Healthcare

Retrospective 2024 and

Trends 2025

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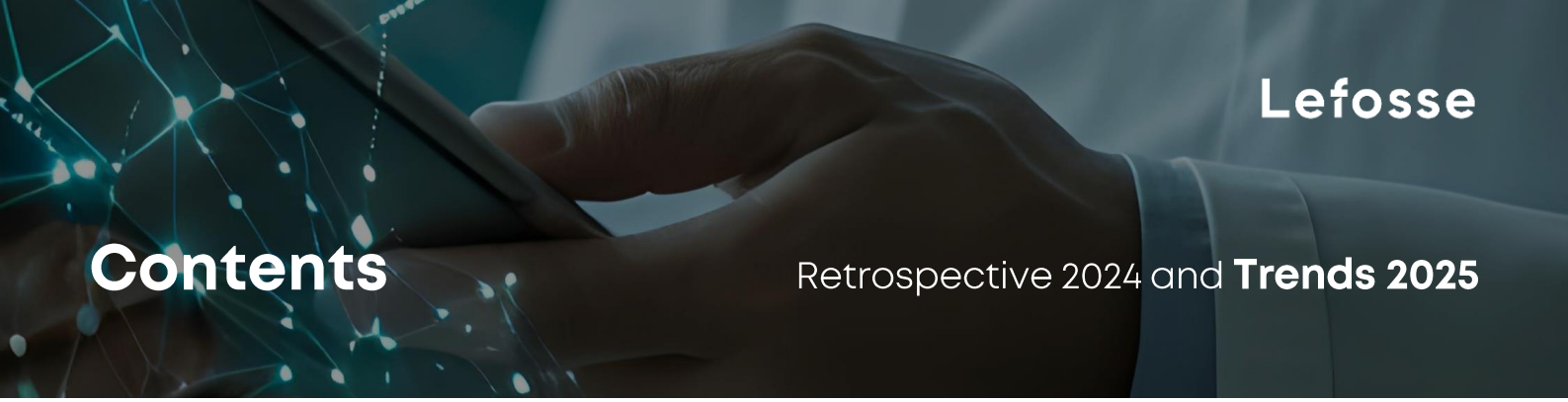

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Retrospective 2024 and **Trends 2025**

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National Minimum Wage Floor for Nursing and other healthcare Professions

The National Minimum Wage for Nursing continues to be a central issue in the Brazilian health sector, with significant consequences for both the public and private sectors. Established by Law No. 14,434/2022, this wage floor establishes minimum amounts to be paid to nurses, nursing technicians and assistants, and midwives throughout the country. Despite important advances, the challenges for its implementation and financing continue to be debated, involving collective bargaining, legislative initiatives and coordination between the public and private sectors.

In the private sector, the implementation of the wage floor is subject to collective bargaining, in accordance with the decision of the Federal Supreme Court in Direct Action of Unconstitutionality No. 7,222, which determined that the issue should be addressed through collective agreements or collective labor disputes, in order to mitigate risks of mass layoffs and possible disruptions to healthcare services.

In the public sector, payment of the wage floor is subject to complementary financial assistance from the Federal Government. Since August 2023, the National Health Fund has been transferring this assistance to state, municipal and Federal District funds, pursuant to Constitutional Amendment No. 127 and specific Ministry of Health regulations. The Nursing Wage Floor Caravan, an initiative by the Secretariat of Labor and Education Management in Health, toured all Brazilian states during the year, guiding managers and institutions on implementing and operationalizing the wage floor. The Federal Government's proposed budget for 2025 includes BRL 11 billion to guarantee payment of the nursing wage floor.

In addition to nursing, discussions on minimum wage floors for other healthcare professions have also been gaining relevance, driven by the growing demand for recognition of these professionals in the post-pandemic era. The establishment of wage floors for professions such as physiotherapists, occupational therapists, and social workers, for example, is already being discussed in the National Congress, reflecting the importance of public policies that align remuneration and financial sustainability in the health sector.

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The progress of the discussion on the National Minimum Wage Floor for Nursing and other healthcare professions represents a milestone in the recognition and appreciation of healthcare professionals in Brazil. However, the process requires effective coordination among public managers, private employers, and representatives of professional categories to ensure financially viable and effective implementations, avoiding negative impacts on employability, and the continuity and quality of healthcare services.

Definition of the incorporation of advanced therapy products into the ANS List

The incorporation of advanced therapy products into the Brazilian Supplementary Health Agency's (ANS) List of Healthcare Procedures and Events (List) was also a topic of wide debate within Brazil's supplementary health sector.

In March 2024, the 10th Federal Civil Court of São Paulo granted an urgent injunction suspending the effects of the ANS Collegiate Board of Directors' (Dicol) decision that approved Technical Note No. 03/2023/GCITS/GGRAS/DIRAD-DIPRO/DIPRO (Technical Note No. 03/2023). This technical note excluded advanced therapy drugs from the rules outlined in §§ 10 and 13 of Article 10 of Law No. 9,656/1998, subjecting them to the standard procedure for updating the ANS List. The decision was the result of an annulment action filed by the Pharmaceutical Products Industry Union (Sindusfarma), in Case No. 5037147-80.2023.4.03.6100.

Advanced therapy products, which include advanced cellular therapy, gene therapy, and tissue engineering, have been classified by the Brazilian Health Surveillance Agency (Anvisa) as a special category of medicines, under Anvisa's Dicol Resolution (RDC) No. 505/2021. On the other hand, in Technical Note No. 03/2023, the ANS determined that these products do not fall within the general rules for drugs coverage adopted in supplementary health and should be submitted to the standard procedure for updating the ANS List.

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The urgent injunction was granted based on the probable legitimacy of the claim, especially with regard to the ANS's lack of competence to create distinctions between medications. The decision highlighted the potential risk to patients from the denial of coverage for advanced therapy products.

This ongoing case may set an important precedent for the incorporation of advanced therapy products into the supplementary health system. The sector is keeping a close eye on the outcome, which will be decisive in defining the availability and access to this special category of drugs.

New legal and regulatory framework for clinical research

After almost a decade of discussions in the National Congress, 2024 marked the sanction of Law No. 14,874, which establishes a legal framework for clinical research in Brazil. This new legislation introduces important advancements for the sector, in particular the definition of clear rules for the continuation and conclusion of post-clinical trial treatments, including the creation of a post-study access plan, which must be approved by the Research Ethics Committee (CEP) before the research begins. In addition, the law establishes shorter deadlines for ethical and regulatory analysis of protocols, enhances participants protections – such as guaranteeing anonymity of personal data and prohibiting remuneration or granting of advantages to participants –, and provides for the creation of the National Research Ethics System.

As part of its proposal to reduce bureaucracy and speed up the clinical research process in Brazil, Anvisa has also took significant steps with the publication of RDC No. 945. This regulation establishes guidelines and procedures for carrying out clinical trials with the aim of registering new drugs in the country. Among the key innovations is the possibility for the sponsor to import the investigational products for research before the dossier has been analyzed by Anvisa.

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In addition, the resolution introduces a more agile and flexible procedure for assessing dossiers for the clinical development and clinical trials, based on risk and complexity analysis.

With these changes, 2025 is expected to be a year of growing investment and new opportunities in Brazil's clinical research sector. The new rules aim not only to simplify processes, but also to position Brazil as a more attractive destination for conducting clinical research, promoting the advancement of science and innovation in the country.

Flexibility in the allocation of collateral assets by health maintenance organizations

In October 2024, ANS introduced significant changes to the rules governing collateral assets for Health Maintenance Organizations (HMOs) with the publication of Normative Resolution No. 614. This resolution, which amended Normative Resolution No. 521, brought important changes to the allocation limits for real estate as collateral assets, with a focus on increasing HMOs' financial management capacity and sustainability.

Among the changes is the increase in the allocation limit for healthcare-related real estate and investment funds shares, which can now comprise up to 50% of collateral assets, compared to the previous limit of 20%. These funds must be exclusively dedicated to the expansion, renovation, modernization, purchase, or construction of medical-hospital and diagnostic facilities, as well as outpatient clinics and primary care centers. In addition, the combined limit for the sum of these assets was raised from 28% to 58%, further expanding HMOs' flexibility.

The expectation is that these changes will increase liquidity for HMOs by providing greater flexibility in the allocation of collateral assets. This, in turn, is anticipated to increase investment capacity and strengthen the financial sustainability of the supplementary health sector.

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Updated rules for changing the hospital network

In June 2024, ANS issued Normative Resolution No. 609, which extended the effective date of Normative Resolution No. 585. The new implementation date for the updated rules governing changes to hospital network of health plans has been set for December 31, 2024, allowing HMOs more time to adapt to the changes.

The new rules aim to increase transparency and security for health plan beneficiaries and apply to both the withdrawal of a hospital from the network and the substitution of one hospital for another. Among the main changes is the extension of the portability rules. Beneficiaries will now be able to transfer their portability without the need to comply with the minimum waiting periods or to maintain the same price range as the original plan if a hospital in their municipality of residence or where the plan was contracted is excluded or replaced.

In addition, HMOs must individually notify beneficiaries about exclusions or changes to the hospital network in their municipality of residence, including urgent and emergency services, 30 days in advance of the end of the service provision.

Another important change is the requirement that if the hospital to be excluded is responsible for up to 80% of the hospitalizations in its service region, the HMO cannot just remove it from the network but must replace it with a new one. In this replacement, the substitute provider must offer the same services as the excluded hospital, as well as be located in the same municipality. It will also be necessary to maintain or upgrade the qualification level of the hospital to be replaced.

In 2025, these changes are expected to usher in a new phase in the relationship between HMOs and beneficiaries, as well as promote greater competitiveness between HMOs, leading to a more diverse and higher-quality offering of hospital services.

What should change in the market in 2025?

Reformulation of outpatient plan rules

In October 2024, ANS intensified the discussion about reformulating the rules governing outpatient health plans, which only cover consultations and exams, without including hospitalizations. The initiative aims to provide more affordable alternatives to consumers, especially those who currently rely on discount cards to access healthcare services.

ANS has launched the Public Consultation (TPS) No. 5, inviting society to contribute with suggestions for revising and improving the current rules for these plans. The aim is to encourage the safe commercialization of products with outpatient cover for consumers. Contributions were received until October 31, 2024. The issue was also the subject of a public hearing.

The proposal is facing resistance from consumer protection authorities, who are concerned about the potential lack of access to hospital admissions, when necessary, which could increase the litigation.

The final decision, which will be shaped by the extensive debate on the issue, could redefine Brazil's health plan market, expanding the available options and meeting the needs of different user profiles.

What should change in the market in 2025?

Progress on AI regulation and its impacts on healthcare

Bill of Law (PL) 2,338/2023, presented by Senator Rodrigo Pacheco, seeks to regulate Artificial Intelligence (AI) in Brazil, with a focus on systems classified as high-risk. It proposes a set of obligations for AI operators to protect rights, avoid irreversible harm and discrimination, and ensure personal data protection. A key aspect of PL 2,338/2023 is the classification of health as a high-risk sector.

The inclusion of health as a high-risk category may impact healthcare services and HMOs that use AI. For healthcare services, this classification could mean the need to implement additional compliance measures. HMOs will also have to structure internal processes to monitor and manage the risks associated with the use of AI, as well as guaranteeing the protection of beneficiaries' personal data.

In December 2024, the Federal Senate approved the bill of law, which now proceeds to the Chamber of Deputies for consideration.

What should change in the market in 2025?

ANS' Regulatory Sandbox

In December 2024, ANS approved Normative Resolution No. 621, which sets out the rules for the creation and operation of an experimental regulatory environment (i.e. Regulatory Sandbox) in Brazil's supplementary health sector. The Regulatory Sandbox was developed to promote innovation, offering a controlled environment where companies can test new products, services and business models under temporary authorizations, with the suspension or relaxation of certain rules within the Agency's competence.

The proposal was widely discussed during Public Consultation No. 138, held between October and November 2024. ANS received 159 contributions from various sectors of society, including citizens, healthcare professionals, entrepreneurs, and government authorities. These contributions were fundamental to the drafting of the final regulation.

The main objectives of the Regulatory Sandbox include (i) encouraging innovation in the supplementary health sector; (ii) promoting the development of new products, services, technologies, and solutions; (iii) reducing costs and time required to develop these innovations; (iv) improving ANS's current regulatory framework; and (v) stimulating competition and reducing barriers to entry in the sector.

The Regulatory Sandbox will be implemented through the publication of a participation notice, approved by ANS' Dicol and provided on the Agency's website. For each notice, a specific Sandbox Committee will be set up to select participants and supervise activities related to the experimental regulatory environment.

ANS' Regulatory Sandbox is expected to contribute to the modernization of Brazil's supplementary health sector, allowing new products, services and business models to be developed and implemented quickly, safely, and effectively, as well as attracting new investments and stimulating competition within the sector.

What should change in the market in 2025?

Discount cards

In December 2024, ANS approved a public call notice with the aim of receiving subsidies to regulate healthcare discount cards through a Regulatory Sandbox.

Discount cards are an alternative for people seeking more affordable access to medical consultations and exams without the need to join a traditional health plan. Currently, it is estimated that between 40 and 60 million Brazilians use this product, which offers discounts on various medical services through partnerships with clinics, laboratories, and other providers.

The decision to regulate discount cards was driven by a decision from the Superior Court of Justice, which recognized ANS's competence to regulate and supervise this product, in the context of AgInt in AREsp No. 2,183,704/SP.

The regulation of discount cards is expected to open up new opportunities in the health market, guaranteeing greater organization, transparency, and security. This initiative could help to consolidate discount cards as a complementary option, offering viable and accessible alternatives for different consumer profiles. With regulation, the sector is likely to continue to evolve, promoting partnerships and innovations that expand access to healthcare in a balanced, sustainable and efficient way.

What should change in the market in 2025?

Improvement of the pricing and readjustment policy of health plans

In December 2024, ANS approved a series of measures to reformulate the pricing and readjustment policy of health plans. During the 616th Dicol Meeting, a number of documents and proposals were reviewed and approved, including the Regulatory Outcome Assessment on electronic contracting of health plans (online sales), the approval of the TPS No. 4 report, and the Regulatory Impact Analyses of the four topics included in the Pricing and Readjustment Policy.

The reformulation covers four main topics: readjustment of collective plans, financial regulation mechanisms (such as cost-sharing and deductibles), online sales of health plans, and technical pricing review of individual/family health plans.

Among the proposals approved is the definition of new parameters for the readjustment of collective plans. ANS is proposing to increase the size of contract groupings, from 29 beneficiaries to up to 1,000 for collective corporate plans and for all collective association-based plans. In addition, the Agency has defined criteria for the readjustment clause, prohibiting the accumulation of financial and claim-based adjustment indices.

ANS also approved the holding of a public hearing on January 28th and 29th, 2025, to discuss each of the issues, and a public consultation, which will take place until February 3rd, 2025. These initiatives aim to guarantee the active participation of society in the process of defining the new rules, promoting a broad and transparent debate.

By improving the pricing and readjustment policy, ANS seeks to promote positive impacts in the sector, highlighting aspects such as sustainability, clear and transparent rules, increased competition, more balanced regulation, improved quality of services and easier access to health plans. As 2025 progresses, the sector is expected to adapt to the anticipated changes, with further developments likely to emerge throughout the year.

What should change in the market in 2025?

New rules for payment default notifications

In December 2024, ANS approved the temporary suspension of the effectiveness of Normative Resolution No. 593, which establishes new rules for notifying health plans' beneficiaries of payment defaults. The decision, endorsed during the 616th Dicol Meeting, postpones the implementation of the new rules to February 1, 2025, providing an additional period for HMOs and beneficiaries to adapt to the changes.

The new rules aim to ensure that consumers are notified in the event of payment default, offering them the opportunity to regularize payment and avoid contract cancellation or exclusion from the health plan.

The rules apply to contracts for which the beneficiary is responsible for payment in the following cases: (i) individual or family health plans; (ii) collective corporate health plans established by individual entrepreneurs; and (iii) collective health plans for former employees, public servants, beneficiaries of self-management entities, or those who pay directly to a benefit maintenance organization.

One of the novelties brought in by the new rule are the forms of notification, which can be made by electronic means according to the data provided by the beneficiary to the HMO and contained in their record. Among the options are: e-mail with a digital certificate or read receipt confirmation; mobile text messaging; messaging through mobile device applications with encrypted communication; and recorded phone calls with data confirmation by the caller. However, notifications sent via SMS or mobile applications will only be considered valid once the recipient has replied, confirming receipt.

With the implementation of the new rules, ANS hopes to increase transparency and efficiency in communication between HMOs and beneficiaries, reducing the number of cancellations due to payment defaults and promoting a better relationship within the supplementary health sector.

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Opportunities

- **Regulations for self-management entities:** As one of the priority topics in the Regulatory Agenda for 2023-2025, ANS has been discussing the modernization of regulations applicable to self-management entities and has even launched TPS No. 3 to gather contributions from society on the subject. The initiative aims to provide greater clarity and transparency to the rules, as well as establishing the applicable regulatory obligations.

- **Impacts of the tax reform on health plan services:** Key considerations include (i) reduction of tax rates for certain healthcare services (e.g. surgical, gynecological, psychiatric services, etc.); (ii) differentiated regimes for entities that provide health plan-related activities; and (iii) tax exemptions for non-profit entities that provide health plan services in the form of a self-management entity, among others. These changes could have a direct impact on the costs and prices of health services and plans.

- **ANPD Regulatory Agency and health data:** In December 2024, the Brazilian Data Protection Authority (ANPD) published Resolution No. 23, which approved its Regulatory Agenda for 2025-2026. This agenda includes a specific item on the review of rules related to health data, which will consider the specificities of the Unified Health System (SUS) and the entities processing data in the sector, such as HMOs.

- **Open Health and health data interoperability:** The movement related to health data interoperability and the Open Health is gaining traction in the health sector. These initiatives aim to facilitate the secure sharing of information among different systems and agents, improving the coordination of care and the efficiency of services. The authorities are promoting discussions on the subject, which is expected to yield important developments in 2025.

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Points of attention

- **Presidential veto on the Clinical Research Law:** In 2025, Congress is expected to deliberate on whether to uphold or overturn the presidential veto on provisions of the Clinical Research Law (Law No. 14,874/2024), among them the five-year requirement for continuing to supply the drug free of charge after the study has ended.

- **Change in ANS' Presidency:** The end of 2024 marked the end of the term for ANS Director-President, Mr. Paulo Rebello. The President of the Republic published an order nominating Mr. Wadih Damous to hold the position. The Federal Senate still has to approve the President's nomination. In any case, the change indicates a possible strategic redirection for Brazil's supplementary health sector. While the Federal Senate is considering the nomination made by the Presidency of the Republic, Mr. Jorge Antônio Aquino Lopes will serve as interim president of ANS.

- **Changes in Anvisa's Presidency and Board of Directors:** Similarly, the end of 2024 marked the end of terms for Anvisa's president and directors. The President of the Republic published an order naming Mr. Leandro Pinheiro Safatle to the position of Director-President, Ms. Daniela Marreco Cerqueira to take over as Second Director, and Mr. Diogo Penha Soares to take over as Fifth Director on April 1, 2025 (when Mr. Alex Machado Campos' term ends). While the Federal Senate is considering the nominations made by the Presidency of the Republic, Mr. Rômison Rodrigues Mota will serve as interim president of Anvisa.

- **Health Plans Bill of Law:** Scheduled for consideration in 2025, Bill of Law 7,419/2006 proposes significant changes to the legislation applicable to health plans. The text is facing widespread mobilization from agents in the sector and consumer protection entities and could redefine the relationship between HMOs and beneficiaries.

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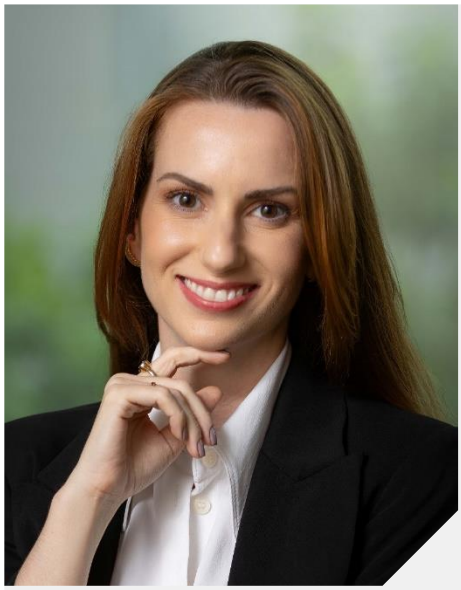
- **Fraud in health plans:** The rising of fraud against health plans has increasingly worried Brazil's supplementary health sector. In 2024, several cases were investigated, financially impacting both HMOs and beneficiaries. For 2025, it is expected that stricter measures will be implemented to control and combat fraud, including the use of technology, in addition to greater integration between agents in the sector, ANS and other authorities to identify irregularities, as well as intensified inspection and punishment actions to combat this practice and protect HMOs and consumers.

- **Co-payment in collective corporate health plans:** In the context of case IncJulgRREmbRep-1001740-49.2019.5.02.0318, TST is discussing whether shifting health plans funding to a co-payment model characterizes a harmful change for employees who were already entitled to the benefit. The decision, under the repetitive appeals system, will set a binding precedent, which could affect the costs of this benefit for the companies that offer it.

- **CPI and cancellation of health plans:** The increase in unilateral cancellations of health plan contracts has prompted a Parliamentary Inquiry Commission (CPI) request in the Chamber of Deputies, as well as the conduction of administrative proceedings by consumer protection authorities and the signing of agreements between agents in the supplementary health sector and government authorities during 2024. Due to its relevance, the issue is likely to suffer new developments in 2025.

- **Single Agency and incorporation of health technologies into ANS List:** The debate on the creation of a Single Agency for Health Technology assessment (HTA) has been gaining momentum. The proposal seeks to unify the efforts of ANS List Update Commission (Cosaúde) and SUS Commission for the Incorporation of Health Technologies (Conitec). In 2025, even if not all the agents involved are on board, this initiative may move forward, directly impacting the process of incorporating health technologies into the public and supplementary health system.

What does our partner say?



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Throughout 2024, we witnessed intense debates and crucial definitions shaping the Brazilian health sector, laying the groundwork for a 2025 filled with opportunities and challenges. On the regulatory front, several milestones and updates were approved, and the sector must remain vigilant in adapting quickly to these changes. 2025 promises to be decisive for the health sector, with significant administrative, legislative, and judicial developments that could redefine market dynamics.

The implementation of regulatory sandboxes, the establishment of rules for discount cards, the reformulation of the pricing and readjustment policy for health plans, and updates to outpatient health plans regulations, among other key topics, are expected to deeply impact the sector's regulatory and economic framework.

In addition, the enforcement of regulations on hospital networks changes and payment default notifications, for instance, underscores the constant need for adaptability and compliance among stakeholders. In this context, companies and professionals must be prepared to identify and seize opportunities, as well as face challenges, structuring solutions that align innovation, sustainability, and legal certainty."

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