HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

Authors:
Andrea Abascal Marín and Andrés Sepúlveda Matteo, Bofill Mir Abogados
aabascal@bofillmir.cl

LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

1. Please provide a bird's eye view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

The Chilean healthcare system is a mixed system, in which the public and private sectors coexist, both playing a fundamental role in its functioning. The main state entity responsible for healthcare in Chile is the Ministry of Health (Ministerio de Salud de Chile or MINSAL), which is tasked with the country's healthcare planning and structuring the national budget in this area. It operates through two subsecretariats:

- the Subsecretariat of Public Health, whose primary function is to lead health strategies for the population; and
- the Subsecretariat of Healthcare Networks, which is primarily responsible for designing, proposing, and evaluating mechanisms for the technical and administrative coordination and integration of the Healthcare Network (ie, public hospitals).

Through Law 19,378, the Municipal Health Statute was established, creating a system where certain healthcare services are managed by local municipalities rather than the central government.

The private healthcare system, on the other hand, is organised through clinics, medical offices, vaccination centres and other private entities, which provide healthcare services paid for by users or partially or fully financed through private health insurance providers (Instituciones de Salud Previsional or ISAPREs) or other insurers.

2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.

In Chile, as previously mentioned, the healthcare system operates as a mixed system, consisting primarily of a public insurance system, the National Health Fund (Fondo Nacional de Salud or FONASA), and a private insurance system, composed of ISAPREs.

Public system: FONASA

FONASA operates on a redistribution model, where beneficiaries contribute seven per cent of their taxable income to a solidarity fund. This fund provides access to a single health plan, regardless of the contributions or health conditions of contributors. Beneficiaries are categorised into four groups (A, B, C and D) based on income levels, which determine the

coverage of health services they can access.

FONASA offers two modes of care:

- institutional mode: all medical services are provided through organisations within the National Health Services System (Sistema Nacional de Servicios de Salud or SNSS), ensuring access for all FONASA beneficiaries; and
- free-choice mode: available to beneficiaries in groups B, C and D. This mode provides services through private facilities and professionals contracted by FONASA, as well as public hospitals, where beneficiaries can select their treating physician.

FONASA covers health promotion, prevention, treatment, rehabilitation, palliative care for terminal illnesses and other medical services. Financial coverage includes consultations, examinations, diagnostic and surgical procedures, hospitalisations, obstetric care, treatments, medical supplies and other necessary services.

Private system: ISAPREs

ISAPREs are private entities operating under an insurance model that are authorised to receive and manage the mandatory seven per cent health contribution of workers' taxable income (or higher amounts, if agreed). Enrolment in the ISAPRE system is formalised through a healthcare contract that defines the beneficiary's rights, obligations and available services.

3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?

Local regulations establish a supervisory system for healthcare financing, led by the Superintendence of Health. This entity is responsible for regulating and overseeing both public and private healthcare providers and insurers. Its primary objective is to protect individuals' rights and promote the quality and safety of healthcare services.

The Superintendence of Health monitors both ISAPREs and FONASA, and holds sanctioning authority for non-compliance by healthcare providers in various areas, including financing and reimbursement. This oversight ensures adherence to established standards and safeguards the proper functioning of the healthcare system.

4. Has there been a change to healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?

The Covid-19 pandemic did not substantially modify the financing and reimbursement system of our healthcare system. In general, state efforts focused on securing the supply of vaccines, which, in the case of Chile, was successful. The country had access to vaccines from various providers, ensuring broad national coverage in this regard.

5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?

Access to the healthcare system in Chile is universal. As previously mentioned, for patients, there is a public and private healthcare system, administered through FONASA and ISAPREs, respectively. Any person, even without a source of income, can enrol in

FONASA, which is responsible for providing healthcare coverage. Enrolment in FONASA allows access to public healthcare services either free of charge or at very low cost, though with limited choice for the user. By contrast, ISAPREs offers health plans tied to the mandatory seven per cent salary contribution made by workers. These plans are not universally accessible but limited to contributors whose seven per cent health contribution can cover the plans offered.

Additionally, ISAPREs may deny services to users based on pre-existing conditions, whereas FONASA is legally mandated to accept any user, regardless of the individual's medical history.

In Chile, the provision of medical or clinical services requires compliance with current health regulations. This entails, among other requirements, the formation of a legal entity, obtaining a commercial license, and, most importantly, securing health operation authorisation granted by the corresponding Regional Health Authority (Secretaría Regional Ministerial de Salud or SEREMI). This authorisation follows the guidelines set by the Undersecretary of Public Health (Subsecretaría de Salud Pública).

It is important to note that specific regulations apply to different types of services, with distinct regulatory frameworks governing clinical laboratories, procedure rooms, chemotherapy administration facilities and other medical services. These regulations set forth legal requirements that must be met before authorisation to operate is granted.

Pharmaceutical products must be registered with the Instituto de Salud Pública (ISP); otherwise, they cannot be supplied to patients. Only in exceptional cases, when required for public health reasons, may the authorities authorise the importation of unregistered medications.

Most medical devices do not require prior registration and can be imported, as long as they comply with Chile's import regulations. Additionally, they must be stored in an authorised facility upon arrival. However, certain medical devices, such as condoms, syringes and surgical gloves, require prior registration before they can be imported and marketed in Chile.

Finally, to supply pharmaceuticals and medical devices to the government and the public healthcare network, providers must be registered in the Registro de Proveedores del Estado. This registration process ensures that suppliers comply with healthcare and labour regulations, and identifies their ultimate beneficiaries within their corporate structure. The system also aims to promote the participation of small businesses as government suppliers.

HEALTH INSURANCE FINANCING AND COVERAGE

6. How are health insurance carriers financed? How are premiums determined?

In Chile, health insurance is a mandatory institution that applies to all workers.

In other words, every worker is entitled to health insurance, which the employer is required to provide.

The above has materialised in the existence of mandatory social insurance against occupational accidents and diseases, established under Law 16.744. This insurance is funded through employer contributions, amounting to 0.9 per cent of the employee's salary, which may increase if the employee's work is deemed particularly hazardous. This insurance is therefore entirely financed by the employer and is legally mandatory to cover illnesses or

accidents arising from work-related activities.

On the other hand, there is a broad range of health insurance services in Chile, provided by private insurers. These health insurance plans can be contracted individually or collectively, are voluntary in nature, have a defined validity period and reimburse expenses covered under the contracted policy. As previously mentioned, FONASA and ISAPREs provide coverage for their affiliates; therefore, these private health insurance plans operate in areas not covered by FONASA or ISAPREs.

Premiums for private health insurance are determined based on an internal calculation by insurance companies, which includes the applicant's age, coverage risks, the scope of insurance and number of illnesses or accidents covered. Generally, the higher the risk or coverage, the higher the insurance premium.

It is important to mention that private insurance companies in Chile are supervised by the Financial Market Commission (Comisión para el Mercado Financiero).

7. How is the coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in-person medical appointments and telemedicine appointments?

Medical service coverage in Chile is provided by FONASA in the public system and by the respective ISAPRE in the private system. In both cases, the entity responsible for regulating this coverage is the Superintendence of Health, a governmental body tasked with ensuring that healthcare providers comply with the applicable regulations.

Regarding the coverage itself, FONASA operates as a public and universal system accessible to anyone, offering a general health coverage plan. Under this system, all pathologies are covered; however, access times depend on the availability of healthcare professionals and other factors. Additionally, the beneficiary's ability to choose the hospital for treatment is limited, particularly concerning private clinics.

Conversely, ISAPREs, being private entities, offer health plans where the affiliate selects the specific percentage of coverage and enjoys greater flexibility in choosing healthcare providers. This includes the ability to receive treatment at preferred private clinics, subject to monetary coverage limits specified in the contracted plan.

There is no significant difference in coverage for in-person medical appointments and telemedicine appointments in Chile. Notwithstanding the above, it is important to mention that private ISAPRE plans may include preferential clauses for telemedicine services at their discretion, and, in fact, many of them offer free telemedicine consultations for their affiliates. However, there is no specific regulation that prioritises telemedicine over in-person care or vice versa.

It is important to note that both private and public coverage often do not include the provision of orphan or high-cost drugs, resulting in a gap in coverage, financing and reimbursement for these types of medications. Consequently, they must be privately funded unless covered under a specific legal framework, such as the Ricarte Soto Law or Explicit Health Guarantees Law.

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and

ambulatory (outpatient) settings financed and reimbursed?

The coverage of services provided by hospitals, both in inpatient (stationary) and outpatient (ambulatory) settings, depends on whether the patient is enrolled in FONASA (the public system) or an ISAPRE (the private system).

FONASA beneficiaries receive hospital care within the public healthcare network, which consists of state or municipal health establishments that form part of Chile's public health system. In this regard, FONASA covers:

- financial coverage for all medical care and interventions;
- access to care within the public or private network;
- Acceso Universal con Garantías Explícitas (AUGE)/Explicit Health Guarantees (Régimen de Garantías en Salud or GES) Program;
- Emergency Law;
- Ricarte Soto Law; and
- special programmes: Bono PAD and others currently under congressional review, such as the 'Seguro Clase Media' for catastrophic illnesses.

In FONASA, affiliates belonging to all the groups benefit from the 'Copago Cero' programme. This programme grants them full exemption from out-of-pocket payments, ensuring entirely free access to public healthcare services.

On the other hand, in the case of ISAPREs, hospital coverage, both inpatient and outpatient, depends on the health contract signed between the ISAPRE and the contributor. This contract determines which services are covered.

In general, ISAPREs offer both hospital and outpatient services, either under a free-choice modality or with preferential provider networks, where coverage varies depending on the selected clinics. In this system, the higher the contributor's payment, the greater the coverage and freedom to choose healthcare providers and services.

In the case of ISAPRE coverage, it is common for a portion of the costs not to be covered under the existing contract, requiring the contributor to pay the difference out of pocket. The amount varies depending on the plan's coverage. While the contributor may always choose to receive care at clinics with higher coverage, if the contributor opts for a more prestigious clinic with lower coverage under their plan, the individual must assume the responsibility of privately paying the remaining balance.

9. How are the prices of such services determined? How is economic efficiency controlled?

In the public system, prices are generally standardised for FONASA patients. The Ministry of Health sets applicable tariffs annually for both the Institutional Care and Free Choice Care modalities through an Exempt Resolution. In the same act, the authority determines the services covered, adjusts prices, when necessary, and adds or removes services. This regulation also includes the cost of supplies involved in public health services. Consequently, in the public healthcare system, there is indeed price regulation that public entities must offer to their users.

In the private sector, ISAPREs negotiate prices and coverage with private clinics and

healthcare entities. Therefore, there is no fixed regulation that determines the prices these entities must offer to their affiliates, and the prices depend on the coverage of each health plan. Consequently, it is a system that does not have price regulation. If a user of an ISAPRE (private health insurer) wishes to receive care in the public health system, it is the ISAPRE itself that determines the level of coverage for the user.

In addition to the above, it is important to mention that there are relevant transparency provisions in Chilean regulations, especially through Law No 20,584, which regulates the rights and duties of individuals in relation to actions linked to their healthcare. This law stipulates that every person has the right to receive sufficient, timely, truthful and understandable information from the institutional healthcare provider, whether in visual, verbal or written form. Furthermore, it establishes that the healthcare services or types of healthcare actions offered or available, as well as the mechanisms through which these services can be accessed and their costs, must be disclosed. This applies to both public and private healthcare entities, meaning that, in any case, users have the right to know the costs of each service and healthcare action.

At the public level, efficiency is controlled by the Ministry of Health through annual audits to determine health expenditure and the execution of health services within the public network. Additionally, the annual health budget is discussed in the Chilean Congress, making it important for authorities to maintain control over spending efficiency to determine the critical areas where the budget needs to be increased.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?

As previously explained, regarding services provided by physicians, therapists, laboratories and other healthcare service providers in the private sector, users can access the private healthcare system whether they are affiliated with the ISAPRE or FONASA. The main difference is that, in the private healthcare system, FONASA beneficiaries who are enrolled in the Libre Elección (Free Choice) modality can access private clinics that have agreements with FONASA, but they also have to pay a copayment, which has three levels: the first is the least expensive and the third is the most expensive. For patients enrolled in the Atención Institucional (Institutional Attention) modality, this coverage is lower because this modality prioritises care in the public healthcare system. On the other hand, ISAPRE affiliates access private healthcare services according to the coverage specified in their health contracts, which determine the coverage amounts and what are covered by the ISAPRE itself, as well as the percentage that remains uncovered and must be paid out-of-pocket by the affiliate. Thus, private clinics and healthcare services receive the amounts they charge according to their official fees.

Additionally, for both affiliates of the ISAPRE and FONASA, it has become very common to purchase health insurance for care at specific private clinics and healthcare providers, with the aim of achieving complete coverage in the event of the need for both outpatient and surgical or clinical care. These insurance plans cover amounts not covered by the ISAPRE or FONASA and are even offered by private clinics for treatment in their facilities. These are predominantly private in nature and are regulated by the Financial Market Commission (Comisión para el Mercado Financiero).

11. How are the prices of such services determined? How is economic efficiency controlled?

Prices in the private healthcare sector are typically defined by the entities providing the services, whether clinical, laboratory or outpatient, and there is little to no state intervention in determining these prices.

In general, prices vary depending on the reputation of the clinic and the recognised quality of its medical services, the complexity of the required services and the specialty needed by patients. In any case, these prices are determined by the service provider.

The provisions of Law No 20,584 also apply in the private sector, which regulates the rights and duties of individuals in relation to actions linked to their healthcare. This law stipulates that every person has the right to receive sufficient, timely, truthful and understandable information from the institutional healthcare provider, whether in visual, verbal or written form. Furthermore, it establishes that the healthcare services or types of healthcare actions offered or available, as well as the mechanisms through which these services can be accessed and their costs, must be disclosed.

Economic efficiency in the private sector is analysed by each entity individually, and there is no direct state intervention in this analysis, which is typically carried out internally through audits. Notwithstanding the above, the Health Superintendence oversees these services, ensuring there is no discrimination, that the prices disclosed are respected and that services generally comply with the standards set by the Chilean health system.

PHARMACEUTICALS AND MEDICAL DEVICES

12. How are pharmaceuticals and medical devices financed and reimbursed?

It depends on the specific pharmaceutical product or medical device in question. In Chile, the healthcare system has been structured as a mixed care system, which is composed of FONASA from the public perspective and ISAPREs from the private sector. Individuals must choose one or the other. This mixed system also applies to the financing and reimbursement of pharmaceutical products.

FONASA

Medication financing depends on the care modality and location:

- Institutional mode:
  - full coverage for medical services, supplies and medications provided in primary care facilities; and
  - partial coverage, based on the beneficiary's category, for services and medications in high-complexity facilities like hospitals.
- Free-choice mode:
  - medications are not guaranteed under this modality; and
  - complementary insurance mechanisms, such as the GES, the Ricarte Soto Law and the Pharmacy Fund (Fondo de Farmacias or FOFAR), are available to supplement medication costs.

As a result, pharmaceutical products not covered by FONASA must be financed through

these mechanisms or directly by the beneficiary.

ISAPREs

Medication coverage under ISAPREs depends on the terms of the healthcare contract. Consequently, not all pharmaceutical products are necessarily covered under this system.

It is essential to mention Law No 19.966, which establishes a health guarantee system. This system sets out the benefits for promotional, preventive, curative, rehabilitation and palliative care, as well as the programmes that FONASA must cover for its beneficiaries in the institutional care modality.

Regarding medications, financial protection provides coverage for studies, medications and other services during diagnosis, treatment and follow-up of the relevant health issue. Currently, this financial protection is linked to 85 health problems established by decree.

Thus, in general, access to medications not covered by specific regulations is typically borne by the users themselves, who pay out of pocket for what is not covered.

13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?

In Chile, State purchases are centralised through the Central de Abastecimientos del Sistema Nacional de Servicios de Salud (CENABAST), which allows the government to access better prices due to the large volume of medications being acquired. This process is conducted through public tenders, meaning there is no direct state negotiation power. Instead, competition among suppliers is based on offering the best price, as price is the most relevant factor for awarding the tender.

On the other hand, the determination of prices for consumers is not regulated and is left to the free determination of pharmacies, except for medications covered by special regulations, which are provided at no cost to consumers. Chilean law only regulates the prohibition of laboratories and drug distributors from offering preferential prices to pharmaceutical chains, allowing only volume-based discounts and prohibiting the establishment of differences that may be discriminatory or arbitrary.

The main regulation governing medication prices currently is Law No 21.198, also known as the CENABAST Law. This law allows pharmacies to acquire medications at preferential prices through CENABAST but requires them to sell these medications to the public at maximum prices set by the authorities.

Economic efficiency in the private sector is largely shaped by competition between different entities, given the strong market dynamics and the wide range of private providers. In the public sector, the execution of highly competitive tenders is the best measure to ensure efficiency in the provision of products at favourable prices.

LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT

14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.

The most significant litigation in matters of financing and reimbursement that has been observed is the judicialisation of high-cost treatments. This means that patients affected by

rare diseases, which are not covered by specific regulations, have sued FONASA or their respective ISAPREs for the financing and coverage of such products.

The form of litigation has been through so-called '*recursos de protección*' (constitutional protection remedies), which are precautionary actions aimed at safeguarding fundamental rights. In general, the constitutional guarantees invoked in these cases to request the financing of high-cost drugs not covered by specific laws have been the right to life and physical integrity, equality before the law and the right to health protection.

This litigation process can take up to two years in total. Generally, there is an established precedent that, in cases where the provision of the medication is essential for the patient's survival, the Higher Courts of Justice have ruled in favour of the constitutional protection remedies, thereby ensuring the survival of the affected patients.

RECENT DEVELOPMENTS AND TRENDS

15. What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes or trends for healthcare financing and reimbursement, and briefly indicate how these may foreseeably affect the medical sector in the near future.

A strong trend has been observed in Chile with the so-called 'ISAPRE crisis', which has led to the departure of affiliates from private health entities and their transition to FONASA. This has resulted in a strengthening of private health insurance offered by insurers and clinics, as users who have opted for FONASA have supplemented their coverage with health insurance. This has introduced a new dynamic to the Chilean healthcare sector.

On the other hand, the discussion of Ley de Fármacos II (Pharmaceuticals Law II), which includes provisions for the regulation of pharmaceutical prices and the establishment of medication tariffs, remains stalled in Congress and does not seem to be resuming. A potential new discussion on these matters is pending and could have impacts, particularly regarding medications, prices and access.

Finally, measures for access to treatments and pharmaceutical products have been widely discussed and we believe they will undoubtedly be the subject of future discussions, especially considering the trend towards increased litigation concerning high-cost treatments.