Life Sciences and Healthcare

Newsletter

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Anvisa approves new National Program for Prevention and Control of Infections in Healthcare Services

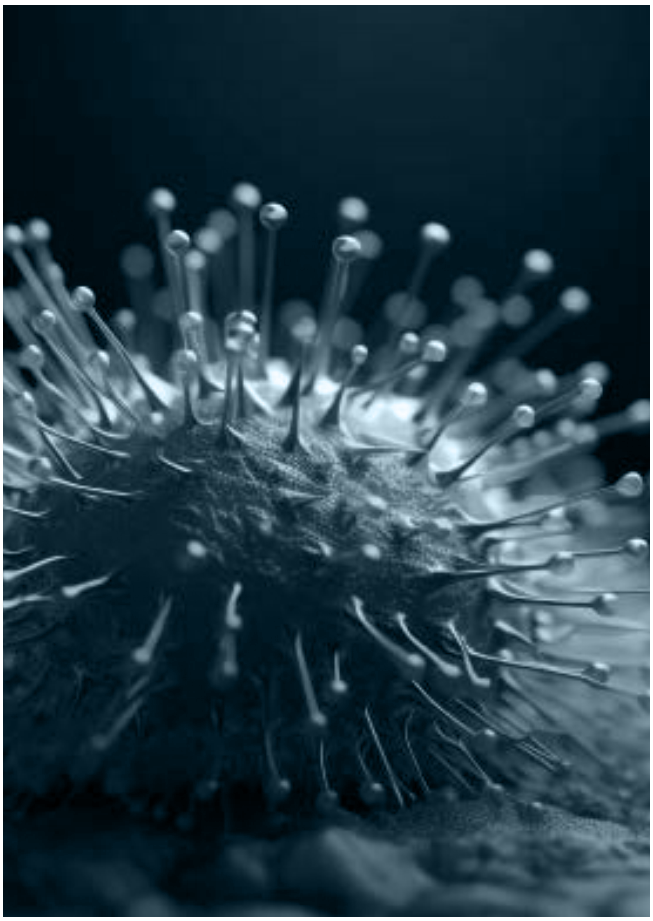
The National Health Surveillance Agency (Anvisa) approved, in February 2026, the National Program for Prevention and Control of Healthcare-Associated Infections (PNPCIRAS, in Portuguese), as well as the Integrated Plan for Health Surveillance Management of Patient Safety in Healthcare Services.

Both projects establish, for the period from 2026 to 2030, general or specific objectives, goals, indicators, and strategic-operational plans, as well as align with the guidelines of the World Health Organization (WHO) and the National Patient Safety Program of the Ministry of Health, respectively.

The main objectives of PNPCIRAS are to promote and implement programs for prevention and control of Healthcare-Associated Infections (HAIs) in all spheres of care, as well as Antimicrobial Resistance (AMR).

Regarding the Integrated Plan for Health Surveillance Management of Patient Safety in Healthcare Services, the main objectives are to promote surveillance, reporting, and investigation of incidents and adverse events at all levels of care, as well as to strengthen the National Health Surveillance System.

The Integrated Plan for 2026-2030 was coordinated by Anvisa, with support from the Committee for Supporting Healthcare Surveillance Actions for Patient Safety in Healthcare Services (Coviss in Portuguese), and received contributions from the National Council of Health Secretaries (Conass), the National Council of Municipal Health Secretaries (Conasems), the Ministry of Health, the Health Departments of the 27 federated states, the Patient Safety Centers of Health Surveillance (NSP Visa), and the Health Surveillance Working Group (GT-Visa).



Anvisa releases new models of controlled prescriptions

Anvisa made available, in February 2026, new models of special controlled prescriptions, according to Ordinance No. 344/1988, which regulates substances subject to special control.

The update occurred after Resolution of the Collegiate Board (RDC) No. 1,000/2025, published at the end of 2025, came into force, allowing prescribers and institutions to directly print these prescriptions. As a result, the prior physical supply of prescription books by local health authorities is no longer required, changing the procedure for obtaining the documents used in the prescription of controlled medications.

Anvisa clarified that RDC No. 1,000/2025 does not modify the requirements, technical criteria, or qualifications established by Ordinance No. 344/1988. The rules regarding substances subject to special control, types of prescriptions, mandatory information, expiration dates, requirements for the identification of prescribers, patients, and medications, as well as obligations related to the custody and control of prescriptions, remain unchanged. The new regulation only stipulates the way prescriptions are printed, without changing the sanitary regime applicable to the prescription and dispensing of these medications.

With the availability of the new models, the previously released prescriptions have been revoked and are no longer considered valid for regulatory purposes. After the official publication of the new formats, only these models are accepted for the prescription of medications subject to special control, and professionals and institutions must adapt their procedures to the currently valid documents. The revocation of the previous models aims to prevent the simultaneous use of different versions of prescriptions in the national territory.

The new models can be checked in the National System for Prescription Control, maintained as a reference base for standardized documents used in the prescription of substances under special control. The system brings together the updated formats and centralizes the information required to guide the correct filling and use of prescriptions, supporting prescription, dispensing, and oversight activities within the scope of sanitary control.

New law authorizes the sale of medications in supermarkets in Brazil

Law No. 2,158/2023, published on March 23, 2026, defines rules for the sale of medications within supermarkets, authorizing the installation of pharmacies or drugstores in the sales area of these establishments, provided that this is made in a physically defined, segregated, and exclusive environment for pharmaceutical activities.

The text establishes that the pharmacy may operate under the same tax identity as the supermarket or under a contract with a licensed drugstore, maintaining the existing sanitary and technical requirements, such as an adequate structure for pharmaceutical consultations, traceability, and specific storage conditions. This structure must ensure control of temperature, ventilation, lighting, and humidity, as well as compliance with applicable regulatory standards.

The legislation also requires the mandatory presence of legally qualified pharmacists throughout the operating hours of the pharmacy installed in the supermarket, ensuring the technical supervision required for the dispensing of medications. Pharmacies included in these establishments must follow the same pharmaceutical assistance standards observed in traditional drugstores, including procedures for receiving, storing, and dispensing medications. The text also specifies that medications cannot be displayed in open areas, communicable spaces, or without complete physical separation, prohibiting offers on counters, stands, or gondolas external to the exclusive pharmacy space. Thus, all sales must occur within the defined environment and comply with the regulations of the National Health Surveillance Agency (Anvisa).

For medications subject to special control, the approved text establishes that delivery to consumers may only occur after payment, maintaining the procedure already adopted in conventional drugstores. Alternatively, these products may be transported from the service counter to the payment location in a sealed, tamper-proof, and identifiable package, so as to preserve safety and regulatory control.

These rules aim to ensure the integrity of the medication until it is effectively delivered to the buyer, and to prevent inadequate access during the purchase process. Such measures apply regardless of whether the pharmacy operates under the CNPJ (Corporate Taxpayer Register) of the supermarket or through partnership with a licensed drugstore, as both must comply with the requirements imposed by the current sanitary legislation.

Additionally, the law allows pharmacies located in supermarkets to contract digital channels and e-commerce platforms for logistics and delivery to consumers, provided that full compliance with sanitary regulations

is guaranteed. The processing of the bill in the House of Representatives was expedited following the approval of an urgency request, allowing for direct voting in a plenary session without going through thematic committees, which advanced the final decision. The measure received 315 favorable votes and 38 against, as recorded during the session.

PIC/S public consultation of on revision of the Good Manufacturing Practices Guide is open

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) opened, in March 2026, international public consultations on proposals for the revision of two annexes of the Good Manufacturing Practices Guide. The documents under consultation aim to update guidelines applicable to the manufacture of medications, based on regulatory and industrial practices in force in the countries participating in the cooperation scheme. The public consultations are based on conceptual documents that outline the foundations, objectives, and key technical points that may be modified in the respective annexes of the guide.

The proposed revision specifically addresses the manufacture of medicinal gases and provides for a limited update of the current text (Annex 6). The points addressed include the incorporation of technologies currently used in the industry, the use of computerized systems in production processes, and specific adjustments aimed at aligning with regulatory and operational practices already observed in the sector. The public consultation regarding this annex was opened for the period between February 11 and April 11, 2026, allowing interested parties to express their views on the suggested changes to the document. The second document submitted for public consultation refers to the revision of Annex 15, which addresses qualification and validation. The proposal seeks to broaden the scope of the annex to include manufacturers of active pharmaceutical ingredients and assess updates aligned with the review of ICH Q9 (R1) guidelines related to quality risk management. The public consultation regarding this annex occurs between February 9 and April 9, 2026, during which interested parties can submit technical comments on the proposed points for revision.

Participation in public consultations occurs through the submission of comments on the platform indicated by PIC/S and is open to manufacturers, professionals from the regulated sector, and other interested parties. Anvisa, as an authority participating in PIC/S, announced the opening of the consultations to the national sector, aiming to allow technical contributions from Brazilian players to be considered in the process of revising the international guidelines on Good Manufacturing Practices.

Anvisa forms a working group to conduct a pilot project on personalized cosmetics

Anvisa published, on October 15, 2025, Call Notice No. 18/2025 to select up to five innovative projects to participate in the Pilot Project of the Experimental Regulatory Environment, known as Regulatory Sandbox, dedicated to the customization of personal care products, cosmetics, and perfumes.

The notice opened space for interested companies to submit proposals for testing business models based on the customization of formulations directly at points of sale, under temporary and controlled regulatory conditions. Applications remained open until January 2026, and the process resulted in the structuring of a pioneering initiative in the country, aimed at regulatory experimentation of emerging technologies in the sector. In February 2026, Anvisa formalized the creation of the Working Group (WG) responsible for technically conducting all stages of the project, including the preliminary analysis of proposals, in-depth technical assessment, and development of the protocol that will define the regulatory flexibility parameters applicable to those selected.

The WG established to support the Regulatory Sandbox was tasked with monitoring, supervising, and evaluating the implementation of each selected project. Its activities include analyzing the documentation presented by companies, continuously monitoring the execution of work plans, and preparing reports for the Agency's Collegiate Board regarding the granting, maintenance, or possible revision of temporary authorizations granted under the project. The group will also consolidate the results and regulatory learnings obtained during the testing period, providing essential technical support for future decisions by Anvisa on the potential creation of a definitive regulatory framework for the customization of cosmetics in the country. In addition to its evaluative function, the WG is responsible for ensuring that all activities conducted in the experimental environment occur under adequate sanitary conditions, ensuring traceability, proper supervision, and compliance with applicable requirements.

The development of this pilot project coincides with relevant changes brought about by Law No. 15,154/2025, which amended Law No. 6,360/1976 to simplify the procedures for the regulation of artisanal cosmetics and personal care products. The new legislation exempts these items from registration, subjecting them to simplified rules, which broadened the scope of issues related to cosmetics that require specific regulatory oversight.

The topic has also been included in Anvisa's Regulatory Agenda for 2026-2027, which now prioritizes the customization of cosmetics as an area for which regulations should be

introduced. This alignment between legislative changes, regulatory agenda, and the new experimental environment facilitates an integrated analysis of sanitary, technological, and operational impacts, both in the context of simplified artisanal production and of customization conducted directly at the point of sale.

Throughout the execution period, the selected projects will be continuously monitored, within the conditions outlined in the notice and the technical protocol developed by the WG. At the end of the experimental phase, the resulting information, evidence, and analyses will be consolidated and evaluated by the Agency to support decisions on the potential adoption of permanent regulation for this mode of production.

ANS regulates the technical-assistance visit in health plan operator

The National Supplementary Health Agency (ANS in Portuguese) published, on March 13, 2026, Normative Resolution No. 666, which regulates the technical-assistance visit aimed at identifying serious administrative abnormalities of an assisting nature in health plan operators.

The rule was approved by the Collegiate Board and is based on the competencies provided for in Law No. 9,961/2000 and in Regimental Resolution No. 21/2022, establishing formal guidelines for conducting in-person activities focused on evaluating the quality of services offered by operators. This visit is an administrative measure linked to the Monitoring of Assistance Risk, being conducted through field action in the operator's facilities with the aim of establishing a diagnosis related to the products and services directly or indirectly provided to beneficiaries.

The specific regulation states that the technical action should focus on assistance processes and the reliability of information sent to the Agency, without confusing it with sanction-based oversight activities. The Normative Resolution defines that the technical-assistance visit will be preceded by a planning process developed within the framework of the Periodic Monitoring Plan of Assistance Risk, which determines priority criteria among operators eligible for evaluation. This planning considers elements such as sectoral context, operational capacity of the Agency, and action lines of the Department of Standards and Product Qualification.

The rule also provides that operators classified as being in an imminent risk situation, characterized by sudden and generalized lack of assistance to beneficiaries, will be excluded from the schedule of this specific stage, as they require distinct regulatory measures. The scope of the visit will be defined beforehand in the monitoring plan and may cover internal processes, assistance outcomes, and an analysis of the quality of services provided, including when outsourced, in order to produce a detailed diagnosis of the operator's assisting performance.

The resolution establishes that operators must be previously informed about the technical-assistance visit, by sending a letter at least 15 days in advance. This communication must contain information such as identification of the operator, date, time, and place of the visit, documents to be made available, and the request for the presence of the legal representative or designated person.

The field action may include examining internal processes, checking the reliability of data sent to the Department of Standards and Product Qualification, and verifying operational and assistance information related to the

healthcare of beneficiaries. The rule also establishes that the visit should not apply to conduct regarded as violations to sector regulations, avoiding overlap with oversight procedures already provided for in supplementary health legislation.

The resolution came into effect on the date of its publication in the Official Gazette, revoking IN DIPRO No. 53/2017 and IN DIPRO No. 59/2022.

Anvisa discusses update of Normative Instruction that establishes the lists of constituents, limits of use, claims, and supplementary labeling of dietary supplements

During the 4th Public Meeting of the Collegiate Board of Anvisa, held on March 24, 2026, the Agency discussed some topics related to the dietary supplements market, which were on the agenda of the 4th Ordinary Meeting of 2026.

The items under discussion include item 2.2, reported by director Daniela Marreco Cerqueira, which addresses the proposal for a Normative Instruction intended to amend Normative Instruction No. 28/2018. This regulation establishes the lists of authorized constituents, limits of use, allowed claims, and requirements for supplementary labeling applicable to dietary supplements. The proposal is part of the Regulatory Agenda and was made available beforehand for analysis as a draft submitted for consideration by the Collegiate Board.

The draft Normative Instruction proposes the inclusion of new constituents authorized for use in dietary supplements, such as baru almond oil, microalgae oil from Schizochytrium sp. containing DHA, polyphenols from açaí, and açaí anthocyanins. It also provides for the inclusion of new microorganisms classified as probiotics, as well as the authorization

of a specific association of probiotic strains with fructooligosaccharides. The text also proposes the definition of minimum and maximum usage limits for certain constituents, including polyphenols and anthocyanins from açaí and the new listed probiotics, with the aim of updating the currently applicable parameters.

In addition to changes related to composition, the proposal includes the expansion of authorized claims for certain nutrients and ingredients. New claims related to the normal function of the nervous system attributed to thiamine, vitamin B6, and vitamin B12, as well as claims aimed at gastrointestinal health associated with the use of probiotics, are anticipated. The draft also presents specific claims related to reducing the risk of upper respiratory tract infections for specific populations, subject to the conditions of use and limits established in the proposed regulation.

The text of the draft reinforces the requirements for supplementary labeling applicable to dietary supplements, including new mandatory warnings for products containing freeze-dried açaí concentrate and certain probiotics. These warnings vary according to the ingredient and the target audience of the product, and must be clearly stated on the labels, in accordance with the general rules already established for this category of products.

The approval of this draft will result in adjustments to the current regulatory framework, requiring companies to adapt their formulation, regulatory classification, labeling, and technical documentation of dietary supplements covered by the regulation.

Anvisa publishes new regulations applicable to Cannabis for medicinal purposes

On February 3, 2026, Anvisa published a new set of regulations that redesigns the regulatory framework applicable to *Cannabis sativa L.* in Brazil.

The resolutions introduce the regulation on the cultivation of the plant in Brazil for medicinal purposes and relevant changes in its classification as a controlled product, in the rules applicable to scientific research and the experimental regulatory environment, as well as in the regime for manufacturing, importing, and marketing medicinal products derived from it. The regulatory package consists of RDCs No. 1,011/2026, 1,012/2026, 1,013/2026, 1,014/2026, and 1,015/2026, which will regulate the activities involving Cannabis for scientific, medical, and pharmaceutical purposes.

The main changes include the update of SVS/MS Ordinance No. 344/1998 through RDC No. 1,011/2026, which promotes the reclassification of Cannabis sativa L. that produces a proven concentration of THC equal to or less than 0.3% to List C1, subjecting it to the special control regime. This change replaces the previous classification of the plant on List E, intended for prohibited substances and plants, and allows for the regulated circulation of low-THC derivative products by means of a Special Control Prescription in two copies and registration in

the National System for the Management of Controlled Products (SNGPC in Portuguese).

In the realm of scientific research, RDC No. 1,012/2026 establishes the requirements for cultivating the plant species exclusively for such purposes. The activity is now permitted only for legal entities previously authorized by Anvisa, including scientific, technological, and innovation institutions (ICTs), educational institutions recognized by the Ministry of Education, law enforcement agencies, and establishments holding Special Authorization for the manufacturing of pharmaceutical inputs or medications. The regulation imposes strict safety, control, and traceability requirements for the cultivated plants, including the implementation of monitoring plans, physical protection barriers, records on the access to cultivation areas, and detailed documentation of the activities performed, prohibiting any form of marketing of the material produced within the scope of research.

Additionally, RDC No. 1,013/2026 regulates the cultivation of Cannabis sativa L. with THC levels equal to or less than 0.3% intended for medical and pharmaceutical purposes, following the ruling issued by the Superior Court of Justice in Special Appeal No. 2024250/PR. The resolution establishes that only establishments holding Special Authorization may engage in activities involving the plant, including acquisition, cultivation, research, import, storage, distribution, and supply. The regulation also establishes traceability and control requirements for the production chain, requiring documentation that proves the genetic origin of the plant species and the capacity to produce plants with THC concentration within the permitted limit.

Another relevant innovation is the creation of an experimental regulatory environment (sandbox) through RDC No. 1,014/2026, dedicated exclusively to research and development activities related to Cannabis for medical purposes. The model allows for controlled testing in an environment supervised by the health authority, aimed at producing scientific evidence, identifying public health risks, and evaluating potential existing regulatory barriers. Participation in the sandbox is temporary and supervised, does not authorize the commercial exploitation of the tested activities, and does not replace the regulatory requirements applicable to registration and sanitary certification stages.

Finally, RDC No. 1,015/2026 reformulates the Sanitary Authorization regime for medicinal products derived from Cannabis, revoking RDC No. 327/2019 and establishing new requirements for the manufacturing, importing, and marketing of these products. The main updates include the possibility of inhalation, oral, buccal, sublingual, or dermatological routes of administration, as well as the establishment of commercial names. Both this topic and the new permission for pharmaceutical compounding of preparations containing exclusively CBD will be regulated later by Anvisa.

Except for the regulatory sandbox, which takes effect from the date of publication, and the new regulation that will replace the current RDC No. 327/2019, which will come into effect on May 4, 2026, the other regulations will come into effect on August 4, 2026, establishing a transition period for regulated agents and for the health authorities responsible for overseeing the activities.

Partner responsible for the newsletter

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