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 healthcare economy in Brazil is an interplay between the public and private sectors, designed to address the needs of a population of over 216 million people. The Brazilian Constitution sets forth healthcare as a universal right and a duty of the state. In this sense, the Brazilian Public Health System (Sistema Único de Saúde or SUS) is the public healthcare provider for more than 75 per cent of the population, considering that only 25 per cent is covered by private healthcare insurers.

The SUS is managed by the federal, state and municipal governments, which have co-responsibilities. The Ministry of Health (MoH) oversees national SUS policies, but relies on states and municipalities for implementation. States develop regional policies, coordinate the SUS at their level, and provide technical and financial support to municipalities. Municipalities handle public health services, formulate local policies and manage operations in compliance with state and federal guidelines.

The private sector also participates in the SUS. By law, the participation of the private sector occurs when resources are insufficient to guarantee healthcare coverage to the population. Philanthropic and non-profit entities have preference, but there is no impediment to the participation of regular private institutions. Patients' organisations support patients by advocating for patient rights, raising awareness and funding treatments, especially for rare diseases.

In an ancillary context, the private sector operates through healthcare plans regulated by the National Regulatory Agency for Private Health Insurance and Plans (Agência Nacional de Saúde Suplementar or ANS). Healthcare plans are contracted directly by beneficiaries (individual healthcare plan), companies (employer-based healthcare plan) or associations (healthcare plan by association).

The supplementary health ecosystem involves many stakeholders, such as healthcare insurers, service providers (laboratories, hospitals and healthcare professionals), policyholders,

brokers, benefit management organisations, industry and others, who interact directly or indirectly to enable access to and delivery of care. Healthcare insurers provide services through a network, but may allow beneficiaries to freely choose providers, with reimbursement limited by the contract.

The judiciary also plays an important role in health issues, with patients often suing the government or insurers for the adjudication of their constitutional rights. Such a phenomenon in Brazil is called '*Judicialização*'. It cost the MoH more than BRL 2bn ($317m) in 2024 and private insurers BRL 15bn ($2.3bn) over the last four years.

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

The SUS is financed by taxes paid by the population, collected by the federal, state, federal district and municipal governments. Each entity is responsible for making a minimum application of the collected funds to public health services. Key legal instruments include:

- Law 8,080/1990 (Organic Health Law): provides organisation, financing and reimbursement related to the SUS.
- Law 8,142/1990: addresses community participation and intergovernmental healthcare funding mechanisms.
- Complementary Law 141/2012: provides the minimum percentage to be applied by each entity of the Federation to health services

Specifically, SUS reimbursement is regulated by the following legal instruments:

- Decree 7,646/2011: regulates the Healthcare Technology Assessment (HTA) procedure that selects medicines and treatments that will be reimbursed by the SUS.
- MoH's Ordinance 2/2017: defines the groups of medicines according to the supply responsibility of the federal, states, district and/or municipal governments.

The private sector also participates in the SUS through negotiations/agreements with the public administration, including:

- Technologies Reimbursement Agreements: The MoH negotiates discounts with suppliers based on demand assessed during HTA procedures.
- Private and Public Partnerships (PPP): PPP is an alternative for financing public health infrastructure and services with private companies' involvement (eg, as Hospitals). Currently there are 23 PPPs signed in the health sector in Brazil, according to Radar PPP data.
- Partnership for Productive Development (PDP): Relaunched in 2024, under the National Strategy for Economic-Industrial Health Development Complex (Complexo Econômico-Industrial da Saúde or 'CEIS'), PDPs involve transferring technology for local production of medicines by public laboratories to reduce SUS vulnerabilities.

The financing and reimbursement mechanisms in Brazil's supplementary healthcare sector, by turn, are governed by a set of legal and regulatory provisions, including:

- Law 9,656/1998: regulates private healthcare plans.
- Law 9,961/2000: establishes the creation of the ANS and defines its responsibilities and competencies.

- ANS Normative Resolution 565/2022: sets forth the criteria for applying adjustments to healthcare plans' financial contributions.
- ANS Normative Resolution 566/2022: sets forth guidelines and specific procedures for regulating supplementary health services and reimbursement in the case of network unavailability.

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

The MoH is the primary federal entity overseeing healthcare in Brazil. It is responsible for: policy formulation, budget management and monitoring.

Key MoH's departments and bodies are:

- Department of Budget and Financing (Departamento de Orçamento e Finanças or DEOF): oversees the allocation and management of financial resources for the SUS.
- National Health Fund (Fundo Nacional de Saúde or FNS): acts as the financial arm, managing funds transferred to state and municipal health secretariats.
- Department of Health Logistics (Departamento de Logística em Saúde or DLOG): responsible for executing agreements with products' suppliers.
- Department of Management of Demands of Judicialisation (Departamento de Gestão das Demandas em Judicialização na Saúde or DJUD): organises and promotes the fulfilment of court orders.
- Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex (Secretaria de Ciência, Tecnologia e Inovação e do Complexo Econômico-Industrial da Saúde or SECTICS): formulates, implements and evaluates MoH actions for health science and technology development. It also coordinates the HTA procedure and has the final say on technology reimbursement by the SUS.
- National Commission for the Incorporation of Technologies (Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde or CONITEC): the HTA authority. CONITEC's recommendations influence reimbursement decisions made by SECTICS.

At the federal level, linked to MoH, other relevant departments and bodies are:

- The National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária or ANVISA): regulates pharmaceuticals, medical devices and other health products, ensuring their safety and efficacy.
- Chamber for the Regulation of the Pharmaceutical Market (Câmara de Regulação do Mercado de Medicamentos or CMED): a multi-agency body that includes ANVISA and the MoH that is responsible for regulating medicines prices in both public and private markets.
- National Regulatory Agency for Private Health Insurance and Plans (Agência Nacional de Saúde Suplementar or ANS): regulates the private health insurance sector by licensing insurers, overseeing their activities, and mediating disputes between insurers and beneficiaries.
- National Health Council (Conselho Nacional de Saúde or CNS): a deliberative

advisory body that oversees the formulation and monitoring of healthcare policies in Brazil, which includes the evaluation of financial and operational performance.

At the state and municipal levels, the key departments and bodies are:

- Secretariats of Health: responsible for implementing and overseeing healthcare policies within their jurisdiction, as well as managing funds and budget.
- The National Council of Health Secretariats (Conselho Nacional de Secretários de Saúde or CONASS) and National Council of Municipal Health Departments (Conselho Nacional de Secretarias Municipais de Saúde or CONASEMS): they have several responsibilities related to the political representation of state and municipal health secretariats before the federal government.

The judiciary also plays a critical role in *Judicialização*, influencing public spending and determining responsibility for costs across government levels. Industry trade associations (eg, the Brazilian Association of Health Insurers (Associação Brasileira de Planos de Saúde or ABRAMGE) and the Pharmaceutical Industry Union (Sindicato da Indústria de Produtos Farmacêuticos or Sindusfarma)) also have an important role in representing private companies and advocating for their interests.

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

The Covid-19 pandemic had a significant impact on healthcare financing and reimbursement in Brazil, prompting shifts in policy, funding priorities and reimbursement mechanisms to address the health crisis. Some examples are:

- Emergency funds were created to support pandemic-related expenses, including vaccines, hospitals and supplies. By December 2022, the federal government spent BRL 38bn ($6bn) on vaccines,[1] reaching 93 per cent of the adult population. BRL 400bn ($63bn) funded the 'Emergency Aid' programme, which provided about BRL 4,000 ($630) to 68m Brazilians between in 2020 and 2022.[2]
- Despite there being no changes in CONITEC's regulations (Decree 7,646/2021), which establish a 180-day (+90 days) deadline for HTA decisions, CONITEC and SECTICS approved, until December 2012, five (out of nine requests) medicines indicated for Covid-19 in an average time of four months.
- ANVISA took several measures during the pandemic. Among them, it published or changed a set of regulatory instruments with the aim of improving Brazil's response capacity to the pandemic, making procedures more flexible and providing more agility to technical analyses and decision-making.

In the private sector, the highlight was companies and public laboratories contributing to vaccine manufacturing and distribution, for example: (1) Butantan and Sinovac; and (2) Fiocruz and AstraZeneca.

The ANS also implemented a set of emergency measures to mitigate the effects of the health

[1] See www.gov.br/saude/pt-br/assuntos/noticias/2022/dezembro/governo-federal-investiu-r-38-bilhoes-em-vacinas-covid-19-e-criou-logistica-inedita-permitindo-alta-cobertura-vacinal-dos-brasileiros accessed 8 May 2025.
[2] See https://portaldatransparencia.gov.br/coronavirus accessed 8 May 2025.

crisis and ensure the continuity of essential services. For instance, the temporary suspension of the contractual premium and the expansion of the flexibility of prudential regulation allowing autonomy in managing resources that back technical provisions.

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?

In Brazil, the healthcare system provides broad access to patients and medical service providers/suppliers through the SUS and the regulated private market. Conditions for access and admission vary depending on the role (patient or provider) and the specific circumstances of treatment or reimbursement.

All residents, regardless of nationality or income, have free access to SUS services, including emergency care for tourists and undocumented immigrants. Private healthcare is available to those with health insurance or through direct payments. Providers and suppliers seeking public funding or reimbursement through the SUS must be accredited, initiate HTA procedures, participate in public procurements, and comply with MoH and ANVISA standards.

In private healthcare, beneficiaries access the system by purchasing healthcare plans, with risk selection being prohibited. In some cases, access to certain services may be subject to waiting periods.

Healthcare providers are accredited by healthcare insurers, whose contract shall outline essential aspects, such as remuneration and adjustment criteria. In the case of the free choice of service providers, beneficiaries must pay for the service and request reimbursement from the insurer.

HEALTH INSURANCE FINANCING AND COVERAGE

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

In Brazil, health insurance enrolment is not mandatory. Hence, the primary funding source of healthcare plans is the premium paid by policyholders. Premiums are determined using actuarial methodologies, which consider the risk, age bracket, type of coverage, network, medical inflation, historical data of the loss ratio and average cost per event.

Beneficiaries may also pay co-payments to prevent excessive claims, a percentage of the cost of the service, based on the use of the plan.

Considering the high premium adjustment, there has been much litigation surrounding this issue, and due to the lack of transparency in the calculation, adjustments are often perceived as abusive or disproportionate. The judiciary is frequently called upon to question the reasonableness of adjustments, the criteria transparency, and the proportionality between the percentage and healthcare costs.

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?

The regulation of medical coverage by healthcare plans was primarily established by Law

9,656/1998 and ANS, which defines the Minimum Mandatory Coverage List. This list is regularly updated and establishes the essential services that insurers must offer. Such updates consider clinical efficacy, safety, cost-effectiveness and the financial impact of new incorporations.

There are no differences in coverage for in-person medical and telemedicine appointments. Healthcare plans must cover telemedicine consultations if they adhere to the same quality standards as in-person consultations.

Brazilian legislation does not mandate coverage for off-label medications, but court orders have required insurers to cover them if registered by ANVISA and clinically justified. Orphan drugs also face challenges, as they are often excluded from the Minimum Mandatory Coverage List due to high costs and limited data, yet courts have ruled that insurers must fund them.

The same reasoning applies to innovative therapies, such as gene and immunotherapies. Given the high costs and complexity, the ANS has established specific rules for their inclusion in the Minimum Mandatory Coverage List, ensuring that only those therapies meeting clinical efficacy, safety and cost-effectiveness requirements are incorporated, based on the HTA.

HOSPITAL SECTOR

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

Hospital services in Brazil may be provided by the private sector, primarily financed through private health insurance plans or direct payments made by patients, or by the public sector, funded by the government through the SUS.

In the private sector, the predominant reimbursement model is fee-for-service, where hospitals charge separately for each service provided, such as consultations, diagnostic tests, surgery or treatments. Prices for these services are typically pre-negotiated between hospitals and health insurers.

An alternative approach, through fixed or bundled payments, is sometimes employed for specific treatments or procedures, such as surgery or chronic disease management. Under this model, hospitals charge a single payment that covers all services related to a particular condition or procedure.

The fee-for-service system has been subject to criticism. Critics argue that it incentivises quantity over quality and increases the risk of fraud. There have been discussions about adopting alternative payment models, such as performance-based fees, which aim to reduce healthcare costs and discourage fraudulent practices. In 2019, ANS published a guide for implementing value-based remuneration models. It is worth noting that the document is merely suggestive, introducing innovative proposals for the private sector, aiming to modernise the remuneration of hospitals, clinics and professionals, and to improve service quality and optimise resource utilisation.

The relationship between insurers and hospitals has also experienced fluctuations linked to

the current system. In 2023, the National Association of Private Hospitals (ANAHP) published a study revealing that, between 28 August and 2 September 2023, payment delays by insurers resulted in outstanding debts totalling BRL 2.3bn, approximately 16 per cent of the gross revenue of the evaluated group of hospitals. According to the same study, the amount of hospital charges denied by insurers amounted to BRL 1.29bn, equivalent to nine per cent of the gross revenue of the assessed hospitals.[3]

Brazilian law allows the private sector to assist the SUS by providing resources, delivering healthcare services or managing operations using their funds, provided they adhere to public administration guidelines and operate under formal agreements with public institutions. Philanthropic and non-profit organisations in the healthcare field are prioritised for offering services to the SUS and also receive certain tax incentives. However, when these entities cannot fully meet demand, which is a frequent scenario, the government may contract services from private, for-profit providers to address gaps and ensure the population's healthcare needs are met.

Finally, it is important to highlight that private healthcare providers are required to compensate the SUS for the costs incurred when beneficiaries of private health plans receive treatment through the public system.

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

In Brazil's private healthcare sector, the prices of hospital services are established through negotiations between hospitals and health insurers or directly set by hospitals for patients without insurance. These prices can vary depending on factors such as the hospital's location and reputation, and the complexity of the services provided.

For insured patients, contracts between hospitals and healthcare insurers specify pricing structures, payment schedules and the methodology for adjustments. These agreements must comply with regulations set by the ANS.

In the public sector, the SUS provides free healthcare services to all residents, regardless of nationality or income, including emergency care for foreigners.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

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

Healthcare services provided by private practitioners, therapists, laboratories and other service providers in Brazil are primarily financed through private health insurance plans or out-of-pocket payment from patients.

Reimbursement for these services typically follows one of the following methods:

[3] See www.anahp.com.br/noticias/novas-praticas-de-planos-de-saude-paralisam-ate-16-dos-pagamentos-para-hospitais-privados/ accessed 8 May 2025.

Predefined amounts through written agreements with insurers
In this scenario, the healthcare provider is part of the insurer's accredited network and offers services to the insurer's clients at predefined rates for procedures or fixed amounts, which are paid directly by the insurer to the provider.

ANS regulates contracts between healthcare providers and insurance plans under ANS Resolutions 503/2022 and 512/2022. This regulation mandates that contracts must be formalised in writing and include specific provisions, such as: (1) the agreed pricing for services provided; (2) criteria, methodology and frequency for price adjustments; and (3) billing and payment timelines and procedures. ANS Resolution 363 prohibits contract terms that link price adjustments to the insurer's claims ratio or that reduce the nominal value of the contracted services.

It is worth noting that the Brazilian Medical Association (Associação Médica Brasileira or AMB) recommends that the medical sector adhere to the Brazilian Hierarchical Classification of Medical Procedures (Classificação Brasileira Hierarquizada de Procedimentos Médicos or CBHPM), which establishes a minimum ethical standard for the remuneration of medical procedures within the supplementary healthcare system, serving as a reference framework for medical practice. However, Brazilian legal precedents have determined that the CBHPM is not binding.

Out-of-pocket payment with subsequent reimbursement
If the contract establishes that patients may freely choose the service provider, patients pay the healthcare provider directly and, on request by the patient, the insurer then reimburses the patient according to the terms of the health insurance policy.

These methods may apply to procedures listed under the ANS List of Healthcare Procedures and Events, which outlines minimum coverage requirements for private health insurers, or to non-standard or more complex services, depending on the circumstances.

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

Prices for services provided in private healthcare practices in Brazil are not directly established by the government. Instead, they are determined through free-market negotiations between private health insurers and healthcare providers or directly with individual patients. Nonetheless, competition and the regulatory framework of ANS may affect these negotiations.

PHARMACEUTICALS AND MEDICAL DEVICES

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

The SUS provides free and universal healthcare services, as mandated by Article 196 of the Constitution. Essential medicines and medical devices are supplied at no cost to patients under the SUS. The process is governed by Law 12,401/2011, which established CONITEC. CONITEC evaluates health technologies, including treatments, drugs and medical devices, for incorporation into the SUS based on: (1) scientific evidence of safety and efficacy; and (2) economic evaluation to ensure cost-effectiveness and budgetary feasibility (HTA).

The evaluation process takes up to 180 days, during which reports are subject to public consultation before final decisions are made. Approved treatments are incorporated into the SUS through the Clinical Protocols and Therapeutic Guidelines (CPTG).

In the private sector, healthcare insurers must cover at least the treatments and drugs listed in the Minimum Mandatory Coverage List, which is updated biennially and includes high-complexity procedures and transplant coverage. Health insurance plans also cover implantable medical devices, such as prosthetics and orthotics, if a surgical procedure is required for their insertion or removal.

It is worth noting that, as a rule, healthcare insurers are required to supply patients with drugs administered in hospital settings.

For items not covered under the SUS or ANS guidelines, patients may resort to legal action, invoking Article 196 of the Constitution, to compel the government to supply the needed medication or treatment. According to the higher courts' precedents, the granting of medications not supplied by the SUS requires the presence of the following conditions: (1) proof, through a detailed and substantiated medical report issued by the physician treating the patient, of the indispensability or necessity of the medication, as well as the ineffectiveness of the drugs provided by the SUS for treating the condition; (2) financial incapacity to bear the cost of the prescribed medication; and (3) registration of the drug with ANVISA, in accordance with the uses authorised by the agency.

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

In the public sector, the prices of pharmaceuticals and medical devices may be influenced by the Health Price Database (Banco de Preços em Saúde or BPS), a system that records information on public and private purchases. It plays a key role in government procurement, as it is part of the National Government Procurement Portal (Portal Nacional de Contratações Públicas or PNCP), an official platform that centralises and mandates the publication of acts required under procurement and administrative contract laws.

The BPS supports government procurement by serving as a reference for price research and is used to: (1) control and research prices across Brazil; (2) strengthen SUS negotiating power and facilitate acquisitions at market-competitive prices; (3) optimise the allocation of government resources; (4) enhance transparency in public spending; (5) serve as a reference for price research, including regionalised data, statistical analysis, market concentration by active ingredient and price comparisons; and (6) track procurement history and monitor price trends for purchasing institutions. However, it is important to note that the BPS functions as a reference rather than imposing strict limits on specific prices.

Regarding the general pricing of pharmaceuticals in Brazil, prices are strictly regulated by the CMED, an inter-ministerial body with ANVISA serving as its Executive Secretariat. CMED is responsible for setting maximum drug prices, promoting competition, monitoring sales practices and imposing penalties for non-compliance. To be commercialised in Brazil, a drug must have its maximum price approved by CMED.

Pharmacies and drugstores, as well as laboratories, distributors and importers, are not allowed to charge prices for medications higher than those established by CMED. The list of maximum permitted prices for the sale of drugs is updated monthly. The Maximum Consumer Price (Preço Máximo ao Consumidor or 'PMC') represents the highest price authorised for retail sales, such as in pharmacies and drugstores.

The Maximum Government Procurement Price (Preço Máximo de Aquisição Governamental or PMVG) is the highest price allowed for the sale of medications listed in specific resolutions (primarily including medications provided by government authorities and/or those of public interest or required to comply with court orders). It is determined by applying a mandatory minimum discount to the Factory Price (Preço Fábrica or PF), which is the maximum price at which a laboratory or distributor may sell a medication in the Brazilian market. Currently, this mandatory minimum discount is set at 21.53 per cent.

It is worth noting that the BPS, as explained earlier, enables comparisons between private and public sector prices while also considering CMED data, which assists CMED in determining the PMVG.

Additionally, companies must report annual sales volumes and revenues to maintain compliance, and products not commercialised for three consecutive years are deactivated in the Medicines Market Monitoring System (Sistema de Acompanhamento de Mercado de Medicamentos or SAMMED), requiring a new CMED assessment for reactivation.

With regard to the pricing of medical devices, besides the information provided by the BPS to support government procurement (as explained above), it is important to highlight that ANVISA Resolution 478/2021 mandates economic monitoring of selected devices, particularly those with significant financial impact on the SUS or the supplementary health system, such as defibrillators, stents, pacemakers and valve prostheses.

This monitoring process involves the continuous oversight of medical device pricing and other relevant economic data to address information asymmetry in the medical device market. This process includes: (1) publishing historical pricing statistics; (2) defining and disclosing technical attributes; and (3) releasing other relevant information as determined by ANVISA, while safeguarding legally protected confidential information.

The monitoring efforts aim to reduce market information asymmetry by disclosing technical attributes that enable the grouping of products with similar characteristics and providing statistics on actual pricing. These results may serve as benchmarks for both government and private procurement of medical devices.

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.

Initially, it is worth highlighting that discussions surrounding limitations on the provision of drugs and treatments by the government for individuals are a recurring topic in Brazilian courts. On this matter, in September 2024, the Supreme Federal Court (Supremo Tribunal

Federal or STF) concluded the rulings on Extraordinary Appeals 1.366.243 and 566.471, addressing two key issues:

- the passive procedural legitimacy of the federal government in lawsuits concerning the provision of medications approved by ANVISA but not included in the SUS; and
- the obligation of the government to provide drugs not reimbursed by the SUS, regardless of their cost.

As a result of these judgments, the following binding precedents have been established:

Binding Precedent 60

Administrative requests and reviews for drugs within the public healthcare network, any judicialisation of such matters, and their subsequent administrative and judicial outcomes must comply with the terms of the three inter-federative agreements approved by the STF under a collaborative judicial governance model. These agreements include, for instance, comprehensive rules regarding jurisdictional competence, the funding of medications to be purchased as a result of court decisions, the pricing of such medications, judicial review of administrative decisions denying medications under the SUS and the need for a national platform centralising all information related to these demands

Binding Precedent 61

Judicial authorisation for drugs registered with ANVISA but not included in the SUS's official dispensing lists may be granted if the plaintiff meets the following cumulative criteria:

- administrative denial of the requested medication;
- evidence of illegality in the non-inclusion of the medication by CONITEC, absence of a request for inclusion, or undue delay in processing such a request;
- lack of an alternative medication available in the SUS dispensing lists or therapeutic protocols;
- proof, based on evidence-based medicine, of the drug's efficacy, accuracy, effectiveness, and safety, supported exclusively by high-quality scientific evidence such as randomised clinical trials, systematic reviews or meta-analyses;
- demonstration of clinical necessity substantiated by a detailed medical report outlining previous treatments; and
- proof of financial incapacity to afford the medication independently.

Court decisions must also adhere to specific procedural safeguards to avoid nullity, including:

- evaluating the administrative action or omission by CONITEC or the denial of the medication request at the administrative level based on the circumstances and public health policies governing the SUS;
- verifying compliance with the above criteria with input from technical advisory bodies whenever available; and
- notifying the competent public health authorities to assess the potential inclusion of

the medication in the SUS for broader public use, if judicially approved.

Another important ruling was issued by the STJ in Special Appeal 1.945.959. The court held that government entities are entitled to judicially demand reimbursement from private health insurers for expenses incurred under the SUS when they have complied with a court order to provide healthcare services to an insured patient.

This decision reinforces the principle that private health insurers must bear the financial burden for services provided to their beneficiaries, even when those services are delivered through the public health system due to judicial intervention.

Orphan drugs and treatments for rare diseases remain a contentious issue. Notwithstanding the foregoing, as observed on Extraordinary Appeal 657.718, regarding a case involving the request for the provision of experimental drugs, courts increasingly require evidence of efficacy and cost-effectiveness, relying on technical input from specialised governmental bodies.

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.

Within CEIS, there is the Local Development and Innovation Program (Programa de Desenvolvimento e Inovação Local or PDIL), which comprises projects aimed at developing new technologies in Brazil. The MoH received 175 PDIL and 147 PDP proposals by September 2024, which are currently under analysis by the Ministry.

Binding Precedent 61, which settled stricter criteria for judicially supplied high-cost medicines not reimbursed by the SUS is expected to reduce court-ordered treatments in the coming years.

The ANS created the regulatory sandbox as an important tool for enabling controlled experimentation with new business models and technologies. The goal is to promote the development of more personalised products. ANVISA also initiated a regulatory process in November 2024 to collect contributions from society regarding the regulatory sandbox.

At the same time, discussions on creating a unified regulatory agency are progressing to centralise and harmonise regulatory guidelines nationwide regarding the reimbursement of new technologies.

Another key legal issue involves disputes over premium adjustments for group healthcare plans, with an increasing focus on the transparency of the calculation.