in digital health, and harmonising laws to address fragmentation. By implementing these measures, Chile can strengthen its health data governance, fostering innovation and ensuring secure, inclusive, and efficient healthcare systems for all its citizens.

