

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

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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 Constitution of the Republic of Ecuador establishes that the purpose of the national healthcare system shall be the development, protection and recovery of capacities and potentialities for a healthy and integral life, recognising social and cultural diversity.

In Ecuador, health economics regulations are aimed at guaranteeing the efficiency of healthcare systems, which translates into achieving the best results with the least possible consumption of resources and in the shortest possible time. This approach seeks to redirect healthcare services so that they can provide quality, safety and satisfaction in patient care.

The regulation considers that healthcare professionals should be able to make appropriate use of resources; be free to choose healthcare options with the patient's wellbeing as a priority; and be able to investigate and evaluate the impact on health of the policies and programmes of the country's health authority.

In this area, the Ministry of Health plays a predominant role as the national health authority, which determines the public policies applicable to the Public Health Network, as well as to the Complementary and Private Network.

Notwithstanding the above, the Ecuadorian Social Security Institute (Instituto Ecuatoriano de Seguridad Social or IESS), the Armed Forces Social Security Institute (Instituto de Seguridad Social de las Fuerzas Armadas or ISSFA) and the Police Social Security Institute (Instituto de Seguridad Social de la Policía Nacional or ISSPOL) are also responsible for implementing these policies.

On the other hand, the private sector includes clinics, private hospitals, doctor's offices and private insurers that provide medical services to those who can pay for them or have supplemental insurance.

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

According to the Constitution of the Republic, health is a right guaranteed by the state, whose realisation is also linked to the exercise of other rights, such as the right to water, food, education, physical culture, work, social security, healthy environments and others that support an adequate standard of living.

The state guarantees this right through economic, social, cultural, educational and environmental policies, and permanent, timely and non-exclusionary access to programmes, actions and services for the promotion and comprehensive care of health, sexual health and reproductive health. The provision of health services is governed by the principles of equity, universality, solidarity, interculturality, quality, efficiency, efficacy, precaution and bioethics, with a gender and generational approach.

All citizens have the right to free and specialised healthcare, as well as free access to medicines, either through the Ministry of Public Health (Ministerio de Salud Pública or MSP) or the Social Security System.

The financing of the public system comes mainly from the state budget, supplemented by mandatory contributions from employers and workers.

The provision and financing of health services are regulated by the following norms: Constitution of the Republic, Organic Health Law, Social Security Law, Organic Monetary and Financial Code Book III.

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

The most relevant entity for the regulation and control of financing and reimbursement of health services is the MSP, as the national health authority.

Notwithstanding the above, the establishment of tariffs applicable in the public sector regarding benefits to the National Health System is carried out with the participation of the following bodies: National Undersecretariat for Health Governance (MSP), National Directorate for the Articulation of the Public and Complementary Health Network (Red Privada Complementaria or RPC), Health Directorate of the Armed Forces, Social Security Institute of the Armed Forces (Instituto de Seguridad Social de Fuerzas Armadas or Issfa), Ministry of the Interior, National Health Directorate of the National Police, ISSPOL, General Directorate of ISSPOL, Ecuadorian Social Security Institute, and Directorate of the General Individual and Family Health Insurance (IESS).

At the private level, the Superintendence of Companies, Securities and Insurance is the entity that controls the private insurance system.

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

According to the Ministry of Health, the Covid-19 pandemic had a significant economic impact on health services in Ecuador. Data from the Ministry of Health released information on additional costs invested by the government of almost \$897m, of which 67 per cent was executed by the MSP and 31 per cent by the IESS, according to the results of the Health Satellite Accounts (CSS) 2022. Of this total investment, \$363m was allocated to the National Vaccination Plan.

Once the crisis stage caused by the pandemic was overcome, a significant impact remained on the Ecuadorian health system:

Increased government spending

Resources allocated to address health emergencies, the construction of temporary hospitals and the purchase of vaccines were increased. Regulatory projects were generated that also regulated the declaration of health emergencies, the allocation of resources in such cases, and the importation of medicines and supplies without sanitary registration.

Acceleration of processes

Rapid financing was implemented for acquiring critical medical supplies through the General State Budget, for which the health sector is one of the priority sectors.

Budgetary changes

Funds were redistributed to prioritise public healthcare.

Strengthening telemedicine

Telemedicine was strengthened to ensure access to care in times of confinement.

During the pandemic, the National Policy on Digital Transformation of the Health Sector was also issued. It was updated in January 2025.

The National Policy will strengthen the governance and coordination of digital health to ensure a regulatory and organisational framework that allows for better decision-making, as well as the correct assignment of responsibilities at the institutional level. In this way, multi-sectoral collaboration will be promoted to integrate policies and regulations that enhance interoperability, data protection and efficiency in the provision of health services.

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?

According to the Constitution of the Republic, the state must guarantee the right to health, in accordance with the principles of equity, universality, solidarity, interculturality, quality, efficiency, efficacy, precaution and bioethics, with a gender and generational approach.

In this sense, all individuals, communities, peoples, nationalities and collectives are considered holders, and therefore enjoy the rights guaranteed in the Constitution and international instruments, particularly the right to health, through the Comprehensive Public Health Network (Red Pública Integral de Salud or RPIS), composed of the following bodies:

- the MSP;
- the IESS; and
- the ISSPOL and ISSFA.

Notwithstanding the foregoing, social security is governed by specific legislation according to which all persons who receive income from the performance of any work or the rendering of a physical or intellectual service are 'obliged to apply for protection' under the Universal Compulsory Insurance of its Members, in their capacity as members, in particular: the employee in a relationship of subordination; the self-employed; the professional in free exercise; the administrator or employer of a business; the owner of a sole proprietorship; and the self-employed minor; among others.

Finally, the companies that finance integral prepaid healthcare services and the insurance companies that offer insurance with private medical assistance coverage are part of the National Health System, to whose public policies they are obligatorily subject. Patients may voluntarily join private insurers and prepaid health services companies; however, this does not limit the possibility of receiving free care in any of the facilities of the public system.

The procurement of goods and services is regulated by the Organic Law of the National Public Procurement System and the health licensing regulations issued by the Health Authority.

For the provision of goods, such as medical supplies and drugs, bidders must be registered in the State Suppliers Registry.

The procurement of drugs and other strategic goods determined by the national health authority and entered into by the authorities that provide health services is carried out under a special regime, particularly a reverse auction, according to which the price of the product is prioritised.

The provision of medical services is also provided through the RPC, which corresponds to a set of health facilities that are contracted when the RPIS health centres are unable to meet patient demand.

In these cases, patients are referred to the RPC and the Ministry of Health covers the costs directly.

Some examples of entities that are part of the PRC are: the Junta de Beneficencia de Guayaquil, Sociedad Protectora de la Infancia de Guayaquil, Sociedad de Lucha Contra el Cáncer, Cruz Roja Ecuatoriana (Ecuadorian Red Cross) and Sociedad de la Infancia de Guayaquil.

The MSP issued the National Health System Benefits Tariff, which is a technical instrument that regulates the economic recognition of the health services provided by the facilities that make up the National Health System.

HEALTH INSURANCE FINANCING AND COVERAGE

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

The IESS is a decentralised public entity of an autonomous nature created by the Constitution of the Republic, endowed with regulatory, technical, administrative, financial and budgetary autonomy, with legal personality and its own assets, whose non-delegable purpose is to provide Universal Compulsory Insurance to its affiliates throughout the national territory.

In accordance with the Law, the benefits of Universal Compulsory Insurance for its members are financed with the following resources:

- mandatory individual contribution of members;
- compulsory employer contributions from private and public employers;
- mandatory financial contribution of the state;
- technical reserves of the intergenerational solidarity retirement plan;
- balances of the individual accounts of members of the mandatory individual savings retirement plan;
- revenue from the payment of dividends on public and private debt with the IESS for employer obligations;
- revenue from the payment of dividends on the national government's debt with the IESS;
- income of any kind produced by property, fixed assets and shares, and participations in companies administered by the IESS;
- income from the sale of the assets of each insurance company managed by the IESS;
- revenue from health services rendered by IESS medical units, which are delivered to the General Health Insurance Budget Fund;
- resources of any kind assigned to each insurance company by virtue of special laws for the fulfilment of its purposes; and,
- inheritance, legacies and donations.

In relation to mandatory contributions, the Law indicates that, for the purpose of calculating contributions to the Mandatory Universal Insurance of its affiliates, it will be understood that the taxable material is all income susceptible to pecuniary appreciation, received by the affiliated person or, in the case of unpaid work in the home, by the individual's family economic unit.

The contribution is made in the following percentages: employers (11.15 per cent) and workers (9.45 per cent). The voluntary contribution percentage to the IESS is 17.6 per cent of the unified basic salary.

At the private level, the 'Organic Law regulating the companies that finance integral prepaid healthcare services and the insurance companies that offer medical assistance insurance coverage' was enacted, which, in relation to the establishment of premiums, provides that plans and

programmes must offer coverage to individuals, whether as holders, beneficiaries, dependents or insured persons, so that they receive, in exchange for a contribution, individual contribution or premium, the amount of which depends on the plan contracted, the perks and timely and quality benefits provided by health professionals, health establishments or the dispensation of medicines and medical devices.

Any person who has an employment, marital or common-law relationship with the applicant or policyholder, or a family relationship up to the fourth degree of consanguinity and second degree of affinity, may be considered as a beneficiary or insured of a plan or programme of comprehensive prepaid healthcare services and insurance with medical assistance coverage.

Notwithstanding the previous rules, private insurance premiums are regulated by the Superintendence of Companies, Securities and Insurance. They are calculated based on factors such as age, medical history and the desired level of coverage, within a framework of tariff freedom supervised by law.

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?

Private insurers are subject to the provisions of the 'Organic Law that regulates companies that finance comprehensive prepaid healthcare services and insurance companies that offer medical assistance insurance coverage'.

In accordance with this Law, all plans and programmes of companies that finance comprehensive prepaid healthcare services and of insurance companies that offer medical assistance insurance coverage must contain the details of the benefits covered; and guarantee users' effective access to ambulatory, pre-hospital, hospital, emergency and urgent medical services, in accordance with the contracted plan.

Companies that finance integral prepaid healthcare services and insurance companies that offer medical assistance insurance coverage must be able to assume the costs of contractually stipulated health services and health benefits; and to directly or indirectly assume or accept and assign risks, with an indemnity or indemnifying nature, respectively, in the areas indicated below:

- disease prevention services, whether primary, secondary or tertiary, as a fundamental aspect that promotes universal access to healthcare;
- professional ambulatory care in general medicine, and in the various specialties and sub-specialties practiced in the different health establishments and at home when justified by the patient's state of health or the impossibility of mobilising the patient;
- pre-hospital care, including land, air or river transportation, legally authorised, which can be accessed within or outside the country, in accordance with the contracted plan;
- hospital care as indicated by the health professional attending the patient;
- attention in cases of urgency and emergency;
- care of normal, risky or complicated pregnancies;
- attention of congenital, genetic and hereditary diseases, with full coverage;
- care of pre-existing conditions, with limited coverage;
- care of chronic, catastrophic, degenerative and rare diseases, in accordance with the contracted plan;
- comprehensive oncological care;
- organ transplants;
- health services for people with disabilities;
- all diagnostic and therapeutic follow-up and control procedures subsequent to each disease

or accident treated and referred to specialties and sub-specialties;

- diagnostic aids, complementary and specific, requested by a prescriber and in accordance with the contracted plan;
- anatomopathological, genetic and congenital disease studies;
- access to medications in any pharmacy authorised by the competent authority, the cost of which will be totally or partially covered by direct payment or reimbursement, according to the contracted plan;
- attention for psychiatric illnesses with organic basis; and
- dental health benefits.

The aforementioned services and benefits must be grounded on evidence-based medicine, in accordance with the health supply and technology approved and available in the country or abroad, as established in the contracted plan and with coverage as mandated by the Law.

Telemedicine is growing, but the MSP Telemedicine Regulation (2020), which is included in the Digital Health Agenda 2023–2027, regulates its implementation, guaranteeing that services meet quality and confidentiality standards; however, there are no special conditions contemplated in the regulation in relation to coverage in medical plans.

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?

Article 367 of the Constitution of the Republic states: 'the social security system is public and universal, may not be privatized and shall attend to the contingent needs of the population. The protection of contingencies will be effective through the mandatory universal insurance and its special regimes. That the system will be guided by the principles of the national system of social inclusion and equity, obligatory nature, sufficiency, integration, solidarity and subsidiarity'. In the first paragraph of Article 370, it also states that the IESS is responsible for the provision of the contingencies of mandatory universal insurance to its affiliates.

In accordance with the above, Article 116 of the Social Security Law establishes the right of the insured to freedom of choice of healthcare providers, subject to the Law and the tariff approved by the IESS.

Thus, in the public sector, services are financed by the state through the general budget and individual or employer contributions from its affiliates. Health services are free of charge for users.

For the private sector, companies that finance integral prepaid healthcare services and insurance companies that offer medical assistance insurance coverage, through an organised financing system, by virtue of the payment of contributions, individual contributions, fees or premiums, may offer health benefits or medical assistance insurance coverage through the following modalities that may be chosen by the user:

- open: that in which the user, at the individual's choice, receives healthcare through third-party providers not related to the companies;
- closed: that in which the user receives healthcare only through healthcare providers related to the companies; and
- mixed: that in which the user receives healthcare through a combination of the open and closed modalities.

The specific conditions are agreed upon through a contract. The object of the contracts for the provision of integral prepaid healthcare services contain the financing obligation; the details of the

health benefits subject to the contract approved by the Superintendence of Companies, Securities and Insurance; its contents; scope; and limits.

The object must also contain the details of the health benefits subject to the co-payment modality; and the percentages to be covered by each contracting party; as well as establish the documentary requirements necessary for the reimbursement of the payments made by the user. The deadline for such reimbursement to be covered, according to the contractual percentage attributed to the company, in no case may exceed 60 days.

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

Article 182 of the Organic Health Law established that the National Health Authority shall regulate and approve the rates for health services.

Through Ministerial Agreement No 00088-2019, the tariff of benefits for the National Health System was issued, which is a technical instrument that regulates the economic recognition of the provision of health services, both institutional and professional, provided by public and private health institutions within the framework of the comprehensive and complementary public network of the National Health System. This integrates the relative value units of the procedures and the monetary conversion factor that allows establishing the amount of payment for each of the procedures used for healthcare.

In the private sector, price determination is free, but insurers can negotiate rates with hospitals to include them in their networks.

Economic efficiency is monitored through audits, oversight by the National Health Authority, and the application of cost-effectiveness strategies.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

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

In the private sector, providers establish fees that may be paid by the patient or reimbursed by private insurers, as regulated by the Organic Monetary and Financial Code, Book III.

In Ecuador, the financing and reimbursement of services provided by physicians, therapists, laboratories and other healthcare providers is structured mainly through the National Health System, which includes both public and private sector services. This system comprises a network of state, private and community institutions that provide medical care.

Article 32 of the Constitution of the Republic of Ecuador established that health is a right guaranteed by the state. The state must guarantee permanent and timely access to health promotion and care services without discrimination.

The Organic Health Law establishes provisions on how companies that finance comprehensive prepaid healthcare services and healthcare insurance must operate, ensuring that such services are provided according to quality and access standards.

Healthcare financing can come from a variety of sources, including state allocations, health insurance contributions and direct payments by patients.

In the health insurance arena, reimbursement to providers is usually made after the service is rendered, according to the protocols established by each insurance company or health system. This includes the submission of invoices and receipts validating the care received.

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

As stated in the MSP Tariff, medical professional services estimate the quantified value of the complexity of the medical expense through a systematic and detailed list of procedures that are codified based on the Current Procedural Terminology (CPT) of the American Society of Physicians, which is the standard international nomenclature of the codes of such procedures.

At the level of public institutions, the professional services component is regulated according to the organisational and operational characteristics of each institution.

In Ecuador, prices for services provided by physicians, therapists, laboratories and other providers may vary according to the availability of services and the number of patients seeking care, as well as the quality of care.

Economic efficiency is overseen by the MSP, through its affiliated entities, which can carry out audits and controls to ensure that services are provided efficiently.

The Organic Health Law and its regulations establish the regulatory framework that contemplates the rights of patients, ensuring that services are accessible and of quality, as well as the powers of the state to audit and regulate service providers.

Prices are generally free in the private sector, but subject to indirect regulation by competition and agreements with insurers.

PHARMACEUTICALS AND MEDICAL DEVICES

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

In Ecuador, pharmaceuticals and medical devices are financed and reimbursed mainly through two channels: the public health system and the private sector. The process is governed by various regulations and laws that ensure access to these products under conditions.

In the case of the public health system, this is done mainly through the MSP and IESS. These institutions manage public funds for the purchase and distribution of medicines and medical devices in public hospitals and health centres. The public sector does not provide reimbursement, except in exceptional cases as provided by law.

In this area, the government finances essential drugs, which are included in the National Basic Drug List (Cuadro Nacional de Medicamentos Básico or CNMB), as stipulated in the Organic Health Law. High-cost or specialised drugs, such as orphan drugs, are generally available through specific public financing programmes.

In the private sector, pharmacies, clinics and hospitals purchase pharmaceuticals and medical devices through contracts with suppliers. Patients must usually cover the full cost of these products through direct payments or private health insurance. Drug prices are regulated in Ecuador.

Reimbursement in this sector depends on the conditions of health insurance. Insurance companies in Ecuador cover part or all of the cost of medicines and medical devices, as long as the treatment or device is within the conditions agreed in the policies.

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

In Ecuador, the pricing and control of economic efficiency in the pharmaceutical and medical device sector is based on a legal framework that regulates both drug pricing and market competition. Competent authorities, such as the MSP, Pricing Council, Superintendence of Economic Competition and IESS, participate in the supervision and control of these processes to ensure the

accessibility, quality and economic efficiency of products in the country.

Drug prices are regulated by the National Council for Price Setting and Review of Drugs for Human Use, in accordance with the provisions set forth in Executive Decree No 400, which issues the Regulation for the Price Setting of Drugs for Human Use and Consumption, and determines the regimes applicable to each market segment, with the purpose of resolving and disseminating the corresponding ceiling prices.

The retail pricing regimes for medicines are either liberalised or regulated. In the case of the latter, the Council establishes a ceiling or maximum price for each market segment for strategic and new medicines

For medical devices, there is no price control.

The competent regulatory authorities supervise commercial practices to prevent anti-competitive and abusive behaviour that may affect economic efficiency.

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.

In Ecuador, the Constitutional Court has dealt with several emblematic cases and litigation related to healthcare financing and reimbursement, which have had a significant impact on citizens' rights, particularly on access to health services and compliance with public policies in this area. Among the most relevant are:

Refusal of reimbursement by the IESS (Ruling No 002-18-SCN-CC)

Summary

A patient insured by the IESS filed a constitutional appeal for the refusal of the social security system to reimburse medical expenses from an urgent surgical intervention outside the public network. The refusal was based on the lack of prior authorisation by the institution.

Decision

The Constitutional Court ruled that the IESS cannot refuse to reimburse medical expenses if the service is urgent and the affiliate cannot access care within the public health network in adequate time. In this case, the Court protected the right to health and the protection of the rights of affiliates, highlighting the obligation of the IESS to guarantee medical coverage, even outside its network of services.

Obligation of the state to guarantee access to free health services (Judgment No 36-17-CC)

Summary

Several people filed a lawsuit arguing that the state was not guaranteeing access to free healthcare in public facilities, violating the rights established in the Constitution, especially for people with serious illnesses requiring specialised treatment.

Decision

The Constitutional Court established that the state has the obligation to ensure full and free coverage of essential medical services, especially in cases of serious illnesses. In addition, it emphasised that the health sector authorities could not shift the responsibility of providing medical care to individuals due to administrative or financial problems.

Case on the Coverage of the National Vaccination Plan (Ruling No 34-15-CC)

Summary

A group of citizens filed an appeal before the Constitutional Court due to the lack of coverage in the National Vaccination Plan of certain vaccines that were not included in the basic health scheme of the MSP, arguing that this affected public health and violated the right to health.

Decision

The Constitutional Court ruled in favour of the plaintiffs, obliging the state to ensure full coverage of the National Vaccination Plan, regardless of the type of vaccine, and guaranteeing that all persons have access to immunisation services at no cost, in accordance with international public health standards.

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.

In Ecuador, the health sector presents significant regulatory changes and challenges in terms of healthcare financing and reimbursement. These include:

Health system and IESS reforms

Reform of the National Health System

The National Assembly has begun to discuss reforms to the Organic Health Law, with the aim of improving efficiency and access to public health services. At the public policy level, the aim is to decentralise health management, promoting more autonomy for local governments.

IESS reform

Reforms are being proposed to improve the quality of care and coverage, especially in terms of specialised medical services and medicines. These reforms also seek to address the financial deficit of the IESS, which has been a constant concern in recent years.

Sustainability and financing of the health system

Financial crisis of the public system

The lack of financing in the health sector continues to be a major issue. The country's economic crisis has hindered the state's ability to adequately finance the public health system.

Universal coverage

A Universal Health Fund has been proposed as part of a series of reforms to strengthen the health system. This is intended to ensure long-term financing for basic medical care and essential medicines.

Implementation of health technologies

Telemedicine

In recent years, telemedicine has been promoted as a solution to improve access to medical services, especially in rural areas. In the wake of the Covid-19 pandemic, the use of digital platforms for medical consultations accelerated, and this continues to be a growing trend.

Policy on pharmaceutical products for human use and consumption

Reforms in legislation regulating prices and access to medicines have been proposed, with the aim of improving the availability and quality of pharmaceutical products. The government is taking steps towards improving the regulation of drug prices and ensuring their accessibility.

Changes in drug and medical device regulation could facilitate access to quality products but could also create difficulties for suppliers in terms of profit margins in the market.

Major health system reforms are being contemplated in Ecuador for the next few years, with an emphasis on financial sustainability, digitisation and improving access to care. While these reforms seek to improve efficiency and coverage, they also present significant challenges for the medical sector, including adapting to new technologies, managing limited resources and the need to ensure equity in access to health services.