The Right to Health in the Laws and Policies for Universal Access to Medicines in Chile

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<tbody>
<tr>
<td>AFHS</td>
<td>Armed Forces Health System</td>
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<tr>
<td>CASEN</td>
<td>Encuesta de Caracterización Socioeconómica Nacional</td>
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<td>CENABAST</td>
<td>Central Nacional de Abastecimiento</td>
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<td>CSCs</td>
<td>Civil Society Councils</td>
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<td>EHG</td>
<td>Explicit Health Guarantees</td>
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<td>ELMA</td>
<td>Essential Laws for Medicines Access</td>
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<td>FONASA</td>
<td>Fondo Nacional de Salud</td>
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<td>GDP</td>
<td>Gross Domestic Product</td>
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<tr>
<td>ICESCR</td>
<td>International Covenant on Economic, Social and Cultural Rights</td>
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<td>ISAPRES</td>
<td>Instituciones de Salud Previsional</td>
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<td>LICs</td>
<td>Low-Income Countries</td>
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<td>MICs</td>
<td>Middle-Income Countries</td>
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<td>NGO</td>
<td>Non-governmental Organization</td>
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<td>NHS</td>
<td>National Health Services</td>
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<td>NMF</td>
<td>National Medicines Formulary</td>
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<td>OECD</td>
<td>Organization for Economic Co-operation and Development</td>
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<td>PHCD</td>
<td>Pharmacy Fund For Chronic Non-Communicable Diseases</td>
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<td>SDGs</td>
<td>Sustainable Development Goals</td>
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<td>UHC</td>
<td>Universal Health Coverage</td>
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<td>WHO</td>
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EXECUTIVE SUMMARY

The right to the highest attainable standard of health is enshrined in many international treaties ratified by Chile. A fundamental requisite to ensure the right to health is to guarantee access to essential medicines. The recognition of the right to health and access to medicines in national legal frameworks and the implementation of national policies including medicines in the schemes of the UHC, are two approaches used to promote universal access to medicines. The objective of this project was to investigate whether and how the right to health is reflected in the national legal and policy framework for universal access to medicines in Chile. Laws and policy documents were collected by completing an Essential Laws for Medicines Access (ELMA) country profile, through a non-systematic review in legal and health on-line libraries, databases, web portals, and academic databases. The rights to health protection, life and physical and mental integrity are recognized in the Chilean constitution. The Health Goals for the Decade 2000-2010 were a turning point, showing the conviction of Chilean State to ensure access to affordable essential medicines for all. These commitments were materialized in the Laws that embodied the comprehensive reform of the health sector in the country during the early 2000’s. This reform took into consideration the majority of vulnerable groups of Chilean society and strengthened the citizen participation, transparency and accountability of the health system. The example of Chile may serve as inspiration for countries with a strong private health sector seeking to increase the access to essential medicines with limited public health expenditures.

INTRODUCTION

Right to health, Universal Health Coverage and Access to medicines

The right to the highest attainable standard of health without the distinction of race, religion, political belief, economic or social condition, emerged as one of the fundamental rights of every human being in the World Health Organization (WHO) constitution,(1) and was also recognized in the article 25.1 of the Universal Declaration of Human Rights.(2) In addition, the right to health has been enshrined in several international and regional human rights treaties, being the most important one the International Covenant on Economic, Social and Cultural Rights (ICESCR).(3) The ICESCR ratified by 165 countries, stands out due to its binding nature on states, and establish in Article 12, that ensuring access to healthcare services for all is one of the four steps needed for the realization of the right to health. Moreover, the General Comment Nº 14 on the Right to Health adopted by the Committee on Economic, Social and Cultural Rights, highlights in paragraph 43(d) that access to essential medicines is part of State’s minimum core obligations to realize the right to health.(4)

The right to health has been recently defined as an "emergent human right" as it has been progressively recognized and introduced in different ways in international instruments and domestic legislation, especially in the last two decades. Its legitimacy as an enforceable right has increased jointly with the development of its interpretation, conceptualization and operationalization.(5) Furthermore, human-rights approaches with particular focus on the right to health, are of great relevance in the light of two global
policy phenomena whose importance has been steadily increasing in the last twenty years and that shape the access to medicines situation worldwide: the growing push for the Universal Health Coverage (UHC) achievement, and the increase of intellectual property protection as a result of the adoption of the Word Trade Organization Agreements on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Since is not the subject of the present project, the second won’t be further discussed.

The UHC has been endorsed by the most important global health and development organizations including, among others, the WHO, the United Nations Children’s Fund, the International Labour Organization and the World Bank Group.(6) According to the WHO, the UHC means that all people have access to needed health services including promotive, preventive, rehabilitative and palliative care, of sufficient quality to be effective, and ensuring that the use of these services does not expose any user (or his/her family members) to financial hardship.(7) Likewise, UHC is viewed by some as a fundamental driver of the third global health transition after the public health improvements including sanitation and basic sewerage that lead to the demographic transition, and the scale control of many communicable diseases which resulted in the epidemiological transition.(8)

On 25th September 2015, the member states of the United Nations adopted the Agenda for Sustainable Development 2015-2030. This agenda includes the Sustainable Development Goal (SDG) 3 consisting of “Ensuring healthy lives and promote well-being for all at all ages” which in the section 3.8 specifically highlights the importance of “access to safe, effective, quality and affordable medicines and vaccines for all” as a cornerstone of the UHC.(9) Despite the consensus surrounding the importance of the UHC, the various interpretations lack a clear common definition and scope, as well as the most appropriate strategies towards its achievement. Hence, although the WHO declared that it is “the practical expression of the right to health”, this is not necessarily true if human rights principles and in particular the right to health obligations, are not taken into consideration carefully when it comes to its design, implementation and evaluation.(10)(11) In addition, as stressed by some authors, this can be challenging in the current era of dominant neoliberal global policy frameworks where the right to health is sometimes jeopardized.(12) The greatest risk of some strategies towards the realization of UHC is the exclusion from the health benefits and the health system’s improvements of the poorest, marginalized and most vulnerable populations, including rural communities, ethnic minorities or migrants.(13)(14)(15) Thus, scholars have recently aimed at establishing the core elements that the UHC must include to be consistent with human rights obligations and to optimize its potential as a driver for the realization of right to health; who should be covered, what services should be included, how should it be financed, what is the minimum required funding, what kind of transparency or accountability mechanisms are needed or who should be involved in its design and implementation.(5)(13)(16)(17)(18) Furthermore, as countries progress towards the achievement of the UHC, policy makers faced difficult choices regarding the expanding of some services over others for a fair resource allocation. Nevertheless, a proper understanding and interpretation of the right to health can help in various ways the priority setting within expanding health systems.(18)
No government can fulfill the right to health nor achieve UHC without guaranteeing access to essential medicines which are, according to the WHO’s concept, “those that satisfy the priority needs of the population”. (19) Five major barriers hamper universal access to essential medicines: lack of financing, unaffordability, lack of medicines of assured quality and safety, misuse of essential medicines, and insufficient development of missing essential medicines. (20) This paper focuses on laws and policies that deal with financing and affordability issues to provide essential medicines in the context of the UHC.

Medicines are one of the most important components of the health expenditure worldwide, accounting for a quarter of the global health expenditure. Therefore, the way in which they are financed is a key factor that determines their accessibility and affordability by the population. (20) Whereas in rich countries the vast majority of this expenditure comes from public government expenditures on drugs, in many Low and Middle-income countries the main financing source of drugs are private Out-of-Pocket (OOP) payments, which are inefficient and inequitable pushing in many occasions families and individuals into financial hardships. According to the Lancet Commission on Essential Medicines’ last estimates, the absolute minimum government expenditure needed to provide a basket of 201 drugs in LMICs included in the 2015 WHO Model List of Essential Medicines, is 13 $ per capita, per year. Nonetheless, the vast majority of Low-Income countries (LiCs) and some Middle-Income countries (MiCs), don’t reach the absolute minimum expenditure, and the half of their pharmaceutical expenditure comes from private OOP payments. (20)

Since one of the main aspirations of the UHC is to protect individuals from catastrophic health expenditures, it is quite evident that states must ensure the provision of a basket of essential medicines in order to achieve the UHC and the progressive realization of the right to health. (20) However, despite the presence of the right to health in international law and in the global health agenda, millions of people worldwide lack access to essential medicines. (20)(21) Among the different strategies that countries can adopt aiming at promoting the universal access to medicines, one of them is to recognize the right to health and access to medicines in their national legal frameworks. (22)(23) This can be achieved by the introduction of medicines-related rights in national constitutions, by the constitutional recognition that International Treaties signed by the state, acquired automatically the status of national law; and by including health and medicines-related rights in other domestic laws or policies, such as for universal health coverage. (24)(25)

However, some are skeptical with this approach since they fear that making the obligations under the right to health more explicit in their domestic law, may involve a disruptive influence on countries’ efforts to set priorities efficiently and fairly. This concern has been shown by states that have intensively achieved the universal health coverage and count on well-established mechanisms for prioritizing drugs to be reimbursed, such as the United Kingdom. (18) The tensions between some interpretations of the right to health and fair priority setting processes, have been extensively appreciated in the last two decades in some Latin American countries. (26)(27) For instance, one study showed that in Costa Rica more than 70 % of the successful court cases for medicines outside the agreed benefit packages, concerned medications that according to the standard criteria of clinical effectiveness, severity of disease, strength of evidence and cost-effectiveness, would have been considered as low priority. (28)
Nevertheless, some scholars consider that the interpretation that the right to health involves the right of an individual claiming before the state to any medical treatment he or she may need, regardless of the cost, is inconsistent with the international human rights law.(18)(29)(30) On the contrary, the inclusion of explicit right to health provisions in national legal frameworks may entail a mechanism for civil society and health planners to demand additional resources to the appropriate delivering of health services (including medicines) already classified as high priority. In addition, the right to health can also provide a legal basis to ensure that prioritized medicines and health interventions are provided without discrimination or exclusion issues and may contribute to diminish power asymmetries between the different groups of the society, and between governments and citizens.(18) Moreover, the recognition of the right to health in national legal frameworks may serve as a starting point for further development of laws and policies in accordance to these obligations, aimed to expand the financial coverage, and the medicines included in the health benefits packages.(25)

To conclude, the right to health has the operational and conceptual capacity to make a unique contribution especially in the design and implementation of complex and long term health policies and interventions.(31) Therefore, it is well-suited to play a fundamental role in the fulfilment of the UHC and consequently in the improvement of the access to medicines situation worldwide. The right to health is not only a goal but a valuable tool to influence global policies to comply with the “No one must be left behind” principle encompassed in the SDGs.

The Chilean Background

Chile, located in the southwestern tip of South America, is a High-income country (HIC) since 2013 according to the World Bank and became the first South American country in joining the Organization for Economic Cooperation and Development (OECD) in 2010. (32) It has been one of Latin America’s fastest-growing economies in the last decades and holds one of the highest Gross Domestic Products (GDP) of the region. The good economic performance along with the social emphasis of the governments that have ruled the country from the beginning of the 21st century, have allowed a significant poverty reduction from a 29.1% in 2000 to 7.9% in 2015.(32) Despite these good indicators, with a Gini Coefficient of 0.465 (ranging from 0, perfect equality, to 1, perfect inequality) Chile is one of the most unequal countries in terms on income distribution.(33) In addition, it has one of the lowest percentages of public health expenditure and one of the highest percentages of OOP payments of the Latin America & Caribbean region.(34) With respect to its international commitments concerning health, it is one of the countries that have ratified the ICESCR, making Covenant rights including the right to health articulated at the international level legally binding at the national level.

The military coup carried out by Augusto Pinochet against the democratically elected government of the socialist President Salvador Allende in 1973, radically changed the modern history of the country. Chile became the first country were neoliberal economic measures were applied thoroughly transforming its economy and institutions. The beginning of the implementation of neoliberal free-market economic policies affected many areas of Chilean economy, including health and pension systems.(35) As a result, there was a radical re-orientation of social policies supposing the end of the welfare
state. (36) Although during the so called "golden" period (1985-1997) the country’s GDP per capita doubled and the economy experienced a 7.1% growth, the application of neoliberal policies led to negative socioeconomic consequences including the increase of poverty, income inequality and unemployment. As the social dissatisfaction increased, the military government was forced to take some social assistance measures to alleviate the situation targeting the poorest segments of the population. (35) At the same time that the provision of basic services to the poorest increased, the social provisions to the middle and working classes diminished, hindering the social security system which had substantially improved during the governments of Eduardo Frei and Salvador Allende. (37) The first governments after the arrival of democracy, continued with the application of neoliberal policies. However, these measures were combined with a significant increase in the social expenditure, leading to economic growth, improvement in the standard of living of both the poorest and the middle classes and a significant poverty reduction. (35)

As far as health is concerned, in 1952 Chile played a pioneering role in Latin America with the creation of the National Health Service (NHS) through the integration of the different existing bodies regarding health: the facilities of the Workers Social Security System, and the facilities of the Ministry of Health which served the poor. Due to this unprecedented step in the desegregation of healthcare in the region, the NHS emerged as the cornerstone of the Chilean Health System, and the government’s role as a health service provider was strengthened with the focus on maternal and child health and communicable diseases. Major investments in health professionals training along with mandatory residencies for doctors in rural areas, resulted in significant achievements in health coverage by the end 1970’s, when most of the population had access to basic health services. (38)(39)

The comprehensive reforms in the health sector during the 1980s introduced by Pinochet’s Regime, lead to a progressive privatization of the public Chilean Health System. In 1979 the National Health Fund (FONSASA, by its Spanish acronym) was created, which entailed a separation between healthcare and resource management. In 1980 the municipalization of the primary health centers started, triggering inequity in resource availability among rich and poor local governments. In the same year, a new constitution which recognized the “right to health protection” and the role of private health insurances and providers was adopted through a fraudulent plebiscite. (40)(41) Subsequently, in 1981 the Private Institutions of Social Security (ISAPRES, by its Spanish acronym) were created, and citizens were given the choice to devote their payroll contributions to FONASA (public system) or to the recently established ISAPRES. (39)(40) This embodied the major milestone in the privatization process of the Chilean Health System. (35)

In the 1990s the democratic governments returned to power, maintaining the same model of healthcare organization, service provision and financing, but undertaking reforms aimed at increasing financial support and quality of the services of FONASA, while enacting stricter rules to regulate ISAPRES. (35)(39) Nonetheless, the health reform enforced by the Chilean government since the beginning of the 2000s, with the right to health in the center and special focus in equity and solidarity, was a major step towards the achievement of the UHC. The reform, supported by five laws, had the Explicit Health Guarantees (EHG) as a cornerstone, which compel public and private health insurance to provide specific guarantees to the diagnosis, treatment and follow up of 80 prioritized health problems covering access, timely access, financial protection and quality. (38)(39)
Currently, the Chilean Health system can be described as a mixed system both in insurance and services provision, which shows high coverage rates and reasonably good health outcomes. According to the data of the last National Socioeconomic Characterization Survey (CASEN by its Spanish acronym) carried out in 2015, the 77.3 % of the Chilean population is affiliated to FONASA whereas the 15.1 % is covered by one of the thirteen authorized ISAPRES. In addition, a 3% of Chileans are affiliated to the Armed Forces Health System (AFHS) meaning that a 95.5 % of Chilean population is insured.(42) However, a considerable part of the Chilean population is not protected from catastrophic health expenditures and the system fragmentation leads to an underfunded overwhelmed public sector and an elitist private one used by the wealthiest sectors of society. (38)(43)(44) As far as medicines are concerned, the access situation along with the financial protection have formally improved in Chile in the last two decades. This was the result of the introduction of the EHG, the establishment of a pharmacy fund for chronic diseases which provide free medicines for Diabetes, Hypertension and Dyslipidemia for those treated in the public system,(45) and the implementation of a financial protection system for high cost diagnostics and treatments applicable to all Chilean health systems.(46) This formal improvement can be empirically appreciated in the persistent reduction during the last twenty years of the OOP payments for medicines, which has taken place in every population quintile with the exception of the richest.(47) However, in spite of these achievements OOP payments for medicines is still the most important component of the OOP expenditure in health, representing a 31.5% of it and unevenly affecting the poorest quintiles of society.(47) In the same line, the pharmaceutical per capita expenditure as share of the GDP remains very low, being only a 0.9% of GDP (the lowest proportion in the OECD).(48) As a result, affordability represents a barrier to access medicines especially for those drugs excluded from the reimbursement programs above mentioned, and for the poorest quintiles of society.(48) The last CASEN carried out in 2015, showed that problems to access to medication, including financial problems, are more frequent in the poorest quintiles, in rural versus urban populations, and in indigenous versus non indigenous citizens.(42)

This evidence suggests that the core principles of human rights- universality, non-discrimination, equitable distribution, and progressive realization- could strengthen access to essential medicines in Chile.

The study of the laws and policies supporting the last health reforms affecting access to medicines in Chile could help to identify which instruments embrace human rights principles with the potential to impact universal access to medicines. This analysis may help to reveal how Chile’s legal and policy framework should evolve to better promote universal access to medicines. Given the Public/Private nature of the Chilean health system, this study is particularly useful to determine laws and policies aiming at assuring equal access to medicines in countries with a notable presence of the private sector.

**OBJECTIVES**

The overall goal of this project was to investigate whether and how the right to health is reflected in the national legal and policy framework for universal access to medicines in Chile.
The specific objectives were:

1. To identify the commitments that Chile has at an international level to provide access to essential medicines as part of the right to health, and whether these commitments are directly applicable to Chile’s legal system.

2. To determine the obligations of the Chilean government and the rights of individuals concerning access to medicines in constitutional law and whether these can be enforced before domestic courts.

3. To determine the political commitments that the Chilean government has made in national policies to provide access to essential medicines.

4. To identify the legal obligations adopted in Chilean (secondary) legislation and regulation relating access to medicines or reimbursement or universal health coverage.

**METHODOLOGY**

Laws and policy documents concerning access to essential medicines in Chile were collected in their original language (Spanish) by completing an Essential Laws for Medicines (ELMA) report, through a non-systematic review in the data sources mentioned below. The selected fragments of these laws and policy documents were later translated to English by the author, and are included in both languages in the ELMA report (Annex 1-4). The ELMA report presents standard format for analyzing and collecting national legislations and policies in support of universal access to essential medicines from a human rights perspective. It was piloted in 2010 as a collaboration between the Widener School of Law (Prof Michelle Forzley) and the Department of Essential Medicines and Pharmaceutical Policies of the World Health Organization in Geneva (Dr. Hans Hogerzeil). That report presented pilot studies in the legislation of different countries and has been used as a starting point for further country studies performed by the Global Health Law Groningen Research Centre. The first ELMA format, slightly modified an updated was the one used as a starting point in this project.

Through ratification of International Human Rights Treaties, governments commit to ensure that their domestic laws and policies are consistent with the obligations included in those treaties.(49) Although is neither a guarantee nor an essential step, constitutional rights to health and medicines have been identified as a relevant indicator of government’s commitment towards the progressive realization of the right to health. First, they are illustrative of the country’s national values and conceptions about health and medicines and contribute to the creation of a supportive environment. Secondly, given that the constitution is the legal basis of a country, the rights recognized on it can serve as inspiration for the later design of laws and policies respectful with these rights, while establishing mechanisms for their enforceability.(25)(24) Another possible approach towards the recognition and promotion of the right to health within national legal frameworks is to include human rights in other domestic laws and regulations.(24) Although these legal instruments are easier to modify or reject and have a lower rank than the constitutional provisions, on the other hand they are easy to be created and approved.
Domestic legislation is approved by the national legislative body and serves as a precedent for further policy development. National regulations have the same legal status than legislation, but unlike them, they are used for the technical implementation of other laws or policies by setting rules or specific standards. In comparison with legislation, regulations are easier and faster to pass and change. The most relevant documents that define the health policies in a country are indicative of the extent to which the obligations adopted in the constitution and in other domestic legislation, are considered when the government design health programs for its subsequent implementation. In addition, political goals adopted in government’s Health Plans can sometimes lead to legislative actions in order to achieve these goals. Finally, Health Plans can also be considered as a reflection of the political commitment towards a certain issue, in this case, access to essential medicines and medicines affordability in Chile.

The data sources used in this project were the following:

**Primary data sources:**

- **For International laws:** Chile’s international commitments to provide access to essential medicines were found in the *United Nations Treaty Collection Database*.
- **For Domestic Laws:** The Spanish version of the Political Constitution of the Republic of Chile was accessed on the website of the *Library of the National Congress of Chile* (Biblioteca del Congreso Nacional de Chile) and the English version of the constitution was consulted in the database *Constitute*; relevant constitutional provisions regarding the recognition of the right to health and the government’s responsibility to ensure access to healthcare, medicines, goods or health facilities were retrieved. Domestic legislation currently in force regarding access to medicines and universal health coverage was collected from the following on-line libraries, databases and web portals including: *Natlex, International Social Security Association, Parline Database on National Parliaments, World Legal Information Institute, and The World Law Guide*. Relevant laws were also extracted from the web portals of the *Ministry of Health*, in particular from the websites of the *Chile’s Public Health Institute* as well as the *National Medicines Agency*. The laws found in the previously mentioned sources were searched again in the *Library of the National Congress of Chile* to double-check and pertinent fragments of the laws were selected. The fragments of these laws about medicines safety, quality and rational use were not included in this project.
- **For Policy documents** (i.e. national health plans, government reports): In order to identify the political commitments and conceptions with regard to access to medicines in Chile, a search in the following databases was performed: *WHO Country Planning Cycle Database, WHO Member states, WHO Essential Medicines and Health Technologies Information Portal, Pan American Health Organization, World Bank UHC country summaries, and World Bank UHC studies*. The website of the *Chilean Ministry of Health* including the web portals of the *Chile’s Public Health Institute*, the *National Medicines Agency* and the *National Central Supplier* were also consulted. National health plans and other official policy documents concerning access to medicines and medicines reimbursement that were drafted since 2000 (when the health reform started) were selected and relevant fragments were included. Fragments regarding medicines safety, quality and rational use were not taking into consideration in this project.
Secondary data sources (i.e. published reports about laws, and policies): in order to perform a more comprehensive collection of laws and policies aimed to ensure access to essential medicines in Chile, a snowball search of them was performed in English and Spanish in PubMed, Google Scholar, and Google. When using search terms the Spanish words “medicinas” “medicamentos” “fármacos” or in English “medicines”, “drugs” and “pharmaceuticals” were used interchangeably and the search was always repeated for the three terms. Other terms used were “Chile”, “leyes”, “políticas”, “acceso”, “precio” “Cobertura Universal de Salud”, in English “laws”, “policies”, “access”, “price” “Universal Health Coverage”.

The court cases claiming access to essential medicines in Chile which are included in the second section of the ELMA report (Annex 2) are the result of a search in Eschr-net law database, Global Health and Human rights database and in the searcher tool Jurischile. Once the case was located in one of these databases its “Rol” number was introduced in the searcher of the Chilean Supreme Court of Justice to be checked.

RESULTS AND DISCUSSION

Chile’s health system observes certain state duties and protects individual rights to health. These obligations and rights are articulated in three types of legal/policy documents: international law, domestic constitutional law, national policies, and national legislation. This section first describes Chile’s international law commitments in treaties enshrining health rights and its application in its domestic legal system. Then this section examines domestic constitutional law and describes the rights and obligations regarding health and medicines as well as their enforceability before domestic courts. National Policies that were crafted to give shape to the national health system during the period of the health reform in the early 2000s are then analyzed, and the national health goals related to government’s obligation and strategies to provide universal access to medicines to Chilean population are described. In the last part of the section, national legislation is examined and the rights and obligations under the Universal Health Coverage are presented. In addition, Chilean domestic legislation is approached from a human rights perspective and laws concerning the protection of vulnerable groups, citizen participation, transparency accountability, and safeguards mechanisms are discussed.

1. INTERNATIONAL COMMITMENTS

a) Chile’s commitments to treaties enshrining health rights

Starting in 1966 with the signature of the International Convention on the Elimination of All Forms of Racial Discrimination, Chile has signed and ratified numerous International Human Rights Treaties that protect and promote the right to health.(50) Some of these treaties entail direct obligations regarding health care that states must comply for the realization of the right to health of its general population, whereas others emphasize the importance of addressing vulnerable groups (children, women, indigenous populations, disabled people) through the adoption of particular measures in order to safeguard and promote with equity, the health of all its citizens. Annex 1 includes a table showing a complete overview of the international treaties that Chile has ratified, in which year, and what specific commitments to health it has made in each treaty.
The ratification of these international treaties has direct implications for the government of Chile to provide access to medicines. The right to health in the ICESCR includes as one of the core government’s obligation, the duty to provide essential medicines.(3) The Convention on the Elimination of All Forms of Discrimination against Women includes the state obligation to provide appropriate services regarding pregnancy, natal and post-natal care, granting free services when necessary.(51) Among these services medicines are fundamental, so it can be concluded that the government must provide affordable medicines during pregnancy and the post-natal period to every woman. The opportune and affordable provision of essential medicines to every Chilean child, is an indispensable requisite to comply with the obligations of ensuring the survival and development of the child to the maximum extend, providing the necessary medical care to so, as stated in the Convention on the rights of the Child.(52) As can be extracted from the International Convention of the Protection of the Rights of all Migrants Workers and Members of their families, the Chilean government must also provide migrants with the medicines needed for the preservation of their life or the avoidance of irreparable harm to them regardless of their legal or employment status.(53) In accordance with the provisions of the United Convention on the Rights of Persons with Disabilities, states must ensure that disabled people can access to the medicines that they may specifically require due to their particular health conditions.(54) Finally, through the ratification of the Indigenous and Tribal Peoples Convention, Chile committed to ensure that Indigenous people enjoy “the highest attainable standard of physical and mental health” for which medicines are indispensable.(55) In line with the obligations contained in this treaty, the government must guarantee that these medicines are affordable and available within the indigenous communities, and that traditional indigenous medicines are also taking into account when planning health interventions. Given that 11% of Chileans are indigenous including Mapuches, Aymaras and other indigenous groups these obligations are quite relevant in the country.(56)

b) Applicability of international law in Chile’s domestic legal system

The Chilean Political Constitution adopted in 1980 had normative void with respect to the procedures that should be followed to incorporate the ratified International treaties (including human rights treaties) into the national legal system, as well as its position in Chile’s legal hierarchy.(57)(58)

With the aim of remedying this lack, two amendments were introduced in the constitution. Currently, the Article 5 of the constitution (modified in 1989) defines the nature of the human rights contained in international instruments, and the article 54 (introduced in 2005), regulates the incorporation process of the treaties.(57)

The new paragraph introduced in article 5 in 1989 disposes that “It is the duty of the State’s organs to respect and promote those rights, guaranteed by this Constitution, as well as by international treaties which have been ratified by Chile and that are in force”. Although some argue that it reaffirms the constitutional or even the supraconstitutional status of the international commitments (including the Supreme Court), the Chilean Constitutional Court refused that interpretation and affirmed that every international treaty is hierarchically subordinated to the constitution.(57)(59). The Article 54 establishes that “The approval of a treaty will require, in each Chamber, the quorum that corresponds, in accordance with article 66, and shall be submitted, in the pertinent, to the
formalities of a law”. In another paragraph article 54 states that “The provisions of a treaty may only be repealed, amended or suspended in the manner provided in the treaties themselves or in accordance with the general rules of international law”.

Although there’s still controversy, after the amendments of 2005 some have defined Chile as a moderate dualist system; while in order to incorporate international provisions they need to be approved by both chambers and submitted in the pertinent to the formalities of a law (dualism), on the other hand for the purposes of modification or reservation the rules to be followed are the ones established in the treaty itself or in the international law, what along with the established in article 5 represent a monist counterpart.

2. CONSTITUTIONAL RIGHTS

a) Rights and obligations

In Chile, the rights to life and to the physical and mental integrity of the person, as well as the right to health protection are recognized in the article 19 of the Constitution. In addition, the right to social security is also included in such article. The article 19.9 specifies that “the State protects the free and equal access to actions for the promotion, protection and recovery of health and for the rehabilitation of the individual” and establishes that it “will also be responsible for the coordination and control of the health-related actions”. There are two constitutional provisions in which the neoliberal political conception prevailing in the country at the time the constitution was drafted can be appreciated. Article 19.9 says that “It is a preferential duty of the State to ensure the implementation of health-related actions” but then adds “whether provided through public or private institutions” directly involving the private sector in the health services provision. In like a manner, such article recognizes that “Every person shall have the right to choose the health care system that he wishes to join, be it State-owned or private”. Taking into consideration these provisions it can be concluded that the constitutional obligations of the Chilean state are more oriented to coordinate, organize and protect health and health-related actions, rather than stressing its role as a preferential health provider. This conception of the role that the state must play with respect to the health of its citizens was reflected in the reforms that took place in the health sector during the 1980s, which involved the strengthening of the private health sector to the detriment of the public one.(35) One example was the creation of the private health system which originated the ISAPRES through the Decree with force of law Nº3 in 1981.(60)

To conclude, there is no single reference to medicines/drugs/pharmaceuticals or health technologies in the legal supreme text but there are multiple direct and indirect references to health protection and health care. Whole constitutional fragments of the articles discussed above can be found in Annex 1.

b) Enforceability

Another aspect to be taken into account is whether the constitutional rights above mentioned can be enforceable in domestic courts. The answer to this question can be found in the article 20 of the constitution, which states that anyone that suffers deprivation, disruption or threat in his/her legitimate exercise of the constitutional rights enshrined in article 19 of the constitution, is entitled to concur personally or through someone in his/her behalf to the respective Court of Appeals. In addition, it is stressed
that such courts “shall immediately take the measures it deems necessary to restore the rule of law and ensure the due protection of the affected party, notwithstanding the other rights that he may assert before the authority or the corresponding courts.” The right to appeal before the judicial authorities if the constitutional rights are jeopardized is even recognized under the state of exception, as it is reflected in article 45. Furthermore, article 30 claims that “Any person who is disrupted in his rights by the Administration of the State, its organisms or municipalities, will be able to complain before the courts that the law establishes”.

As far as the right to health is concerned, the article 20 of the constitution specifies that if guarantees and rights established in article 19.9 final paragraph, related to the right to choose either a public or a private health care system are violated, individuals can appeal before the courts. However, the other paragraphs of the article which refer to the most important responsibilities and duties of the Chilean state concerning health, such us the protection of equal access to promotion, protection and recovery of health actions, or the duty of the state of ensuring the implementation of health-related actions, are formally excluded from this possibility. Thus, it can be concluded that the exclusive reference made in article 20 to the last part of paragraph 9 of the article 19, limits the enforceability of the health-related commitments before courts. Whole constitutional fragments of the articles discussed above can be found in Annex 1.

c) Domestic litigation for access to medicines

In spite of the formal limitation to the enforceability of the right to health protection previously discussed, there have been recently cases claiming access to medicines in Chile. This process consisting of the judiciary claiming of the right to health by an individual or and organized group of patients or Non-governmental organizations (NGOs), is known as “litigation” or “judicialization” of access to medicines and it is a global phenomenon on the rise.(44)

In the case of Chile the progressivist interpretation that the Supreme Court have adopted regarding the constitutional right to health in the last years, have been identified as the reason for the incipient number of lawsuits.(44) The most part of the court cases claiming access to medicines are filed against ISAPRES, mainly due to abusive increases in the insurance premiums.(44)(61) In other cases, petitioners brought actions against ISAPRES claiming catastrophic coverage after the private insurance refusal of financing a certain treatment. In the cases included in this project (Annex 1), the constitutional rights claimed by the complainants were the right to life and the right to health protection. In the successful cases (the ones that resulted in the granting of the drug to the petitioners) the judges appealed to the same fundamental constitutional rights, health protection and life, to render a judgment in favor on the claimants. The fact that the most part of the lawsuits in Chile are filed against ISAPRES may have two possible interpretations. First, that Chilean private health sector is more prone to abusive behaviors affecting the right to health than the public one. And second, that since the population covered by such private health insurers belong to the highest-socioeconomic strata, they may enjoy better access to justice and could be more aware of their rights. In Annex 1 six cases claiming access to essential medicines from 2001 to 2016 are summarized. Patient’s claims along with the court’s arguments used to justify their judgments are included.
Litigation has had a substantial effect in the improvement on the access to medicines situation in many countries, including Chile where three million individuals were benefited when risk-adjusted premiums were declared unconstitutional by the Constitutional Tribunal.(62)

However, the judicialization of access to medicines has important risks that must be analyzed. Two main equity-related concerns have been identified. One, given that access to justice is conditioned by socio-economic factors alike the access to health, the judicialization process may reinforce existing inequalities since those that already have better access to drugs are more like to enjoy a better access to the judicial system. And two, individual judicial actions seeking access to medicines may result in horizontal inequities since not everyone received benefits in the same way and through the same mechanisms.(62) Health litigation can also have negative effects in the efficiency of resource-limited health systems functioning in a context of new life-saving expensive drugs and increasing complexities in health care provision, resulting from demographic and epidemiological transitions. In some cases, litigation may force health systems to deliver costly new treatments whose clinical effectiveness has not been properly proved and that are not included in the official medicines list used for reimbursement. One implication of this is that in some cases the priority setting is defined by courts rather than by the ministry of health which may lead to ‘suboptimal decisions for society as a whole, given the opportunity cost of no deliver other services’. (27)(62) In order to protect countries with mature social security systems from the possible distorting effects of health litigation, a proper definition of the constitutional guarantees which include, for instance, a reference to the national list of medicines is critical to prevent abuse.(27)

Chile is a HIC with a well-functioning social security system which has made in the last two decades substantial efforts aiming at expanding the coverage of health services among its population including access to essential medicines. The country has a National Medicines Formulary (NMF) and a legal instrument to prioritize the diseases (including treatments) to be included in the social security schemes, the EHG (both will be further discussed in the next section). Thus, the medicines reimbursed in Chile are selected on the basis of epidemiological studies, economic evaluations and demand and supply capacity of the Chilean Health system. In this context, the overuse of litigation resulting from a reductionist an individualistic view of the right to health, would jeopardize the available limited resources by forcing the state to reimburse high cost-treatments which wouldn’t have been prioritized otherwise. Nevertheless two facts justify the need of redress mechanisms in Chile to safeguard human rights. First, the existence of a powerful private health sector in the country which, according to the courts, has incurred in some abusive practices. Secondly, it is important to emphasize that technical selection criterion of medicines based on epidemiological and cost-effectiveness studies, may neglect individuals or groups suffering from life-threatening illnesses that are less prevalent or for which there is a single treatment whose effectiveness has not been fully proven. In the next section we will see how Chilean authorities have tried to solve this problem.

To conclude, when drafting the new constitution of Chile, it will be important to establish redress mechanisms which can be used as last resort measure while ensuring that they are include in such a way that don’t lead to an overused of health litigation. For doing so, the example of South Africa may serve as an inspiration due to its clarity. In the section 27
of South Africa’s Constitution which is devoted to the rights to health care, food, water and social security, it is stated that “The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights.”(63)

3. POLICY DOCUMENTS

The Health Goals for the decade 2000-2010 contained the Chilean political objectives respecting health at the time that the comprehensive health reform previously discussed was carried out.(64) In such plan, the obligation of the state to ensure access to essential medicines was clearly expressed, as follows; "The state must ensure that all people have access to health care and that the economic situation of families is not an obstacle or is undermined by the impact of high-cost benefits, such as emergency care, the treatment of chronic diseases or complex services". For achieving this goal measures to increase the financial protection in order to improve the access to essential medicines such as setting limits to any copayment, including independent workers in the health insurance schemes, or establishing a financial protection system for indigent and people with lower incomes were contemplated in the plan. The National Medicines Policy approved in 2004 aimed “To ensure the availability and access to the entire population of the essential medicines contained in the National Formulary, of guaranteed efficacy and quality, safe, affordable and whose rational use leads to achieve the maximum benefits in the health of people as well as a control of the expenditure they represent”.(65) The section 5 of the text was devoted to Political Guidelines and Lines of Action, including the point 5.1 about Guarantee in the Access and Availability of Drugs. This point contained the line of action 4, which was to incorporate in the bill of the EHG, the access to drugs as an explicit guarantee for the patients suffering from prioritized pathologies. In the same section, some lines of actions aiming to reinforce the presence of generics drugs in the country were included. Among them, “to modify the sanitary regulations with respect to drugs quality in order to guarantee their equivalence” and “to establish the conditions in which the user can access to the exchange of the prescribed pharmaceutical product according to its commercial name, by an equivalent generic” are worth to be highlighted. This document also shows the government’s intention to address the particular problems that marginalized and isolated populations face regarding access to medicines. The next National Health Strategy “Elije Vivir Sano” (Choose to Live Healthy) covers the ten years period from 2011 to 2020 and specifically devotes two goals to medicines-related issues.(66) The Goal 7.4 on the Strengthening of the Financing of the Sector, starts by acknowledging that the most important component of OOP spending in the country is medicines expenditure. Thus, the fourth line of action in this area is “the formulation of a medicines policy, which allows its insurance coverage and stimulates the use of drugs with lower prices”, which was seen by the government as one of the strategies with greatest potential to reduce direct payments. The goal 8.3 is to Improve the Quality of Medicines and Health Technologies. The multiple challenges that Chile faces to expand the access to medicines and health technologies in a context of limited resources are acknowledged, as well as the fact that the expenditure in medicines is a major burden especially for the poorest quintiles. As far as medicines are concerned, the impact goal established is to focus the activity “on a group of 100 essential drugs, reviewed and updated with a defined periodicity” ensuring that they are accessible to the population (especially for those who
benefit from the public system) and that they comply with characteristics of quality and rationality in their use.

The importance of the study of these texts also lies in the lessons that can be extracted from their retrospective analysis. In the first place, Chilean government’s goals and strategies regarding access to drugs, drugs affordability and medicines inclusion in the health insurance schemes were not merely intentions, since they have been progressively included and put in place to a great extent, through the approval of laws and regulations. Accordingly, a clear relationship can be established between the conceptions and the goals included in these documents, and the successive approval of laws during these years such us the Law 19966 (2004) which included an explicit guarantee regarding access to medicines to treat certain prioritized diseases;(67) the “Pharmaceuticals” Law 20724 (2014) on the modification of the Sanitary Code which was a first attempt to facilitate the use of bioequivalent drugs;(68) or the Law 20850 (2015) which aims to assure financial protection against the catastrophic costs of high-priced diagnostic and treatments;(69) In second place, the study of these documents allows appreciating a clear continuity in terms of the objectives to be achieved in this area, as well as in the strategies to be followed for their attainment during the 20 years period covered by these policy documents. This is indicative of the political commitment of the country regarding the affordable access to medicines of all the population. Complete fragments of the discussed policies can be found in Annex 3.

4. LEGISLATION

Chile’s health system is a mixed system with a public and a private sector. The health system is governed by multiple laws that lay out the State obligations and individual rights, population coverage, medicines included and direct costs. Table 1 includes the main laws and regulations that will be discussed in this section specifying whether they regulate FONASA, ISAPRES or both. Chilean legislation and regulation related to UHC and access to medicines is included in Annex 4, which direct links to the official texts. Annex 4 also includes relevant fragments of them with respect to the recognition of the right to health, universal health coverage, access to medicines and medicines reimbursement.

Table 1. Summary of Discussed Laws and Regulations

<table>
<thead>
<tr>
<th>LAWS AND REGULATIONS</th>
<th>FONASA</th>
<th>ISAPRES</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ministerial Decree Nº 1 with force of law (2006) which Fixes the Rewritten,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coordinated and Systematized text of the Decree Nº 2.763 (1979), and Laws Nº</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Law Nº 20.584 (2012) which regulates the Rights and Duties of People in Relation</td>
<td></td>
<td></td>
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<tr>
<td>to Actions related to their Health Care.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>to their Health Care.</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>• Ministerial Decree Nº 264 (2003) on the approval of the regulation of the National</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicines Formulary.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Law Nº 20.724 (2014) on the modification of the sanitary code on matters of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy Regulations and Medicines.</td>
<td></td>
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<tr>
<td>Event</td>
<td>X</td>
<td>X</td>
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<td>----------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Ministerial Decree Nº 43 (2010) which modified the Decree Nº264 (2003), which approves the regulation of the National Medicines Formulary.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exempt Resolution 1187 (2014) of the Ministry of Health, on the Approval of the Pharmacy Fund for Chronic Non-communicable Diseases in Primary Health care.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Exempt Decree 63 (2016) of the Ministry of Health, on the Approval of the General Technical norm Nº 0184 which establishes Protocol of Procedure for the submission of requests for Extraordinary Auspices.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Law Nº 20.500 (2011) on Associations and Citizen Participation on Public Management.</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Chilean legislation is complex and parts of laws are often repealed, modified or replaced by other laws or decrees without clearly specifying the validity of the amended law. In some occasions laws are rewritten, grouped and systematized through a ministerial decree with its own articles, but then other legal texts referred to the original articles of the grouped laws, rather than to the articles of the new decree. There are also doubled-articulated laws, whose articles were difficult to name and understand.

For simplicity, the laws mentioned in this document are those most recent/currently in force.

**a) Universal Health Coverage**

**a.1) Rights and obligations under legislation for UHC**

The Ministerial Decree Nº 1 with force of law (2006) specifies the government’s responsibility and functions in health matters.(70) Its article 1 establishes that the Ministry of health and other institutions are responsible for “exercising the State’s role of guaranteeing free and equal access to health promotion, protection and recovery and rehabilitation of the sick person; As well as coordinating, controlling and, when appropriate, carrying out such actions”. In the same way as in the constitution, the last sentence than limits the implementation of health actions “when appropriate”, reinforces the supervisor role of the state over its service delivery function. In addition, Article 133 sets that the bodies that integrate the National System of Health Services have the obligation of the execution of the actions that “that tend to assure the health of the inhabitants of the Republic”. With respect to the rights granted to Chilean citizens, article
131 of this legal text recognizes the constitutional right of health protection, whose exercise includes "free and equal access to health promotion, protection and recovery and rehabilitation activities, as well as freedom to choose the health care system public or private that each person wishes to embrace". Again, as in the constitution, the right to health is directly linked with the right to choose between the public and the private health systems. In addition, Law 20584 (2012) includes in its article 2 that despite the health provider (public or private) everyone has the right to receive in a “timely manner and without arbitrary discrimination” their correspondent actions of promotion, protection and recovery of his/her health. (71)

Although the words medicines/drugs/pharmaceuticals doesn’t appear in these legal instruments there are clear references to them under the recovery and rehabilitation actions referred to in the articles discussed.

As far as medicines are concerned, the vast majority of the Chilean legal architecture that regulates the access to medicines comes mainly from the health reform that took place in the beginning of the 2000’s. Despite the fact that the strong role of the private health sector in the Chilean Health System was maintained after the approval of these laws, these reforms meant a change in the paradigm; from a more liberal one with the state having and invigilator task, to a one based on enforceable rights which concern both the public and the private sectors. The Decree No 264 (2003) which approved the regulation of the NMF obliges the state, in its article 4, to ensure the mandatory availability of all the medicines included on it “for all the population that requires it”. (72) The considerations section of this Decree is a great instrument to explain the conception of the Chilean State in relation to medicines after the major health system reform; health is defined as an essential need of the human person which constitute a priority for the State; the irreplaceable role of medicines in healthcare is stressed; and ensuring the availability and access to medicines of the population is qualified as imperative. Another important characteristic of this Decree is that it specifically subordinates these actions to the “resources that society can provide for this purpose”. This can be interpreted either as the acknowledgment of the scarcity of resources in order to pave the way for the introduction of cost-effectiveness criteria when selecting drugs to be reimbursed, or as a loophole for the State to use the lack of resources as an excuse for not providing everyone with essential medicines. The Law No 19.966 (2004) is the cornerstone of the access to medicines in Chile since it establishes specific guarantees to the diagnosis, treatment and follow up of certain prioritized diseases including access, timely access, financial protection and quality. (67) In addition, in its article 2 specifies the mandatory compliance of the benefits regime by both systems as follows; “The National Health Fund and the ISAPRES must ensure these guarantees to their respective beneficiaries”. These guarantees grant rights to citizen as indicated in article 2; “The Explicit Health Guarantees will be constituents of rights for the beneficiaries and their compliance may be demanded before the National Health Fund or the Institutions of Social Security, the Superintendence of Health and other corresponding bodies.” This law meant a fundamental step towards the right to health realization of Chilean citizens, as it seeks to unify both the services provided in the public and the private sectors and the quality of them, while expanding the health benefits and granting enforceable rights to the Chileans with respect to their health. The Law No 20.724 known as “Pharmaceuticals law” also imposes obligations on the State in its article 94, by affirming that correspond to the Ministry of health “to ensure the
access of the population to quality, safe and effective medicines or pharmaceutical products” through actions carried out by itself or through other dependent institutions.(68) This law also establishes the responsibility of the Central Supplier of the National Health Services (CENABAST by its Spanish acronym) to ensure the availability of medicines in the health sector. The Law № 20850 (2015) which grants benefits and financial protection to high-cost diagnostics and treatments, also grants rights to the beneficiaries and entitle them to claim those rights against the corresponding authorities in case of non-compliance.(69)

a.2) Population covered

The legal instrument that determines the affiliates and beneficiaries of the public and the private systems is the Ministerial Decree 1 with force of law (2006).(70) Original fragments with regard to these questions are included in the Annex 4. In summary, there are considered FONASA’s beneficiaries people than contribute with the 7 % of their monthly income for health to FONASA, as well as their legal dependents. They are also considered FONASA’s beneficiaries people without resources which are financed by the State through a direct fiscal contribution. With regard to ISAPRES, there are considered beneficiaries people that contribute with the 7 % of their monthly income to an Isapre (or with more money in case the price of the health plan agreed is more expensive than the mandatory legal contribution), their legal dependents and other persons accepted by the Isapre.(73)

Article 160 of the abovementioned decree classifies the FONASA’s affiliates in four groups according to their income level (see table), in order to determine the proportion of the total cost of the benefits that the beneficiaries must pay.

Table 2. Groups of FONASA’s Affiliates according to income

<table>
<thead>
<tr>
<th>Group</th>
<th>Affiliates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>Indigent or people without resources and beneficiaries of the welfare pensions along with their legal charges.</td>
</tr>
<tr>
<td>Group B</td>
<td>“Affiliates whose monthly income does not exceed the minimum monthly income applicable to workers over eighteen years of age and under sixty five years of age.”</td>
</tr>
<tr>
<td>Group C</td>
<td>“Affiliates whose monthly income is higher than the minimum monthly income applicable to workers over eighteen years of age and under sixty-five years of age and does not exceed 1.46 times that amount, unless the beneficiaries depending on them are three or more, in which case they will be considered in Group B.”</td>
</tr>
<tr>
<td>Group D</td>
<td>“Affiliates whose monthly income is higher by 1.46 times the minimum monthly income applicable to workers over eighteen years of age and under sixty-five years of age, provided that the beneficiaries who depend on them are not more than two. If the beneficiaries that depend on them are three or more, they will be considered in Group C.”</td>
</tr>
</tbody>
</table>
a.3) Medicines selected

UHC includes the EHGs, which are composed of a basic package of medicines available in both the public and private systems. In addition to the EHG, there is a financial protection system for high costs treatments for specific health conditions such as immunological, oncological and rare or infrequent diseases, which is available to the beneficiaries of the public and private health systems and the AFHS. The medicines included in these benefits are based on the NMF, whose regulation was approved by the Decree Nº 264 in 2004, and was subsequently modified by Decree Nº 43 in 2010.(74) The NMF is "the official document of the Republic of Chile that contains the selected list of pharmaceutical products indispensable for an efficient therapy based on the epidemiological reality of the country and the scientific evidence, whose quality must be guaranteed." According to its article 2 an indispensable pharmaceutical product is defined as “A drug that is basic, of the highest importance and precise to meet the health care needs of the majority of the population and to address those pathologies declared a priority in government health plans.” The article 5, modified by the Decree 43 in 2010, establishes the selection criteria for including medicines in the National Formulary, which are: 1) Indispensable according to the previous definition; 2) Prove safe and effective; 3) Evidence-based and conform with therapeutic guidelines or protocols and address priority conditions; 4) Cost-effective.(74) Once a medicine has been selected to be part of the National Formulary of Medicines, it can be considered for being included in the EHG, what means that they will be totally or partially reimbursed depending on the affiliation groups discussed above.(70) Article 13 of Law Nº 19.966 explains that in order to determine the list of health priorities to be included as part of the EHG, factors such as the health status of the population, the cost-effectiveness of the interventions and their contribution to the extension or quality of life will be considered. For doing show, as described in the next article, epidemiological studies, systematic reviews of the effectiveness of the intervention, economic evaluations and studies of the potential demand and supply capacity of the Chilean Health System will be carried out.(67)

a.4) Cost to patients

The percentage of the costs to be paid for a disease included in the EHG (including the drugs) is established in the Law Nº 19.966 as part of the Financial Protection Guarantee.(67) In the case of FONASA, groups A and B, and people over 60 years as well as people that receive welfare pensions the cost is zero. People belonging to group C must pay 10% with a limit of 21 contributions for one disease, and 31 contributions for two or more diseases. The Group D pays the 20% of the benefits with different limits depending also of the number of EHG diseases. On the other hand, ISAPRES ´affiliates are to pay the 20% of the benefits according to the reference tariff available in each Isapre which a limit of 29 or 41 contributions depending if the affiliate is taking advantage of one or more diseases.(75)

Moreover, this law establishes an Additional Financial Coverage to FONASA and ISAPRES beneficiaries understood as "the financing of 100% of the co-payments originated only by diseases or health conditions contained in the Explicit Health Guarantees referred to in this law, which exceed the deductible referred to in subsection second". In addition to this financial protection mechanism, there is place a catastrophic insurance for FONASA's
users which are treated in the public system, that covers the 100% of the costs of serious diseases that are considered catastrophic. In the case of the private system, some ISAPRES offers an additional coverage for catastrophic diseases, which includes the 100% of the expenses incurred in excess of the deductible to pay as established in the contract.(75)(73)

The legal backbone formed by the laws grouped under the Ministerial Decree 1 and the five laws passed during the reform of the beginning of the 21st century, has been progressively complemented in order to expand the coverage and improve the access to medicines with other laws and regulations approved in the recent years. In 2014, the Exempt Resolution 1187 on the approval of the Pharmacy Fund for Chronic Non-communicable Diseases (PHFCD) was a significant measure that improved the access to medicines situation of the patients treated in the public system. As the resolution claims in its component 1, this fund aims to provide the “Population served in Primary Care facilities with timely access to medications and support in adherence to treatment” by considering for “people with non-communicable diseases and in particular with cardiovascular health problems, the timely purchase and delivery of drugs”. In accordance to this regulation, the fund is providing free of cost and timely medicines for the treatment of Type 2 Diabetes, High Blood Pressure, Dyslipidemia and supplies for the management of the diabetic foot.(76)

Another case was the Law Nº 20850 (2015) which established a financial protection system for high cost treatments and diagnostics to all beneficiaries of Chile’s Health care systems (FONASA, ISAPRES and AFHS) as set in its article 1.(69) According to its article 2, a high-cost treatment is understood as “The drug, food or medical elements associated with diseases or health conditions and essential services for diagnostic confirmation and monitoring, which by their cost prevent access to them or by accessing, impact catastrophically in the expenditure of the beneficiaries”. As established in the same article, the financial protection granted under this law is “the total value of the diagnostic confirmation benefits and the high cost treatments”. Due to its universal nature since it affects the beneficiaries of the different Chilean Health Systems, to the scope of its coverage (100% of the costs) which prevent patients from catastrophic expenditures, and to the fact that covers rare or less frequent but life-threatening diseases that wouldn’t be prioritize according to the selection criteria of the EHG, this law embodied a fundamental step towards the progressive realization of the right to health in Chile.

Aware that despite the different measures of financial protection established in the aforementioned laws and regulations, there were patients who would still be unable to face the costs of their treatments, The Chilean Health system has a last resort measure for Fonasa’s users; the Extraordinary Aid Fund.(77) This fund, regulated by the technical norm 0184 established in the exempt nº 63 of 2016, is administrated by the highest health ministerial authority. Request for this extraordinary assistance “require a medical and socioeconomic analysis with a background, which allows prioritizing the demand, making it possible to provide highly complex care to the most vulnerable beneficiaries”. As a rule, the cost of the treatment covered by this mechanism is partial, and its total financing would be complemented by other governmental bodies as well as by the person or his/her family. The most relevant criteria for being eligible for receiving this economic support are, being a FONASA’s user in the institutional modality, being beneficiary of any of the
social programs working in the country, or belonging to a family in social vulnerability. In addition, a fundamental requirement is that the drug for which compensation is requested must have a Sanitary Register granted by the Institute of Public Health. Among the prioritization criteria, there’s one that doesn’t respond to any technical or socioeconomic reason and draws attention due to its discriminatory nature. This is the case of including “Officials of the health sector and their families” among the prioritized groups for granting this financial protection. Given that the Extraordinary Aid Fund is directly administrated by the Ministry of Health, and that it is specifically highlighted in the exempt the need of a socioeconomic analysis to prioritize demand, the inclusion of such criteria is not justified.

b) Right to Health Approach in the Health System

b.1) Vulnerable Groups in the Chilean Legislation and Regulation

The non-discrimination human right principle emphasizes that the benefits for the progressive realization of the right to health must be shared among all the individuals of society, including the ones belonging to the most vulnerable groups. A way of checking if the domestic Chilean laws regarding health and access to medicines are in line with this human right principle is to see if these groups are specifically addressed. Table 3 offers an overview of the relevant legislation, the vulnerable group(s) it aims to protect, and the relevant rights or services it enshrines.

<table>
<thead>
<tr>
<th>Vulnerable Group</th>
<th>Law/Regulation</th>
<th>Health-related Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women and Children</td>
<td>• Ministerial Decree 1 with force of Law (2006)</td>
<td>• Right to state protection during pregnancy and up to the sixth month of the birth of the child, which shall include pregnancy and puerperium control.</td>
</tr>
<tr>
<td></td>
<td>• Law Nº 20.379 (2009)</td>
<td>• The newborn child up to six years of age shall also have the right to the protection and control of the State’s health.</td>
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<tr>
<td></td>
<td></td>
<td>• Creates an Integrated protection system “Chile Crece Contigo” which guarantees benefits for children in vulnerable situations including technical aids for children with disabilities.</td>
</tr>
<tr>
<td>Elderly (over 60 years old)</td>
<td>• Ministerial Decree 1 with force of Law (2006)</td>
<td>• Free care in the public system network.</td>
</tr>
<tr>
<td></td>
<td>• Law Nº 19.966</td>
<td>• EHG benefits free of costs.</td>
</tr>
<tr>
<td>People without resources and Indigent people</td>
<td>• Ministerial Decree 1 with force of Law (2006)</td>
<td>• Free care in the public health network</td>
</tr>
<tr>
<td>Migrants</td>
<td>• Ministerial Decree Nº 67 (2015)(78)</td>
<td>• Right to receive the same health benefits than indigents and people without resources.</td>
</tr>
</tbody>
</table>
In some cases vulnerable groups are entitled to receive additional benefits in order to properly address its particular health needs. This is the case of women and children or the Elderly whose special benefits are included in the table. In other cases, the legislation aims at compensating the inherent difficulties that some groups of society may suffer with regard to access to health care and health benefits due to its mental or physical conditions, or to special situations, such as imprisonment. Particularly relevant is the inclusion of undocumented immigrants to the health insurance benefits. This measure reflects in first place the commitment of the Chilean government to protect the right to health of the underprivileged regardless of their legal status. In second place, it shows the government’s awareness and responsiveness towards the new situations of vulnerability that arise in the country. Both circumstances, “the legal obligation of the organism of the Public Health System to grant health care to the inhabitants” and “the increase of migrants in the country, who don’t yet possess immigration documents”, are considered in the text of the Ministerial Decree mentioned in the table. The Chilean experience with respect to irregular immigrants can serve as an example for other countries facing the same situation. As far as the indigenous populations are concerned, the health laws contain provisions in order to assure that cultural sensitive approaches are included in the design and implementation of policies and programs that address them, maximizing its effectiveness and improving their health as much as possible. The health status of the different Chilean’s Indigenous groups is of great importance for the country, since they make up a significant 11% of the population.(56)

One aspect to take into consideration is that the most part of these laws were approved during or after the comprehensive health sector reform of the beginning of the 2000’s. Thus, it can be concluded that the reform carried out in Chile and lately expanded by the successive governments has been comprehensive, since have focused not only in the health of the citizens easier to reach but also in the most vulnerable sectors of society. However, LGBTI people who may be victims of discrimination in health care are not specifically included in the commented laws and other laws devoted to promote and protect their health were not found, which may reflect a lack of attention of the government to these persons. Therefore, more attention needs to be paid to this group in

<table>
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<tr>
<td></td>
<td>• Law Nº 20.584 (2012) • Right to receive healthcare with “cultural relevance”.</td>
</tr>
<tr>
<td>Mentally/Physically Disabled</td>
<td>• Law Nº 20.584 (2012) • Right to receive timely health care of the same quality of non-disabled people.</td>
</tr>
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<td></td>
<td>• Law Nº 20.255 (2008)(80) • Establishment of a National Commission for the Protection of the Rights of Persons with Mental Illnesses and Regional Protection Commissions, to ensure the protection of rights and advocacy of persons with mental or intellectual disabilities in the health care delivered by public or private providers.</td>
</tr>
<tr>
<td>Prisoners</td>
<td>• Law Nº 20584 (2012) • Right to receive timely health care of the same quality of non-prisoners.</td>
</tr>
</tbody>
</table>
order to better adapt the health services to them (especially to transgender people) being able to effectively tackle their health needs improving its health status.

b.2) Citizen Participation

A right to health approach in the health system requires citizen participation, transparency and accountability. The first Agenda for Citizen Participation published in 2006, has been successfully renewed every four years and the current one covers the period from 2014 to 2018, showing the commitment to maintain an empowered and active civil society in health issues.(81) The 2006-2010 Agenda recognized that the indissoluble link between citizen participation and social protection is vital for the democratic development and aimed to incorporate citizens in the formulation, execution and evaluation of public policies through the institutionalization of regular practices of citizen inclusion. This text which set the basis for the subsequent agendas consisted of four programmatic axes: Citizen Right to public information, Participatory Public Management, Strengthening Civil Society and Non-Discrimination and Respect for Diversity.(81)

The legal landmark with respect to citizen participation was the approval in 2011 of the Law Nº 20.500 on Association and Citizen Participation in Public Management.(82) Article 69 of this law recognizes individuals “the right to participate in their policies, plans, programs and actions”, and through article 70 obligates every organ of the State to establish specific modalities for the participation of citizens and organizations. This legal text in its article 74 regulates the establishment of advisory Civil Society Councils (CSCs). Another remarkable step was the approval of the Exempt Resolution Nº 31 which set a General Rule of Citizen Participation in Public Health Management.(83) This rule defined citizen participation in Public Health as the specific application of the rights included in other domestic laws, such as the right of equality to participate in national life, the right to freedom of opinion and the right to petition, as well as the rights to the publicity of public information.

The Civil Society Councils are a mechanism of citizen participation through which representatives of organized civil society are linked to the organs of state administration. Its character is merely consultative and its composition should be diverse, plural and representative, including members of civil society related to the issues of competence of the public administration body.(82) These councils have been promoted in recent years as part of the implementation of the different agendas of citizen participation. There are currently in place CSCs in the most relevant health institutions of the country, including CENABAST, the Institute of Public Health, FONASA and the Superintendence of Health.(84)(85)(86)

The CSCs of FONASA have, among others, the objectives of promoting constantly in time the health rights in the society and in the organizations that their represent, as well as ensuring that public decisions favor the general interest.(86) The contribution with ideas in the analysis of public policies that seek to improve the procurement and supply of pharmaceuticals is the main aim of CENABAST’S CSCs.(87)

By being represented in the bodies of citizen participation of the most important health institutions of Chile, civil society groups are well positioned to promote policies and
actions towards the universal access to medicines in different manners. The CSCs may be of help during the priority setting processes by identifying specific access or affordability problems faced by vulnerable groups, or other particular situations where the access to medicines is being hampered that may be overlooked by the government. In addition, these councils can serve as a microphone for groups that are generally underrepresented in the public institutions. The CSCs can also contribute to the improvement of the current tools that promote the access to medicines in Chile by translating complains and suggestions from civil society to the bodies of the State administration. Finally, in spite of their consultative nature, by being involved in the internal processes of the state bodies CSCs are located in the front line to identify practices or policies that may negatively affect the access to medicines situation, and bring them to the attention of civil society and the general population.

The recently approved Law Nº 20850 on the establishment of a Financial Protection System for Diagnoses and High-cost Treatments, includes in its article 22 the creation of a Citizen Commission of Surveillance and Control.(69) In accordance with the law this commission is composed by four representatives of patient’s associations along with representatives from scientific associations, and medical schools. The task of this commission is to monitor the functioning of the system in order to advice the ministers of health and finance. Being included in the monitoring system of one of the most important mechanism of financial protection of the country, is a great opportunity for civil society to be heard, to express their necessities, and to keep the system accountable. The main challenge of this commission is to ensure that the patient associations included in it are diverse and representative; avoiding that only the associations with greater political and economic power have access to the commission.

The measures undertaken by Chile to strengthen the role of civil society as well as the citizen participation in the field of health, contribute to the establishment of people-centered health systems. Thus, citizens can play a relevant role in their health care at the same time that the acceptability of health policies and interventions increase.

Relevant fragments of the laws and resolutions discussed are included in Annex 4, including more specific details such as the composition of these committees or other rules on their functioning.

**b.3) Transparency and Accountability**

Two laws regulate the transparency and accountability obligations of the state administration in Chile. The Law 20285 (2008) on Access to Public Information and the Law 20500 (2011) on Citizen Participation in Public Management.(82)(88) The Law 20285 states in its article 3 that the public function should be exercised with transparency, promoting the knowledge of the procedures and decisions adopted in its exercise. This law also grants every Chilean citizen the right to request and received information from every organ of the State administration (article 10) and in article 11, defines the principles that the organs of the state must follow to comply with this right. The Council for Transparency, whose main aim is to guarantee the right to access information of Chilean citizens, was also created by this law, being another remarkable aspect. The Law 20500 (2011) states in its article 71, that each body of the state
administration must make publicly available, the relevant information concerning its policies, programs or budgets. In the next article the law imposes the obligation to the State organs of giving public account of the management and budgetary execution of its policies, programs and actions.

Specifically within the field of healthcare, the Law 20584 (2012) established in its article 8, that everyone has the right to received “sufficient, timely, truthful and understandable information” about the ways of making complaints and suggestions or the healthcare that the respective providers offer as well as the value of them.(71) Elements of transparency were also included in article 27 of the Law 20850 on the establishment of a financial protection system for high-cost medicines and diagnostic tools. This law contemplated the creation of an information system to be implemented by the National Health Fund, in order to monitor and control the granting of the benefits, as well as the expenditure executed for each of them.(69) It is stressed in the same article that this information must be publicly available and monthly updated.

Transparency and accountability are comprehensively defined and enshrined in Chile’s legal instruments that regulate the obligations of the State organs, as well as in the law that specifically establishes the duties of the health administration. In addition, transparency and accountability elements have been concretely included in some of the laws recently approved to provide access to essential medicines.

b.4) Safeguards and Redress Mechanisms

The laws approved since the health sector reform in the 2000’s are constituent of rights for its beneficiaries, and include mechanisms for its enforceability. The Law 19966 (2004) on the EHGs, set up the mandatory compliance of the benefits regulated in the law and established in its article 24 that in case of non-compliance the affected person may claim before the Superintendence of Health. The sanctions that the Superintendence may exercise are also defined.(67) The same redress mechanisms were set up in the Law 20850 (2015) which established a financial protection system for high-cost medicines and diagnostic tools.(69) Moreover, the Law 20584 (2012) which regulates Chilean’s rights and duties with respect to their health care established that apart from the mechanisms available in the current legislation, any person can claim compliance with the rights conferred by this law before the health provider.(71)

At a different level, Chile has two important agencies whose main and specific function is to promote and protect human rights. The Human Rights Department of the Chilean Ministry of Foreign Affairs has, among others, the aim of promoting and protecting the civil, political, economic, social and cultural human rights of very Chilean, emphasizing in the rights of vulnerable populations in accordance with the international commitments of the country.(89) In addition, Chile counts on the National Institute of Human Rights, an independent but publicly financed law organization, with the purpose of protecting and promoting the human rights established in the domestic and international law. One of the core functions of this institution is to deduct legal actions before the courts of justice within the scope of its competence to protect human rights.(90)

The presence of two permanent bodies that advocate for the promotion and respect of human rights, one of them with the capacity to deduct legal actions; the fact that safeguard and redress mechanism are specifically included in the health laws recently approved in the country; and the legal recognition to claim compliance with the rights included the
Law Nº 20584; constitute a solid legal basis to safeguard the fulfillment of the health obligations included in the domestic legislation of Chile.

5. LIMITATIONS

The aim of this project was not to assess the actual implementation or the real effect of the laws and policy documents promoting access to essential medicines in Chile, but just to describe and analyse the Chilean legal and policy framework regarding access to medicines, in the light of the right to health. This project relied on searching for information which was dispersed and sometimes difficult to track down. In the few cases in which relevant information regarding some of the topics under study was found in an official policy document or in government’s websites or guidelines, but not in the legal primary source, it was also considered for the project. The Chilean constitution and other Chilean legal texts sometimes contain obscure language or blurred fragments as well as lack of conceptual clarity, hampering its understanding. The author is not a law expert and has carried out the whole translation of the legal fragments included in the project by itself, without peer review. Given that some of the sources of information for this project were national health plans documents and guidelines, this project was dependent on the frequency of publication, availability and quality of these documents.

CONCLUSIONS

Chile has ratified numerous international treaties acquiring the commitment to the progressive realization of the right to the highest attainable standard of health of all its citizens, including the most vulnerable groups of society. As it has been discussed in the introduction, access to affordable medicines is a fundamental requisite in order to achieve that goal. The right to health is reflected in the Chilean constitutional law where the rights to health protection, life and physical and mental integrity are recognized. The constitution also includes multiple direct and indirect references to medicines under the necessary actions for health protection, promotion and recovery. These constitutional rights are being increasingly used to denounce abusive practices of the ISAPRES or to claim catastrophic coverage after the refusal of financing a certain treatment by the correspondent public or private insurer.

The right to access to medicines as part of the right to health has been a fundamental element of the two last national health strategies, and was plainly recognized in the national medicines policy that rose during the health reform. In particular, the Health Goals for the Decade 2000-2010 were a turning point as far as the access to essential medicines is concerned. The conviction of the Chilean State to ensure access to health care including medicines, regardless the economic situation of the families, was the underlying idea that led to the fundamental health reforms that have taken place in the first two decades of this new century. These political commitments have materialized in laws that clearly entitle Chilean citizens to access a significant number of drugs. Through the approval of these laws the country has adopted two strategies to guarantee the access to essential medicines to all its citizens, in order to progressively comply with its international and domestic obligations with respect to the right to health. First, the granting of access and financial protection to a number of prioritized diseases according to
evidence-based criteria based on epidemiological, cost-effectiveness analysis and supply and demand capacity studies of the Chilean health sector. The maximum exponent of this approach is the law No. 19,966 on the Explicit Health Guarantees but it can also be appreciated in the implementation of the Pharmacy Fund for Chronic Non-communicable Diseases. The second approach is the establishment of safeguards mechanisms to address people whose diseases aren’t prioritized to be part of the EHG; because they are not sufficiently relevant for the country in terms of prevalence; because the treatment is too expensive; or because the treatment needed is not able to prove enough cost-effectiveness. This second strategy is embodied in the Law Nº 20850 which established Financial Protection System for High Cost Diagnosis and Treatments, or in the above mentioned Extraordinary Aid Fund. One remarkable characteristic of the reforms carried out in Chile in the last two decades, has been the progressive expansion of the benefits included in the health insurance schemes as part of the reform. Thus, the EHG which included 25 priority health conditions in 2005, were expanded to 69 in 2010 and to 80 in 2014 (91). The Health conditions included in the Financial Protection System for High Cost Diagnosis and Treatments have also increased from 11 in 2015, to 14 with the recent inclusion of three new diseases in the program coverage. (46)

The analysis of the Chilean domestic legal framework from a human rights approach also reveals good performance in general terms. The comprehensive reforms in the Chilean health sector expanded the population covered; increased the benefits offered in the social security schemes; improved the financial protection of the Chilean citizens; took into consideration the most vulnerable groups of society; and were accompanied by the strengthening of Citizen Participation, transparency and accountability in the health sector. The Law Nº 20.500 on Association and citizen participation in public management recognized the right of Chilean citizens to actively participate in the political life of the country, through the introduction of different participatory mechanisms in Chilean institutions. In addition, the Law Nº 20.285 on Access to Public Information imposed the obligation to the state organs of exercising the public function with transparency and promoting the knowledge of the decisions and procedures adopted during its exercise. Chile has also safeguard and redress mechanisms in case human rights contemplated in their domestic legal instruments or in the international law are not respected, as well as two bodies devoted to the protection and promotion of these rights.

In order to improve the access to medicines situation keeping on truck of the progressive realization of the right to health, in accordance to its international commitments and its domestic legal obligations, Chile should: expand the health conditions and treatments included in the EHG and in the Financial Protection System for High-cost Diagnostics and treatments; increase the number of drugs provided free of cost to the users of FONASA as part of the PHFCD; and prioritize vulnerable populations such as LGBT people that seems to be disregarded by the health authorities. Given the good economic indicators of the country, and the scarce public health expenditure especially in comparison with the other
members of the Organization for Economic Cooperation and Development (OECD), there’s room for increasing it in case it were necessary for the implementation of some of the above mentioned recommendations. For doing so, the Chilean health system could expand the share of revenues that come from general taxation, as suggested by the OECD. The OCDE has also recommended Chile to establish a unified social security system for the entire population, in the longer term. This may contribute to alleviate the current inequalities in health care, aligning the country more with the human right principle of non-discrimination.

The example of Chile might serve as an inspiration for countries with a strong participation of the private sector in health, which aimed to progressively equalize the benefits granted in the public and private systems, including access to medicines. Chile has been considered a high-income country since 2013, meaning that at the time that the most part of the reforms were carried out it was an upper-middle income country. This suggests that its example may be followed by countries with similar economic profiles which seek to improve the coverage of the health insurance schemes, including access to medicines, with limited public health expenditures. From Chile’s experience there also are some lessons that can be extracted with regard to elements needed when a comprehensive health reform is to be undertaken. First, the definition of clear and ambitious political objectives in the national health plans based on an evidence-base analysis of the situation in the country, taking into account its epidemiological and demographic situation to define health priorities. Secondly, the translation of these political commitments into laws, which provide a sufficient legal basis for the reform and contribute to their effective implementation. And thirdly, a political commitment over time is needed to complete the reforms that couldn’t be carried out, while identifying new needs to be addressed at the same time that the already reached objectives are improved. This project is also illustrative of all the elements that determine the formal access to essential medicines in a country and how they interact and influence each other; from the international commitments acquired in the international law or the fundamental rights recognized in its constitution, to the domestic legislation and regulations in force in the country, passing through the goals established in its successive national health plans.

ACKNOWLEDGEMENTS

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This Master Final Project wouldn’t have been possible without the involvement of Joan Tallada in all its stages.
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**Essential Laws for Medicines Access** project - Profile of Chile

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**ANNEX I**

## State commitments in international treaties

<table>
<thead>
<tr>
<th>Treaty</th>
<th>Health-related Commitments</th>
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<tbody>
<tr>
<td><strong>International Covenant on Economic, Social and Cultural Rights (ICESCR)</strong></td>
<td>States must follow some steps in order to achieve the highest attainable standard of physical and mental health, including: “the prevention, treatment and control of epidemic, endemic, occupational and other diseases” and the “creation of the conditions which would assure to all medical service and medical attention in the event of a sickness”. The right to social security including social insurance is also recognized in the treaty.</td>
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<tr>
<td><strong>Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)</strong> (Amendment to article 20, paragraph 1 of the Convention on the Elimination of All Forms of</td>
<td>States must take the appropriate measures to eliminate the discriminations that women suffer in the field of healthcare. States must ensure appropriate services regarding pregnancy, natal and post-natal care, and adequate nutrition during pregnancy and lactation. Free services must be established when necessary.</td>
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<tr>
<td>Convention</td>
<td>Date of Entry</td>
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<tr>
<td>Discrimination against Women?) Optional Protocol</td>
<td>Dec 10th 1999</td>
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<tr>
<td>Convention of the Rights of the Child (CRC)</td>
<td>Jan 26th 1990 Aug 13th 1990</td>
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<tr>
<td>ILO Convention 169 (Indigenous and Tribal Peoples Convention)</td>
<td>Sept 15th 2008</td>
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<tr>
<td>International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families</td>
<td>Sept 24th 1993 Mar 21st 2005</td>
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<tr>
<td>International Convention on the Elimination of All Forms of Racial Discrimination (ICERD)</td>
<td>Oct 3rd 1966 Oct 20th 1971</td>
</tr>
<tr>
<td>International Covenant on Civil and Political Rights (ICCPR)</td>
<td>Sept 16th 1969 Feb 10th 1972</td>
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<tr>
<td>States must ensure access for persons with disabilities to health services. States must ensure that health care services and interventions provided to persons with disabilities are of the same quality and affordability standards that the ones offered to the general population. This concerns the area of sexual and reproductive health and population-based public health programs. States must provide persons with disabilities with the special services that they may need due to their health conditions.</td>
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</table>
## Implementing & enforcing human rights standards in the domestic legal system

<table>
<thead>
<tr>
<th>Is the nation a monist or a dualist system, or a mix? Are international treaties directly enforceable in domestic courts? Under which circumstances?</th>
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<tbody>
<tr>
<td>➢ Political Constitution of the Republic of Chile (1980):</td>
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<tr>
<td>Article 5, amended 1989:</td>
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<tr>
<td>“The exercise of the sovereignty is limited by the respect to the essential rights that emanate from the human nature. It is the duty of the State’s organs to respect and promote those rights, guaranteed by this Constitution, as well as by international treaties which have been ratified by Chile and that are in force.”</td>
</tr>
<tr>
<td>“El ejercicio de la soberanía reconoce como limitación el respeto a los derechos esenciales que emanan de la naturaleza humana. Es deber de los órganos del Estado respetar y promover tales derechos, garantizados por esta Constitución, así como por los tratados internacionales ratificados por Chile y que se encuentren vigentes.”</td>
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<tr>
<td>Article 32 (15):</td>
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<td>“To conduct political relations with foreign powers and international organizations, and conduct negotiations; conclude, sign and ratify the treaties that it deems appropriate to the interests of the country, which shall be submitted for Congressional approval as prescribed in article 54 Nº1º. The discussions and deliberations on these matters shall be secret if the President of the Republic so demands it;”</td>
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| “Conducir las relaciones políticas con las potencias extranjeras y organismos internacionales, y llevar a cabo las negociaciones; concluir, firmar y ratificar los tratados que estime convenientes para los intereses del país, los que deberán ser sometidos a la aprobación del Congreso conforme a lo prescrito en el
Artículo 54 Nº 1°. Las discusiones y deliberaciones sobre estos objetos serán secretos si el Presidente de la República así lo exigiere;

Article 54.1 amended in 2005, previously article 50:

“The powers of the Congress are to approve or reject the international treaties presented by the President of the Republic prior to their ratification. The approval of a treaty will require, in each Chamber, the quorum that corresponds, in accordance with article 66, and shall be submitted, in the pertinent, to the formalities of a law (...) The Congress may suggest the formulation of reservations and interpretative declarations to an international treaty, during the process of its approval, as long as they proceed in conformity to what is established in the treaty itself or in the general rules of international law.”

“Son atribuciones del Congreso: Aprobar o desechar los tratados internacionales que le presentare el Presidente de la República antes de su ratificación. La aprobación de un tratado requerirá, en cada Cámara, de los quórum que corresponda, en conformidad al artículo 66, y se someterá, en lo pertinente, a los trámites de una ley. (...) El Congreso podrá sugerir la formulación de reservas y declaraciones interpretativas a un tratado internacional, en el curso del trámite de su aprobación, siempre que ellas procedan de conformidad a lo previsto en el propio tratado o en las normas generales de derecho internacional.”

“The measures that the President of the Republic adopts or the agreements that he celebrates to comply with a treaty in force will not require new congressional approval, unless they concern matters of law. The treaties celebrated by the President of the Republic in exercise of his regulatory authority will not require congressional approval.”

“Las medidas que el Presidente de la República adopte o los acuerdos que celebre para el cumplimiento de un tratado en vigor no requerirán de nueva aprobación del Congreso, a menos que se trate de materias propias de ley. No requerirán de aprobación del Congreso los tratados celebrados por el Presidente de la República en el ejercicio de su potestad reglamentaria.”

“The provisions of a treaty may only be repealed, amended or suspended in the manner provided in the treaties themselves or in accordance with the general rules of international law. It corresponds to the President of the Republic the exclusive power to denounced a treaty or withdraw from it, for which he shall ask for the opinion of both branches of the Congress, in the case that the treaties have been approved by it. Once the denunciation or withdrawal has produced its effects in conformity with the provisions of the international treaty, it shall cease to have effect in the Chilean legal system”

“Las disposiciones de un tratado sólo podrán ser derogadas, modificadas o suspendidas en la forma prevista en los propios tratados o de acuerdo a las normas generales de derecho internacional. Corresponde al Presidente de la República la facultad exclusiva para denunciar un tratado o retirarse de él, para lo cual pedirá la opinión de ambas Cámaras del Congreso, en el caso de tratados que hayan sido aprobados por éste. Una vez que la denuncia o el retiro
produzca sus efectos en conformidad a lo establecido en el tratado internacional, éste dejará de tener efecto en el orden jurídico chileno.”

**Does the national constitution: recognize the right to health? Specify the government’s responsibility to ensure access to health care/services/facilities/goods or to provide medicines or recognize medicines rights in another way?**

<table>
<thead>
<tr>
<th>Political Constitution of the Republic of Chile</th>
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<tr>
<td>Article 19: The constitution guarantees all persons:</td>
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<tr>
<td>1. “The right to life and to the physical and mental integrity of the person.”</td>
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<tr>
<td>“El derecho a la vida y a la integridad física y psíquica de la persona.”</td>
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<tr>
<td>9. “The right to health protection: The State protects the free and equal access to actions for the promotion, protection and recovery of health and for the rehabilitation of the individual. It will also be responsible for the coordination and control of the health-related actions. It is a preferential duty of the State to ensure the implementation of health-related actions, whether provided through public or private institutions, in the form and conditions prescribed by law, which may establish compulsory contributions. Every person shall have the right to choose the health care system that he wishes to join, be it State-owned or private.”</td>
</tr>
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“El Estado protege el libre e igualitario acceso a las acciones de promoción, protección y recuperación de la salud y de rehabilitación del individuo. Le correspondará, asimismo, la coordinación y control de las acciones relacionadas con la salud. Es deber preferente del Estado garantizar la ejecución de las acciones de salud, sea que se presten a través de instituciones públicas o privadas, en la forma y condiciones que determine la ley, la que podrá establecer cotizaciones obligatorias. Cada persona tendrá el derecho a elegir el sistema de salud al que desee acogerse, sea éste estatal o privado;”

18. “The right to social security. The laws governing the exercise of this right shall be of qualified quorum. State action will be directed to ensure the access of all inhabitants to uniform basic benefits, whether they are granted through public or private institutions. The law may establish compulsory contributions.
The state shall supervise the proper exercise of the right to social security;”

“El derecho a la seguridad social. Las leyes que regulen el ejercicio de este derecho serán de quórum calificado. La acción del Estado estará dirigida a garantizar el acceso de todos los habitantes al goce de prestaciones básicas uniformes, sea que se otorguen a través de instituciones públicas o privadas. La ley podrá establecer cotizaciones obligatorias. El Estado supervigilará el adecuado ejercicio del derecho a la seguridad social;”

If the constitution recognizes the right to health, are constitutional commitments enforceable in domestic courts?

Article 20:

“He that by arbitrary or illegal acts or omissions suffers deprivation, disruption or threat in the legitimate exercise of the rights and guarantees established in article 19, number 1, 2, 3 fifth paragraph, 4, 5, 6, 9 final paragraph, 11, 12 ,13, 15, 16 in what is relative to the freedom to work and the right to free choice and freedom to contract, and what is set out in the fourth paragraph, 19, 21, 22, 23, 24, 25 may concur personally, or through anyone on his behalf, to the respective Court of Appeals, which shall immediately take the measures it deems necessary to restore the rule of law and ensure the due protection of the affected party, notwithstanding the other rights that he may assert before the authority or the corresponding courts. Likewise, the recourse of protection will also proceed in the case of number 8 of article 19, when the right to live in a pollution-free environment is affected by an unlawful act or omission attributable to a particular authority or person.”

“El que por causa de actos u omisiones arbitrarios o ilegales sufra privación, perturbación o amenaza en el legítimo ejercicio de los derechos y garantías establecidos en el artículo 19, números 1°, 2°, 3° inciso quinto, 4°, 5°, 6°, 9° inciso final, 11°,12°, 13°, 15°, 16° en lo relativo a la libertad de trabajo y al derecho a su libre elección y libre contratación, y a lo establecido en el inciso cuarto, 19°, 21°, 22°, 23°, 24°, y 25° podrá ocurrir por sí o por cualquiera a su nombre, a la Corte de Apelaciones respectiva, la que adoptará de inmediato las providencias que juzgue necesarias para restablecer el imperio del derecho y asegurar la debida protección del afectado, sin perjuicio de los demás derechos que pueda hacer valer ante la autoridad o los tribunales correspondientes. PROCEDERÁ, también, el recurso de protección en el caso del N°8° del artículo 19, cuando el derecho a vivir en un medio ambiente libre de contaminación sea afectado por un acto u omisión ilegal imputable a una autoridad o persona determinada.”

Article 45:
“The courts of justice may not qualify the bases or the factual circumstances invoked by the authority to declare states of exception, notwithstanding what is established in article 39. However, with regards to particular measures that affect constitutional rights, there will always be a guarantee to appeal before the judicial authorities through the appropriate recourses.”

“Los tribunales de justicia no podrán calificar los fundamentos ni las circunstancias de hecho invocados por la autoridad para decretar los estados de excepción, sin perjuicio de lo dispuesto en el artículo 39. No obstante, respecto de las medidas particulares que afecten derechos constitucionales, siempre existirá la garantía de recurrir ante las autoridades judiciales a través de los recursos que corresponda.”

Article 38:

“Any person who is disrupted in his rights by the Administration of the State, its organisms or municipalities, will be able to complain before the courts that the law establishes, notwithstanding the responsibility which could affect the functionary that caused the damage.”

“Cualquier persona que sea lesionada en sus derechos por la Administración del Estado, de sus organismos o de las municipalidades, podrá reclamar ante los tribunales que determine la ley, sin perjuicio de la responsabilidad que pudiere afectar al funcionario que hubiere causado el daño.”

If access to medicines as part of the right to health is enforceable in domestic courts, have there been recent cases claiming access to medicines?

✓ Corte Suprema de Justicia [C.S.J.] [Supreme Court of Chile], October 9th, 2001, “N. R. V. v. SERVICIO DE SALUD METROPOLITANO DE ORIENTE Y MINISTRO DE SALUD” Rol: 3.599-2001-10-16 (Chile).  

“Petitioners brought an action against the Ministry of Health and the Public Health Service, seeking protection for their constitutional rights to life and freedom from discrimination, in regards to their ability to access medicines and health treatment for HIV/AIDS. Petitioners argued that HIV/AIDS should be considered a public health issue and, consequently, the Ministry of Health should establish and implement health policies aimed at combating the disease. Furthermore, petitioners asserted the State’s failure to establish policies for the access to medicines and health treatment constituted discrimination against HIV/AIDS patients.”

The court denied legal protection to the petitioners claim considering that the Executive power via the Ministry of Health was the only body
empowered to establish health policies. Given that there were laws and regulations allowing access to the medicines and health treatments concerned in this case, no violation of the constitutional right to life or a discriminatory practice from the state was observed by the court.

✓ Corte Suprema de Justicia (Supreme Court of Chile), June 1st, 2009, “MYRIAM DE LAS MERCEDES ZUÑIGA QUINTANILLA CONTRA FONASA” Rol: 2499-2009.
Petitioner brought action against FONASA based on her right to health protection due to insurance refusal to provide her with “Multitarget” (Sunitibit) for the cancer that she was suffering, since it was not include in the AUGE Program. The court stated that no regulation has more force than the constitution, which forces the state and its agents to protect people’s right to life and health protection, so FONASA must provide the patient with the drug without delays.

Petitioner brought action against the ISAPRE (Chilean private health insurance institutions) “Fundación Banco Estado” as a result of its refusal to provide catastrophic coverage according to the Explicit Health Guarantees, for the treatment with Herceptin (Trastuzumab), which she required for her breast cancer. Claimant argued that the constitutional guarantees provided in articles 19 (right to health protection) and 20 had been violated. According to the court, the respondent (ISAPRE) couldn’t refuse the coverage of the costs of the drug Herceptin in the terms that was requested by the claimant. By doing so, the ISAPRE had engaged in an illegal and arbitrary act that jeopardized claimant’s right to life, since the privation form treatment would imply a significant decrease in the patient’s quality of life and survival expectations. Therefore, there was enough evidence to conclude that a serious damage was being inflicted to the claimant affecting her fundamental right to life. Hence, the ISAPRE must take the necessary measures to re-establish the rule of law, including financing and providing the drug to the patient under the terms of the financial coverage granted in the Explicit Health Guarantees System.

Petitioner brought action against the ISAPRE “MAS VIDA S.A.” due to the insurer’s refusal to fund the treatment of a patient with Paroxysmal Nocturnal Hemogloburin as a catastrophic disease, affecting the constitutional guarantees provided in Article 19 N° 1 and 2 of the Political Constitution of the Republic. The ISAPRE stated that since the drug was not registered in the Public Health Institute nor included in the National Formulary of Medicines, it was not obliged to provide the drug to the patient. Although the sanitary code establishes that any pharmaceutical product can’t be neither commercialized, nor distributed without previous registration in the Institute of Public Health, it also states that the health authority shall provisionally authorized without previous registration a pharmaceutical product for urgent medical use, clinical trials or scientific
research. Hence, in spite of the lack of registration, the drug “Soliris” (Eculizumab) was commercialized in Chile because it is indispensable for the patients with the above mentioned disease, as medicine with urgent medicinal drug. In addition, the users of the Public Health System, were able to access the drug, with charge to the Extraordinary Fund that covers high cost treatments. Thus the court concluded that the refusal of the ISAPRE constituted an arbitrary act that threatened the right to life on the patient, affecting likewise his equality before the law since the public health systems users have access to the drug after certain procedures. The court ruled that the ISAPRE must finance the drug under the Additional Coverage for Catastrophic Diseases.


After the refusal of the Ministry of Health to cover the cost of the treatment of her breast cancer with Herceptin, claimant sought access to the drug as part of the Explicit Health Guarantees and Additional Coverage for Catastrophic Illnesses, on the basis of the right to life and the right to mental and physical integrity. The court observed that the above mentioned claimant’s fundamental right was being jeopardized by the decision made by the Ministry of Health. Therefore, the Ministry of Health must provide and finance the drug to the patients.


Petitioner brought action against the ISAPRE “Cruz Blanca” as consequence of its refusal to grant coverage for the drugs “Sofosbuvir” and “Daclatasvir” as were prescribed by her doctor for the treatment of Hepatitis C. The ISAPRE considered that since they were outpatient drugs, its coverage was excluded from the health agreement and from the basket of the Explicit Health Guarantees and couldn’t be object of the Additional coverage for Catastrophic Diseases. In addition, the ISAPRE argued that the above mentioned treatments were not included for the Hepatitis C treatment in the list of the Explicit Health Guarantees, so they mustn’t be financed and provided. However, the Explicit Health Guarantees regulation considers a special coverage for these treatments that although they are not included in the referred list, they are included in the protocols or clinical guidelines defined by the Ministry of Health for the treatment of various pathologies (which was the case of “Sofosbuvir” and “Daclatasvir”. Therefore, the court ruled that by no providing the drugs to the patient, the ISAPRE was incurring in an infringement of the constitutional guarantees previously mentioned and is not justify by any means. Hence, the court confirmed the sentence that forced the ISAPRE to finance and provide the treatment to the patient.
# ANNEX 3

## Policies and guidelines

Which national policies or guidelines are related to access to medicines? Please list the relevant documents.

<table>
<thead>
<tr>
<th>National Policies:</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Health Goals for the decade (2000-2010)</td>
</tr>
<tr>
<td>✓ National Health Strategy (2011-2020)</td>
</tr>
<tr>
<td>✓ Pharmacy Fund for Chronic Non-communicable Diseases in Primary Health Care (2014)</td>
</tr>
</tbody>
</table>

Do any of these policies or guidelines specify the government’s responsibility to ensure access/provide medicines?

### National Policies

- ✓ Health Goals for the decade 2000-2010:

  “The state must ensure that all people have access to health care and that the economic situation of families is not an obstacle or is undermined by the impact of high-cost benefits, such as emergency care, the treatment of chronic diseases or complex services. In this sense, the Government proposes, in order to protect access and opportunity and ensure that health objectives are met:

  - To incorporate independent workers, to ensure effective universal coverage and equal rights and obligations.
  - To set limits to any co-payments, to provide effective access and social protection to all contributors and their charges.
To promote a financing system that effectively materializes the values of equity, effectiveness and economic efficiency.

Fiscal financing to the health protection of indigent and people with lower incomes.”

“El estado debe procurar que todas las personas tengan acceso a la atención de salud y que la situación económica de las familias no sea un obstáculo o se vea menoscabada por el impacto de prestaciones de alto costo, como pueden llegar a serlo la atención de urgencia, el tratamiento de las enfermedades crónicas o las prestaciones complejas. En tal sentido, el Gobierno se propone- a fin de que se protejan el acceso y oportunidad y se aseguren cumplir los objetivos sanitarios:-

Incorporar a los trabajadores independientes, para asegurar una efectiva cobertura universal e igualdad en derechos y obligaciones.

Fijar límites a los eventuales copagos, para brindar un efectivo acceso y protección social a todos los cotizantes y sus cargas.

Promover un sistema de financiamiento que efectivamente materialice los valores de equidad, efectividad y eficiencia económica.

Financiamiento fiscal para proteger sanitariamente a los indigentes y a personas de menores ingresos”

✓ National Medicines Policy in the Health Reform (2004):

“1. PURPOSE

To ensure the availability and access to the entire population of the essential medicines contained in the National Formulary, of guaranteed efficacy and quality, safe, affordable and whose rational use leads to achieve the maximum benefits in the health of people as well as the control of the expenditure they represent "

1. PROPOSITO

“Asegurar la disponibilidad y acceso a toda la población a los medicamentos indispensables contenidos en el Formulario Nacional, de eficacia y calidad garantizada, seguros, de costo asequible y cuyo uso racional lleve a conseguir los máximos beneficios en la salud de las personas como en el control del gasto que ellos representan”
5.I. GUARANTEE ON THE ACCESS AND AVAILABILITY OF MEDICINES

“1° The population through public or private health insurance and according to the conditions established in the respective laws (…), will have access to the medicines contained in the National Formulary (FN) which will be available in quantity and opportunity.

2° Access to medicines by users is facilitated by having generic products equivalent to the reference pharmaceutical product.

Lines of action: 1. Modify health regulations on the quality of medicines to ensure equivalence. (...) 3. To establish the conditions under which the user can access the change of the prescribed pharmaceutical product according to commercial name, by a generic equivalent.

3° The establishments of S.N.S.S. and the ones dependent on it, will assure to their users the availability of the medicines contained in the Pharmacological Arsenals elaborated on the basis of the National Formulary (…)

4° The sanitary authority will have through the establishments of S.N.S.S., a mechanism so that the population of those marginal or isolated areas that do not have authorized community pharmacies, can access pharmacotherapy.”

“1° La población a través de los seguros de salud públicos o privados y de acuerdo a las condiciones establecidas en las leyes respectivas (…), tendrá acceso a los medicamentos contenidos en el Formulario Nacional (F.N.) los que estarán disponibles en cantidad y oportunidad.

2° El acceso a los medicamentos por parte de los usuarios, se facilita al disponer de productos genéricos equivalentes al producto farmacéutico de referencia.

Líneas de acción: 1. Modificar las regulaciones sanitarias sobre la calidad de los medicamentos para garantizar su equivalencia.

(…) 3. Establecer las condiciones en que el usuario puede acceder al cambio del producto farmacéutico prescrito según denominación comercial, por un genérico equivalente.

3° Los establecimientos del S.N.S.S. y dependientes del mismo, asegurarán a sus usuarios la disponibilidad de los medicamentos contenidos en los Arsenales Farmacológicos elaborados sobre la base del Formulario Nacional (…)

4° La autoridad sanitaria dispondrá a través de los establecimientos del S.N.S.S., un mecanismo para que la población de aquellas zonas marginales o
5.5 ORGANIZATION FOR THE IMPLEMENTATION, DEVELOPMENT AND EVALUATION OF DRUG POLICY

3º: “Civil society organizations and medicines’ user groups will be actively involved in the formulation and development of drug policies.”

“Las organizaciones de la sociedad civil y grupos de usuarios de medicamentos, tendrán una participación activa en la formulación y desarrollo de las políticas de medicamentos.

✓ National Health Strategy 2011-2020
Goal 7.4: “As mentioned in the situation analysis, the most important component of out-of-pocket spending is medicines spending. The fourth line of action in this area is the formulation of a policy of medicines, which allows its insurance coverage and stimulates the use of drugs with lower prices. This is seen as one of the strategies that would have the greatest impact in reducing direct payments. The success of such a strategy is based on the achievement of several previous steps, such as the requirement of bioequivalence in the promotion of the use of generic drugs, or the incorporation of evaluation of health technologies in the case of decisions regarding which medicines to include in the coverage and which not.”

“Como se mencionó en el análisis de situación, el componente más importante del gasto de bolsillo es el gasto en medicamentos. La cuarta línea de acción en este ámbito es la formulación de una política de medicamentos, que permita la cobertura de éstos por parte de los seguros y que estimule el uso de los medicamentos de precios más bajos. Esta se vislumbra como una de las estrategias que mayor impacto tendrían en la disminución de los pagos directos. El éxito de una estrategia de este tipo se basa en el logro de distintos pasos previos, como la exigencia de bioequivalencia en la promoción de uso de medicamentos genéricos, o la incorporación de evaluación de tecnologías sanitarias en el caso de las decisiones respecto de qué medicamentos incluir en la cobertura y cuáles no.”

Goal 8.3: “In relation to SP (Sanitary Products) and ST (Health Technologies) the following strategies are proposed: (1) prioritized medicines; (2) accreditation of good manufacturing practices; (3) therapeutic equivalence; (4) active surveillance system; (5) security inventory; (6) rationality in the use of medicines; (7) list of prioritized technologies; (8) technology quality certification; and (9) technology surveillance. In terms of drugs, the impact goal has been established in terms of focusing the activity on a group of 100 essential drugs, reviewed and updated with a defined periodicity. It is crucial to ensure that they comply with characteristics of quality and rationality in their use, and that, above all, are accessible to the population, especially for those who benefit from the public health system.”
“En lo que dice relación con los PM (Productos Sanitarios) y TS (Tecnologías Sanitarias) se plantean las siguientes estrategias: (1) medicamentos priorizados; (2) acreditación de buenas prácticas de manufactura; (3) equivalencia terapéutica; (4) sistema de vigilancia activa; (5) inventario de seguridad; (6) racionalidad en el uso de medicamentos; (7) listado de tecnologías priorizadas; (8) certificación de calidad de tecnologías; y (9) vigilancia de tecnologías. En el tema de fármacos, la meta de impacto se ha establecido en términos de focalizar la actividad en un grupo de 100 medicamentos esenciales, revisados y actualizados con una periodicidad definida. Es crucial lograr que éstos cumplan con características de calidad y racionalidad en su uso, y que, por sobre todo, sean accesibles para la población, en especial para aquella beneficiaria del sistema público de salud.”

✓ Pharmacy Fund for Chronic Non-communicable Diseases in Primary Health Care (2014):

3.1 General Objective: "To contribute to the delivery of accessible and timely health services to the beneficiary population in charge of Primary Care by improving the access and availability of medicines to individuals and families affected, among others, by non-communicable diseases with priority in cardiovascular health problems, so as to enhance the opportunity and technical quality, in health care, in an integral way and with a family health approach."

“Contribuir a la entrega de servicios de salud accesibles y oportunos a la población beneficiaría a cargo de la Atención Primaria mejorando el acceso y la disponibilidad de medicamentos a las personas y familias, afectadas entre otras, por enfermedades no transmisibles con prioridad en problemas de salud cardiovascular, de manera de potenciar, la oportunidad y calidad técnica, en las atenciones de salud, de forma integral y con un enfoque de salud familiar.”

3.2 Specific Objectives:

"1. To grant in Primary Health Care, timely access of the population to drugs defined in the basic arsenal of the Health Service, for non-communicable diseases with priority in cardiovascular health problems”. Hypertension, diabetes and dyslipidemia (2015 sectorial ministerio de salud)"

"1. Otorgar en Atención Primaria de Salud, acceso oportuno de la población a medicamentos definidos en el arsenal básico del Servicio de Salud, para enfermedades no transmisibles con prioridad en problemas de salud cardiovasculares.”

En este contexto, los países deberán desarrollar una acción conjunta para sensibilizar y fortalecer la incorporación de los medicamentos esenciales en los programas de cobertura o dotación de medicamentos en los servicios de salud, realizando los esfuerzos necesarios para garantizar su financiamiento oportuno y adecuado.”
**ANNEX 4**

### Legislation & Regulation

**Which national legislation/regulation is related to access to medicines? Please list all relevant legislation/regulation currently in force.**

<table>
<thead>
<tr>
<th>Ministerial decree which groups the laws approved before the health sector reform, which are still in force:</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Ministerial <a href="#">Decree 1</a> with force of law (2006) which fixes the rewritten, coordinated and systematized text of the decree No 2.763 (1979), and laws No 18.933 (1990) and No 18.469 (1985).</td>
</tr>
<tr>
<td>Laws that supported the health sector reform in the 2000’s:</td>
</tr>
<tr>
<td>• Law <a href="#">No.19888</a> (2003) establishes the necessary financing to ensure government’s priorities social objectives.</td>
</tr>
<tr>
<td>• Law <a href="#">No.19895</a> (2003) establishes different standards of solvency and protection of persons incorporated to Private Health Insurance Institutions (ISAPRES), pension fund managers and insurance companies.</td>
</tr>
<tr>
<td>• Law <a href="#">No.19966</a> (2004) on the establishment of “Explicit Health Guarantees”.</td>
</tr>
<tr>
<td>• Law <a href="#">No.20015</a> (2005) which modifies the law No.18933 regarding the Private Health Insurance Institutions.</td>
</tr>
<tr>
<td>Other relevant laws:</td>
</tr>
<tr>
<td>✓ Law <a href="#">No.20584</a> (2012) on the regulation of the rights and duties of people with regard to actions related to their healthcare.</td>
</tr>
<tr>
<td>✓ Law <a href="#">No.20724</a> (2014) on the modification of the Sanitary Code with respect to regulation of pharmacies and drugs.</td>
</tr>
<tr>
<td>✓ Law <a href="#">No.20850</a> (2015) establishes a financial protection system, for high cost diagnoses and treatments.</td>
</tr>
</tbody>
</table>
Do any of these legislative/regulatory acts specify the government’s responsibility to ensure access/provide medicines? Please insert the relevant provisions from legislation/regulation.

Ministerial Decree 1 with force of law (2006) which fixes the rewritten, coordinates and systematized text of decree law No.2763 and Laws No. 18933 and No.18.469

Art 1: “The Ministry of Health and the other bodies contemplated in this book are responsible for exercising the State’s role of guaranteeing free and equal access to health promotion, protection and recovery and rehabilitation of the sick person; As well as coordinating, controlling and, where appropriate, carrying out such actions.”

“Al Ministerio de Salud y a los demás organismos que contempla el presente Libro, compete ejercer la función que corresponde al Estado de garantizar el libre e igualitario acceso a las acciones de promoción, protección y recuperación de la salud y de rehabilitación de la persona enferma; así como coordinar,
controlar y, cuando corresponda, ejecutar tales acciones.”

Art 131: “The exercise of the constitutional right to health protection includes free and equal access to health promotion, protection and recovery and rehabilitation activities, as well as freedom to choose the health care system public or private that each person wishes to embrace.”

“El ejercicio del derecho constitucional a la protección de la salud comprende el libre e igualitario acceso a las acciones de promoción, protección y recuperación de la salud y a aquéllas que estén destinadas a la rehabilitación del individuo, así como la libertad de elegir el sistema de salud estatal o privado al cual cada persona desee acogerse.”

Art 133: “The organisms that integrate the National System of Health Services are responsible for the execution of the actions that tend to assure the health of the inhabitants of the Republic”

“Los organismos que integran el Sistema Nacional de Servicios de Salud son responsables de la ejecución de las acciones que tiendan a asegurar la salud de los habitantes de la República”

✓ Law No. 19.966 (2005)

Art 1: “The General Regime of Health Guarantees, (...) is an instrument of health regulation that forms an integral part of the Health Benefits Regime referred to in Article 4 of Law No. 18,469, prepared according to the National Health Plan and the resources available in the country. It will establish promotional, preventive, curative, rehabilitative and palliative benefits, and the programs that the National Health Fund must cover to its respective beneficiaries, in its institutional care modality, in accordance with the provisions of Law No. 18,469.”

“El Régimen General de Garantías en Salud, (…) es un instrumento de regulación sanitaria que forma parte integrante del Régimen de Prestaciones de Salud a que se refiere el artículo 4° de la ley Nº 18.469, elaborado de acuerdo al Plan Nacional de Salud y a los recursos de que disponga el país. Establecerá las prestaciones de carácter promocional, preventivo, curativo, de rehabilitación y paliativo, y los programas que el Fondo Nacional de Salud deberá cubrir a sus respectivos beneficiarios, en su modalidad de atención institucional, conforme a lo establecido en la ley Nº 18.469.”

Art 2: “The General Guarantees Regime will also contain explicit health guarantees related to access, quality, financial protection and opportunity with which the benefits associated with a prioritized set of programs, diseases or health conditions indicated by the corresponding decree must be granted. The
National Health Fund and the Private Institutions of Social Security (ISAPRES) must ensure these guarantees to their respective beneficiaries. The Explicit Health Guarantees will be constitutive of rights for the beneficiaries and their compliance may be demanded before the National Health Fund or the Institutions of Social Security, the Superintendence of Health and other corresponding bodies.”

“El Régimen General de Garantías contendrá, además, Garantías Explicitas en Salud relativas a acceso, calidad, protección financiera y oportunidad con que deben ser otorgadas las prestaciones asociadas a un conjunto priorizado de programas, enfermedades o condiciones de salud que señale el decreto correspondiente. El Fondo Nacional de Salud y las Instituciones de Salud Previsional deberán asegurar obligatoriamente dichas garantías a sus respectivos beneficiarios. Las Garantías Explicitas en Salud serán constitutivas de derechos para los beneficiarios y su cumplimiento podrá ser exigido por éstos ante el Fondo Nacional de Salud o las Instituciones de Salud Previsional, la Superintendencia de Salud y las demás instancias que correspondan”

Art 4: “For the purposes provided in Article 2, the following definitions shall apply:

a) Access Explicit Guarantee: obligation of the National Health Fund and the Private Institutions of Social Security (ISAPRES) to ensure the granting of guaranteed health benefits to the beneficiaries of laws No. 18,469 and No. 18,933, respectively, in the form and Conditions established by the decree referred to in article 11.

b) Quality Explicit Guarantee: granting health benefits guaranteed by a registered or accredited provider, according to Law No. 19,937, in the form and conditions determined by the decree referred to in Article 11.

c) Opportunity Explicit Guarantee: maximum term for the granting of guaranteed health benefits, in the form and conditions determined by the decree referred to in article 11. (…)”

“Para los efectos previstos en el artículo 2°, se entenderá por:

a) Garantía Explicita de Acceso: obligación del Fondo Nacional de Salud y de las Instituciones de Salud Previsional de asegurar el otorgamiento de las prestaciones de salud garantizadas a los beneficiarios de las leyes N° 18.469 y N° 18.933, respectivamente, en la forma y condiciones que determine el decreto a que se refiere el artículo 11.

b) Garantía Explicita de Calidad: otorgamiento de las prestaciones de salud garantizadas por un prestador registrado o acreditado, de acuerdo a la ley N°
19.937, en la forma y condiciones que determine el decreto a que se refiere el artículo 11.

c) Garantía Explicita de Oportunidad: plazo máximo para el otorgamiento de las prestaciones de salud garantizadas, en la forma y condiciones que determine el decreto a que se refiere el artículo 11.(…)

✔ Law No. 20850 (2015):

Art 13: “Mandatory provision of diagnostic confirmation and treatment benefits. The National Health Fund must provide mandatory compliance to the Financial Protection System for Diagnoses and High-Cost Treatments that regulates this law for the beneficiaries indicated in its article 2º. The benefits contemplated in the System will be granted with the explicit guarantees indicated in letters b) and c) of article 4 of Law No. 19,966, in addition to the financial guarantee contemplated in this law.”

“Obligatoriedad del otorgamiento de las prestaciones de confirmación diagnóstica y de los tratamientos. El Fondo Nacional de Salud deberá dar cumplimiento obligatorio al Sistema de Protección Financiera para Diagnósticos y Tratamientos de Alto Costo que regula esta ley para los beneficiarios señalados en su artículo 2º. Las prestaciones contempladas en el Sistema se otorgarán con las garantías explícitas señaladas en las letras b) y c) del artículo 4º de la ley N°19.966, además de la garantía financiera contemplada en esta ley”

✔ Law No. 20584 (2012):

Art 2: “Everyone has the right, regardless of the provider who carries out the actions of promotion, protection and recovery of his or her health and rehabilitation, to have them given in a timely manner and without arbitrary discrimination, in the forms and conditions determined by the Constitution and Laws.”

“Toda persona tiene derecho, cualquiera que sea el prestador que ejecute las acciones de promoción, protección y recuperación de su salud y de su rehabilitación, a que ellas sean dadas oportunamente y sin discriminación arbitaria, en las formas y condiciones que determinan la Constitución y las leyes.”

✔ Ministerial Decree 264 (2003):

“Taking into consideration:
1. That health is one of the essential needs of the human person and its full satisfaction constitutes a social mandate that is a priority for the State.

2. In health care, both preventive and curative, medicines play an irreplaceable role.

3. That it is imperative to ensure the availability and access to the entire population of drugs essential for effective and safe therapy and effective access to the population that is compatible with the resources that society can provide for this purpose.”

“Considerando:

1.- Que la salud es una de las necesidades esenciales de la persona humana y su satisfacción plena constituye un mandato social prioritario para el Estado.

2.- Que en la atención de la salud, tanto preventiva como curativa, los medicamentos juegan un papel insustituible.

3.- Que es imperativo asegurar la disponibilidad y el acceso a toda la población de los medicamentos indispensables para una terapia efectiva y segura y de un acceso efectivo a la población que sea compatible con los recursos que la sociedad pueda disponer para este efecto.”


Art 4: “The medicines that constitute the National Formulary of Medicines must be available in the country for all the population that requires it and it will be up to the sanitary authority to arbitrate the mechanisms that allow the availability of those that are not commercialized in the country. The pharmaceutical products that make up the National Formulary of Medicines shall be of mandatory existence in pharmacies (…)”

“Los medicamentos que integran la nómina del Formulario deben estar disponibles en el país para toda la población que lo requiera y corresponderá a la autoridad sanitaria arbitrar los mecanismos que permitan la disponibilidad de aquellos que no se encuentren comercializados en el país. Los productos farmacéuticos que constituyen el Formulario Nacional de Medicamentos serán de existencia obligatoria en farmacias (…)”

✓ Law No. 19039 modified by the Law No.19996 (2005) replacing the previous Art 51 for the following:

Art 51: “A compulsory license application shall be requested in the following cases:

1) Where the patent holder has engaged in conduct or practices declared to be contrary to free competition, in direct relation to the use or exploitation of the
patent in question, by the firmness or expulsion of the Defense Court Of Free Competition.

2) Where, for reasons of public health, national security, public non-commercial use, or national emergency or other extreme emergency declared by the competent authority, the granting of these licenses is justified."

“Procederá pronunciarse respecto de una solicitud de licencia no voluntaria en los siguientes casos:

1) Cuando el titular de la patente haya incurrido en conductas o prácticas declaradas contrarias a la libre competencia, en relación directa con la utilización o explotación de la patente de que se trate, según decisión firme o ejecutoriada del Tribunal de Defensa de la Libre Competencia.

2) Cuando por razones de salud pública, seguridad nacional, uso público no comercial, o de emergencia nacional u otras de extrema urgencia, declaradas por la autoridad competente, se justifique el otorgamiento de dichas licencias.”


Art 1, 12: “The word "commercial" shall be inserted in the first subparagraph of Article 49, after the word "exploitation"; And add the following final paragraph: "The patent does not confer the right to prevent third parties from importing, exporting, manufacturing or producing the subject matter protected by a patent in order to obtain the registration or sanitary authorization of a pharmaceutical product. The previously said don’t allow the commercialization of these products without the authorization of the patent holder.” (Bolar expection).”

“Incorpórase en el primer inciso de su artículo 49 la palabra "comercial", a continuación de la palabra "explotación"; y agrégase el siguiente inciso final: “La patente de invención no confiere el derecho de impedir que terceros importen, exporten, fabriquen o produzcan la materia protegida por una patente final: el objeto de obtener el registro o autorización sanitaria de un producto farmacéutico. Lo anterior no faculta para que dichos productos sean comercializados sin autorización del titular de la patente.”

✓ Law No.20850 (2015):

Art 15: “In such circumstances, provided that there is no other therapeutic alternative in the Chilean market at the maximum industrial price referred to in Article 7 and only for the purpose of ensuring the supply of medical devices and guaranteeing the population the continuity of the treatments found Incorporated into the System referred to in this law, with the prior authorization of the Ministry of Health, the National Health Service System Supply
Center may, exceptionally, import and distribute them, regardless of whether they have health authorization or registration, as long as the Procedure regulated in Article 31 or, as long as their supply is restored.

In the case of products subject to industrial property rights, it will be understood that the circumstances described above constitute public health reasons for the effects of the provisions of number 2 of article 51 of Law No. 19.039, Industrial Property, whose restated, coordinated and and systematized text was established by the decree with force of law Nº3, of 2006, of the Ministry of Economy, Development and Reconstruction. The request referred to in Article 51 bis B of that legal body shall be submitted by the director of the Central Supply of the National System of Health Services.”

“En tales circunstancias, siempre que no exista en el mercado chileno otra alternativa terapéutica al precio máximo industrial referido en el artículo 7º y sólo con la finalidad de asegurar el abastecimiento de los productos sanitarios y garantizar a la población la continuidad de los tratamientos que se encuentran incorporados al Sistema del que trata esta ley, previa autorización del Ministerio de Salud, la Central de Abastecimiento del Sistema Nacional de Servicios de Salud podrá, excepcionalmente, importarlos y distribuirlos, independientemente si cuentan o no con autorización o registro sanitarios, mientras se inicie el procedimiento regulado en el artículo 31 o bien, mientras se restablece su abastecimiento.

En el caso de productos sujetos a derechos de propiedad industrial, se entenderá que las circunstancias antes descritas constituyen razones de salud pública para los efectos de lo dispuesto en el número 2 del artículo 51 de la ley Nº19.039, de Propiedad Industrial, cuyo texto refundido coordinado y sistematizado fue fijado por el decreto con fuerza de ley Nº3, de 2006, del Ministerio de Economía, Fomento y Reconstrucción. La solicitud a que hace referencia el artículo 51 bis B de ese cuerpo legal será presentada por el director de la Central de Abastecimiento del Sistema Nacional de Servicios de Salud.”

For health insurance/universal health coverage schemes: Who can access medicines? What is the population? Which costs are covered for insured people? Which medicines are provided? How are they selected? Please insert the relevant provisions from legislation/regulation.
Financing of the Social Health Insurance (FONASA/ISAPRE):
Ministerial Decree No. 3500 (1980)
Art 84: “The workers referred to in the previous article (dependent workers) shall be entitled to the health benefits established in the laws. (…) Without prejudice to other income and the corresponding tax contribution, in order to finance said benefits, In the respective pension institution, a contribution of seven per cent of his taxable remuneration, (…)”

“Los trabajadores a que se refiere el artículo anterior (trabajadores dependientes), tendrán derecho a las prestaciones de salud establecidas en las leyes (…)Sin perjuicio de otros ingresos y del aporte fiscal que corresponda, para el financiamiento de dichas prestaciones, deberán enterar, en la respectiva institución de previsión, una cotización del siete por ciento de sus remuneraciones imponibles.(…)”

Art 92: “Independent workers who receive income in the respective year from those mentioned in the first paragraph of Article 90, shall be subjects to the contributions established in Title III and to seven percent to finance health benefits that will find out in the National Health Fund, when applicable. These contributions shall be paid in accordance with what is established in the fourth and fifth paragraphs of this article and article 92 F. The independent members referred to in the third paragraph of Article 90, shall be subject to the contributions established in the Title III and seven percent to finance health benefits, which will be collected by the Administrator and informed by the National Health Fund.”

“Los trabajadores independientes que en el año respectivo perciban ingresos de los señalados en el inciso primero del artículo 90, estarán afectos a las cotizaciones que se establecen en el Título III y a un siete por ciento destinado a financiar prestaciones de salud las que se enterarán en el Fondo Nacional de Salud, cuando correspondan. Dichas cotizaciones se pagarán de acuerdo a lo establecido en los incisos cuarto y quinto del presente artículo y en el artículo 92 F. Los afiliados independientes a que se refiere el inciso tercero del artículo 90, estarán afectos a las cotizaciones que se establecen en el Título III y a un siete por ciento destinado a financiar prestaciones de salud, que será recaudado por la Administradora y enterado en el Fondo Nacional de Salud.”

Sustainable Financing of Explicit Health Guarantees System:

✔ Law Nº 19888 (2003) on the establishment of the necessary financing to ensure government’s priority social objectives:

Art 1: “Replace in article 14 of the Law on Sales and Services Tax contained in article one of Decree Law No. 825, 1974, from the date in each case indicated, the percentage to be specified:
(A) "18%" by "19\%", as from 1 October of the year 2003 (…)

“Sustitúyese en el artículo 14 de la Ley sobre Impuesto a las Ventas y Servicios, contenida en el artículo primero del decreto ley N° 825, de 1974, a contar desde la fecha que en cada caso se indica, el porcentaje que pasa a especificarse:

a) "18\%" por "19\%", a contar del 1 de octubre del año 2003,(…)”

FONASA:

Who is covered?
✓ Ministerial Decree 1 with force of law (2006):
Art 135: “They shall have the condition of Regime’s affiliates:

a) Workers dependent on the public and private sectors. In the case of persons who have made contributions for at least four months in the last twelve calendar months by virtue of contracts for a specific work, they shall remain members for a period of twelve months from the month to which the last contribution was made. In any case, dependent workers hired daily by shifts or days, who register at least sixty days of contribution in the previous twelve calendar months, shall maintain membership during the twelve months following the last contribution;

b) Independent workers who pay contributions for health;

c) Persons who pay contributions under any statutory pension scheme as imposing volunteers, and

d) Persons who receive a pension of any kind or subsidy for incapacity for work or unemployment.”

“Tendrán la calidad de afiliados al Régimen:

a) Los trabajadores dependientes de los sectores público y privado. Tratándose de personas que hayan efectuado cotizaciones, al menos, durante cuatro meses en los últimos doce meses calendario en virtud de contratos por obra o faena determinada, mantendrán la calidad de afiliados por un período de doce meses a contar del mes al que corresponde la última cotización. En todo caso, los trabajadores dependientes contratados diariamente por turnos o jornadas,
que registren, al menos, sesenta días de cotizaciones en los doce meses calendario anteriores, mantendrán la calidad de afiliados durante los doce meses siguientes a aquel correspondiente a la última cotización;

b) Los trabajadores independientes que coticen para salud;

c) Las personas que coticen en cualquier régimen legal de previsión en calidad de imponentes voluntarios, y

d) Las personas que gocen de pensión previsional de cualquier naturaleza o de subsidio por incapacidad laboral o por cesantía.”

Art 136: “They shall be beneficiaries of the scheme:

a) The affiliates mentioned in the previous article;

b) The originators for which the persons indicated in letters a) and d) of the previous article receive a family allowance;

c) Persons who, with respect to the affiliates mentioned in letters b) and c) of the previous article, fulfill the same qualifications and requirements required by law to be originators of the family allowance of a dependent worker;

d) The pregnant woman, even if she is not affiliate neither beneficiary, and the child up to six years of age, for the purpose of granting the benefits referred to in article 139; e) Persons without resources or indigent and those who receive the welfare pensions referred to in Decree Law No. 869 of 1975;

f) The originators of the family allowance established in Law No. 18.020, and

g) Persons who are entitled to an unemployment subsidy in accordance with Law No. 19.728 and their family allowance´s originators.”

“ Serán beneficiarios del régimen:

a) Los afiliados señalados en el artículo anterior;

b) Los causantes por los cuales las personas señaladas en las letras a) y d) del artículo anterior perciban asignación familiar;
c) Las personas que respecto de los afiliados señalados en las letras b) y c) del artículo anterior cumplan con las mismas calidades y requisitos que exige la ley para ser causante de asignación familiar de un trabajador dependiente;

d) La mujer embarazada aun cuando no sea afiliada ni beneficiaria, y el niño hasta los seis años de edad, para los efectos del otorgamiento de las prestaciones a que alude el artículo 139;

e) Las personas carentes de recursos o indigentes y las que gocen de las pensiones asistenciales a que se refiere el Decreto Ley N° 869, de 1975;

f) Los causantes del subsidio familiar establecido en la Ley N° 18.020, y

g) Las personas que gocen de una prestación de cesantía de acuerdo a la ley N° 19.728 y sus causantes de asignación familiar.”

Art 137:

“The incorporation to the Regime will be automatically produced upon acquiring any of the conditions indicated in the previous articles and will remain as long as they subsist. The members must make for the National Health Fund the contributions destined to finance the health benefits that are established in the Legislative Decrees N°s. 3.500 and 3501, of 1980, or in the respective organic laws of the pension institutions to which they belong. “

“La incorporación al Régimen se producirá automáticamente al adquirirse cualquiera de las calidades indicadas en los artículos anteriores y se mantendrá mientras ellas subsistan. Los afiliados deberán efectuar para el Fondo Nacional de Salud las cotizaciones destinadas a financiar las prestaciones de salud que se establecen en los decretos leyes N°s. 3.500 y 3.501, de 1980, o en las respectivas leyes orgánicas de las entidades previsionales a las que pertenecen.”

Art 138: “The beneficiaries will be entitled to receive from the General Health Guarantees System the following benefits:

b) Curative medical care including consultation, examinations and diagnostic and surgical procedures, hospitalization, obstetric care, treatment, including medicines contained in the National Formulary, and other health care and actions to be established,”

“Los beneficiarios tendrán derecho a recibir del Régimen General de Garantías en Salud las siguientes prestaciones:

b) Asistencia médica curativa que incluye consulta, exámenes y procedimientos diagnósticos y quirúrgicos, hospitalización, atención obstétrica,
treatment, included the medications contained in the National Formulary, and other health actions that shall be established,”

**Which costs are covered?**

Art 159: “The affiliates, with the exceptions established by this law, shall contribute to the financing of the value of the benefits and care that they and the respective beneficiaries request and receive from the Regime, by direct payment, in the proportion and form indicated below. The value of the benefits will be the one that fixed by the tariff approved by the Ministries of Health and of Finance as a proposal of the National Health Fund.”

“Los afiliados, con las excepciones que establece esta ley, deberán contribuir al financiamiento del valor de las prestaciones y atenciones que ellos y los respectivos beneficiarios soliciten y que reciban del Régimen, mediante pago directo, en la proporción y forma que más adelante se indican. El valor de las prestaciones será el que fije el arancel aprobado por los Ministerios de Salud y de Hacienda a proposición del Fondo Nacional de Salud.”

Art 160: “For the purposes of the provisions of the previous article, persons affected by this law will be classified according to their income level in the following groups:

Group A: Indigent or people without resources, beneficiaries of welfare pensions referred to in Decree Law No. 869 of 1975, and originators of the family allowance established in Law No. 18,020.

Group B: Affiliates whose monthly income does not exceed the minimum monthly income applicable to workers over eighteen years of age and under sixty-five years of age.

Group C: Affiliates whose monthly income is higher than the minimum monthly income applicable to workers over eighteen years of age and under sixty-five years of age and does not exceed 1.46 times that amount, unless the beneficiaries depending on them are three or more, in which case they will be considered in Group B.

Group D: Affiliates whose monthly income is higher by 1.46 times the minimum monthly income applicable to workers over eighteen years of age and under sixty-five years of age, provided that the beneficiaries who depend on them are not more than two. If the beneficiaries that depend on them are three or more, they will be considered in Group C.”

“Para los efectos de lo dispuesto en el artículo anterior, las personas afectas a esta ley se clasificarán, según su nivel de ingreso, en los siguientes grupos:
Grupo A: Personas indigentes o carentes de recursos, beneficiarios de pensiones asistenciales a que se refiere el Decreto Ley N° 869, de 1975, y causantes del subsidio familiar establecido en la Ley N° 18.020.

Grupo B: Afiliados cuyo ingreso mensual no exceda del ingreso mínimo mensual aplicable a los trabajadores mayores de dieciocho años de edad y menores de sesenta y cinco años de edad.

Grupo C: Afiliados cuyo ingreso mensual sea superior al ingreso mínimo mensual aplicable a los trabajadores mayores de dieciocho años de edad y menores de sesenta y cinco años de edad y no exceda de 1,46 veces dicho monto, salvo que los beneficiarios que de ellos dependan sean tres o más, caso en el cual serán considerados en el Grupo B.

Grupo D: Afiliados cuyo ingreso mensual sea superior en 1,46 veces al ingreso mínimo mensual aplicable a los trabajadores mayores de dieciocho años de edad y menores de sesenta y cinco años de edad, siempre que los beneficiarios que de ellos dependan no sean más de dos. Si los beneficiarios que de ellos dependan son tres o más, serán considerados en el Grupo C.”

Art 161: “The State, through the National Health Fund, will contribute to the financing of the medical benefits referred to in this law, in a percentage of the amount indicated in the tariff set in accordance with article 159. That percentage will be determined, each time as required, by the Ministries of Health and Finance; Shall cover the total value of benefits for groups A and B, and may not be less than 75% for Group C, or 50% for Group D.

However, by joint resolution of the Ministries of Health and Finance, for medicines, prostheses and dental care, different percentages from those indicated in the preceding paragraph.

Regarding the benefits that derive from pathologies or health states that are considered catastrophic, this bonus may be higher than the indicated percentages. The percentage contribution of the Fund to the care of childbirth may not be less than 75% for group D.”

“El Estado, a través del Fondo Nacional de Salud, contribuirá al financiamiento de las prestaciones médicas a que se refiere esta ley, en un porcentaje del valor señalado en el arancel fijado en conformidad al artículo 159. Dicho porcentaje se determinará, cada vez que así se requiera, por los Ministerios de Salud y Hacienda; cubrirá el valor total de las prestaciones respecto de los grupos A y B, y no podrá ser inferior al 75% respecto del Grupo C, ni al 50% respecto del grupo D.

Sin embargo, por resolución conjunta de los Ministerios de Salud y de Hacienda, podrán establecerse, para los medicamentos, prótesis y atenciones
odontológicas, porcentajes diferentes de los señalados en el inciso precedente.

Respecto de las prestaciones que deriven de patologías o estados de salud que se consideren catastróficos, dicha bonificación podrá ser superior a los indicados porcentajes. El porcentaje de contribución del Fondo a la atención del parto no podrá ser inferior al 75% para el grupo D.”

✓ Law 19.966 (2004):

Art 4: “d) Financial Protection Explicit Guarantee: the contribution to be made by the member by benefit or group of benefits, which must be 20% of the value determined in a Regime reference tariff. Notwithstanding the foregoing, the National Health Fund shall cover the total value of the benefits, with respect to Groups A and B referred to in Article 29 of Law No. 18,469, and may offer financial coverage greater than that provided in The preceding paragraph to persons belonging to groups C and D indicated in the same article, in accordance with the rules established in Title IV of Law No. 18.469.”

“d) Garantía Explicita de Protección Financiera: la contribución que deberá efectuar el afiliado por prestación o grupo de prestaciones, la que deberá ser de un 20% del valor determinado en un arancel de referencia del Régimen.

No obstante lo anterior, el Fondo Nacional de Salud deberá cubrir el valor total de las prestaciones, respecto de los grupos A y B a que se refiere el artículo 29 de la ley N°18.469, y podrá ofrecer una cobertura financiera mayor a la dispuesta en el párrafo anterior a las personas pertenecientes a los grupos C y D señalados en el mismo artículo, de acuerdo con las normas establecidas en el Título IV de la ley N°18.469.”

Art 6: “Additional financial coverage is understood as the financing of 100% of the co-payments originated only by diseases or health conditions contained in the Explicit Health Guarantees referred to in this law, which exceed the deductible referred to in subsection second.”

“Se entenderá por cobertura financiera adicional el financiamiento del 100% de los copagos originados sólo por enfermedades o condiciones de salud contenidas en las Garantías Explicitas en Salud de que trata esta ley, que superen el deducible a que se refiere el inciso segundo.”

✓ Exempt Resolution 1187 (2014) of the Ministry of Health, on the approval of the Pharmacy Fund for Chronic Non-communicable Diseases in Primary Health care:

Component 1: “Population served in Primary Care facilities with timely access to medications and support in adherence to treatment.

This component considers for people with non-communicable diseases, and in particular with cardiovascular health problems, the timely purchase and
delivery of drugs defined in the basic package of Primary Care of each Health Service (...)

"Población que se atiende en establecimientos de Atención Primaria con acceso oportuno a medicamentos y apoyo en la adherencia al tratamiento.

Este componente considera para personas con enfermedades no transmisibles, y en particular con problemas de salud cardiovasculares, la compra y entrega oportuna de medicamentos definidos en el arsenal básico de Atención Primaria de cada Servicio de Salud (...)."

✓ **Exempt Decree Nº 63 (2016) of the Ministry of Health, on the approval of the general technical norm Nº 0184 which establishes Protocol of procedure for the submission of requests for extraordinary auspices.**

1. **PRESENTATION OF THE EXTRAORDINARY AID FUND. COMPLEX BENEFITS ASSISTANCE.**

"The administration of the Extraordinary Aid Fund is in the Cabinet of the highest ministerial authority, through this fund it is possible to grant contributions in the financing of complex services.

Requests for Extraordinary Assistance require a medical and socioeconomic analysis with a background, which allows prioritizing the demand, making it possible to provide highly complex care to the most vulnerable beneficiaries.

This extraordinary benefit may be preferentially partial in relation to the cost of the benefit and its total financing, could be generated by contributions from the person, his / her family, the community of origin, local, provincial, regional, central government and the sponsoring entity Of the partnership among others."

"La administración del Fondo de Auxilios Extraordinarios radica en el Gabinete de la máxima autoridad Ministerial, a través de este fondo es posible otorgar aportes en el financiamiento de prestaciones complejas.

Las solicitudes de Auxilio Extraordinario requieren de un análisis médico y socioeconómico con antecedentes, que permita priorizar la demanda, posibilitando la atención de alta complejidad a los beneficiarios más vulnerables.

Este beneficio extraordinario podría tener un carácter preferentemente parcial en relación al costo de la prestación y su financiamiento total, podría generarse con aportes de la persona, su familia, la comunidad de origen, el gobierno local, provincial, regional, central y la entidad patrocinadora de la
soicitud entre otros.”

2.1 BASIC CRITERIA

"1. Financing will be granted only to users of FONASA.
2. Beneficiaries of public insurance whose indication of treatment, supplies or examinations, has been made under the institutional modality. (…)
4. The application must specify the exact amount requested to the Extraordinary Assistance Fund in the Driver Office and / or social report.
5. The medicines requested to the Extraordinary Assistance Fund must have a Sanitary Registry granted by the Institute of Public Health. (…)

"1. Sólo se otorgará financiamento a usuarios y usuarias de FONASA.
2. Beneficiarios (as) de seguro público cuya indicación de tratamiento, insumos o exámenes, ha sido realizado bajo la modalidad institucional. (…)
4. La solicitud debe especificar el monto exacto solicitado al Fondo de Auxilio Extraordinario en el Oficio conductor y/o informe social.
5. Los medicamentos solicitados al Fondo de Auxilio Extraordinario deben disponer de Registro Sanitario otorgado por el Instituto de Salud Pública. (…)

2.2 SOCIAL CRITERIA FOR THE REQUEST PRIORITIZATION.

“Applications will be prioritized in the following groups:

1. Beneficiaries of Social Programs such as: “Chile Solidario” and “Chile Crece Contigo” and others.
2. Family in situation of Social Vulnerability (…).
3. Officials of the health sector and their families.”

“Se priorizarán las solicitudes en los siguientes grupos:
1. Beneficiarios de Programas Sociales como: Chile Solidario y Chile Crece Contigo y otros.

2. Familia en situación de Vulnerabilidad Social (…).

3. Funcionarios del sector salud y sus familiares.”

2.4 EXCLUSION CRITERIA FOR FINANCING GRANTING.

"1. Permanent treatments (…)

5. Requests for financing of supplies, medicines or others, financed by FONASA programs.

6. Everything covered by AUGE.

11. Treatments of FONASA’s users under free choice mode.

12. Applications for cancer treatment funding, which after evaluation at the Technical Commission of the Department of Comprehensive Cancer Management and other tumors, has been chosen a different from that requested by the treating physician.

14. Health conditions covered by the financing system established in Law.20850"

"1. Tratamientos permanentes (…)

5. Solicitudes de financiamiento de insumos, medicamentos u otros, financiados por programas de FONASA.

6. Todo lo cubierto por AUGE.

11. Tratamientos de usuarios FONASA bajo modalidad de libre elección.

12. Las solicitudes de financiamiento de tratamientos de cáncer, que luego de su evaluación en la Comisión Técnica del Departamento de Manejo Integral del Cáncer y otros tumores, se ha entregado a una sugerencia distinta a lo solicitado por el médico tratante.
14. Condiciones de salud cubiertas por el sistema de financiamento establecido en la Ley.20850

6.1 REQUIREMENTS FOR CANCER TREATMENT.

"- The financing of treatments that are found in protocols and / or clinical guidelines defined in technical norms drafted by the Ministry of Health will be provided.

- For applications where there is no protocol, scientific evidence that allows the technical analysis of the application must be attached."

"- Se aportará el financiamiento de tratamientos que se encuentren en protocolos y/o guías clínicas definidas en normas técnicas impartidas por el ministerio de salud.(...)

- Para aquellas solicitudes en que no exista protocolo, deberá adjuntar evidencia científica que permita el análisis técnico de la solicitud."

✔ Law No.20850 (2015):

Art 1: "Object of the law. A Financial Protection System is created for the granting of those high-cost diagnoses and treatments that declare the supreme decree of the Ministry of Health, referred to in Article 5, and will form part of the General System of Guarantees in Health to which the Article 134 of the decree with force of law Nº1, 2005, of the Ministry of Health refers to, which establishes the restated, coordinated and systematized text of Decree Law No. 2763, of 1979, and Laws Nos. 18.933 and 18.469.

The National Health Fund must ensure this financial protection to all beneficiaries of Chile's health care systems.

Excluded from this law are the benefits effectively covered: A) By laws No. 16.744, which establishes rules on occupational accidents and diseases, and No. 18.490, on compulsory insurance for personal accidents caused by motor vehicle traffic and B) By the Private Health Insurance Contract through the Additional Coverage for Catastrophic Diseases (CAEC).

Thus, beneficiaries of Private Institutions of Social Security (ISAPRES), in order to access the guarantees contemplated in this law, must first apply the additional coverage of catastrophic diseases contemplated in the health insurance contracts when appropriate. Otherwise, the provisions of this law will be applied without exclusions."
“Objeto de la ley. Créase un Sistema de Protección Financiera para el otorgamiento de aquellos diagnósticos y tratamientos de alto costo que declare el decreto supremo del Ministerio de Salud, a que hace referencia el artículo 5º, y formará parte del Régimen General de Garantías en Salud al que se refiere el artículo 134 del decreto con fuerza de ley Nº1, de 2005, del Ministerio de Salud, que fija el texto refundido, coordinado y sistematizado del decreto ley Nº2.763, de 1979, y de las leyes Nos 18.933 y 18.469.

El Fondo Nacional de Salud deberá asegurar esta protección financiera a todos los beneficiarios de los sistemas previsionales de salud de Chile.

Se excluyen de la presente ley las prestaciones efectivamente cubiertas: A) Por las leyes Nº16.744, que establece normas sobre accidentes del trabajo y enfermedades profesionales, y Nº18.490, sobre seguro obligatorio de accidentes personales causados por circulación de vehículos motorizados y B) por el Contrato de Salud Previsional a través de la Cobertura Adicional para Enfermedades Catastróficas (CAEC).

De este modo, los beneficiarios de las instituciones de salud previsional, para acceder a las garantías contempladas en esta ley, deberán impetrar primero la cobertura adicional de enfermedades catastróficas contemplada en los contratos de salud previsional cuando fuere procedente. En caso contrario, se les aplicará las disposiciones de esta ley sin exclusiones.”

Art 2: “Definitions. For the purposes set forth in this law, the following definitions shall apply:

a) High cost diagnoses: The set of benefits that are demonstrably useful for the confirmation and subsequent control and treatment of the pathology, when these diagnostic benefits prevent access to treatment or catastrophically impact on the beneficiary's expense.

b) High-cost treatment: The drug, food or medical elements associated with diseases or health conditions and essential services for diagnostic confirmation and monitoring, which by their cost prevent access to them or by accessing, impact Catastrophically in the expenditure of the beneficiaries.

c) Beneficiaries: Those of the health insurance systems, excluding the benefits referred to in the third paragraph of Article 1.

d) Financial Protection System: An ordered set of benefits and rights under which the National Health Fund is obliged to ensure the granting of diagnostic confirmation and high-cost treatment to beneficiaries, in accordance with this law.

e) Financial protection: That constituted by the coverage of the total value of the diagnostic confirmation benefits and the high cost treatments for all the beneficiaries of this law. "

“Definiciones. Para los efectos previstos en esta ley, se entenderá por:

a) Diagnósticos de alto costo: El constituido por el conjunto de prestaciones demostradamente útiles para la confirmación y posterior control y tratamiento de la patología, cuando dichas prestaciones diagnósticas impiden el acceso al tratamiento o impactan catastróficamente en el gasto del beneficiario.

b) Tratamiento de alto costo: El constituido por medicamentos, alimentos o elementos de uso médico asociados a enfermedades o condiciones de salud y por las prestaciones indispensables para su confirmación diagnóstica y seguimiento, que por su costo impiden el acceso a éstos o accediendo, impactan catastróficamente en el gasto de los beneficiarios.

c) Beneficiarios: Los de los sistemas previsionales de salud, con exclusión de las prestaciones a que se refiere el inciso tercero del artículo 1º.

d) Sistema de Protección Financiera: Conjunto ordenado de prestaciones y derechos en virtud del cual el Fondo Nacional de Salud se encuentra obligado a asegurar el otorgamiento de la confirmación diagnóstica y los tratamientos de alto costo a los beneficiarios, conforme a la presente ley.

e) Protección financiera: Aquella constituida por la cobertura del valor total de las prestaciones de la confirmación diagnóstica y los tratamientos de alto costo respecto de todos los beneficiarios de esta ley.”

ISAPRES:


Article 2: “The Private Institutions of Social Security shall also be obliged to ensure the granting of the benefits and financial coverage that the National Health Fund confers at least in its modality of free choice, in the terms of article 31 of this law.”

“Las Instituciones de Salud Previsional estarán también obligadas a asegurar el otorgamiento de las prestaciones y la cobertura financiera que el Fondo Nacional de Salud confiere como mínimo en su modalidad de libre elección, en los términos del artículo 31 de esta ley.”

Article 24: “The National Health Fund and the Private Institutions of Social Security must give mandatory compliance to the Explicit Health Guarantees that contemplate the Regime that regulates this law with its respective beneficiaries.”

“El Fondo Nacional de Salud y las Instituciones de Salud Previsional deberán dar cumplimiento obligatorio a las Garantías Explicitas en Salud que
contemple el Régimen que regula esta ley para con sus respectivos beneficiarios”.

☑ Ministerial Decree 1 with force of law (2006)

Art 184: “Those affiliated to the Regime established in Book II of this Law that choose to contribute their health contribution to an Private Institution of social security, must sign a contract in accordance with the provisions of this Law.”

“Los afiliados al Régimen que establece el Libro II de esta Ley que opten por aportar su cotización para salud a alguna Institución, deberán suscribir un contrato de acuerdo a lo establecido en esta Ley.”

Art 189: “For the granting of the services and health benefits provided by this law, the persons indicated in article 184 must sign an indefinite contract, with the Private Institution of Social Security of their choice.

In this contract, the parties will freely agree to the services and benefits included, as well as the form, modality and conditions of their granting. However, such contracts must include, as a minimum, the following:

a) The Explicit Guarantees regarding access, quality, financial protection and opportunity contemplated in the General System of Health Guarantees, in conformity with the provisions of the law that establishes this Regime.

Likewise, a supplementary plan to the Explicit Health Guarantees mentioned above must be agreed (...). This plan must include, at least, the benefits and financial coverage that is set at least for the modality of free choice that must be granted by the National Health Fund, in accordance with the provisions of the General Regime of Health Guarantees.

Likewise, Private Institutions of Social Security should inform their members about the existence and coverage of the Financial Protection System for High-Cost Diagnoses and Treatments, and, when appropriate, transfer to the Fund for High-Cost Diagnostics and Treatments the resources that in concept of additional coverage of catastrophic diseases correspond to grant.”

“Para el otorgamiento de las prestaciones y beneficios de salud que norma esta ley, las personas indicadas en el artículo 184 deberán suscribir un contrato..."
de plazo indefinido, con la Institución de Salud Previsional que elijan.

En este contrato, las partes convendrán libremente las prestaciones y beneficios incluidos, así como la forma, modalidad y condiciones de su otorgamiento. Con todo, los referidos contratos deberán comprender, como mínimo, lo siguiente:

a) Las Garantías Explicitas relativas a acceso, calidad, protección financiera y oportunidad contempladas en el Régimen General de Garantías en Salud, en conformidad a lo dispuesto en la ley que establece dicho Régimen.

Asimismo, se deberá pactar un plan complementario a las Garantías Explicitas señaladas precedentemente (…). Este plan deberá contemplar, a lo menos, las prestaciones y la cobertura financiera que se fije como mínimo para la modalidad de libre elección que debe otorgar el Fondo Nacional de Salud, de acuerdo a lo dispuesto en el Régimen General de Garantías en Salud.

Asimismo, las instituciones de salud previsional deberán informar a sus afiliados respecto de la existencia y cobertura del Sistema de Protección Financiera para Diagnósticos y Tratamientos de Alto Costo, y, cuando proceda, transferir al Fondo para Diagnósticos y Tratamientos de Alto Costo los recursos que por concepto de cobertura adicional de enfermedades catastróficas corresponda otorgar”

Art 189 (modified by law 20.015): “b) The Supplementary Health Plan, which may contain one or more of the following modalities for the granting of services or benefits:

A.- Free choice plan: one in which the choice of the health provider is resolved at the discretion of the affiliate or beneficiary, without intervention of the Private Institution of Social Security (…)

B.- Closed plan: one whose structure only contemplates the financing of all health care through certain providers individualized in the plan, not providing access to benefits under the modality of free choice. (…)

C.- Plan with preferred providers: one whose structure combines care under the modality of free choice and the financing of benefits through certain providers previously individualized in the plan.”

“b) El Plan de Salud Complementario, que podrá contener una o más de las siguientes modalidades para el otorgamiento de las prestaciones o beneficios: 

A.- Plan libre elección: aquel en que la elección del prestador de salud es resuelta discrecionalmente por el afiliado o beneficiario, sin intervención de la
Institución de Salud Previsional.(

B.- Plan cerrado: aquel cuya estructura sólo contempla el financiamiento de todas las atenciones de salud a través de determinados prestadores individualizados en el plan, no previéndose el acceso a las prestaciones bajo la modalidad de libre elección. (…)

C.- Plan con prestadores preferentes: aquel cuya estructura combina la atención bajo la modalidad de libre elección y el financiamiento de beneficios a través de determinados prestadores previamente individualizados en el plan.”

ARMED FORCES:

✓ Law No.19465 (1996):

Who is covered?

Art 2: “The Health System of the Armed Forces assures its beneficiaries the right to free and equal access to curative medicine and, in addition, to personnel in active service, the right to preventive medical care.”

“El Sistema de Salud de las Fuerzas Armadas asegura a sus beneficiarios el derecho al libre e igualitario acceso a la medicina curativa y, además, al personal en servicio activo, el derecho a la asistencia médica preventiva.”

Art 7 modified by law No.20735 (2014): "They will be beneficiaries of the Health System of the Armed Forces:

a) The personnel of plant of the Armed Forces;

b) Reserve staff called to active duty;

c) Personnel dependent on the Armed Forces which, under special laws, is subject to the social security and social security system established by Law No. 18.948;

d) The orignators of family allowance of the personnel indicated in the previous letters, even if they do not perceive this benefit,
e) Those originators for the family allowance referred to in the preceding letters, commissioned abroad, provided that they receive the family allowance of letter d) of article 200 of the decree with force of law No. 1, 1997, of the Ministry Of National Defense, which establishes the personnel status of the Armed Forces, and is studying in institutions of basic, secondary, technical and higher education, recognized by the State where the commission is fulfilled.

“Serán beneficiarios del Sistema de Salud de las Fuerzas Armadas:

a) El personal de planta de las Fuerzas Armadas;

b) El personal de reserva llamado al servicio activo;

c) El personal dependiente de las Fuerzas Armadas que en virtud de leyes especiales se encuentre acogido al régimen previsional y de seguridad social que establece la ley N° 18.948;

d) Los causantes de asignación familiar del personal señalado en las letras anteriores, aun cuando no perciban dicho beneficio,

e) Los causantes de asignación familiar del personal señalado en las letras anteriores, comisionado al extranjero, siempre que por ellos se perciba la asignación familiar de la letra d) del artículo 200 del decreto con fuerza de ley N° 1, de 1997, del Ministerio de Defensa Nacional, que establece estatuto del personal de las Fuerzas Armadas, y se encuentren estudiando en instituciones de la enseñanza básica, media, técnica y superior, reconocidas por el Estado donde se cumple la comisión.”

Art 8: "The incorporation to the Health System of the Armed Forces will be automatic, from the moment in which any of the requisites or conditions indicated in the previous article are acquired and will be maintained while they subsist.

However, the staff who retires with the right to a pension granted by the Armed Forces Social Security and Social Security Agency will not lose the status of beneficiary of the System, as long as they do not choose to join another health benefits regime. ”

“La incorporación al Sistema de Salud de las Fuerzas Armadas será automática, desde el momento en que se adquiera cualquiera de las calidades o condiciones señaladas en el artículo anterior y se mantendrá mientras ellas subsistan.

Sin embargo, no perderá la calidad de beneficiario del Sistema, el personal que se retire con derecho a pensión otorgada por el Organismo de Previsión y
Seguridad Social de las Fuerzas Armadas, en tanto no opte por afiliarse a otro régimen de prestaciones de salud.”

Art 16: “The benefits of curative medicine will be as follows:

a) Medical care, comprising consultation, examinations and diagnostic, therapeutic and surgical procedures; hospitalization, including medication, obstetric care, treatments and other health care and actions that are established. Excluded are drugs prescribed in outpatient care, except those determined by the administering authority of the respective Fund;

b) Dental care, excluding that which means the use of materials and technology of high cost for purely aesthetic purposes, without prejudice to the fact that this can be done by the interested parties;

c) Execution of specialized treatments or exams with which the agencies of the Health System of the Armed Forces do not count, previous authorization granted according to the respective institutional procedure;

d) Acquisition of prostheses, orthoses and other elements prescribed for the rehabilitation of the individual, in the form determined by the respective Health Fund;

e) Urgent care, including professional treatment and medication used in it, and (f) promotion, protection and other general health-related actions as determined in the programs and plans of the respective institution.”

“Las prestaciones de medicina curativa serán las siguientes:

a) Atención médica, que comprende consulta, exámenes y procedimientos diagnósticos, terapéuticos y quirúrgicos; hospitalización, incluidos los medicamentos, atención obstétrica, tratamientos y demás atenciones y acciones de salud que se establezcan. Se excluyen los medicamentos prescritos en la atención ambulatoria, salvo aquellos que determine la autoridad administradora del Fondo respectivo;

b) Atención odontológica, con exclusión de aquella que signifique el empleo de materiales y tecnología de elevado costo con fines meramente estéticos, sin perjuicio de que ésta pueda efectuarse con cargo a los interesados;

c) Realización de tratamientos o exámenes especializados con los que no cuenten los organismos del Sistema de Salud de las Fuerzas Armadas, previa
autorización otorgada conforme al respectivo procedimiento institucional;

d) Adquisición de prótesis, órtesis y demás elementos prescritos para la rehabilitación del individuo, en la forma que determine el Fondo de Salud respectivo;

e) Atención de urgencia, incluyendo el tratamiento profesional y los medicamentos empleados en ella, y f) Acciones de promoción, protección y otras de carácter general, relativas a la salud, determinadas en programas y planes de la respectiva Institución.”

Affordability:

Art 29: “The percentage of bonus with which the Fund will contribute to the payment of curative medicine benefits will be one hundred percent (100%) for the imposing in active service and fifty percent (50%) for those originators for family allowance, even if they do not receive this benefit. The difference between the amount of the Fund and the value of the benefits, where applicable, shall be covered by the beneficiary.”

“El porcentaje de bonificación con que el Fondo contribuirá al pago de las prestaciones de medicina curativa será de un cien por ciento (100%) para el imponente en servicio activo y de un cincuenta por ciento (50%) para sus causantes de asignación familiar, aun cuando no perciban dicho beneficio. La diferencia que resulte entre la cantidad con que concurra el Fondo y el valor de las prestaciones, cuando corresponda, deberá ser cubierta por el propio beneficiario.”

Art 28: “In order to meet the expenses demanded by the curative medicine benefits, there will be a Curative Medicine Fund in each of the Institutions of the Armed Forces, which will be formed with the following resources:

a) With a tax of five and a half percent (5.5%) of the total taxable remuneration received by active duty personnel assigned to the social security and social security scheme established by Law No. 18.948;

b) With a tax of one and a half percent (1.5%), on the taxable remuneration of the active duty personnel of the Armed Forces, subject to the social security and social security system established by Law No. 18.948, which Shall be covered by the employer; (...)”

“Para concurrir a los gastos que demanden las prestaciones de medicina curativa existirá un Fondo de Medicina Curativa en cada una de las Instituciones de las Fuerzas Armadas, el que se formará con los siguientes recursos:
a) Con una imposición del cinco y medio por ciento (5,5%) del total de las remuneraciones imponibles que perciba el personal en servicio activo afecto al régimen previsional y de seguridad social que establece la ley N° 18.948;

b) Con una imposición del uno y medio por ciento (1,5%), sobre las remuneraciones imponibles del personal en servicio activo de las Fuerzas Armadas, afecto al régimen previsional y de seguridad social que establece la ley N° 18.948, la que será de cargo del empleador; (…)

How are medicines selected for being used in the health programmes in Chile and which are provided?

✓ Ministerial Decree 1 with force of law (2006)
Art 138: “The beneficiaries will be entitled to receive from the General Health Guarantees System the following benefits:

b) Curative medical care including consultation, examinations and diagnostic and surgical procedures, hospitalization, obstetric care, treatment, including medicines contained in the National Formulary, and other health care and actions to be established.”

Art 11:
“The Explicit Health Guarantees shall be prepared by the Ministry of Health, in accordance with the procedure established in this law and in the regulations, and shall be approved by supreme decree of said Ministry, also subscribed by the Minister of Finance.”

“Las Garantías Explicítas en Salud serán elaboradas por el Ministerio de Salud, de conformidad con el procedimiento establecido en esta ley y en el reglamento, y deberán ser aprobadas por decreto supremo de dicho Ministerio suscrito, además, por el Ministro de Hacienda.”

Article 12: “When initiating the process to establish the Explicit Health Guarantees, the Ministry of Finance will establish the framework of resources available for financing in the National Health Fund and the value of the Universal Premium, expressed in units of development, to which these Guarantees must be adjusted.”

“Al iniciar el proceso destinado a establecer las Garantías Explicítas en Salud, el Ministerio de Hacienda fijará el marco de los recursos disponibles para su financiamiento en el Fondo Nacional de Salud y el valor de la Prima Universal, expresado en unidades de fomento, al que deberán ajustarse dichas
Art 13: “The elaboration of the proposal for Explicit Health Guarantees will consider the development of studies with the objective of determining a list of priorities in health and interventions that consider the health situation of the population, the effectiveness of the interventions, their contribution to the extension or quality of life and, if possible, their cost-effectiveness.

To this end epidemiological studies should be developed, including disease burden, systematic reviews of the effectiveness, economic evaluations, potential demand and supply capacity of the Chilean health system.”

“La elaboración de la propuesta de Garantías Explicitas en Salud considerará el desarrollo de estudios con el objetivo de determinar un listado de prioridades en salud y de intervenciones que consideren la situación de salud de la población, la efectividad de las intervenciones, su contribución a la extensión o a la calidad de vida y, cuando sea posible, su relación costo efectividad.

Para ello se deberán desarrollar estudios epidemiológicos, entre otros de carga de enfermedad, revisiones sistemáticas sobre la efectividad, evaluaciones económicas, demanda potencial y capacidad de oferta del sistema de salud chileno.”

Art 14: “Considering the studies indicated in the preceding article, and the experience and the national and foreign scientific evidence, a list of diseases and their associated benefits will be made, and from those should be excluded the ones from which there is no evidence of representing a benefit for the survival or quality of life of those affected. Likewise, the cost of incorporating them into the Regime should be estimated, according to the public and private sector’s supply capacity and the potential demand for such interventions.”

“Considerando los estudios señalados en el artículo precedente, y la experiencia y la evidencia científica nacional y extranjera, se confeccionará un listado de enfermedades y sus prestaciones asociadas, debiendo descartarse de éstas todas aquéllas para las cuales no haya fundamentos de que significan un beneficio para la sobrevivencia o la calidad de vida de los afectados. Asimismo, se deberá estimar el costo de incorporarlas al Régimen, de acuerdo con la capacidad de oferta de los sectores público y privado y con la demanda potencial de tales intervenciones.”

Art 15: “The proposal will be submitted to a process of verification of the cost expected by beneficiary of the prioritized set with explicit guarantees, through a study called for such purposes, which will be directed and coordinated by the Ministry of Health.

The National Health Fund and the Private Institutions of Social Security will intervene in the process, in the form and conditions established by this law and
the regulations, and must provide all necessary information, in the form and conditions requested by the Ministry of Health.”

“La propuesta se someterá a un proceso de verificación del costo esperado por beneficiario del conjunto priorizado con garantías explícitas, mediante un estudio convocado para tales efectos, que será dirigido y coordinado por el Ministerio de Salud.

El Fondo Nacional de Salud y las Instituciones de Salud Previsional intervendrán en el proceso, en la forma y condiciones que dispongan esta ley y el reglamento, y deberán proporcionar toda la información necesaria, en la forma y condiciones que el Ministerio de Salud solicite.”

✓ Ministerial Decree 3, (2016) on the approval of Explicit Health Guarantees of the Explicit Health Guarantees ‘Regime. The Health Problems that constitute the Explicit Health Guarantees during the period 2016-2019 are listed in this decree.

✓ Ministerial Decree 264 (2003):

Art 1: “The National Formulary of Medicines is the official document of the Republic of Chile that contains the selected list of pharmaceutical products indispensable for an efficient therapy based on the epidemiological reality of the country and the scientific evidence, whose quality must be guaranteed.”

“El Formulario Nacional de Medicamentos es el documento oficial de la República de Chile que contiene la nómina seleccionada de productos farmacéuticos indispensables para una eficiente terapéutica sustentada en la realidad epidemiológica del país y la evidencia científica, cuya calidad debe ser garantizada.”

Art 2: “a) Essential pharmaceutical product: A drug that is basic, of the highest importance and precise to meet the health care needs of the majority of the population and to address those pathologies declared a priority in government health plans.”

“a) Producto farmacéutico indispensable: Medicamento que es básico, de la mayor importancia y preciso para satisfacer las necesidades de atención de salud de la mayor parte de la población y para abordar aquellas patologías declaradas prioritarias en los planes de salud del Gobierno.”

Art 5 modified by the decree No.43 (2009): “The drugs that make up the National Formulary will be selected on the basis of the following criteria, in order of priority:

1. Products defined as indispensable.
2. Products with proven safety and efficiency.

3. Products that comply with the principles of evidence-based medicine, especially those that integrate pharmacotherapy incorporated into clinical norms, therapeutic guides or protocols that are approved to address the most prevalent and priority pathologies, within the framework of The health objectives of the country.

4. Products that demonstrate a better effectiveness versus cost.”

“Los medicamentos que integran el Formulario Nacional serán seleccionados sobre la base de los siguientes criterios, en orden de prioridad:

1. Productos definidos como indispensables.

2. Productos con seguridad y eficacia demostrada.

3. Productos que cumplen los principios de la medicina basada en la evidencia, en especial aquellos que integran la farmacoterapia incorporada en las normas clínicas, guías terapéuticas o protocolos que se aprueben para abordar las patologías de mayor prevalencia y aquellas prioritarias, en el marco de los objetivos sanitarios del país.

4. Productos que demuestren una mejor efectividad versus costo.”

Art 6 modified by Decree No.43 (2010): “The responsibility for the follow-up and updating of the Formulary shall correspond to the Undersecretariat of Public Health of this Ministry, which by means of a supreme decree shall constitute a technical and scientific commission, of an advisory nature, of permanent operation, whose functions and other regulations shall be determined in the same decree.”

“La responsabilidad del seguimiento y actualización del Formulario corresponderá a la Subsecretaría de Salud Pública de este Ministerio, el que mediante decreto supremo constituirá una comisión técnico-científica, de carácter asesor, de funcionamiento permanente, cuyas funciones y demás regulaciones serán determinadas en el mismo decreto.”

Art 7 modified by Decree No.43 (2009): “The update of the Formulary will be made in general terms every two years, without prejudice to any additions or eliminations that may be made at the time they are requested.
For both purposes, the Commission may propose, at the request of Health Services, other public and/or private institutions of the country, both the updating and the specific incorporation of certain active principles and/or pharmaceutical forms, which must be authorized by decree of the Ministry of Health.

For these purposes, the following considerations should be taken into account:

1. - The pharmaco-therapeutic requirements to be incorporated into the clinical guidelines and protocols that will be used in the public care system.

2. - The substantiated suggestions made by the pharmacy and therapeutic committees of health care establishments.

3. - The results of the utilization studies available for specific therapeutic groups.

4. - National and international drug-surveillance reports.

5. - Systematic reviews on evidence-based medicine.”

"La actualización del Formulario se realizará en términos generales cada dos años, sin perjuicio de las incorporaciones o eliminaciones que puedan efectuarse en la oportunidad en que sean requeridas.

Para ambos efectos la Comisión podrá proponer de motu propio, a solicitud de Servicios de Salud, otras instituciones públicas y/o privadas del país, tanto la actualización como la incorporación específica de determinados principios activos y/o formas farmacéuticas, las que deberán ser autorizadas por decreto del Ministerio de Salud.

Para estos propósitos se deberán tener presentes las siguientes consideraciones:

1. - Los requerimientos fármaco-terapéuticos para incorporar a las guías clínicas y protocolos que se emplearán en el sistema de atención público.

2. - Las sugerencias fundamentadas que realicen los comités de farmacia y terapéutica de los establecimientos asistenciales.

3. - Los resultados de los estudios de utilización disponibles para grupos terapéuticos específicos.
4.- Los informes de fármaco-vigilancia nacionales e internacionales.

5.- Las revisiones sistemáticas sobre medicina basada en la evidencia.”

- Law No. 20850 (2015):

Art 5: “Of the decree that determines the diagnoses and Treatments of High Cost with system of financial protection. High-cost treatments for specific health conditions with a financial protection system, such as oncological, immunological and rare or infrequent diseases, will be determined through a supreme decree of the Ministry of Health, also signed by the Minister of Finance, in Accordance with the procedure established in this law and in the regulation. Only high cost diagnoses and treatments that comply with the following copulative conditions may be incorporated into this decree:

a) That the cost of the diagnoses or treatments is equal to or greater than that determined in the threshold referred to in Article 6.

b) That the diagnoses and treatments have been subject to a favorable scientific evaluation of the evidence, in accordance with Article 7.

c) That the diagnoses and treatments have been recommended in accordance with the provisions of Article 8.

d) That it has been decided to incorporate the diagnoses and the treatments, as indicated in article 9.”

“Del decreto que determina los diagnósticos y Tratamientos de Alto Costo con sistema de protección financiera. Los tratamientos de alto costo para condiciones específicas de salud con sistema de protección financiera, tales como enfermedades oncológicas, inmunológicas y raras o poco frecuentes, serán determinados a través de un decreto supremo del Ministerio de Salud, suscrito también por el Ministro de Hacienda, de conformidad al procedimiento establecido en esta ley y en el reglamento. Sólo podrán incorporarse a este decreto los diagnósticos y tratamientos de alto costo que cumplan con las siguientes condiciones copulativas:

a) Que el costo de los diagnósticos o tratamientos sea igual o superior al determinado en el umbral de que trata el artículo 6º.

b) Que los diagnósticos y tratamientos hayan sido objeto de una favorable evaluación científica de la evidencia, conforme al artículo 7º.

c) Que los diagnósticos y los tratamientos hayan sido recomendados de acuerdo a lo dispuesto en el artículo 8º.
d) Que se haya decidido la incorporación de los diagnósticos y los tratamientos, conforme a lo señalado en el artículo 9°.”

Art 7: “The evaluation of the respective diagnosis or treatment should include, at least, the relative efficacy and effectiveness; safety, economic evaluation, implementation, evaluation of payment terms through the risk-sharing mechanism, budgetary impact, effects on health care networks, available alternatives if any, industrial maximum price; ethical, legal and social implications and the scope and term of review of the evaluation, all in accordance with the technical standard that the Undersecretariat of Public Health dictates.”

“La evaluación del respectivo diagnóstico o tratamiento deberá comprender, a lo menos, la eficacia y efectividad relativas; la seguridad, la evaluación económica, la implementación, la evaluación de las condiciones de pago a través del mecanismo de riesgo compartido, el impacto presupuestario, los efectos en las redes asistenciales, las alternativas disponibles si existieran, precio máximo industrial, las repercusiones éticas, jurídicas y sociales y el alcance y plazo de revisión de la evaluación, todo conforme a la norma técnica que al efecto dicte la Subsecretaría de Salud Pública.”

For health insurance/universal health coverage schemes: Does the law require the beneficiaries of the medicines programme be consulted? i.e. Rural communities, local governments, Public interest NGOs, Patient and consumer groups, Representatives of vulnerable groups, ethnic minorities?

✔ Law No.19937 (2004):

Art 1 which modifies the decree No.2761 (1979):

1) “Replace article 4 for the following: “Article 4. - The Ministry of Health will be responsible for formulating, setting and controlling health policies. Consequently, it will have, among others, the following functions: (...)”

8) Formulate, evaluate and update the strategic guidelines of the health sector or National Health Plan, conformed by the health objectives, national priorities and needs of the people.””

“Artículo 4°.- Al Ministerio de Salud le corresponderá formular, fijar y controlar las políticas de salud. En consecuencia tendrá, entre otras, las siguientes..."
8) Formular, evaluar y actualizar los lineamientos estratégicos del sector salud o Plan Nacional de Salud, conformado por los objetivos sanitarios, prioridades nacionales y necesidades de las personas.”

Art 4 bis: “For the fulfillment of the function indicated in number 8 of the previous article, the Minister of Health shall call for the formation of Consultative Councils, which may be composed of natural persons and representatives of juridical persons, from public and private sector, according to the topics to be treated.”

“Para el cumplimiento de la función señalada en el número 8 del artículo anterior, el Ministro de Salud deberá convocar la formación de Consejos Consultivos, los que podrán ser integrados por personas naturales y representantes de personas jurídicas, del sector público y del privado, de acuerdo a las materias a tratar.”

22) Which introduces after the article 25 the new titles IV and V in the Decree No.2763 (1979).

TITLE IV ON THE NETWORK SELF-MANAGEMENT ESTABLISHMENTS.

Art 25A: “Healthcare establishments dependent on Health Services, which have greater technical complexity, development of specialties, administrative organization and number of benefits, will obtain the quality of "Network Self-Management Establishments", with the attributions and conditions set forth in this Title, if they fulfill the requirements that are determined in the Regulation referred to in the following subsection.”

“Los establecimientos de salud dependientes de los Servicios de Salud, que tengan mayor complejidad técnica, desarrollo de especialidades, organización administrativa y número de prestaciones, obtendrán la calidad de "Establecimientos de Autogestión en Red", con las atribuciones y condiciones que señala este Titulo, si cumplen los requisitos que se determinen en el Reglamento a que se refiere el inciso siguiente.”

Art 25D: “There will be a Consultative Council of Users, which will be composed of 5 representatives of the neighborhood community and 2 representatives of workers of the facility. The Advisory Board will have the role of advising the director of the facility in setting the policies of the establishment and in the definition and evaluation of institutional plans. Likewise, in the first quarter of each year, the Director shall present to the Advisory Board the plan of activities to be carried out by the facility during the year, as well as its annual public account.
“Artículo 25 D.- Existirá un Consejo Consultivo de los Usuarios, el que estará compuesto por 5 representantes de la comunidad vecinal y 2 representantes de los trabajadores del establecimiento. El Consejo Consultivo tendrá la función de asesorar al director del establecimiento en la fijación de las políticas de este y en la definición y evaluación de los planes institucionales.

Asimismo, en el primer trimestre de cada año, el Director presentará al Consejo Consultivo el plan de actividades a desarrollar por el establecimiento durante el año, así como la cuenta pública anual del mismo.”

Exempt Decree No.65 (2010):

1. “The Advisory Council for Adolescents and Young People of the Ministry of Health shall be created, whose objective is to advise the ministerial authorities on the decisions regarding public health policies and services for this population group, in order to have the direct opinion of the Persons to whom they are addressed.”

2. “The Board will be made up of two representatives from each region, who are members of adolescent or youth participation organizations, resulting in a total of 30 counselors, who must be elected in participatory processes, ensuring both the diversity and the representativeness of the counselors. Such election process will be responsibility and will have the direct supervision of the Regional Ministerial Secretaries of Health.”

“El Consejo estará constituido por dos representantes de cada región, que formen parte de instancias de participación adolescente o juvenil, totalizando una cantidad de 30 Consejeros, los que deberán ser elegidos en procesos participativos, que aseguren, tanto la diversidad como la representatividad de los Consejeros. Dicho proceso de elección será responsabilidad y contará con la supervisión directa de los Secretarios Regionales Ministeriales de Salud”

4. “The sessions will have as minimum purpose that the counselors know the state of progress of the Ministry Adolescents and Youth Program, through a public account of the health management given by the Ministry; to plan and evaluate their actions, to dialogue with the ministerial authorities in charge of the organization of health services for them and them; give opinions, prioritize and decide on proposals presented or in relation to other matters that they deem pertinent.”
“Las sesiones tendrán por propósito mínimo que los consejeros conozcan el estado de avance del Programa de Adolescentes y Jóvenes del Ministerio, a través de una cuenta pública de la gestión en salud dada por el Ministerio; planificar y evaluar sus acciones, dialogar con las autoridades ministeriales a cargo de la organización de servicios de salud para ellos y ellas; opinar, priorizar y decidir propuestas frente a lo presentado o frente a otras materias que estimen pertinente.”

✓ **Law No.20500 (2011)** on Associations and citizen participation in public management. This law modifies the law **No.18575** (2001) in its title IV on citizen participation in public management, including the following articles:

Art 69: “The State recognizes individuals the right to participate in their policies, plans, programs and actions.”

“El Estado reconoce a las personas el derecho de participar en sus políticas, planes, programas y acciones.”

Art 70: “Each organ of the State Administration must establish the formal and specific modalities of participation that people and organizations will have within the scope of its competence.”

“Cada órgano de la Administración del Estado deberá establecer las modalidades formales y específicas de participación que tendrán las personas y organizaciones en el ámbito de su competencia.”

Art 74: “The organs of the State Administration shall establish civil society councils of an advisory nature, which shall be formed in a diverse, representative and pluralistic manner by members of non-profit associations that are related to the competence of the respective body.”

“Los órganos de la Administración del Estado deberán establecer consejos de la sociedad civil, de carácter consultivo, que estarán conformados de manera diversa, representativa y pluralista por integrantes de asociaciones sin fines de lucro que tengan relación con la competencia del órgano respectivo”


I. Definitions and scope of enforcement:

1. “Citizen participation in the public health management will be understood as the specific application of the rights to the publicity of the public information; equality to participate in national life; freedom of opinion and right to petition, under the terms of Law No. 20285 and Articles 8 and 19, 12 and 14, all of the Political Constitution of the Republic, the right to association and influence in public management in the terms of Law No. 20500.”

“Se entenderá por participación ciudadana en la gestión pública de salud a la aplicación específica de los derechos a la publicidad de la información pública;
la igualdad para participar en la vida nacional; la libertad de opinión y el derecho de petición, en los términos de la ley No. 20285 y en los artículos 8 y 19, 12 y 14, todos de la Constitución Política de la República, el derecho a asociación e incidencia en la gestión pública en los términos de la ley No. 20500.”

2. “This general rule will apply: to the Ministry of Health, to the Undersecretaries of Public Health and Assistance Networks; To the Regional Ministerial Health Secretariats; National Health Services System, the three Experimental Centers created by the D.F.L. 29, 30 and 31 of 2001 of this ministry; The National Health Fund; The Institute of Public Health; The Superintendence of Health and the Central Supply System of National Health Services.”

“La presente norma general se aplicará: al Ministerio de Salud, a las Subsecretarías de Salud Pública y Redes Asistenciales; a las Secretarías Regionales Ministeriales de Salud; Sistema Nacional de Servicios de Salud, los tres Centros Experimentales creados por los D.F.L 29, 30 y 31 de 2001 de este ministerio; el Fondo Nacional de Salud; el Instituto de Salud Pública; la Superintendencia de Salud y la Central de Abastecimiento de Sistema Nacional de Servicios de Salud.”

III. Civil Society Councils
1. “The Civil Society Councils are representative and participatory bodies in which social actors have an impact on public management.”

“Los Consejos de la Sociedad Civil son órganos de carácter representativo y participativo en que actores sociales inciden en la gestión pública.”

3. “The Sectoral Work Committee on Citizen Participation in Health will report to the Ministry every six months on the representativeness, diversity and effectiveness of the Councils of Civil Society, for which it must coordinate with the organs of the System.”

“El Comité de Trabajo Sectorial de Participación Ciudadana en Salud informará semestralmente al Ministro sobre la representatividad, diversidad y efectividad de los Consejos de la Sociedad Civil para lo cual deberá coordinarse con los órganos del Sistema.”

IV. Advisory Councils and other instances of social participation
1. “Notwithstanding the aforementioned, the various bodies must continue to operate in accordance with the Health Authority Law, including the Councils for Integration of the Assistance Network (CIRA), the Regional Advisory Councils (CAR); The Interreligious Advisory Council created under the Worship Act, as well as; The Local Development Councils, Local Health Committees, among others, all created by virtue of the regulations related to the social participation policies emanated from the Ministry of Health”

“No obstante de lo anterior, deberán continuar en funcionamiento las diferentes instancias de acuerdo a la Ley de Autoridad Sanitaria, entre ellas los
Consejos de Integración de la Red Asistencial (CIRA), los Consejos Asesores Regionales (CAR); el Consejo Asesor Interreligioso creado en virtud de la Ley de Culto, así como; los Consejos de Desarrollo Local, Comité Locales de Salud, entre otras, todas estas creadas en virtud de las normativas relacionadas con las políticas de participación social emanadas desde el Ministerio de Salud.”

2. “Likewise, the institutions created in relation to the strategic and programmatic lines currently in operation, such as the Gender Advisory Council, the Youth Advisory Council, the National Commission for the Protection of the Rights of Persons with Mental Illness.”

“A su vez las instancias creadas en relación a las líneas estratégicas y programáticas actualmente en funcionamiento, tales como Consejo Consultivo de Género, Consejo Consultivo de Jóvenes, Comisión Nacional de Protección de los Derechos de las Personas con Enfermedades Mentales.”

3. “These bodies are expected to meet at least twice a year and have an impact on the formulation, implementation and evaluation of policies related to the specific field of interest, in accordance with their current internal regulations or operating rules.”

“Se espera que estas instancias sesionen un mínimo de dos veces al año y que tengan incidencia en la formulación, implementación y evaluación de políticas vinculadas con el ámbito específico de interés, de acuerdo a su reglamento o normas de funcionamiento interno actualmente vigentes.”

✓ Exempt Resolution No.2683 (2013) on the creation on the CENABAST’s Civil Society Council and the approval of its internal regulation.

1. “The Consultative Council of Supply center of the S.N.S.S. (National System of Health Services from its Spanish initials) is created as an autonomous and non-binding, consultative body, whose objective is to contribute with constructive and quality ideas and opinions, in the analysis of the public policies of the area, seeking to potentiate the development of the market for the procurement and supply of pharmaceuticals and supplies of the Health Sector, which increases the transparency of the generation of savings to the State.”

“Créase el Consejo Consultivo de la Central de Abastecimiento del S.N.S.S., instancia de carácter consultivo, autónomo y no vinculante, cuyo objetivo será contribuir con ideas y opiniones constructivas y de calidad, en el análisis de las políticas públicas del área, buscando potenciar el desarrollo del Mercado de las compras y abastecimiento de fármacos e insumos del Sector Salud, que aumente la transparencia de la generación de ahorros al Estado.”

4. “The following participants concur to the constitution of the Board, without prejudice to introducing new participants or replacing existing ones that do not attend.
- Physicians Without Brand.
- Association of Pharmaceutical and Biochemical Chemists of Chile, A.G.
Title III. On the Council’s Functioning

Art 7: “The Council shall participate, in an advisory manner, in the design, implementation and evaluation of the policies of the Service, in which its opinion is required.”

“El Consejo participará, de forma consultiva, en el diseño, ejecución y evaluación de las políticas del Servicio, en que sea requerida su opinión.”

- Exempt Resolution No.640 (2015) on the approval of citizen participation in the Superintendence of Health

II. On the Modalities of Citizen Participation

1. “(...) The Health Superintendence defines the following mechanisms of citizen participation:
a) Access to Relevant Information.
b) Participatory Public Accounts
c) Citizen Consultation
d) Council of Civil Society.
e) Public Hearing."

“(...)La Superintendencia de salud define los siguientes mecanismos de participación ciudadana:

a) Acceso a Información Relevante.
b) Cuentas Públicas Participativas
c) Consultas Ciudadanas
d) Consejo de la Sociedad Civil.
e) Audiciones Públicas.”

✓ **Exempt Resolution No.204 (2017)** on the approval on the norms for the structure, composition and functioning on the Superintendence’s Civil Society Council.

I. Nature and Purpose of the Council

Art1: “The Civil Society Council of the Superintendence of Health, hereinafter referred to as "the Council", is an advisory, non-binding citizen participation body whose purpose is to represent the opinion of civil society in decision-making processes and follow-up of the public policies emanated from the Superintendence of Health. Representatives of social organizations, associations and non-profit entities of regional or national scope that are related to or interested in policies, plans and programs related to health rights may be members of the Council.”
“El Consejo de la Sociedad Civil de la Superintendencia de Salud, en adelante “el Consejo”, constituye una instancia de participación ciudadana de carácter consultivo y no vinculante, cuyo propósito es representar la opinión de la sociedad civil en los procesos de toma de decisión y seguimiento de las políticas públicas emanadas de la Superintendencia de Salud. Podrán ser parte del Consejo, representantes de organizaciones sociales, asociaciones y entidades sin fines de lucro, de alcance regional o nacional, que estén relacionadas o tengan interés en las políticas, planes y programas vinculados a los derechos en salud.”

II. On the Functions, Composition and Structure of the Council

Art 4: “The council shall be composed of a minimum of six organizations, which shall elect as their counselors a representative (…)”

“El consejo estará constituido por un mínimo de seis organizaciones, las cuales elegirán como consejeros a un representante suyo (…)”

✓ Exempt Resolution No. 3033 (2015) on the Approval of the composition, structure and functioning of FONASA’s Civil Society Councils.

Art 2: “The FONASA Civil Society Councils must meet the following objectives;

- To represent the voice of citizens and their organizations throughout the management cycle of Public Policies.

- To accompany and be consulted in the decision-making processes in FONASA's public policy cycle.

- To develop an annual work agenda that allows the elaboration of proposals, initiatives or observations of the public policies of FONASA.

- To promote and disseminate in a constant way, the health rights in the organizations that they represent, and in the society.

- To promote strategies for the strengthening of the organizations, and to support the formation of new organizations and / or Councils of the Civil Society

- To Participate in the process of citizen consultations, carried out in a virtual or face-to-face manner through Citizen Dialogues.

- To actively participate in the FONASA Participative Public Account process.

- To Promote public decisions that prioritize the general interest of society.”
“Los Consejos de la Sociedad Civil de FONASA deberán cumplir los siguientes objetivos:

-Representar la voz de la ciudadanía y sus organizaciones en todo el ciclo de gestión de las Políticas Públicas.

-Acompañar y ser consultados en los procesos de toma de decisiones en el ciclo de las políticas públicas de FONASA.

-Desarrollar una agenda anual de trabajo que permita elaborar propuestas, iniciativas u observaciones de las políticas públicas de FONASA.

-Promover y difundir de manera constante en el tiempo, los derechos en salud en las organizaciones que representan, y en la ciudadanía.

-Impulsar estratégicas para el fortalecimiento de las organizaciones, y apoyar la conformación de nuevas organizaciones y/o Consejos de la Sociedad Civil.

-Participar en el proceso de las consultas ciudadanas, llevadas a cabo de manera virtual o de modo presencial a través de Diálogos Ciudadanos.

-Participar activamente cada año en el proceso de Cuenta Pública Participativa de FONASA.

-Impulsar decisiones públicas que prioricen el interés general de la sociedad.”

Art 3: “The FONASA’s Civil Society Councils will be made up of organizations with legal personality in force, non-profit, that have an interest in the themes of Public Health, Public Policies and social rights in Health.”

“Los Consejos de la Sociedad Civil de FONASA estarán integrados por organizaciones con personalidad jurídica vigente, sin fines de lucro, que tengan interés en las temáticas de Salud Pública, Políticas Públicas y de derechos sociales en salud.”

Art 6: “The councils must have, at least 5 councilors, one of them fulfilling the duties of Chairman.”

“Los consejos deberán contar, con al menos 5 consejeros/as, de los cuales uno de ellos/as cumplirá las labores de Presidente/a titular (…)”


Tittle II. Paragraph 1: on the Council conformation:
Art 3: “The council will be composed of 11 counselors and 3 interlocutors of the Public Health Institute. The counselors will be:

a) Three members representing the associations of issues related to drugs and medical devices (...)

b) Three members representing the associations related to occupational health (...)

c) A member representing gender-related associations for including the gender approach in Public Health Institute referral documents.

d) Two members representing environmental health related associations for support in the validation of analytical methodologies (...)

e) Two members representing associations linked to clinical laboratory filed for support in proposals of topics and participatory elaboration of documentation for clinical laboratories.”

“El consejo estará integrado por 11 consejeros/as y 3 interlocutores/as del I.S.P. Los consejeros/as serán:

a) Tres miembros que representa las asociaciones de temáticas vinculadas a medicamentos y dispositivos medicos (...)

b) Tres miembros que representan las asociaciones de temáticas vinculadas a la salud ocupacional (...)

c) Un miembro que representa a las asociaciones de temáticas de género para el apoyo en la perspectiva de género en documentos de referencia del I.S.P.

d) Dos miembros que representan a las asociaciones de temáticas vinculadas a la salud ambiental para el apoyo en la validación de metodologías analíticas (...)

e) Dos miembros que representan a las asociaciones vinculadas a temáticas de laboratorio clínico para el apoyo en propuestas de temas y elaboración participativa de documentación para laboratorios clínicos.”

President Decree No.1 (2016) on the creation of the National Council of Citizen Participation and the strengthening of civil society.

Art 1: “The National Council for Citizen Participation and Strengthening of Civil Society shall be created (...), whose purpose is to advise the Presidency of the Republic on the institutionalization of citizen participation and the strengthening of civil society in the country, within the framework of a broad national
debate on the subject.”

“Créase el Consejo Nacional de Participación Ciudadana y Fortalecimiento de la Sociedad Civil (…), que tendrá por objeto asesorar a la Presidencia de la República en materia de institucionalización de la participación ciudadana y el fortalecimiento de la sociedad civil en el país, en el marco de un amplio debate nacional sobre la materia.”

Art 3: “For the fulfillment of its functions of advising the President of the Republic in the mentioned areas, the National Council will perform the following tasks:

a) Collaborate in carrying out a diagnosis on the state of citizen participation and develop a proposal for a reform of Law No. 20500 on Associations and Citizen Participation in Public Management which considers, among other aspects, the Institutionalization of the Civic Participation Council and Strengthening Civil Society."

b) To prepare a report on citizen participation that includes good practices and standards in terms of participation, which will serve the President of the Republic for the elaboration of an Index of Citizen Participation that will allow accounting for the advances and difficulties evidenced on the subject.”

“Para el cumplimiento de sus funciones de asesorar a la Presidenta de la República en las materias señaladas, corresponderá al Consejo Nacional el desempeño de las siguientes tareas:

a) Colaborar en la realización de un diagnóstico sobre el estado de participación ciudadana y desarrollar una propuesta de reforma a la Ley No 20500 sobre Asociaciones y Participación ciudadana en la Gestión Pública que considere, entre otros aspectos, la Institucionalización del Consejo de Participación Ciudadana y Fortalecimiento de la Sociedad Civil.”

b) Elaborar un informe sobre participación ciudadana que recoja buenas prácticas y estándares en materia de participación, que sirva a la Presidenta de la República para la elaboración de un índice de Participación Ciudadana que permita dar cuenta de los avances y dificultades evidenciados sobre el tema.”

✓ Law No. 20584 (2012):

Art 30: "(…)When regulating the existence of ethics committees that attend the consultations of the persons who consider necessary the evaluation of a case from the clinical ethical point of view, the participation of the users in said committee must be assured. (…) The Health Services must have at least one ethics committee, to which they shall be attached the individual private providers of their territory, in case they aren’t attached to any other."
“(…) Al reglamentar la existencia de comités de ética que atiendan las consultas de las personas que consideren necesaria la evaluación de un caso desde el punto de vista ético clínico, se deberá asegurar la participación de los usuarios en dichos comités. (…) Los Servicios de Salud deberán disponer de, al menos, un comité de ética, al cual se entenderán adscritos los prestadores privados individuales de su territorio, en caso de no estarlo a algún otro.”

✓ Law No.20850 (2015):

Art 22: Of the Citizen Commission of Surveillance and Control. There will be a Citizen Commission for Surveillance and Control of the Financial Protection System for Diagnoses and High-Cost Treatments composed of four representatives of patient associations, registered according to article 30; two representatives of scientific associations; two academics from medical schools of some institutionally accredited higher education institution, in accordance with Law No. 20,129, which establishes the National Quality Assurance System for Higher Education, and four health experts appointed by the Minister of Health, one of whom will assume the executive secretariat.

This Commission will have as its function to advise the ministers of Health and Finance, through the monitoring of the functioning of this System and the respective elaboration of recommendations.

“De la Comisión Ciudadana de Vigilancia y Control. Existirá una Comisión Ciudadana de Vigilancia y Control del Sistema de Protección Financiera para Diagnósticos y Tratamientos de Alto Costo integrada por cuatro representantes de asociaciones de pacientes, de las registradas según el artículo 30; dos representantes de asociaciones científicas; dos académicos de facultades de medicina de alguna institución de educación superior acreditada institucionalmente, de conformidad con la ley Nº20.129, que establece el Sistema Nacional de Aseguramiento de la Calidad de la Educación Superior, y cuatro expertos del área de la salud designados por el Ministro de Salud, uno de los cuales asumirá la secretaría ejecutiva.

Esta Comisión tendrá como función asesorar a los ministros de Salud y de Hacienda, a través del monitoreo del funcionamiento de este Sistema y de la respectiva elaboración de recomendaciones.”
For health insurance/universal health coverage schemes: Are there mechanisms for transparency and accountability? I.e. targets, indicators, benchmarks, a plan for monitoring and evaluation

Art 1, 22 which introduces after the article 25 the new titles IV and V in the Decree No.2763 (1979).

TITLE IV ON THE NETWORK SELF-MANAGEMENT ESTABLISHMENTS.

Art 25G “The Facility will be subject to an annual evaluation of Subsecretariat of Assistance Networks to verify compliance with the standards determined by joint resolution of the Ministries of Health and Finance, which will include at least the following subjects:

c) Have successfully implemented systems or mechanisms for management and competence development in areas such as planning and management control; staff Administration; attention and support to the user; financial-accounting management and internal audit; systems of public account to the community, among others.”

“El Establecimiento estará sujeto a una evaluación anual del Subsecretario de Redes Asistenciales, para verificar el cumplimiento de los estándares determinados por resolución conjunta de los Ministerios de Salud y de Hacienda, que incluirán a lo menos las siguientes materias:

c) Haber implementado satisfactoriamente sistemas o mecanismos de gestión y desarrollo de competencias en áreas tales como planificación y control de gestión; administración de personal; atención y apoyo al usuario; administración financiero-contable y auditoría interna; sistemas de cuenta pública a la comunidad, entre otras;”

Art 25J: “By means of a resolution of the Subsecretariat of Assistance Networks, the way in which the user population of the Establishment will be able to express its requests, criticisms and suggestions will be regulated.”

“Mediante resolución del Subsecretario de Redes Asistenciales se regulará la forma en que la población usuaria del Establecimiento podrá manifestar sus peticiones, críticas y sugerencias”
Art 6: The Superintendence of Health shall be created and the following is set as its organic law:

Art 6: “The Superintendence will be responsible for the following functions (...), regarding super-vigilance and control of the Health Guarantees Regime:

5) To periodically disseminate information that allows the contributors and beneficiaries of the Private Health Insurance Institutions and the National Health Fund a better understanding of the benefits and obligations that imposes the aforementioned Guarantee Regime and periodically inform about the rules and instructions issued and interpretations formulated by the Superintendence, in relation to the benefits and obligations of contributors and beneficiaries of Private Health Insurance Institutions and the National Health Fund, with respect to the Health Guarantees Regime.”

“Le corresponderán a la Superintendencia las siguientes funciones (...) respecto de la supervigilancia y control del Régimen de Garantías en Salud:

5) Difundir periódicamente información que permita a los cotizantes y beneficiarios de las instituciones de salud previsional y del Fondo Nacional de Salud una mejor comprensión de los beneficios y obligaciones que impone el referido Régimen de Garantías e informar periódicamente sobre las normas e instrucciones dictadas e interpretaciones formuladas por la Superintendencia, en relación con los beneficios y obligaciones de los cotizantes y beneficiarios de las instituciones de salud previsional y del Fondo Nacional de Salud, respecto del Régimen de Garantías en Salud.”

✓ Law No. 20285 (2008) on Access to Public Information.

Art 3: “The public function is exercised with transparency, in a way that allows and promotes the knowledge of the procedures, contents and decisions that are adopted in its exercise.”

“La función pública se ejerce con transparencia, de modo que permita y promueva el conocimiento de los procedimientos, contenidos y decisiones que se adopten en ejercicio de ella. “

Art 4: “The authorities, regardless of the denomination designated by the Constitution and laws, and officials of the State Administration, must strictly comply with the principle of transparency of public service.

The principle of transparency of the public function is to respect and protect the publicity of the acts, resolutions, procedures and documents of the Administration, as well as of its foundations, and to facilitate the access of any person to that information, through the means and procedures established by law for this purpose.”
“Las autoridades, cualquiera que sea la denominación con que las designen la Constitución y las leyes, y los funcionarios de la Administración del Estado, deberán dar estricto cumplimiento al principio de transparencia de la función pública.

El principio de transparencia de la función pública consiste en respetar y cautelar la publicidad de los actos, resoluciones, procedimientos y documentos de la Administración, así como la de sus fundamentos, y en facilitar el acceso de cualquier persona a esa información, a través de los medios y procedimientos que al efecto establezca la ley.”

Art 10: “Every person has the right to request and receive information from any organ of the State Administration, in the form and conditions established by this law.”

“Toda persona tiene derecho a solicitar y recibir información de cualquier órgano de la Administración del Estado, en la forma y condiciones que establece esta ley. (…)”

Art 11: “The right of access to the information of the organs of the State Administration recognizes, among others, the following principles:

a) Principle of relevance, according to which any information held by the organs of the State Administration is presumed to be relevant (…)

b) Principle of freedom of information, according to which every person enjoys the right to access information held by the organs of State Administration, with the exceptions or limitations established by laws of qualified quorum.

c) Principle of openness or transparency, according to which all information held by the organs of the State Administration is presumed public, unless it is subject to the exceptions indicated.

d) Principle of maximum disclosure, according to which the organs of the State Administration must provide information in the broadest possible terms, excluding only that which is subject to constitutional or legal exceptions.(…)

f) Facilitation principle, according to which the mechanisms and procedures for access to information of the organs of the State Administration should facilitate the exercise of the right. (…)

g) Principle of non-discrimination, according to which the organs of the State Administration must provide information to all persons who request it, under equal conditions, without making arbitrary distinctions and without demanding expression of cause or reason for the request.”
h) Principle of the opportunity, according to which the organs of the State Administration must respond to requests for information within the legal deadlines, with the maximum speed possible and avoiding all kinds of delays.

i) Principle of control, according to which compliance with the norms that regulate the right of access to information will be subject to permanent control, and resolutions that fall on requests for access to information are claimed by an external body.

j) Principle of responsibility, according to which the breach of the obligations imposed by this law on the organs of the State Administration, creates responsibilities and gives rise to the sanctions established by this law.

k) Principle of gratuitousness, according to which the access to the information of the organs of the Administration is gratuitous, without prejudice of the established in this law.”

“El derecho de acceso a la información de los órganos de la Administración del Estado reconoce, entre otros, los siguientes principios:

a) Principio de la relevancia, conforme al cual se presume relevante toda información que posean los órganos de la Administración del Estado (…) 

b) Principio de la libertad de información, de acuerdo al que toda persona goza del derecho a acceder a la información que obre en poder de los órganos de la Administración del Estado, con las solas excepciones o limitaciones establecidas por leyes de quórum calificado.

c) Principio de apertura o transparencia, conforme al cual toda la información en poder de los órganos de la Administración del Estado se presume pública, a menos que esté sujeta a las excepciones señaladas.

d) Principio de máxima divulgación, de acuerdo al que los órganos de la Administración del Estado deben proporcionar información en los términos más amplios posibles, excluyendo sólo aquello que esté sujeto a las excepciones constitucionales o legales.(…)

f) Principio de facilitación, conforme al cual los mecanismos y procedimientos para el acceso a la información de los órganos de la Administración del Estado deben facilitar el ejercicio del derecho (…)

g) Principio de la no discriminación, de acuerdo al que los órganos de la Administración del Estado deberán entregar información a todas las personas que lo soliciten, en igualdad de condiciones, sin hacer distinciones arbitrarias y sin exigir expresión de causa o motivo para la solicitud.
h) Principio de la oportunidad, conforme al cual los órganos de la Administración del Estado deben proporcionar respuesta a las solicitudes de información dentro de los plazos legales, con la máxima celeridad posible y evitando todo tipo de trámites dilatorios.

i) Principio del control, de acuerdo al que el cumplimiento de las normas que regulan el derecho de acceso a la información será objeto de fiscalización permanente, y las resoluciones que recaigan en solicitudes de acceso a la información son reclamables ante un órgano externo.

j) Principio de la responsabilidad, conforme al cual el incumplimiento de las obligaciones que esta ley impone a los órganos de la Administración del Estado, origina responsabilidades y da lugar a las sanciones que establece esta ley.

k) Principio de gratuitidad, de acuerdo al cual el acceso a la información de los órganos de la Administración es gratuito, sin perjuicio de lo establecido en esta ley.”

Art 31: “The Council for Transparency shall be created, as an autonomous corporation of public law, with legal personality and own patrimony.”

“Créase el Consejo para La Transparencia, como una corporación autónoma de derecho público, con personalidad jurídica y patrimonio propio. (…)”

Art 32: “The purpose of the Council is to promote the transparency of the public service, to supervise compliance with the rules on transparency and publicity of the information of the organs of the State Administration, and to guarantee the right of access to information.”

“El Consejo tiene por objeto promover la transparencia de la función pública, fiscalizar el cumplimiento de las normas sobre transparencia y publicidad de la información de los órganos de la Administración del Estado, y garantizar el derecho de acceso a la información.”

✔ Law 20500 (2011) which modifies the law No.18575 (2001) in its title IV on citizen participation on public management including the following articles:

Art 71: “Notwithstanding the provisions of the preceding article, each State Administration body shall make publicly available relevant information about its policies, plans, programs, actions and budgets, ensuring that it is timely, complete and widely accessible.”

“Sin perjuicio de lo establecido en el artículo anterior, cada órgano de la Administración del Estado deberá poner en conocimiento público información relevante acerca de sus políticas, planes, programar, acciones y presupuestos, asegurando que ésta sea oportuna, completa y ampliamente accesible.”

Art 72: “The organs of the State Administration, annually, will give public account of the citizenship of the management of its policies, plans, programs,
actions and of its budgetary execution. Said account must be deconcentrated, in the form and terms established by the rule established in Article 70.”

“Los órganos de la Administración del Estado, anualmente, darán cuenta pública participativa a la ciudadanía de la gestión de sus políticas, planes, programas, acciones y de su ejecución presupuestaria. Dicha cuenta deberá desarrollarse desconcentradamente, en la forma y plazos que fije la norma establecida en el artículo 70.”

✓ **Exempt Resolution No.31 (2015)** on the approval of the general rule of Citizen Participation in Public Health Management.

II. Public Account

1. “The bodies of the System indicated in number 2 of this Resolution will give an annual account of their management, directly to the citizens and in them will include at least:

   1.1 Policies, plans and programs.

   1.2 Budgets.

   1.3 Concrete forms of access to public information.

   1.4 Participatory Public Management.

   1.5 Strengthening of Civil Society.

   1.6 Non-discrimination and respect for diversity”

“Los órganos del Sistema señalados en el número 2 de la presente Resolución rendirán cuenta anual de su gestión, directamente a la ciudadanía y en ellas se incluirá al menos:

   1.1 Políticas, planes y programas.

   1.2 Presupuestos.

   1.3 Formas concretas de acceso a la información pública.

   1.4 Gestión Pública Participativa.

   1.5 Fortalecimiento de la Sociedad Civil.

   1.6 No discriminación y respeto a la diversidad.”
IV. Access to Public Information
1. “The organs of the System must ensure access to public information, at least in terms of article 8 of the Political Constitution and law No.20285 on access to public information.”
   “Los órganos del Sistema deberán asegurar el acceso a la información pública, al menos en los términos del artículo 8 de la Constitución Política y la ley No.20285 sobre acceso a la información pública.”
2. “Notwithstanding those mentioned in the previous paragraph, the Working Committee shall propose a standard for all the organs of the System in terms of access to public information, which each body will render account in the specific terms of number 4.3 of this General Norm. In each organ of the System there must be a Committee of transparency and mechanisms to monitor its operation”
   “Sin perjuicio de lo señalado en el número anterior, el Comité de Trabajo propondrá un estándar para todos los órganos del Sistema en términos del acceso a la información pública, del cual cada órgano rendirá cuenta en los términos específicos del número 4.3 de esta Norma General. En cada órgano del Sistema deberá existir un Comité de transparencia y mecanismos de monitoreo de su funcionamiento.”

XI Integral Citizen Attention System
1. “The Health sector must maintain a Citizen Attention System that integrates different points of contact with the population, whether virtual, telephonic, face-to-face, media written under the single-window system, according to what is established in Law No.19.880 on basis of Administrative Procedures and other regulations in force.”
   “El sector Salud deberá mantener un Sistema de Atención Ciudadana que integre distintos puntos de contacto con la población ya sean virtuales, telefónicos, presenciales, medios escritos bajo el enfoque de ventanilla única, de acuerdo a lo establecido en la Ley No.19.880 de Base de Procedimientos Administrativos y otras normativas vigentes.”
2. “This system will ensure adequate reception and referral of citizen requests according to previously defined protocols and procedures, ensuring compliance with deadlines, quality and relevance of responses, registration of actions, information processing, generation of inputs for the elaboration and implementation of plans to improve care and provision of services.”
   “Este Sistema velará por una adecuada recepción y derivación de las solicitudes ciudadanas de acuerdo a protocolos y procedimientos definidos previamente cautelando el cumplimiento de plazos, calidad y pertinencia de las respuestas, registro de acciones, procesamiento de información, generación de insumos para la elaboración e implementación de planes de mejora de la atención y provisión de servicios.”
Law No. 20.584 (2012):

Art 8: “Everyone has the right to be provided by the institutional provider with sufficient, timely, truthful and understandable information, either visually, verbally or written, regarding the following elements:

a) The health care or types of health actions that the respective provider offers or has available and the mechanisms through which these benefits can be accessed, as well as the value of them.

b) The health conditions required for their care, the background or documents requested in each case and the procedures required to obtain health care.

c) The conditions and obligations contemplated in its internal regulations that the persons must comply while they are inside the health care establishments.

d) The instances and ways of making comments, acknowledgments, complaints and suggestions.

The providers must place and maintain in a public and visible place a letter of rights and duties of the people in relation to health care, the content of which will be determined by resolution of the Minister of Health.”

“Toda persona tiene derecho a que el prestador institucional le proporcione información suficiente, oportuna, veraz y comprensible, sea en forma visual, verbal o por escrito, respecto de los siguientes elementos:

a) Las atenciones de salud o tipos de acciones de salud que el prestador respectivo ofrece o tiene disponibles y los mecanismos a través de los cuales se puede acceder a dichas prestaciones, así como el valor de las mismas.

b) Las condiciones previsionales de salud requeridas para su atención, los antecedentes o documentos solicitados en cada caso y los trámites necesarios para obtener la atención de salud.

c) Las condiciones y obligaciones contempladas en sus reglamentos internos que las personas deberán cumplir mientras se encuentren al interior de los establecimientos asistenciales."
d) Las instancias y formas de efectuar comentarios, agradecimientos, reclamos y sugerencias.

Los prestadores deberán colocar y mantener en un lugar público y visible, una carta de derechos y deberes de las personas en relación con la atención de salud, cuyo contenido será determinado mediante resolución del Ministro de Salud.”

Art 31: “Institutional providers, public and private, will maintain an updated database and other records of free access, with information that contains the prices of benefits, supplies and medicines charged in the care of people.”

“Los prestadores institucionales, públicos y privados, mantendrán una base de datos actualizada y otros registros de libre acceso, con información que contenga los precios de las prestaciones, de los insumos y de los medicamentos que cobren en la atención de personas.”

✓ Law No. 20850 (2015):
Art 27: Information system. The National Health Fund must implement an information system that allows the monitoring, monitoring and control of the granting of the benefits contemplated in the System, as well as the expenditure executed for each one of them, according to the regulation.

The System must also contain a register of health products that have been included in the Financial Protection System for High Cost Diagnostics and Treatments, the respective suppliers, purchase prices and duration of the contracts signed with the National Supply Center National System of Health Services, in accordance with the provisions of article 31. This information must be available on the National Health Fund's website and updated at least monthly.

The information contained in the system must be kept permanently available to the public, through its website, updated at least once a month.”

“Sistema de información. El Fondo Nacional de Salud deberá implementar un sistema de información que permita el seguimiento, monitoreo y control del otorgamiento de las prestaciones contempladas en el Sistema, así como del gasto ejecutado para cada una de ellas, conforme al reglamento.

Asimismo, el Sistema deberá contener un registro de los productos sanitarios que han sido incluidos en el Sistema de Protección Financiera para Diagnósticos y Tratamientos de Alto Costo, los respectivos proveedores, precios de compra y duración de los contratos celebrados con la Central Nacional de Abastecimiento del Sistema Nacional de Servicios de Salud, conforme con lo dispuesto en el artículo 31. Esta información deberá estar disponible en el sitio electrónico del Fondo Nacional de Salud y actualizarse al menos mensualmente.
La información contenida en el sistema deberá mantenerse a disposición permanente del público, a través de su sitio electrónico, actualizado, al menos, una vez al mes.”

<table>
<thead>
<tr>
<th>For health insurance/universal health coverage schemes: Are there safeguards and redress mechanisms in case human rights are violated? i.e. is there a complaints procedure?</th>
</tr>
</thead>
</table>


Art 1: “The National Institute of Human Rights, hereinafter "the Institute", shall be created as an autonomous corporation of public law, with legal personality and its own patrimony.”

 Ceséase el Instituto Nacional de Derechos Humanos, en adelante también "el Instituto", como una corporación autónoma de derecho público, con personalidad jurídica y patrimonio propio.(…)

Art 2: “The purpose of the Institute is to promote and protect the human rights of persons living in the territory of Chile, established in constitutional and legal norms; in the international treaties signed and ratified by Chile and in force, as well as those emanating from the general principles of law, recognized by the international community.”

El Instituto tiene por objeto la promoción y protección de los derechos humanos de las personas que habiten en el territorio de Chile, establecidos en las normas constitucionales y legales; en los tratados internacionales suscritos y ratificados por Chile y que se encuentran vigentes, así como los emanados de los principios generales del derecho, reconocidos por la comunidad internacional. (…)

Art 3: “The Institute shall:

1. Prepare an Annual Report, which shall be submitted to the President of the Republic, the National Congress and the President of the Supreme Court on its activities, on the national situation in the field of human rights and to make recommendations as it deems appropriate for its protection and respect.

2. Communicate to the Government and to the different organs of the State that it deems appropriate, its opinion regarding the situations related to the human rights that occur in any part of the country. (…)}
3. Propose to the organs of the State the measures that it considers should be adopted in order to favor the protection and promotion of human rights.

4. Promote that national legislation, regulations and practices are harmonized with the international human rights treaties ratified by Chile and that they are in force, so that their application is effective.

5. Deduct legal actions before the courts of justice, within the scope of its competence.

In the exercise of this attribution, in addition to claiming a complaint regarding acts that are crimes of genocide, crimes against humanity or war, torture, enforced disappearance of persons, smuggling of migrants or persons trafficking, it may deduct the remedies of protection and amparo respectively enshrined in Articles 20 and 21 of the Constitution, within the scope of its competence. (…)

9.- To disseminate the knowledge of human rights, to promote its teaching at all levels of the educational system, including the training given to the Armed Forces, of Public Order and Security, and to promote research, studies and publications , to award prizes, to sponsor acts and events related to these matters, and to do everything that tends to consolidate a culture of respect for human rights in the country, being able to conclude agreements with public or private organizations, both national and foreign (…) "

“Le corresponderá especialmente al Instituto:

1.- Elaborar un Informe Anual, que deberá presentar al Presidente de la República, al Congreso Nacional y al Presidente de la Corte Suprema sobre sus actividades, sobre la situación nacional en materia de derechos humanos y hacer las recomendaciones que estime convenientes para su debido resguardo y respeto.(…)

2.- Comunicar al Gobierno y a los distintos órganos del Estado que estime convenientes, su opinión respecto de las situaciones relativas a los derechos humanos que ocurran en cualquier parte del país. (…)

3.- Proponer a los órganos del Estado las medidas que estime deban adoptarse para favorecer la protección y la promoción de los derechos humanos.

4.- Promover que la legislación, los reglamentos y las prácticas nacionales se armonicen con los tratados internacionales de derechos humanos ratificados por Chile y que se encuentren vigentes, a fin que su aplicación sea efectiva.

5.- Deducir acciones legales ante los tribunales de justicia, en el ámbito de su competencia.
En ejercicio de esta atribución, además de deducir querella respecto de hechos que revistan carácter de crímenes de genocidio, de lesa humanidad o de guerra, tortura, desaparición forzada de personas, tráfico ilícito de migrantes o trata de personas, podrá deducir los recursos de protección y amparo consagrados respectivamente en los artículos 20 y 21 de la Constitución, en el ámbito de su competencia.(…)

9.- Difundir el conocimiento de los derechos humanos, favorecer su enseñanza en todos los niveles del sistema educacional, incluyendo la formación impartida al interior de las Fuerzas Armadas, de Orden y de Seguridad Públicas, y promover la realización de investigaciones, estudios y publicaciones, otorgar premios, patrocinar actos y eventos relativos a estas materias, y realizar todo aquello que propenda a consolidar una cultura de respeto a los derechos humanos en el país, pudiendo al efecto celebrar convenios con organismos públicos o privados tanto nacionales como extranjeros.(…)”

Art 6: “The Higher Direction of the Institute will correspond to a Council, integrated as follows:

a) Two advisers appointed by the President of the Republic, who must be from different regions of the country.

b) Two advisers appointed by the Senate.

c) Two advisers appointed by the Chamber of Deputies.

d) A director appointed by the deans of the Faculties of Law of the universities that are members of the Council of Rectors and of autonomous universities, in the form determined by the statute.

e) Four directors appointed in the form established by the statutes, by the institutions related to the defense and promotion of human rights that have legal personality in force, registered in the respective register that will be carried out by the Institute.”

“La Dirección Superior del Instituto corresponderá a un Consejo, integrado de la siguiente manera:

a) Dos consejeros designados por el Presidente de la República, quienes deberán ser de distintas regiones del país.

b) Dos consejeros designados por el Senado.

c) Dos consejeros designados por la Cámara de Diputados.
d) Un consejero designado por los decanos de las Facultades de Derecho de las universidades integrantes del Consejo de Rectores y de universidades autónomas, en la forma determinada por el estatuto.

e) Cuatro consejeros designados en la forma que establezcan los estatutos, por las instituciones vinculadas a la defensa y promoción de los derechos humanos que gocen de personalidad jurídica vigente, inscritas en el registro respectivo que llevará el Instituto.”

Art 11: “A National Consultative Council, in which social and academic bodies dedicated to the promotion and defense of human rights and fundamental freedoms will be represented, will advise the Council on all matters within its competence that require, for their proper resolution, of the pronouncement of civil society.”

“Un Consejo Consultivo Nacional, en el que estarán representados los organismos sociales y académicos dedicados a la promoción y defensa de los derechos humanos y las libertades fundamentales, prestará su asesoría al Consejo en todas aquellas cuestiones de su competencia que requieran, para su adecuada resolución, del pronunciamiento de la sociedad civil.”

Law No.20.584 (2012)

Art 30: “Without prejudice to the mechanisms and instances of participation created by law, by regulation or by resolution, every person has the right to make the consultations and claims that he deems pertinent, regarding the health care received. Likewise, users may express in writing their suggestions and opinions regarding such care. Through the Ministry of Health, in consultation with the instances of participation created by law, will regulate the procedures for users to exercise these rights, and the term and manner in which providers must respond or resolve, depending on the case.”

“Sin perjuicio de los mecanismos e instancias de participación creados por ley, por reglamento o por resolución, toda persona tiene derecho a efectuar las consultas y los reclamos que estime pertinentes, respecto de la atención de salud recibida. Asimismo, los usuarios podrán manifestar por escrito sus sugerencias y opiniones respecto de dicha atención. Por medio del Ministerio de Salud, con consulta a las instancias de participación creadas por ley, se reglamentarán los procedimientos para que los usuarios ejerzan estos derechos, y el plazo y la forma en que los prestadores deberán responder o resolver, según el caso.

Art 37: “Without prejudice to the right of individuals to claim before the different bodies or entities that determine the current regulation, any person may claim compliance with the rights that this law confers on the institutional provider, which must have personnel specially qualified for this effect and with a system of registration and written response of the claims raised. The provider must take the appropriate measures to correct the detected irregularities.
If the person considers that the response is not satisfactory or that the irregularities have not been solved, he may appeal to the Superintendency of Health.

A regulation will establish the procedure to be followed the claims, the period in which the provider must communicate a response to the person who made the claim in writing, the record that will be taken to record the claims and other rules that allow an effective exercise of the right referred to in this article.

Likewise, persons shall have the right to request, alternately, the initiation of a mediation procedure, in the terms of Law No. 19.966 and its supplementary rules.”

“Sin perjuicio del derecho de las personas a reclamar ante las diferentes instancias o entidades que determina la normativa vigente, toda persona podrá reclamar el cumplimiento de los derechos que esta ley le confiere ante el prestador institucional, el que deberá contar con personal especialmente habilitado para este efecto y con un sistema de registro y respuesta escrita de los reclamos planteados. El prestador deberá adoptar las medidas que procedan para la acertada solución de las irregularidades detectadas.

Si la persona estimare que la respuesta no es satisfactoria o que no se han solucionado las irregularidades, podrá recurrir ante la Superintendencia de Salud.

Un reglamento regulará el procedimiento a que se sujetarán los reclamos, el plazo en que el prestador deberá comunicar una respuesta a la persona que haya efectuado el reclamo por escrito, el registro que se llevará para dejar constancia de los reclamos y las demás normas que permitan un efectivo ejercicio del derecho a que se refiere este artículo.

Asimismo, las personas tendrán derecho a requerir, alternativamente, la iniciación de un procedimiento de mediación, en los términos de la ley N°19.966 y sus normas complementarias.”

✓ Law No. 19966 (2004)

Art 2: “The Explicit Health Guarantees shall constitute rights for the beneficiaries and their compliance may be demanded by them before the National Health Fund or the Private Institutions of Social Security, the Superintendence of Health and other appropriate instances.”

“Las Garantías Explicitas en Salud serán constitutivas de derechos para los beneficiarios y su cumplimiento podrá ser exigido por éstos ante el Fondo Nacional de Salud o las Instituciones de Salud Previsional, la Superintendencia de Salud y las demás instancias que correspondan.”
Art 24: “The National Health Fund and the Private Institutions of Social Security must give mandatory compliance to the Explicit Health Guarantees that contemplate the Regime that regulates this law with its respective beneficiaries.(…)  
In case of non-compliance, the affected person or person representing him / her may claim before the Superintendence of Health, which may sanction the providers with reprimand or, in case of repeated failure, with suspension of up to one hundred and eighty days to grant the Explicit Health Guarantees, either through the National Health Fund or a Private Institution of Social Security, as well as to grant benefits in the Free Choice Mode of the National Health Fund.”

“El Fondo Nacional de Salud y las Instituciones de Salud Previsional deberán dar cumplimiento obligatorio a las Garantías Explicitas en Salud que contemple el Régimen que regula esta ley para con sus respectivos beneficiarios.(…)  
En caso de incumplimiento, el afectado o quien lo represente podrá reclamar ante la Superintendencia de Salud, la que podrá sancionar a los prestadores con amonestación o, en caso de falta reiterada, con suspensión de hasta ciento ochenta días para otorgar las Garantías Explicitas en Salud, sea a través del Fondo Nacional de Salud o de una Institución de Salud Previsional, así como para otorgar prestaciones en la Modalidad de Libre Elección del Fondo Nacional de Salud.”

✔ Law No.20850 (2015):

Art 1: “The granting of benefits and financial protection of the System that regulates this law will constitute rights for the beneficiaries and their fulfillment may be demanded by them before the National Health Fund and the Superintendency of Health through the Intendance of Funds and Insurance Health Provision, according to the scope of competences that each institution.”

“El otorgamiento de las prestaciones y la protección financiera del Sistema que regula esta ley serán constitutivos de derechos para los beneficiarios y su cumplimiento podrá ser exigido por éstos ante el Fondo Nacional de Salud y la Superintendencia de Salud a través de la Intendencia de Fondos y Seguros Previsionales de Salud, conforme al ámbito de competencias que a cada institución le corresponda.”
For health insurance/universal health coverage schemes: Are vulnerable groups addressed in the law/policy? i.e. children (girls), women, people living in poverty, rural communities, indigenous populations, national (ethnic, religious, linguistic) minorities, internally displaced persons, elderly, disabled, prisoners.

<table>
<thead>
<tr>
<th>Women and Children:</th>
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<tbody>
<tr>
<td>✓ Ministerial Decree 1 with force of law (2006):</td>
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<tr>
<td>Art 139: “Every pregnant woman shall have the right to state protection during pregnancy and up to the sixth month of the birth of the child, which shall include pregnancy and puerperium control. The newborn child up to six years of age shall also have the right to the protection and control of the State’s health. The care of childbirth shall be included in the medical care referred to in Article 138 (b).”</td>
</tr>
<tr>
<td>“Toda mujer embarazada tendrá derecho a protección del Estado durante el embarazo y hasta el sexto mes del nacimiento del hijo, la que comprenderá el control del embarazo y puerperio. El niño recién nacido y hasta los seis años de edad tendrá también derecho a la protección y control de salud del Estado. La atención del parto estará incluida en la asistencia médica a que se refiere la letra b) del artículo 138.”</td>
</tr>
<tr>
<td>✓ Law No.20379 (2009) on the creation of the intersectorial system of social protection and the institutionalization of the subsystem of integral protection to children “Chile Crece Contigo”:</td>
</tr>
<tr>
<td>Art 9: “The Integrated Protection of Children sub-system, called “Chile Crece Contigo”, is created, whose objective is to accompany the development process of children who are treated in the public health system, from their first gestation control to their entry into the school system, at the first level of transition or its equivalent.”</td>
</tr>
<tr>
<td>“Créase el subsistema de Protección Integral de la Infancia, denominado &quot;Chile Crece Contigo&quot;, cuyo objetivo es acompañar el proceso de desarrollo de los niños y niñas que se atiendan en el sistema público de salud, desde su primer control de gestación y hasta su ingreso al sistema escolar, en el primer nivel de transición o su equivalente.”</td>
</tr>
</tbody>
</table>
| Art 12: “Chile Crece Contigo” will guarantee the following benefits for children who are in vulnerable situations:
a) Access to technical aids for children with disabilities.

b) Free access to crib room or equivalent facilities.

c) Free access to kindergartens of extended day or equivalent modalities.

d) Free access to part-time kindergarten or equivalent modalities for children whose father, mother or guardians do not work outside the home.

e) Guaranteed access to "Chile Solidario" to the families of children in gestation that are part of the families referred to in Article 1 of Law No. 19,949."

“Chile Crece Contigo” garantizará las siguientes prestaciones para los niños y niñas que presentan situaciones de vulnerabilidad:

a) Acceso a ayudas técnicas para niños y niñas que presenten alguna discapacidad.

b) Acceso gratuito a sala cuna o modalidades equivalentes.

c) Acceso gratuito a jardín infantil de jornada extendida o modalidades equivalentes.

d) Acceso gratuito a jardín infantil de jornada parcial o modalidades equivalentes para los niños y niñas cuyos padre, madre o guardadores no trabajan fuera del hogar.

e) Acceso garantizado al "Chile Solidario" a las familias de niños y niñas en gestación que formen parte de las familias a que se refiere el artículo 1º de la ley N° 19.949.”

Art 13: “The subsystem "Chile Crece Contigo", in accordance with the regulations, will consider the multiple dimensions that influence child development, granting, under the same conditions, preferential access to the families benefiting from the provision of public services, according to the needs of support to the development of their children, in programs such as leveling of studies; dependent or independent employment insertion; improvement of housing and living conditions; mental health care; family dynamics; judicial assistance; prevention and care of domestic violence and child abuse.

The preferential access will be directed to beneficiary families belonging to the 40% most vulnerable socioeconomically households of the population, as
determined by the instrument indicated in article 5, and that meet the requirements to access the indicated public services offer In the previous section.”

“El subsistema "Chile Crece Contigo", de conformidad con lo que disponga el reglamento, considerará las múltiples dimensiones que influyen en el desarrollo infantil, otorgando, a iguales condiciones, acceso preferente a las familias beneficiarias de la oferta de servicios públicos, de acuerdo a las necesidades de apoyo al desarrollo de sus hijos, en programas tales como nivelación de estudios; inserción laboral dependiente o independiente; mejoramiento de las viviendas y de las condiciones de habitabilidad; atención de salud mental; dinámica familiar; asistencia judicial; prevención y atención de la violencia intrafamiliar y maltrato infantil.

El acceso preferente estará dirigido a aquellas familias beneficiarias que pertenezcan a hogares que integren el 40% más vulnerable socioeconómicamente de la población, según lo determine el instrumento señalado en el artículo 5º, y que reúnan los requisitos para acceder a la oferta de servicios públicos señalada en el inciso anterior”

**People without resources & Indigent People:**

- Ministerial Decree 1 with force of law (2005):
  
  Art 147: “People without resources or indigent people shall be entitled to receive all the benefits provided in this paragraph free of charge.”

  “Las personas carentes de recursos o indigentes, tendrán derecho a recibir gratuitamente todas las prestaciones que contempla este párrafo.”

**Migrant Population:**


  “Taking into consideration:

  The increase of migrants in the country, who don’t yet possess immigration documents.

  The defenselessness in which these people are when they present a disease or health situation that requires professional assistance.

  The legal obligation of the organism of the Public Health System to grant health care to the inhabitants.

  The need to respond to the health care needs of migrants without official permission to reside in the country,
Decree:
Modify Decree No. 110 of 2004, of the Ministry of Health, which establishes circumstances and mechanisms to accredit people as lacking resources or indigent, as follows:

Add in Article 2 the following circumstance No. 4, following the circumstance No. 3:

"Circumstance No. 4: An immigrant who lacks documents or residence permits, who signs a document stating his lack of resources."

“Considerando:

El aumento de personas migrantes en el país, que aún no poseen documentos de inmigración.

La indefensión en que se encuentran estas personas cuando presentan una enfermedad o situación de salud que requiere de asistencia profesional.

La obligación legal de los organismos del Sistema Público de Salud de otorgar atención de salud a los habitantes.

La necesidad de dar respuesta a las necesidades de prestaciones de salud que presentan las personas migrantes sin permiso oficial de residencia en el país.

Decreto:

Modificase el decreto Nº 110 de 2004, del Ministerio de Salud, que fija circunstancias y mecanismos para acuditar a las personas como carentes de recursos o indigentes, en la forma que a continuación se indica:

Agrégase en el artículo 2° la siguiente circunstancia Nº 4, a continuación de la circunstancia Nº 3:

"Circunstancia Nº 4: Tratarse de una persona inmigrante que carece de documentos o permisos de residencia, que suscribe un documento declarando su carencia de recursos."

\textbf{Mentally or Physically-disabled people and Prisoners:}
Law No.20584 (2012):

Art 2: “The attention given to persons with physical or mental disabilities and those who are deprived of their liberty shall be governed by the rules issued by the Ministry of Health to ensure that it is timely and of equal quality.”

“La atención que se proporcione a las personas con discapacidad física o mental y a aquellas que se encuentren privadas de libertad, deberá regirse por las normas que dicte el Ministerio de Salud, para asegurar que aquella sea oportuna y de igual calidad.”

Art 5: “People have the right to a dignified and respectful treatment in their healthcare, at all times and in all circumstances.

Accordingly, providers must:

a) Ensure that adequate and intelligible language is used during care; Take care that people who suffer from a disability, do not have a command of the Spanish language or only have partial knowledge, can receive the necessary and understandable information, through an official of the establishment, if there is, or with the support of a third party who is designated by the person served.”

“En su atención de salud, las personas tienen derecho a recibir un trato digno y respetuoso en todo momento y en cualquier circunstancia.

En consecuencia, los prestadores deberán:

a) Velar porque se utilice un lenguaje adecuado e inteligible durante la atención; cuidar que las personas que adolezcan de alguna discapacidad, no tengan dominio del idioma castellano o sólo lo tengan de forma parcial, puedan recibir la información necesaria y comprensible, por intermedio de un funcionario del establecimiento, si existiere, o con apoyo de un tercero que sea designado por la persona atendida”

Art 29: “Without prejudice to the powers of ordinary courts of justice, the Ministry of Health shall ensure the existence and functioning of a National Commission for the Protection of the Rights of Persons with Mental Illnesses and Regional Protection Commissions, one in each region of the country, whose main function will be to ensure the protection of rights and advocacy of persons with mental or intellectual disabilities in the health care delivered by public or private providers, or in the modalities of community, ambulatory, hospital or emergency care.”

“Sin perjuicio de las facultades de los tribunales ordinarios de justicia, el Ministerio de Salud deberá asegurar la existencia y funcionamiento de una Comisión Nacional de Protección de los Derechos de las Personas con Enfermedades Mentales y de Comisiones Regionales de Protección, una en cada
region del país, cuya función principal será velar por la protección de derechos y defensoría de las personas con discapacidad psíquica o intelectual en la atención de salud entregada por los prestadores públicos o privados, sea en las modalidades de atención comunitaria, ambulatoria, hospitalaria o de urgencia.”

**Indigenous People:**

- Law No.19937 (2004):

Art 4: “The Ministry of Health will be responsible for formulating, setting and monitoring health policies. Consequently, it will have, among others, the following functions: (...)

16.- Formulate policies that allow incorporating an intercultural health approach in health programs in those communes with high indigenous concentration.”

“Al Ministerio de Salud le corresponderá formular, fijar y controlar las políticas de salud. En consecuencia tendrá, entre otras, las siguientes funciones: (...) 16.-Formular políticas que permitan incorporar un enfoque de salud intercultural en los programas de salud en aquellas comunas con alta concentración indígena.”

- Law 20584 (2012):

Art 7: “In those territories with a high concentration of indigenous population, public institutional providers must ensure the right of indigenous people to receive health care with cultural relevance, which will be expressed in the application of an intercultural health model validated before the indigenous communities, which must contain, at least, the recognition, protection and strengthening of the knowledge and practices of the healing systems of indigenous peoples; the existence of intercultural facilitators and signaling in the Spanish language and in the original language of the people that corresponds to the territory, and the right to receive religious assistance specific to their culture.”

“En aquellos territorios con alta concentración de población indígena, los prestadores institucionales públicos deberán asegurar el derecho de las personas pertenecientes a los pueblos originarios a recibir una atención de salud con pertinencia cultural, lo cual se expresará en la aplicación de un modelo de salud intercultural validado ante las comunidades indígenas, el cual deberá contener, a lo menos, el reconocimiento, protección y fortalecimiento de los
conocimientos y las prácticas de los sistemas de sanación de los pueblos originarios; la existencia de facilitadores interculturales y señalización en idioma español y del pueblo originario que corresponda al territorio, y el derecho a recibir asistencia religiosa propia de su cultura.”

**Elderly Population:**


Art 1: “The provisions of this law are intended to establish the creation of the National Service for the Elderly, which will ensure the full integration of the elderly in society, their protection from abandonment and indigence, and the exercise of the rights that the Constitution of The Republic and the laws recognize them.

For all legal purposes, a person is considered to be elder from the 60 years of age.”

“Las disposiciones de la presente ley tienen por objeto establecer la creación del Servicio Nacional del Adulto Mayor, que velará por la plena integración del adulto mayor a la sociedad, su protección ante el abandono e indigencia, y el ejercicio de los derechos que la Constitución de la República y las leyes le reconocen.

Para todos los efectos legales, llámase adulto mayor a toda persona que ha cumplido sesenta años.”

Art 3: “The Service will be responsible for proposing policies aimed at achieving the effective family and social integration of the elderly and solving the problems that affect them.

In particular, it will have the following functions:

a) To study and propose to the President of the Republic the policies, plans and programs that must be made to diagnose and contribute to the solution of the problems of the elderly, to watch over their compliance and to evaluate their execution.

b) Propose, promote, coordinate, monitor and evaluate specific programs for the elderly that are carried out through the State Administration. (…)

d) Foster the integration of the elderly in the family and the community and promote the social integration of older adults so that they remain active for their
own benefit and that of the community. (…)

h) Carry out, by itself or through third parties, training and dissemination programs aimed at achieving the integral development of the elderly in their different areas and levels.

i) Carry out, by itself or through third parties, studies that aim to maintain a permanent diagnosis about the diversity of situations that characterize the older adult.”

“El Servicio se encargará de proponer las políticas destinadas a lograr la integración familiar y social efectiva del adulto mayor y la solución de los problemas que lo afectan.

En especial, le corresponderán las siguientes funciones:

a) Estudiar y proponer al Presidente de la República las políticas, planes y programas que deban efectuarse para diagnosticar y contribuir a la solución de los problemas del adulto mayor, velar por su cumplimiento y evaluar su ejecución.

b) Proponer, impulsar, coordinar, hacer seguimientos y evaluar programas específicos para el adulto mayor que se realicen a través de la Administración del Estado. (…)

d) Fomentar la integración del adulto mayor en el seno de su familia y de la comunidad y promover la inserción social de los adultos mayores de forma que se mantengan activos en beneficio propio y en el de la comunidad. (…)

h) Realizar, por sí o a través de terceros, programas de capacitación y difusión que tiendan a lograr el desarrollo integral del adulto mayor en sus distintas áreas y niveles.

i) Realizar, por sí o a través de terceros, estudios que tengan por objeto mantener un permanente diagnóstico sobre la diversidad de situaciones que caractericen al adulto mayor.”

Art 7: “A fund for the financing of direct support initiatives for the elderly is created, which will be provided with donations and legacies in money accepted by the Service and with the resources annually assigned by the Budget Law. This fund will be administered by the National Service of the Elderly.”
“Créase un fondo concursable de financiamiento de iniciativas de apoyo directo al adulto mayor, el que será provisto con las donaciones y legados en dinero que para él acepte el Servicio y con los recursos que anualmente le asigne la Ley de Presupuestos. Este fondo será administrado por el Servicio Nacional del Adulto Mayor.”

 Law N°20255 (2008) which establishes the pension reform.

Art 1: “A solidarity pension system of elderly and disabled people shall be created, hereinafter referred to as the "solidarity system", supplementary to the pension system referred to in Decree Law No. 3,500 of 1980, in the form and conditions set forth in this Title, which will be financed with state resources. This solidarity system will grant basic solidarity pension benefits to elderly and disabled people and solidarity pension contributions to elderly and disabled people.”

“Créase un sistema de pensiones solidarias de vejez e invalidez, en adelante, "sistema solidario", complementario del sistema de pensiones a que se refiere el decreto ley N° 3.500, de 1980, en la forma y condiciones que el presente Título establece, el que será financiado con recursos del Estado. Este sistema solidario otorgará beneficios de pensiones básicas solidarias de vejez e invalidez y aportes previsionales solidarios de vejez e invalidez.”

Art 3: “People who are not entitled to a pension under any social security scheme and who meet the following requirements will be the beneficiaries of the basic elderly solidarity pension:

a) To be sixty-five years of age.

b) Integrate a family group belonging to the poorest 60% of the population of Chile in accordance with what is established in article 32 of this law.

c) To accredit residence in the territory of the Republic of Chile for a period of not less than twenty continuous or discontinuous years, counted from the moment the petitioner has reached twenty years of age; and in any case for a period of not less than four years of residence in the last five years immediately preceding the filing date of the application to benefit from this Title.”

“Serán beneficiarias de la pensión básica solidaria de vejez, las personas que no tengan derecho a pensión en algún régimen previsional y que reúnan los requisitos siguientes:

a) Haber cumplido sesenta y cinco años de edad.
b) Integrar un grupo familiar perteneciente al 60% más pobre de la población de Chile conforme a lo establecido en el artículo 32 de esta ley.

c) Acreditar residencia en el territorio de la República de Chile por un lapso no inferior a veinte años continuos o discontinuos, contados desde que el peticionario haya cumplido veinte años de edad; y, en todo caso, por un lapso no inferior a cuatro años de residencia en los últimos cinco años inmediatamente anteriores a la fecha de presentación de la solicitud para acogerse a los beneficios de este Título.”

Art 9: “Will be beneficiaries of the solidarity pension contribution system persons who are entitled to one or more pensions governed by Decree Law No. 3,500 of 1980, provided that they comply with the requirements established in letters a), b) and c) of article 3 of this law and that the amount of their basic pension is lower than the value of the maximum pension with solidarity contribution.”

“Serán beneficiarias del aporte previsional solidario de vejez, las personas que sólo tengan derecho a una o más pensiones regidas por el decreto ley N° 3.500, de 1980, siempre que cumplan los requisitos establecidos en las letras a), b) y c) del artículo 3° de la presente ley y que el monto de su pensión base sea inferior al valor de la pensión máxima con aporte solidario.”

**People with Disabilities:**


Art 16: “Persons who are declared disabled in accordance with the provisions of the following article will benefit from the basic solidarity disability pension, provided that they are not entitled to a pension under any social security scheme and comply with the following requirements:

a) Be between eighteen years of age and less than sixty-five years.

b) To be in the situation indicated in letter b) of article 3 of this law.

c) To accredit residence in the territory of the Republic of Chile for a period of not less than five years in the last six years immediately preceding the date of submission of the application for access to the basic joint and several disability pension.

In any case, foreigners will not be able to access the pension established in the present Paragraph, nor to the contribution referred to in the following Paragraph, when the cause of the main impairment resulting from the disability arises from an accident occurring outside the territory of the Republic of Chile. The foregoing, provided that the foreigner does not have the status of resident in Chile, in accordance with the provisions of Decree Law No. 1,094,
of 1975, upon verification of said event.”

“Serán beneficiarias de la pensión básica solidaria de invalidez, las personas que sean declaradas inválidas conforme a lo dispuesto en el artículo siguiente, siempre que no tengan derecho a pensión en algún régimen previsional y cumplan con los requisitos siguientes:

a) Tener entre dieciocho años de edad y menos de sesenta y cinco años.

b) Encontrarse en la situación señalada en la letra b) del artículo 3° de esta ley.

c) Acreditar residencia en el territorio de la República de Chile por un lapso no inferior a cinco años en los últimos seis años inmediatamente anteriores a la fecha de presentación de la solicitud para acceder a la pensión básica solidaria de invalidez.

En todo caso, los extranjeros no podrán acceder a la pensión establecida en el presente Párrafo, ni al aporte a que se refiere el Párrafo siguiente, cuando la causa del principal menoscabo que origine la invalidez provenga de un accidente acaecido fuera del territorio de la República de Chile. Lo anterior, siempre que el extranjero no tenga la calidad de residente en Chile, de conformidad a lo dispuesto en el decreto ley N° 1.094, de 1975, al verificarse dicho evento.”