Machado Meyer

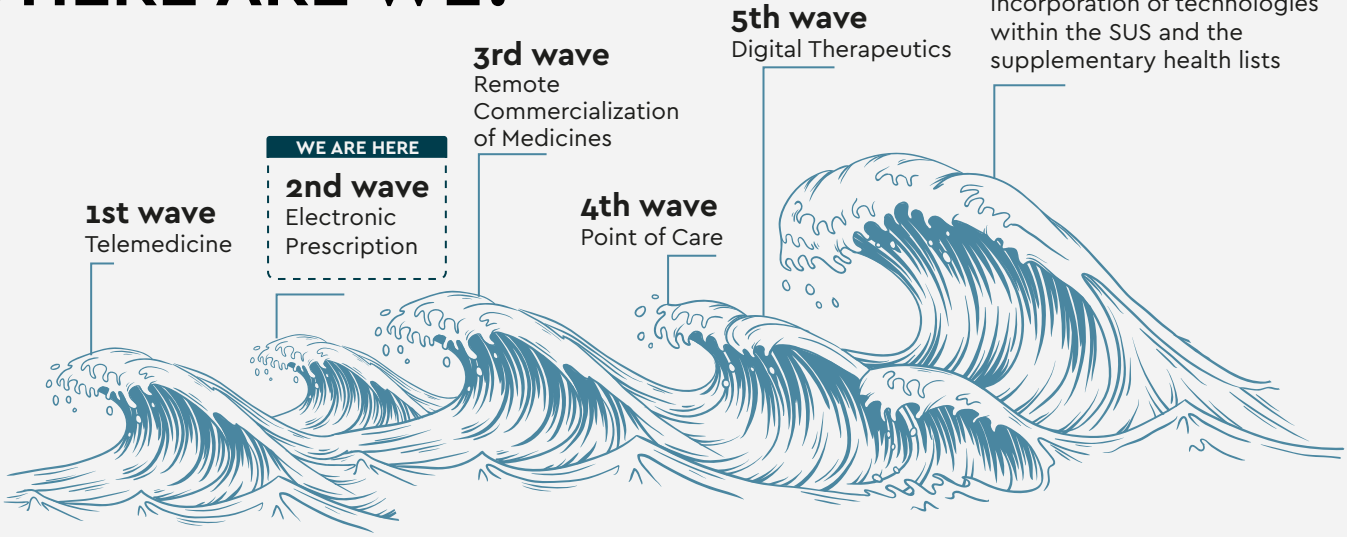
DIGITAL HEALTH IN BRAZIL
REGULATORY LANDSCAPE

The Brazilian health system has been undergoing an intense process of digital transformation, through the application of technological tools such as AI, blockchain, IoT and others in management, research & development, care and public policy processes. This movement requires relevant changes in the sectoral legislation and in the stakeholders's behavior. Our Life Sciences and Healthcare experts bring out the main regulations applicable to the matter, as well as perspectives for the near future.

Key Authorities

Players have a large number of stakeholders and regulatory authorities, among which we highlight: ANVISA, ANS, the Ministry of Health, professional councils (CFM, CFF, CFP, COFEN, among others) and CONEP, in addition to entities that interfere indirectly, such as the ANPD.

DIGITAL HEALTH IN BRAZIL
WHERE ARE WE?



TELEHEALTH

It involves any type of remote health assistance using information and communication technologies for the secure transmission of health data and information, through texts, sounds, images or other appropriate forms (Law No. 14,510/2022).

In addition, each federal professional council has the power to establish ethical standards for the remote execution of services by health professionals, for example:

Telemedicine (CFM)

CFM Resolution No. 2.314/2022

CFM Resolution No. 2.311/2022 (telesurgery)

CFM Resolution No. 2.107/14 (teleradiology)

CFM Resolution No. 2.264/2019 (telepathology)

Telepharmacy (CFF)

CFF Resolution No. 727/2022

Telepsychology (CFP)

CFP Resolution No. 11/2018

Telenursing (COFEN)

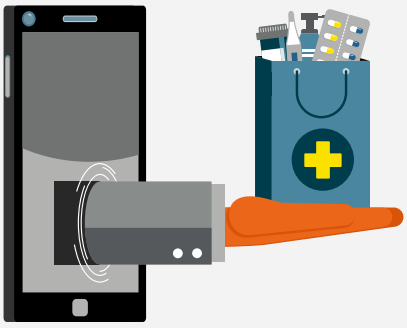
COFEN Resolution No. 696/2022

Telenutrition (CFN)

Key requirements for conducting telehealth include:

- Obtaining the patient's Free and Informed Consent or his/her legal representative.
- Heath professional autonomy.
- Right to refuse telehealth care.
- Safe and quality patient care.
- Secrecy and confidentiality.

Preparation of electronic health documents (e.g. medical records, prescriptions, certificates and reports), **are subject to specific regulations.**



MARKETING OF MEDICINES

Sanitary regulations allow remote delivery of medicines, including those subject to special control.

Expected Updates

It is likely that Anvisa will promote updates in the rules applicable to pharmacy and drugstore services to allow the purchase and sale of drugs subject to special control over the internet.

Moreover, in 2022 the Agency created a Work Group to discuss potential adjustments e-commerce regulation for products subject to health surveillance. The topic remains subject to a Regulatory Impact Analysis (RIA).

Another measure under discussion involves procedures that allow the electronic issuance and sanitary control of Prescription Notifications (applicable to types A, B1, B2, thalidomide and retinoids), which are still provided or numbered by local health authorities only in paper form.

SOFTWARE AS A MEDICAL DEVICE (SAMD)

The development of platforms, algorithms and applications intended for clinical use by patients and/or health professionals may classify these products as software as a medical device (SaMD), which requires prior regularization for commercialization. Some examples include:

- Image or health data processing
- Symptom Triage
- AI for Diagnostic Prediction
- Drug dosimetry
- Fertility control
- Digital therapeutics
- AI for suggestion or support in treatments
- Picture Archiving and Communication System (PACS)
- Planning surgeries or procedures
- Vital signs monitoring and control

Definition

Under current regulatory framework on medical device (RDC Anvisa No. 751/2022) and software as a medical device (RDC Anvisa No. 657/2022), it is any product intended for use in human beings, for any of the following purposes:

- Diagnosing, preventing, monitoring, treating, relieving, or repairing a disease, injury, or disability.
- Investigation, replacement, alteration of anatomy or of a physiological or pathological process or state.
- Lifetime support or maintenance.
- Information provided through in vitro examination of samples from the human body, including organ and tissue donations.
- Design control or support.
- Aesthetic correction and beautification, as well as cleaning, disinfection or sterilization.

Both standards are aligned with the latest international standards from foreign health authorities (e.g. FDA and Health Canada), as well as the International Medical Device Regulators Forum (IMDRF).

The following are not classified as SaMD:

- ✗ Wellness software.
- ✗ Administrative and financial management.
- ✗ Products not regulated by Anvisa.
- ✗ Processing of medical and epidemiological data.
- ✗ Built into a medical device.

Regularization Steps

As a general rule, SaMD are subject to a notification or registration (Marketing Authorization) process, which is based on 22 rules that evaluate the products' features, purpose and action mechanism in order to classify their health risk class.

Class I, Class II → NOTIFICATION

Class III, Class IV → MARKETING AUTHORIZATION

Attention

SaMD regularization also requires prior licenses and authorizations from the developer company.

The SaMD developed exclusively for a health service internal use may be exempted from regularization in specific cases.

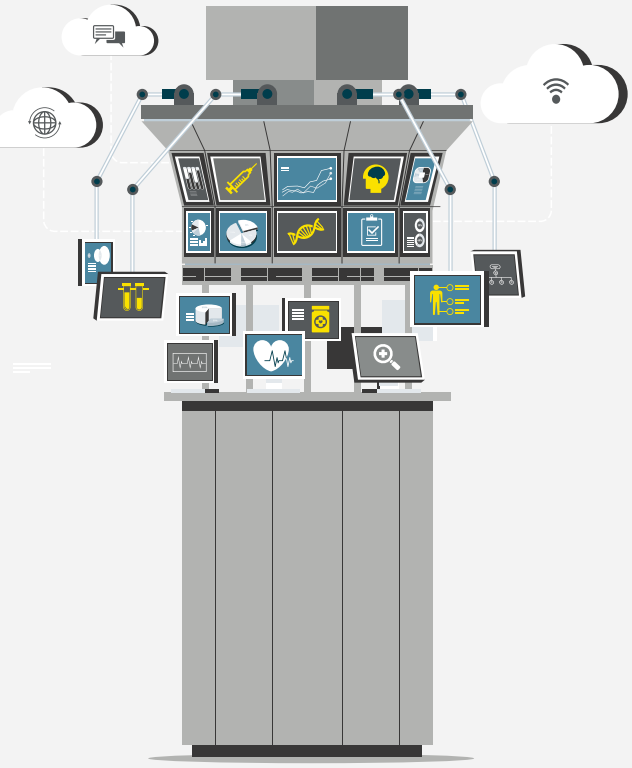
SOME REQUIREMENTS ESTABLISHED BY ANVISA RDC NO. 657/2022 INCLUDE:

- Clinical and analytical validation.
- Safety and efficacy.
- Instructions for Use and Labeling.
- Conducting clinical research to support technical dossiers.
- Compliance with equivalent international or national certifications.

POST-MARKET PHASE

Other regulations should also be considered throughout the software commercialization cycle, including, but not limited to:

- Good manufacturing practices.
- Post-registration or notification changes.
- Technovigilance.
- Cybersecurity in medical devices.
- Incorporation of health technologies in the public system (SUS).
- Incorporation and reimbursement of technologies in the supplementary health sector within the National Agency for Supplementary Health (ANS).



ARTIFICIAL INTELLIGENCE

Brazil is currently discussing Bill No. 2,338/2023, which aims to establish a general legal framework for the use of artificial intelligence. Some of the main aspects address:

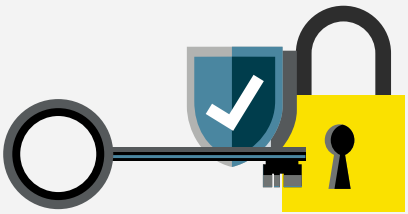
Principles for ethical use of AI systems including: effective human oversight, traceability, non-discrimination, transparency, explainability, auditability, reliability, accountability, accountability, prevention, and mitigation.

Details on standards established by the competent authorities for the inspection.

Users' rights – emphasis on: privacy, protection of personal data, non-discrimination and correction of discriminatory biases – considered points of attention in the scope of the use of AI in health.

According to the text under discussion, AI systems will be subject to a preliminary assessment to classify their degree of risk prior to their entry into the market.

Health applications (including diagnostic and procedural aid) are generally classified as high risk, which may imply more complex governance rules and a continuous assessment covering risks, benefits, likelihood and severity of adverse consequences, mitigation methods and operating logic.



HEALTH DATA PROTECTION

The General Data Protection Law applies to any processing of personal data that offers or provides goods or services to individuals or collects data located in Brazil.

"Personal Health Data" is defined as any data that identifies a person and is:

Health-related (including sex life)

Genetic

Biometric

Moreover, the Ministry of Health defined sensitive personal health data as any data concerning a data subject's health or the health care provided to them that reveals information about their physical or mental health in the present, past or future.

LAWFUL BASIS FOR PROCESSING HEALTH DATA

- Consent
- Regular exercise of rights (e.g. contract)
- Guardianship of health
- Regulatory obligation (e.g., custody of medical records)
- Life Protection
- Research and study
- Regular exercise of rights
- Fraud Prevention

⚠ Interpretation must be associated with ethical and health regulations.

Processing by Research Organs

Public or private non-profit entities may access personal databases to carry out studies and research, in compliance with security practices that include, whenever possible:

Anonymization – using reasonable technical means available at the time of processing, whereby a piece of data loses the possibility of association, directly or indirectly, with a person; or

Pseudonymization – treatment through which data loses the possibility of association, directly or indirectly, except by using additional information kept separately in a controlled environment.
These activities should also consider research ethics standards.

Sharing personal health data is allowed only in the following cases:

- Providing health services, pharmaceutical assistance and health care (including auxiliary diagnostic and therapeutic services) – provided that they are for the individual's benefit.
- Data portability (when requested by the data owner).
- Financial and administrative transactions resulting from the use and provision of health care services.

The risk selection prohibition by HMO's was reinforced by LGPD in the data processing context, whether in the contractualization of any type of product or in the contracting and excluding of beneficiaries.

GET IN TOUCH

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