

WEEKLY REPORT

12/07/2024



ANVISA PRESENTS PROPOSAL ON NEW RULES FOR THE CHAMBER FOR DRUG MARKET REGULATION

On Tuesday (3), Anvisa held a public hearing in Brasília to present the proposal to revise the Internal Regulations of the Chamber for Drug Market Regulation (CMED), as well as to make a specific change to Resolution CMED 2, of March 5, 2004. The presentation was led by CMED's executive secretary, Daniela Cerqueira. A public consultation on the topic was opened, with a deadline for submitting suggestions. The new proposal prepared by the Working Group of the CMED Executive Technical Committee (CTE/CMED) aims to: Update the competencies and attributions of the bodies that make up the CMED; Regulate the representation of the bodies, the organization and functioning of the meetings; Bring more predictability to the CMED's rites and procedures; Introduce modernity, agility and improved governance to the administrative processes under its jurisdiction; Optimize the work carried out by the Executive Secretariat (SCMED), in synergy with the Technical-Executive Committee (CTE) and the Council of Ministers (CM); and Ensure legal certainty in dealing with issues under the jurisdiction of the CMED. [Read more.](#)

ANVISA OPENS CONSULTATION TO REVIEW RULES FOR PRIORITY DRUG REGISTRATION

The National Health Surveillance Agency (Anvisa) will hold a public consultation to discuss the review of the Collegiate Board Resolution (RDC) No. 204, of December 27, 2017, which provides for the classification in the priority category of petitions for registration, post-registration, and prior consent in clinical research of medicines. According to the agency, the current rules are outdated and have failed to generate gains in the evaluation of medicines, such as reducing the time required for analysis. Anvisa is also seeking to adapt the rules to the needs of new technologies. "Many medicines are not covered by the current rules and, even if they are, as in the case of biologicals, the current demand is so high that requests are not evaluated quickly," highlighted Meiruze Freitas, the director responsible for the matter. [Read more.](#)

ANVISA DIRECTOR ACCUMULATES DIRECTORSHIPS AND UNION SEES A VIOLATION OF THE LAW

On November 22, Anvisa (the Brazilian Health Regulatory Agency) approved a resolution that determines that Daniel Meirelles will hold two of the agency's five directorships. The maneuver is an affront to the agency's law, according to the union. Since that date, Meirelles has simultaneously held the third directorate, responsible for areas such as health products, medical devices, toxicology, and tobacco, and the fifth directorate, which deals with health control at ports, airports and borders and in the area of controlled products, such as cannabis. [Read more.](#)

CANCELLATION OF HEALTH INSURANCE CONTRACTS DUE TO NON-PAYMENT HAS NEW RULES

The National Supplementary Health Agency (ANS) announced that new rules for notifying health plan beneficiaries of non-payment are now in effect. According to the regulation that came into effect on Sunday, December 1, in new contracts signed, the user may only have the plan canceled due to default if he or she fails to pay at least two monthly installments, consecutive or not. [Read more.](#)

LISTED FOR ANS, HEAD OF SENACON CALLS HEALTH INSURANCE COMPANIES TO A MEETING IN BRASÍLIA

Listed to take over as CEO of the National Supplementary Health Agency (ANS), the current National Consumer Affairs Secretary, Wadih Damous, has been involved in the sector's agendas. This week, the secretary invited the National Supplementary Health Federation, an entity that brings together health insurance companies, to a face-to-face meeting in Brasília on December 10. The agenda is the significant increase in cancellations and unilateral terminations of health insurance contracts, an issue that falls under the regulatory agency's authority. [Read more.](#)

SENATE PASSES BILL EXEMPTING MEDICINES FROM IMPORT TAX

The Senate Plenary approved, this Wednesday (4), the bill that allows the Ministry of Finance to eliminate the Import Tax rates for medicines under the Simplified Taxation Regime (RTS). The limit for exemption is 10 thousand dollars (around R\$ 60 thousand), for imports by individuals for their own or individual use. [Read more.](#)

SENATE PASSES BILL ESTABLISHING THE NATIONAL CARE POLICY

The Federal Senate passed the National Care Policy this Thursday (5/12), in the Plenary. The approved proposal was reported by Senator Paulo Paim (PT/RS) and now awaits presidential sanction. The Minister of Development and Social Assistance, Family and Fight Against Hunger, Wellington Dias, celebrated the historic milestone of the approval of the law, which has been in the works since the beginning of the current administration of the Federal Government. [Read more.](#)

AGING POPULATION WILL INCREASE DEMAND FOR HEALTH SPENDING, BRAZILIAN TREASURY PROJECTS

The increase in the number of elderly people in the Brazilian population will increase the demand for health spending in the Federal Budget, while the reduction in the number of young people tends to reduce the pressure for resources for education, estimates the National Treasury. The technical body simulated the effect of population dynamics on the trajectory of expenditure in these two areas, considering projections from IBGE (Brazilian Institute of Geography and Statistics). By 2034, there will be an accumulated demand of R\$67.2 billion in additional healthcare, in 2023 values. In education, this value would be negative by R\$23 billion—which does not necessarily mean a cut, but rather the possibility of a smaller expansion of these expenditures. The net effect on the Budget would be R\$44.2 billion in the period. [Read more.](#)

10,000 PATIENTS WITH PROSTATE CANCER PER YEAR DO NOT HAVE ACCESS TO RADIOTHERAPY IN THE SUS

According to data from the Ministry of Health and DataSUS, analyzed by the Brazilian Society of Radiotherapy (SBRT), Brazil has 71 thousand cases of prostate cancer in the country per year, with 75% of these patients relying exclusively on the SUS for treatment, that is, more than 53 thousand patients diagnosed with a malignant tumor in the prostate seek the public network. Radiotherapy is usually indicated in 60% of cases, which means that more than 32 thousand people should be undergoing treatment in the SUS, but this is not the case, as only 22,541 underwent radiotherapy for prostate cancer in 2023 in the Unified Health System (SUS). [Read more.](#)

GOVERNMENT ANNOUNCES MEASURES TO COMBAT RACIAL INEQUALITY IN THE SUS

The Ministers of Health, Nísia Trindade, and Racial Equality, Anielle Franco, announced a package of measures focusing on ethnic-racial diversity within the SUS (Unified Health System). The actions include professional qualification and reserving places in healthcare for black people, indigenous people, quilombolas and people with disabilities, in addition to the expansion of the Mais Médicos program in vulnerable territories and an initiative to reduce maternal mortality among black women by 50% by 2027. [Read more.](#)

MORE HIGHLIGHTS

[Responding to health emergencies requires coordinated action and leadership from the Ministry of Health, says Nísia Trindade](#)

[Ordinance creates working group to monitor the implementation of the Cancer Prevention and Control Network in the SUS](#)

[Ministry of Health has a new protocol that incorporates five procedures for breast cancer in the SUS](#)

[Epilepsy patients go to court over approved therapy that is unavailable on the SUS](#)

BRAZIL NEWS

[EU, Mercosur heave free trade deal over the line but potential obstacles loom large](#)

[What's in the newly finalized EU-Mercosur trade accord?](#)

[South American farmers hail Mercosur-EU deal, wary of fine print](#)

[Planned EU-Mercosur deal is unacceptable, says Elysee](#)

[EU delays deforestation ban but discards changes](#)

[Soy traders push to weaken ban on buying from deforested Amazon](#)

[Brazil's Treasury forecasts \\$3.3 bln deficit in 2024](#)

[Brazil to seek corporate income tax adjustment in 2025, official says](#)

[Brazil central bank to step up rate hike campaign on Dec. 11](#)

[Brazil charges Volkswagen unit with treating farm workers like slaves decades ago](#)

[Brazil's Workers Party out of touch with society, says likely new leader](#)

[Brazilian abortion activist had to go abroad to end pregnancy](#)