WEEKLY REPORT

08/08/2026

BRAZIL'S PUBLIC PROSECUTOR CALLS FOR FULL TRACEABILITY OF FEDERAL HEALTH FUNDS

Brazil's Federal Public Prosecutor's Office (MPF) has recommended that the Ministries of Health, Finance, and Management and Innovation implement mechanisms to track federal health funds through to their final recipients. The recommendation seeks to increase transparency in the transfer and use of public resources, including funds subsequently passed on to social organizations (OSs) and other third-sector entities. The MPF requested that the ministries submit, within 60 days, a detailed report on measures adopted to ensure traceability, including a plan to organize transfers through Transferegov.br, the federal government's platform for managing public fund transfers. The recommendation also calls for the completion of regulatory procedures and implementation of the mechanisms within 90 days. The proposed system should allow real-time disclosure of transfers and subsequent sub-transfers to social organizations, identifying beneficiaries by CPF or CNPJ, amounts paid, the purpose of each contract and supporting documentation for expenditures. Read more.

BRAZIL DEFINES NATIONAL NEGOTIATION RULES FOR ONCOLOGY DRUGS

Brazil's Ministry of Health has established the rules for the national negotiation of oncology medicines under the Oncology Pharmaceutical Assistance Component (AF-Onco). A joint ordinance published on August 6 defines procedures for procurement, federal financing, reimbursement to states, annual demand planning and monitoring of medicine dispensing. Under the new model, oncology services will estimate their annual medicine requirements and submit the data to state health departments, which will consolidate the information and forward it to the Ministry of Health. The federal government will then define quantities for national negotiations and establish price-registration agreements, which will serve as a reference for state purchases. A transition period will apply through December 31, 2026, during which the Ministry will centrally purchase the equivalent of one-quarter of the estimated annual demand for medicines covered by national negotiation. From the first quarter of 2027, financing and reimbursement will be based on records in the AF-Onco prior-authorization and pharmaceutical-assistance management systems. The national negotiation model is one of three procurement mechanisms under AF-Onco and follows the government's July designation of 18 very-high-cost oncology medicines to be acquired through national negotiation or centralized procurement. Read more.

12.7% OF ONCOLOGY THERAPIES ON OFFICIAL LISTS ARE UNAVAILABLE IN BRAZIL'S SUS, INTERFARMA FINDS

A survey by the Association of the Research-Based Pharmaceutical Industry (Interfarma) found that 12.7% of oncology therapies included in official Brazilian government lists are currently unavailable to patients through the Unified Health System (SUS). The analysis highlights a gap between the formal incorporation or listing of medicines and their effective availability within the public healthcare network. According to the study, the presence of a medicine on an official list does not necessarily translate into access for patients. The finding adds to ongoing concerns over delays in implementing decisions on oncology technologies and completing the regulatory and procurement steps required to make treatments available at healthcare facilities. The issue is particularly relevant as the Ministry of Health continues to implement the Oncology Pharmaceutical Assistance Component (AF-Onco), which is reorganizing the financing,

procurement and distribution of cancer medicines in the SUS. The analysis comes amid a broader restructuring of oncology pharmaceutical assistance. In July, the Ministry of Health formally classified 18 medicines as very-high-cost oncology therapies, establishing criteria for centralized procurement or national negotiations coordinated by the federal government. The list includes immunotherapies, targeted therapies and monoclonal antibodies used to treat several major cancers. Read more.

BRAZIL'S HEALTH MINISTRY LAUNCHES FREE COURSES TO STRENGTHEN EARLY CANCER DETECTION IN PRIMARY CARE

Brazil's Ministry of Health has opened enrollment for seven free online courses designed to train primary healthcare professionals and managers in the early detection of cancer. The initiative is part of the Detecta APS Project, developed in partnership with Hospital Israelita Albert Einstein and Hospital Alemão Oswaldo Cruz through the Support Program for Institutional Development of the Unified Health System (Proadi-SUS). The courses cover organized screening, recognition of signs and symptoms of cancer, population-based management, prevention of risk factors and monitoring of screening programs, with specific training on cervical and breast cancer. One 40-hour course, focused on management strategies for early cancer detection in primary care, had remaining places available until August 7, while the other six self-guided courses remain open indefinitely. The program is intended to support implementation of national guidelines for early cancer detection and strengthen coordination across Brazil's healthcare networks. Read more.

BRAZIL LAUNCHES NATIONAL TRAINING PROGRAM TO EXPAND RARE DISEASE DIAGNOSIS IN SUS

Brazil's Ministry of Health has launched a national training program to expand access to genomic medicine and improve the diagnosis of rare genetic diseases through the Unified Health System (SUS). Developed in partnership with the Oswaldo Cruz Foundation (Fiocruz), the 160-hour course began on August 3 and will train professionals working in SUS-authorized Rare Disease Reference Services. The program has 70 participants and covers genetic diseases, clinical genomics, and the analysis and interpretation of genomic tests. The training will run through February 2027, combining synchronous and asynchronous classes. The initiative is intended to strengthen the technical capacity of specialized services across Brazil and increase access to more precise genetic diagnoses. The Ministry estimates that around 13 million Brazilians live with a rare disease, with approximately 70% of these conditions having a genetic origin. Genomic testing can help identify disease-causing DNA alterations, support more accurate diagnoses, guide treatment decisions and provide genetic counseling to families. The initiative represents another step toward expanding precision medicine within the SUS and strengthening the country's infrastructure for rare disease care. Read more.

NEW GUIDELINES INCREASE REQUIREMENTS FOR PATIENTS IN HEALTH LITIGATION

More than half of the new or amended guidelines issued by Brazil's National Forum for Health Judiciary (Fonajus) impose additional requirements on patients seeking healthcare through the courts, according to an analysis by JOTA. The review of 176 guidelines issued by the National Council of Justice (CNJ), including revoked provisions, found that 52.5% of the new or modified texts have a restrictive nature. The analysis indicates that the recent guidelines increasingly seek to establish criteria that patients must meet before requesting judicial intervention, particularly in cases involving medicines and healthcare technologies. The movement reflects an effort to strengthen the technical and evidentiary basis of health litigation and reduce judicial decisions based solely on medical prescriptions or individual claims. The development is relevant to the pharmaceutical industry because Fonajus guidelines influence how judges assess requests for medicines, treatments and health technologies, potentially affecting litigation strategies and access to products that have not been incorporated into the Unified Health System (SUS). The trend also reinforces the importance of technical evidence and documentation in disputes over access to healthcare. Read more.

DISCOUNT HEALTH CARD MARKET FACES REGULATORY UNCERTAINTY AS ANS SEEKS INDUSTRY INPUT

Brazil's National Supplementary Health Agency (ANS) is moving forward with plans to regulate the country's growing market for discount health cards, prepaid cards and similar services, but limited participation from companies has raised concerns about the agency's ability to fully understand the sector before establishing new rules. Only 11 companies submitted contributions to the public call, prompting ANS to extend the deadline to August 18. The products typically provide discounted access to consultations, diagnostic tests, medicines and other health services in exchange for a membership fee or monthly payment. The market is estimated to reach around 60 million users, particularly among lower-income consumers who may not have private health insurance and face longer waiting times within the SUS. However, the sector currently lacks specific regulation and official data on its size and operations. The ANS initiative follows a Superior Court of Justice (STJ) ruling confirming the agency's responsibility to regulate and supervise the market. Read more.

ANS TO REGULATE DISCOUNT HEALTH CARDS, SAYS PRESIDENT WADIH DAMOUS

The National Supplementary Health Agency (ANS) will move forward with regulating health discount cards following a Superior Court of Justice (STJ) decision requiring oversight of the sector, according to ANS Director-President Wadih Damous. The agency has extended until August 18 the deadline for companies to provide information about their business models, after concerns that some questions in the initial questionnaire could lead to their classification as health insurance operators. Damous said the ANS will use the information collected to build a database on a market estimated to serve between 40 million and 60 million users. The agency plans to hold public hearings, consultations and, if necessary, public calls for input before defining the regulatory framework. He stressed that the rules will take into account the sector's specific characteristics. The ANS president also said health insurers will not be prohibited from offering discount cards, but the two businesses will have to remain clearly separated, including through different corporate registrations and brands, with no tied sales. Damous also defended greater coordination among the ANS, Brazilian Health Regulatory Agency (Anvisa), Drug Market Regulation Chamber (CMED) and National Committee for Health Technology Incorporation (Conitec) to address health litigation, rather than creating a single health technology agency. Read more.

ANVISA SEEKS TO CLEAR REGULATORY BACKLOGS BY YEAR-END, SAYS DIRECTOR-PRESIDENT

The Brazilian Health Regulatory Agency (Anvisa) expects to eliminate all major regulatory backlogs by the end of 2026, according to Director-President Leandro Pinheiro Safatle. In an interview with Veja, Safatle said the agency implemented 125 initiatives and a daily monitoring task force to address long-standing queues involving medicines, medical devices, pesticides, food and other regulated products. Anvisa recorded a record first half in terms of evaluations and productivity, with some backlogs already eliminated. Safatle said the agency regulates activities representing approximately one-quarter of Brazil's GDP, making regulatory efficiency strategically important for the economy. He also identified the regulation of health innovation as a growing challenge, particularly personalized and high-cost medicines and medical devices that do not fit easily into traditional regulatory categories. He highlighted the increasing innovation capacity of Brazilian pharmaceutical companies, including the development of biosimilars and novel products. The director-president also addressed the agency's intensified inspections of compounding pharmacies and irregular weight-loss pens imported from Paraguay. Read more.

BRAZILIAN COURTS REJECT NOVO NORDISK APPEALS AND KEEP EMS SEMAGLUTIDE PEN ON MARKET

Brazilian courts have rejected two new appeals by Novo Nordisk in separate disputes involving Ozivy, a semaglutide-based medicine developed by EMS, allowing the product to remain on the

market for now. The decisions were issued by the Federal Regional Court of the 2nd Region (TRF-2) and the Rio de Janeiro State Court (TJ-RJ), which found that Novo Nordisk's claims require further evidence and do not justify urgent measures against the product. In the federal case, Novo Nordisk argued that the name Ozivy improperly combines elements of "Ozempic" and "Wegovy," its own semaglutide brands, and sought suspension of the trademark registration. The TRF-2 upheld the lower court's decision, noting that the trademark registered with Brazil's National Institute of Industrial Property (INPI) carries a presumption of legitimacy and that the dispute requires a more detailed technical and evidentiary assessment. In a separate lawsuit before the TJ-RJ, Novo Nordisk alleged unfair competition, trade-dress infringement and parasitic exploitation, arguing that EMS reinforced the association with its products by marketing Ozivy as the "blue pen of Brazil." Novo Nordisk also claimed that EMS promoted Ozivy for weight control despite its authorization being limited to type 2 diabetes. Read more.

ANVISA COULD APPROVE EIGHT MORE WEIGHT-LOSS PENS BY YEAR-END

Brazil's National Health Regulatory Agency (Anvisa) could approve up to eight additional registrations of injectable weight-loss medicines by the end of 2026, according to the agency. The expected expansion of the market is part of Anvisa's efforts to increase the availability of regulated GLP-1 treatments and reduce demand for irregular products imported from Paraguay. The agency has been accelerating the analysis of applications for new weight-loss products amid rapidly growing demand for GLP-1 therapies in Brazil. Increased competition is expected to expand treatment options and potentially contribute to lower prices, while strengthening the distinction between products approved in Brazil and irregular versions circulating in the market. The development comes as Anvisa intensifies measures against unauthorized weight-loss pens from Paraguay, whose composition, concentration and manufacturing conditions cannot be guaranteed by the Brazilian regulator. The agency has also indicated that greater availability of registered products is an important element in addressing the growth of the irregular market. For the pharmaceutical industry, the expected approvals point to a significant expansion of Brazil's obesity-treatment market, with implications for competition, pricing, market access and regulatory capacity as demand for GLP-1 therapies continues to grow. Read more.

BRAZIL'S SUS DOES NOT YET PROVIDE WEIGHT-LOSS PENS FOR OBESITY TREATMENT

Brazil's Unified Health System (SUS) does not currently provide any injectable weight-loss medication for the treatment of obesity. The Ministry of Health is seeking to accelerate the registration of new medicines with the Brazilian Health Regulatory Agency (Anvisa) and is evaluating whether GLP-1 therapies could eventually be incorporated into the public healthcare system. The main barrier is that no anti-obesity medication in this class has been incorporated into the SUS's list of publicly funded treatments. Incorporation requires an assessment by the National Committee for Health Technology Incorporation (Conitec), followed by a decision by the Ministry of Health. The process considers clinical efficacy and safety, but also the economic impact and feasibility of providing the treatment on a large scale. The scenario could change as competition increases in Brazil. The patent for semaglutide expired earlier this year, potentially opening the market to additional manufacturers and lower-cost versions. Read more.

BRAZILIAN DOCTORS SPLIT OVER WHETHER TO TREAT PATIENTS USING PARAGUAYAN WEIGHT-LOSS PENS

Brazilian physicians are divided over whether to continue monitoring patients who use weight-loss pens purchased illegally in Paraguay and lacking sanitary registration in Brazil. While some doctors fear ethical and legal liability for adverse events involving products whose composition, concentration, origin and storage conditions cannot be guaranteed, others defend continued medical supervision as a harm-reduction strategy. Brazil's medical councils say both approaches can be ethically acceptable. The issue has gained prominence as the use of Paraguayan versions of tirzepatide and other GLP-1 drugs expands in Brazil. The Brazilian

Society of Endocrinology and Metabolism (SBEM) has physicians who refuse to monitor patients using unregistered products, while others recommend switching to medicines approved by the Brazilian Health Regulatory Agency (Anvisa). The Brazilian Federal Council of Medicine (CFM) says physicians may refuse treatment when they consider the product a health risk, while the Regional Medical Council of São Paulo (Cremesp) says doctors who discontinue care must do so ethically, ensuring continuity of assistance and informing patients about the risks. Read more.

BRAZIL'S COMPOUNDING PHARMACY MARKET REACHES R$13.2 BILLION IN REVENUE

Brazil's compounding pharmacy sector generated R$13.2 billion in revenue in 2025, representing real growth of 29.3% over the period analyzed, according to the Panorama Setorial 2026. The sector ended the year with 9,320 establishments, an 11.1% increase over five years, while tax revenues reached a record R$1.82 billion. The study, prepared by the Brazilian Association of Magistral Pharmacies (Anfarmag) in partnership with the Brazilian Institute of Tax and Planning (IBPT), also points to increasing regional expansion. Some 75.5% of new pharmacies opened over the past two years were located in Brazil's North and Northeast regions, indicating continued expansion of personalized medicines beyond major urban centers. Employment also grew, with the number of formally employed professionals rising 13.2% to 69,300 over five years. The sector is also undergoing technological transformation, with artificial intelligence and 3D printing emerging as tools for greater treatment personalization, production efficiency and therapeutic precision. At the same time, the Federal Council of Pharmacy (CFF) emphasized the need for evidence-based regulation and effective sanitary oversight, while highlighting the role of compounding pharmacies in providing individualized therapies. Read more.

BRAZIL'S MEDICINE MARKET EXPECTED TO REACH R$257.8 BILLION IN 2026

Brazil's potential consumer spending on medicines is expected to reach R$257.8 billion in 2026, a 7.9% increase from R$238.9 billion in 2025, according to data from IPC Maps. The study also estimates that the country will have approximately 127,000 pharmacies this year, 3.2% more than in 2025. The Southeast will account for the largest share of potential medicine consumption, at R$131.1 billion, followed by the South (R$48 billion) and Northeast (R$44.2 billion). The Center-West recorded the strongest projected growth, with potential spending increasing 11.5% year-on-year to R$23.1 billion. São Paulo alone leads the national ranking, with estimated annual medicine consumption of R$72.9 billion. The expansion of the pharmacy network is also notable, with nearly 4,000 new establishments added nationwide over the past year. The data point to continued growth in Brazil's pharmaceutical retail market, supported by increasing consumer demand and the expansion of access points for medicines. Read more.

ANVISA REVOKES BAN AND ALLOWS DRUGSTORES TO SELL MEDICINES THROUGH SHOPEE

Brazil's National Health Regulatory Agency (Anvisa) has revoked a preventive measure that had prohibited the advertising and sale of medicines on Shopee since 2022. The decision, formalized through Resolution-RE No. 3,056/2026, follows the entry into force of Law No. 15,357/2026, which expressly allows licensed pharmacies and drugstores to use digital channels and e-commerce platforms for the sale, logistics and delivery of medicines. The change does not amount to unrestricted authorization for medicine sales on the platform. Only medicines duly regularized with Anvisa and sold by pharmacies and drugstores holding the required sanitary licenses may be offered. The decision marks a regulatory shift for Brazil's pharmaceutical e-commerce market, aligning Anvisa's rules with the new legal framework. It could expand the digital reach of licensed pharmacies while maintaining sanitary requirements and regulatory oversight over online medicine sales. Read more.

STUDY IDENTIFIES 49 UNETHICAL PRACTICES ACROSS BRAZIL'S HEALTHCARE SECTOR

A study by the Institute for Health Ethics (IES) and the Public Procurement Research Group at the Pontifical Catholic University of São Paulo (PUC-SP) identified 49 unethical practices across Brazil's healthcare system. The behaviors include bid-rigging and procurement fraud, conflicts of interest, improper payments, abusive denials by health insurers, diversion of public funds, unauthorized sales of products without sanitary registration, and misuse of data and artificial intelligence. Public authorities and the supplementary health sector ranked highest, with nine practices each, followed by conflicts of interest, with eight. Regulatory and sanitary issues accounted for four practices, while billing and taxation, professional ethics, administrative fraud and social organizations each accounted for three. The study concludes that unethical conduct is rarely isolated and is frequently associated with governance weaknesses, inadequate controls, conflicts of interest and inappropriate economic incentives. Read more.

BRAZILIAN COURT SUSPENDS MEC SANCTIONS AGAINST POORLY RATED MEDICAL SCHOOLS

A Federal Court has temporarily suspended sanctions imposed by Brazil's Ministry of Education (MEC) on medical schools that received insufficient results in the National Examination for the Assessment of Medical Training (Enamed). The preliminary decision, issued by the president of the Federal Regional Court of the 1st Region (TRF-1), Maria do Carmo Cardoso, overturned a previous ruling that had upheld the government's use of Enamed results as a basis for sanctions. The decision followed requests from the Brazilian Association of Higher Education Institution Maintainers (ABMES) and the Brazilian Association of Colleges (Abrafi). Of the 350 medical programs evaluated in the latest Enamed results, 107 received scores of 1 or 2, considered insufficient. Government supervision and penalties apply to 99 programs, 87 of them at private institutions. The sanctions included restrictions on new student admissions and other regulatory measures. The suspension is provisional and does not end the supervision process. The Ministry of Education has said it will appeal the decision. Read more.

BRAZIL'S CFM EXPANDS RULES ON PHYSICIANS' CONFLICT-OF-INTEREST DISCLOSURES

Brazil's Federal Council of Medicine (CFM) has expanded transparency requirements for physicians, requiring them to disclose to their respective Regional Medical Council (CRM) professional ties with medical entities, including specialty societies, associations and federations. The information will be made available through a dedicated CFM platform. Under Resolution No. 2,463/2026, published in the Official Gazette on July 30, participation in the production or dissemination of technical content that may affect medical practice is now explicitly considered a professional link. The resolution also defines a conflict of interest as a relationship maintained within the 12 months preceding a technical activity or institutional statement. The new rules amend Resolution No. 2,386/2024, which established transparency requirements for physicians' ties to pharmaceutical, medical supply and medical equipment companies. Read more.

MORE HIGHLIGHTS

Anvisa opens regulatory review of advertising rules for food and medicines

Anvisa warns of risks from improper testosterone use in women

Anvisa opens new regulatory assessment program for innovative medical devices

Anvisa begins implementing rules following court decision on cannabis cultivation

Brazilian interest in health shifts from fitness to medicines, study finds

Study finds no conclusions yet on polylaminin's efficacy for spinal cord injuries

BRAZIL NEWS

Lula leads Bolsonaro but gap narrows ahead of Brazil election, poll shows

Brazilian presidential candidate Bolsonaro names surprise running mate

Brazil cuts rates by 25 bps again, September rate cut in play

Brazil bank CEOs back further easing after fourth straight rate cut

Brazil tightens crypto transfers to curb fraud

Brazil downgrades diplomatic ties with Argentina after Milei insults Lula

Argentina will not act over Brazil diplomatic ties downgrade

US revokes visa of Brazilian ambassador over diplomatic dispute