# WEEKLY REPORT



#### 06/28/2025

### ORGANIZATIONS CELEBRATE THE OVERTURNING OF THE VETO ON THE LAW ABOUT CLINICAL TRIALS INVOLVING HUMAN BEINGS

The overturning on Tuesday (17/6) of the presidential veto on the five-year period for supplying medicines to participants in Clinical Trials (Law 14.874/2024) will contribute to attracting more investments to the country, according to representatives of the pharmaceutical sector. "The stipulated time considers the individual medical needs of each participant. This way, treatment is guaranteed to the patient," said Renato Porto, CEO of the Research Pharmaceutical Industry Association (Interfarma), in a statement. <u>Read more</u>.

#### **GENETIC DIVERSITY IN BRAZIL ATTRACTS INVESTORS FOR CLINICAL TRIALS**

The national clinical research market, which generates R\$11 billion annually, has the potential to receive new investments of R\$5 billion per year. There is a growing interest from local and foreign investors in carrying out these studies in Brazil, especially Chinese pharmaceutical companies, which have been gaining ground and have already surpassed the United States in the volume of clinical studies, according to the Brazilian Association of Clinical Research Representative Organizations (Abracro). However, the arrival of these investments still depends on the removal of some regulatory barriers. There is a global interest in conducting clinical research in Brazil because the country has a population of 200 million people with the greatest genetic variety in the world - which was proven in research led by scientists from USP published in the journal "Science" last month. <u>Read more</u>.

## ANVISA PUBLISHES THE 8TH ANNUAL REPORT ON CLINICAL RESEARCH OF MEDICINES AND BIOLOGICAL PRODUCTS

On Tuesday (24/6), Anvisa published the 8th Annual Report of Activities in the Clinical Research area. The document presents in numbers, in a broad and detailed manner, the main activities related to clinical research of medicines and biological products carried out in the year 2024. The publication presents data on primary and secondary petitions for clinical trials authorized during the period. In addition, it provides relevant information on the time elapsed between the authorization granted by the Agency and the actual start of clinical trials, as well as on the distribution of centers and investigators in Brazil. Clinical trials for rare diseases and programs for assistance access to experimental drugs are also highlighted. <u>Read more</u>.

### ANS SETS A 6.06% CEILING FOR READJUSTMENT OF INDIVIDUAL AND FAMILY HEALTH PLANS

The National Supplementary Health Agency (ANS) limited to 6.06% the annual adjustment percentage that may be applied to regulated individual and family medical assistance health plans (contracted from January 1, 1999, or adapted to Law No. 9,656/98). The percentage is the ceiling valid for the period between May 2025 and April 2026 for contracts of approximately 8.6 million beneficiaries, which represents 16.4% of the 52 million consumers of health care plans in Brazil (data from April 2025). <u>Read more</u>.

#### HEALTH PLANS COULD REDUCE R\$4 BILLION IN DEBTS IF THEY OFFER CONSULTATIONS, SAYS PADILHA

The Ministry of Health estimates that there are R\$9 billion in resources owed by health plans to the Unified Health System (SUS), of which around R\$4 billion could be used to care for

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patients through the "Agora tem Especialistas" program. In an exclusive interview with Estadão/Broadcast, the Minister of Health, Alexandre Padilha, states that the government will use the Reimbursement Valuation Index (IVR), which already exists, to determine the values of procedures and exams. "We will use the same index to avoid legal challenges. In some of the combos, the 'Agora tem Especialistas' table even pays a higher amount than the IVR." <u>Read</u> more.

### BRAZILIANS ARE MORE CONCERNED ABOUT EARLY DETECTION OF PROSTATE CANCER

Prostate cancer treatment generated costs of R\$625 million in outpatient expenses in the Unified Health System (SUS) in 2024, according to data collected by LifesHub, a company specializing in the use of artificial intelligence for data analysis. The amount was distributed across approximately 1.5 million procedures. Most of this amount (R\$491 million) was allocated to clinical treatments such as chemotherapy and specialized monitoring. Hospital care totaled 42.8 thousand records, a number well below the outpatient volume. <u>Read more</u>.

#### HEALTH LAUNCHES SUPER CENTER FOR CANCER DIAGNOSIS WITH FASTER REPORTS

The Minister of Health, Alexandre Padilha , announced, this Friday (27/6), the launch of the Super Center for Cancer Diagnosis which, with the use of cutting-edge technology, will reduce the time required to obtain medical reports for SUS (Unified Health System) patients from 25 to five days . The objective is to make this center responsible for accelerating the diagnosis of the disease in the SUS, being able to issue reports for the whole of Brazil. The launch is an initiative of the "Agora Tem Especialistas" program, which has oncology as one of its priorities. The new center will begin operations in July in an integrated national network focused on telemedicine and with the capacity to perform up to 1,000 reports per day and 400,000 per year. <u>Read more</u>.

### INCORPORATION OF TREATMENTS INTO THE SUS AND SUPPLEMENTARY HEALTH IS THE TARGET OF CRITICISM

Which medications and therapies should be guaranteed to SUS patients and health plan beneficiaries? The debate took a new direction in 2022, when two laws made the rules for incorporation into supplementary health more agile, bringing relief to patient associations, concern to operators and, more recently, triggering pressure for new changes. That year, the minimum list of products offered by supplementary health, the list of procedures, began to be linked to approvals by the National Commission for the Incorporation of Technologies into the Unified Health System (Conitec). With this change, a technology approved for the SUS must, within a period of up to 180 days, begin to be offered by health plans. Another change determined by the Legislature formalized the exemplary nature of the list: the list of products that must be offered is not limited to the items described; it is exemplary if certain conditions are met. <u>Read more</u>.

#### AFTER STF DECISION, 19.8% OF PATIENTS HAD THEIR TREATMENTS INTERRUPTED, SURVEY SHOWS

The Association of the Research Pharmaceutical Industry (Interfarma) is producing a survey on the impact of the decision by the Federal Supreme Court (STF) to establish stricter criteria for the supply of medicines not incorporated into the Unified Health System (SUS). Based on the new criteria, as of May 23, the entity's data indicate that 53.8% of patients continued with their guaranteed treatments, 26.3% of cases were characterized as denied, uncertain or pending supply, and 19.8% had their treatments provided by court order interrupted. A total of 2,052 lawsuits from 1st and 2nd instances were analyzed, with 3,259 requests for the supply of medicines. The lawsuits mention the decisions of theme 6, which defined stricter criteria for non-incorporated medicines, or theme 1234, which established which federative entity should pay for the medicines subject to legal proceedings. The data will be presented to the court in October, when the decision completes one year. <u>Read more</u>.

### MINISTRY OF HEALTH WILL PARTNER WITH CORREIOS TO EXPAND ACCESS TO THE HEEL PRICK TEST

Health Minister Alexandre Padilha announced this Thursday, the 26th, in São Paulo, that the federal government will promote a series of actions to expand the National Neonatal Screening Program (PNTN), increasing the performance of the heel prick test. The news was presented during the event "Health on the Right Path through Prevention", at the Jô Clemente Institute (IJC). According to the government, additional investments of around R\$30 million per year will be made — a 30% increase in current resources — with the aim of reducing the waiting time for test results. The actions will be detailed in a new ordinance, to be published in the coming days. Among the measures is the establishment of a direct contract with the Post Office for the transportation of samples collected in different regions, including the interior of the country and remote areas. The expectation is that the partnership will reduce the wait for diagnosis to up to five days, half the current time. R\$15.2 million will be invested to advance the logistics of distributing the results. <u>Read more</u>.

#### ORDINANCE PUBLISHED THAT REORGANIZES THE RULES OF THE NATIONAL NEONATAL SCREENING PROGRAM

Ordinance GM/MS No. 7,293/2025 was published in the Official Gazette of the Union this Friday (27), which redefines the National Neonatal Screening Program (PNTN) in the Unified Health System (SUS). The new regulation establishes a set of technical, operational and assistance guidelines that reinforce the scope, organization, and quality of the program throughout the country. <u>Read more</u>.

#### HOUSE OF REPRESENTATIVES HOLDS FORMAL SESSION IN HONOR OF NATIONAL HEEL PRICK TEST DAY

The Chamber of Deputies plenary held a formal session on Tuesday (24) in honor of National Heel Prick Test Day. The event was chaired by Representative Hildo Rocha (MDB-MA). Representatives from the Ministry of Health were not present at the session. <u>Read more</u>.

### IN THE ABSENCE OF MEDICAL RESIDENCIES, SPECIALIZATION COURSES ARE GROWING AND CAUSING CONCERN

With the number of medical schools growing at a faster rate than the number of medical residency vacancies, the market has seen an increase in the number of specialization courses offered to recent graduates as an alternative for those who want to pursue a specialty. The proliferation of this type of postgraduate course, however, has raised concerns among industry representatives, who see a lack of control over the quality and function of these programs. The Medical Demographics in Brazil 2025, prepared in partnership between the Ministry of Health, the Faculty of Medicine of the University of São Paulo (FMUSP) and the Brazilian Medical Association (AMB), showed that the accelerated growth of undergraduate medical courses in Brazil, especially in the private sector, was not accompanied by a proportional increase in places in medical residency programs — the main means of training specialists. <u>Read more</u>.

### AFTER ONE YEAR, THE NATIONAL PALLIATIVE CARE POLICY STILL HAS NO OFFICIALLY AUTHORIZED TEAMS

Created in May 2024, the National Palliative Care Policy represented a breakthrough in the provision of care aimed at improving the quality of life of patients with serious, chronic, or terminal illnesses. At least on paper. With just one year completed, its implementation is progressing slowly. To date, no palliative care team has been officially authorized by the federal government, according to Futuro da Saúde. In September of last year, the Ministry of Health regulated the registration of teams through Ordinance SAES/MS No. 2,085, which also added specific procedures to the SUS table. The following month, eleven states had already requested the authorization of matrix and assistance teams. Today, according to the general coordinator of Home Care and Palliative Care of the ministry, Mariana Borges Dias, all states have made the request, which has already been analyzed and approved by the technical area. The

expectation is that the first qualifications will take place this year. Dias said that the Ministry is working to eliminate the barriers but did not specify what they would be. <u>Read more</u>.

#### MORE HIGHLIGHTS

Congressman requests public hearing to discuss budget cuts in Regulatory Agencies

PCDT Rosa completes six months with gaps in access to treatments through the SUS

Anvisa hosts 3rd Workshop on Biological and Biosimilar Products

HPV policy to combat the virus goes to sanction

**BRAZIL NEWS** 

Brazil government begins legal analysis to challenge tax-hike reversal

Brazil central bank plans to hold rates steady even though inflation target not within reach

Brazil central bank sees rate cut debate as premature, says official

Brazil posts narrower-than-expected May primary deficit on strong revenue, lower spending

Brazil corn ethanol boom covers demand as country hikes biofuel mandate

Brazil power regulator warns of potential shutdown due to budget cuts

**IDB approves \$2 billion credit line for Brazil** 

Brazil says Japan, 16 others removed bird flu-related trade restrictions