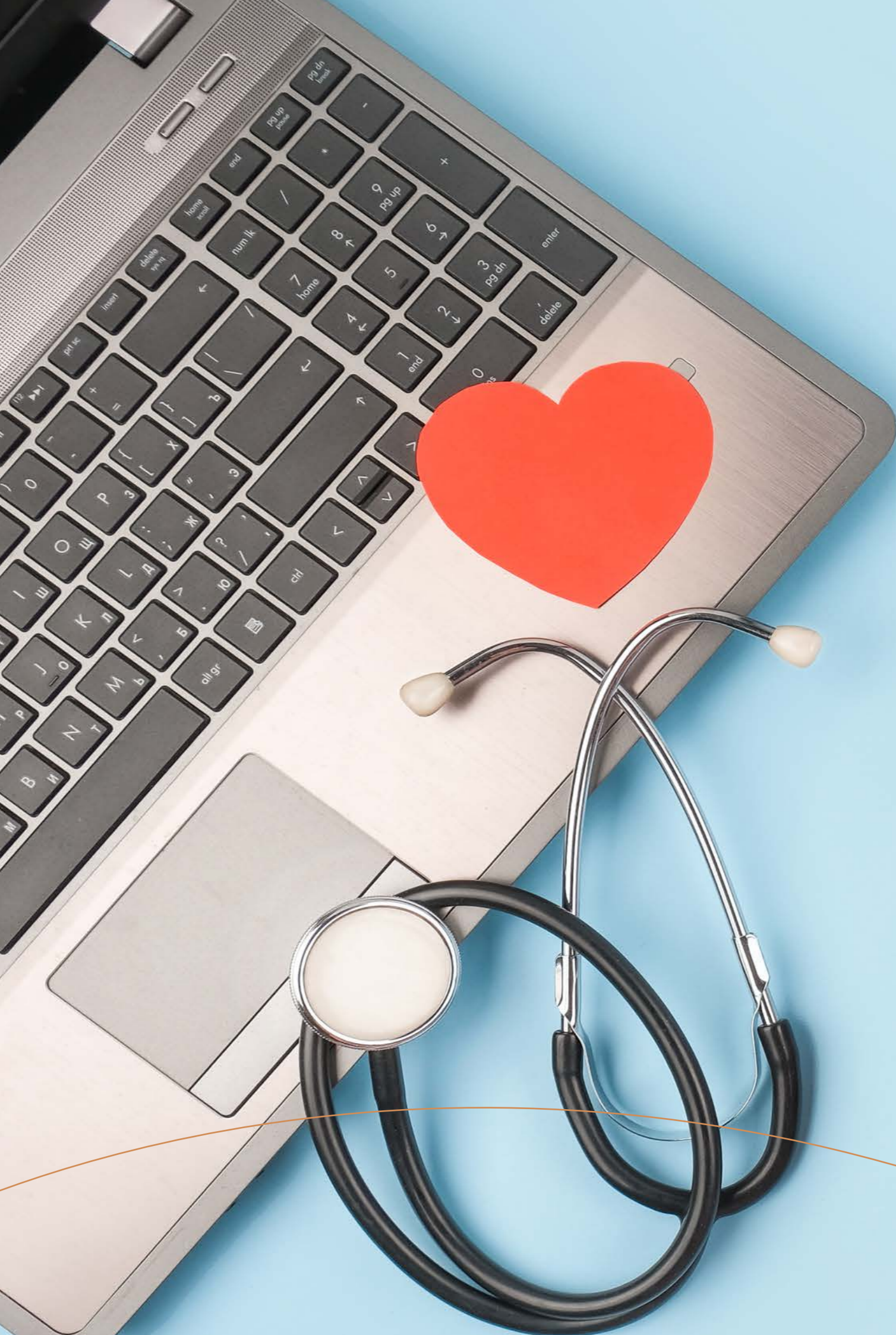




DIGITAL HEALTH
MAIN HIGHLIGHTS OF
THE NEW REGULATIONS

DEMAREST



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DIGITAL HEALTH

MAIN HIGHLIGHTS OF THE REGULATIONS

INTRODUCTION

It is known that the coronavirus pandemic (SARS-COV-2) crisis led to a significant increase in the employment, innovation and development of digital information and communication technologies aimed at facilitating the exchange of information between health professionals and their patients.

Additionally, the application of Information and Communications Technology (ICT) resources has been proven to contribute to the provision of assistance to cities of the countryside, while also benefiting large cities by reducing the overflow resulted from the increase in demand and migration of patients in search of treatment and care. This situation forced competent professional councils to regulate their practices or update existing normative acts.

Over the first semester of 2022, several regulations on telehealth services were published within the scope of numerous specialties and professions. Demarest's Life Sciences team gathered the main recent innovations regarding regulations on Telehealth, Telepharmacy, Telenursing and Veterinary Telehealth, along with the highlights of each one of them.

1. NEW REGULATIONS



TELEHEALTH

Regulations

Resolution of the Brazilian Federal Medicine Council (CFM) No. 2.324, of April 20, 2022

Summary:

Defines and regulates telehealth as a medical service carried out through communication technologies.



TELEPHARMACY

Regulations:

Resolution of the Brazilian Federal Pharmacy Council (CFF) No. 727, of June 30, 2022.

Summary:

Provides for the regulation of telepharmacy services.



TELENURSING

Regulations:

Resolution of the Brazilian Federal Nursing Council (COFEN) No. 696, of May 23, 2022

Summary:

Regulates the provision of telenursing services within the scope of Digital Health.



VETERINARY TELEHEALTH (CVM)

Regulations:

Resolution of the Federal Veterinary Medicine Council No. 1,465, of June 27, 2022

Summary:

Regulates the provision of Veterinary Telehealth services within the scope of veterinary medicine.





2. TELEHEALTH

HIGHLIGHTS OF THE NEW REGULATIONS

SCOPE

The practice of medicine through Digital Information and Communication Technologies (TDICs), for the purposes of care, education, research, prevention of disease and injuries, management and improvement of the health sector. Telehealth can be carried out in real time, online (synchronous) or offline (asynchronous).



FIND OUT MORE ABOUT THE REGULATION

REQUIREMENTS FOR THE PHYSICIAN



Active registration with the respective council;



Qualified electronic signature, ICP-Brasil standard.

DATA SHARING AND PROTECTION

Patient information can only be shared with another professional **once authorized by the patient**, in accordance with security protocols capable of ensuring the confidentiality and integrity of the information.

All telehealth services require explicit consent from patients. The patients or their legal representative must be made aware that their personal information is subject to sharing and that they are entitled to deny permission for such, except in the event of a medical emergency.

SERVICE RECORDS

Telehealth services must be registered on medical records via paper documentation or **electronic information systems** (in the patient's Electronic Health Registry System - SRES), in accordance with rules of representation, terminology, and interoperability.

Data on anamnesis and propaedeutics, results of complementary exams and medical conduct regarding telehealth care must also be kept under supervision of the doctor who provided the service, in his own office or of the technical director (in case of company or institution intervenience).

SECURITY, PRIVACY AND SECRECY

Patient data and imaging included in their medical record must be preserved, in compliance with legal and CFM standards relevant to the protection, handling, integrity, veracity, confidentiality, privacy, irrefutability and the guarantee to physician-patient privilege. In addition, telehealth systems must comply with the Brazilian General Data Protection Law (LGPD) and other regulations that guarantee the right to protection, handling, privacy, and integrity of patient data.

COST OF SERVICES

The Resolution highlights that telehealth services must comply with the ethical standards of in-person care in all its modalities, "including in regard to financial compensation for the service provided". As such, the Council recommends that a prior agreement between doctor/patient/health care providers be entered into regarding prices, similarly to in-person care.

SERVICE MODALITIES

Telehealth can be carried out in the following modalities:



Teleconsultation: medical appointment carried out remotely, via TDICs, with physicians and patients located in different spaces.



Teleinterconsultation: exchange of information and opinions between physicians, via TDICs, which may include the presence of the patient or not, for the purposes of diagnostic, therapeutic, clinical or surgical assistance.



Telediagnosis: medical service carried out remotely (synchronous or asynchronous), including the transmission of graphs, imaging and data for the issuance of medical reports or opinions by a physician who holds a Specialist Qualification Registration (RQE) in the area related to the procedure, in attention to the request of the attending physician.



Telesurgery: Surgical procedure carried out remotely through robotic equipment and secure interactive technologies.



Telemonitoring: medical service carried out remotely under coordination, recommendation, guidance and supervision of a physician, in order to monitor health parameters and/or disease. It is carried out by means of a clinical evaluation and/or direct acquisition of images, signals and data via wearable or implantable devices from the patient's home, a medical clinic specialized in chemical dependence, a long-term institution for elderly people, under clinical or home hospitalization, or during the patient's transfer to a health facility.



Screening: remote evaluation of the patients' symptoms for outpatient or hospital regulation, including allocation of the patient to the appropriate type of care they needs or to a specialist, according to the severity and characteristics of such symptoms.



Teleconsulting: consultancy carried out via TDICs by physicians, managers and other professionals, with the purpose of providing clarifications on administrative procedures and health practices.



IN-PERSON APPOINTMENT

Physicians have the autonomy to **determine whether the first appointment can be in person or not.** Naturally, the gold standard for medical appointments remains as the in-person modality, while telehealth acts as a complementary practice. Remote medical services can never replace the constitutional commitment to ensure in-person care in accordance with the Brazilian Unified Health System’s (SUS) principles of integrity, equity and universality for all patients.

MEDICAL AUTONOMY

Physicians have the autonomy to decide whether to provide telehealth services or recommending in-person care whenever they deem necessary. **Such autonomy is limited to the principles of beneficence and nonmaleficence of the patient and must comply with ethical and legal standards.** As a result, health care operators are entitled to determine whether to include telehealth services in their coverage.

PATIENT CONSENT AGREEMENT

The patient or their legal representative must authorize the provision of telehealth services and the sharing of their images and data through an informed consent agreement submitted via electronic means or media recording of the patient reading the content of the agreement, which must be included in the patient’s SRES.

REQUIREMENTS FOR REMOTE ISSUANCE OF MEDICAL REPORT, CERTIFICATE OR PRESCRIPTION

- a.** Physician identification, including name, CRM (registration number in the Local Medical Council), business address;
- b.** Patient identification and data (address and location where the service was provided);
- c.** Date and time;
- d.** Digitally certified signature of the physician (ICP-Brasil or another legally accepted standard); and
- e.** clarification that the document was issued within the scope of telehealth care.



RESIDENCE REQUIREMENTS FOR LEGAL ENTITIES PROVIDING TELEHEALTH SERVICES

Legal entities providing telehealth services, communication platforms and archiving data must:

- a.** be headquartered in Brazilian territory; and
- b.** be registered at the Local Medicine Council of the state where they are based, supported by the technical responsibility of a physician currently registered with the same Council.



MONITORING

The Local Medicine Councils are in charge of monitoring and assessing telehealth activities in their respective territories regarding the quality of care, doctor-patient relationship and preservation of doctor-patient privilege.

REPEALED RULES

CFM Resolution No. 1,643/2002, published in the Federal Official Gazette of Brazil (DOU) on July 26, 2022, and all provisions to the contrary were repealed.



3. TELENURSING

HIGHLIGHTS OF THE NEW REGULATION

SCOPE

Nursing practice within the scope of digital health, including the employment of Information and Communication Technology (ICT) resources to provide reliable information on the health state of patients, whenever required.



FIND OUT MORE ABOUT THE REGULATION

PRACTICES



Nursing teleconsultation: inherent activity to the nursing practice carried out synchronously, aligned with the Nursing Care Systematization (NCS), following the same method employed during in-person nursing practices. It must consider all stages of the nursing process: nursing history (data collection), nursing diagnosis, nursing planning, nursing implementation and evaluation.



Interconsultation: joint evaluation carried out among nurses or between nurses and other health professionals, with the participation of the user/patient.



Consulting: nurses can carry out consultations among peers and with other health professionals via ICTs, regardless of which location the professional is actively registered.



Monitoring: active contact with user/patient, requiring mandatory previous contact in-person or via ICT in the synchronous modality, for purposes of health monitoring.



Health education: set of practices aimed at contributing to increasing people's autonomy in their self-care, which can be carried out in groups or individually.



Admission of Spontaneous Demand via Information and Communication Technologies (ICT): any contact initiated by the user/patient seeking health care.

REQUIREMENTS FOR NURSES



Active registration in their respective council;



Qualified electronic signature, ICP-Brasil standar

REASONS THAT LEAD TO CONVERSION TO IN-PERSON CARE

- a. clinical need for in-person evaluation;
- b. inadequate virtual environment;
- c. identification problems;
- d. non-consent;
- e. discomfort with the method (of the professional or user/patient);
- f. when the professional or user/patient has technical and/or communication difficulties.

REQUIREMENTS OF THE REGISTRATION FOR NURSING PRACTICES VIA ICT

Medical records of practices carried out via ICTs must comply with the provisions of Article 4 of COFEN Resolution No. 696/2022 and the following:

- a. Nurse identification + COFEN registration;
- b. User/patient identification data;
- c. Means used for nursing consultation;
- d. Informed consent agreement of the user/patient, or their legal guardian;
- e. Nursing proceedings.

PROHIBITIONS ON TELECONSULTATION

Nurses are not allowed to carry out consultations via ICTs to provide care in emergency situations. Whenever the professional identifies alert signs, the care should not be continued. Patients must be instructed to seek an emergency room.



EVENTS THAT DO NOT CONSTITUTE TELECONSULTATION

Interactions via text and/or audio (asynchronous) messages do not constitute a nursing consultation.

It is established that it is not possible to contemplate all steps of the nursing process and the complexity of professional user/patient through communication carried out exclusively via text message or audio. This definition does not exclude the use of such tools for communication within the scope of health care.



REQUIREMENTS FOR COMPANIES TO PROVIDE TELENURSING SERVICES

Active registration with the Local Nursing Council is mandatory for carrying out nursing practices via ICT.

PATIENT CONSENT AGREEMENT

Nursing practices via ICT require an informed consent agreement with the user/patient or their legal guardian. The user/patient is entitled to withdraw such consent at any given time.

Consent may be granted either in writing (paper or electronic document) or verbally, provided that there is a transcription in paper or electronic document in the medical records or collective activity records.

RESPONSIBILITIES OF THE EMPLOYER

It is the employer's responsibility to ensure that their employees are provided with the necessary infrastructure in order to carry out telenursing practices, as well as storing and protecting any data generated as a result of such practices.

MEDICAL PRESCRIPTION AND EXAMS REQUIREMENTS

Issuing medical prescriptions and requesting medical exams remotely requires a valid digitally certified signature issued by the Brazilian Public Key Infrastructure (ICP-Brasil).



4. TELEPHARMACY

HIGHLIGHTS OF THE NEW REGULATIONS

SCOPE

Practice of Clinical Pharmacy carried out remotely via Information Technology and Information and Communication Technology (ICT), synchronously or asynchronously, for purposes of fostering health, protection, monitoring, health recovery, disease prevention and other health problems, as well as resolving of pharmacotherapy issues, to ensure the responsible use of medicines and other digital health technologies.

Telepharmacy can also be employed for teaching and research purposes in health, observing ethical norms and precepts.



FIND OUT MORE ABOUT THE REGULATION

PRACTICES

Telepharmacy can be carried out in the following modalities:



Pharmaceutical teleconsultation: consultation carried out remotely by the pharmacist, synchronously, via Information and Communication Technology (ICT) that enables interaction with the patient or their legal or accompanying person, when necessary, while each party is based in a different location.



Teleinterconsultation: consultation carried out remotely among pharmacists and other health professionals, with or without the presence of the patient or their legal guardian, in order to exchange information and opinions, evaluate clinical cases and opt on the best conduct, with the purpose of optimizing results, preventing diseases and other clinical conditions and promote health.



Telemonitoring: medical service carried out remotely under coordination, recommendation, guidance and supervision of a pharmacist, in order to monitor health parameters and/or disease through clinical evaluation with the acquisition of medical imaging, identification of symptoms, collecting of data via medical equipment or wearable or implantable medical devices. This practice includes the collection of clinical data, its sharing, processing and management, without the need for the patient to be physically present.



Teleconsulting: Consultancy carried out remotely via ICT among pharmacists and other professionals, with the purpose of issuing technical and administrative opinions, in addition to recommending health care actions. It does not include the evaluation of specific clinical cases.

PHARMACIST REQUIREMENTS



Active registration with the respective council. Registration with the respective origin Local Pharmacy Council is sufficient, without the need for any secondary registrations.



Qualified digital signature (ICP-Brasil standard).



Inform the Local Pharmacy Council in your jurisdiction of the modalities and services provided via telepharmacy when requesting the Certificate of Regularity (CR) or the Pharmacist Professional Certificate of Qualification (AAPF).

PROHIBITIONS

Pharmacists are not allowed to remotely assume technical responsibility for pharmacies, clinical analysis laboratories, industries or other establishments, entities, laboratories or sectors of any nature.

ACTIVITIES THAT ARE NOT CONSIDERED TELECONSULTATION

Sale of medicines and other health products via electronic platforms or software.

Interactions carried out asynchronously via text, video or audio messages do not constitute a pharmaceutical teleconsultation, as it is not possible to contemplate all stages of the care process and the complexity of communication between professional and patient or their legal guardian.

TELEPHARMACY REQUIREMENTS FOR COMPANIES

Legal persons that provide platforms or software to subsidize the provision of clinical or telepharmacy services, or those carrying out their activities via telepharmacy must:

- a. have an established representative in Brazil;
- b. be registered with the Local Pharmacy Council of the state where they are located;
- c. have a pharmacist in charge of technical matters; and
- d. meet criteria to be defined by the Federal Pharmacy Council.



AUTONOMY OF THE PHARMACIST

Pharmacists have the autonomy to determine whether patients will be treated via pharmaceutical teleconsultation or in person, basing their decision on clinical-scientific evidence, epidemiological characteristics, potential benefits, patient safety and viability to preserve the quality of care remotely.

REGISTRATION REQUIREMENTS FOR PHARMACEUTICAL PRACTICES VIA ICT

Pharmaceutical teleconsultation, teleinterconsultation and telemonitoring must be kept in the patient's medical record and include, at least, the following information:

- a.** identification data of the pharmacist (full name, signature and registration number at the Regional Pharmacy Council);
- b.** identification data of the patient and their legal guardian, if there is any (name, contact, date of birth, location where care was provided, among others);
- c.** informed consent agreement of the patient or their legal guardian;
- d.** clinical and pharmacotherapeutic history;
- e.** diagnose and assessment of health needs;
- f.** choice of medical conduct and care plan;
- g.** date and time of initiation and completion of the service, according to the time zone of the location where the pharmacist is located.

SERVICE RECORDS

Telepharmacy services must be registered on medical record via paper documentation or electronic information systems (in the patient's Electronic Health Registry System - SRES), in accordance with rules of representation, terminology, and interoperability, and with requirements set by the Security Guarantee Level 2 (NGS2), within the standards of the Brazilian Public Key Infrastructure (ICP-Brazil), or another legally accepted standard.

In addition, all practices carried out via ICTs must be recorded in order to ensure the processing, storage, protection, traceability and security of personal data, with emphasis on sensitive information, and in compliance with the Brazilian General Data Protection Law (LGPD), with the current regulations set forth by the Ministry of Health and by ANVISA, in addition to protecting the privacy of patients.

DATA SECURITY

Patient data and imaging resulted from telepharmacy practices and included in the patient's medical record must be preserved, in compliance with legal standards relevant to the protection, handling, integrity, veracity, confidentiality, privacy, irrefutability and the guarantee to doctor-patient privilege.

DATA SHARING CONSENT

The consent of the patient (data holder) or their legal guardian to share the data is mandatory, in particular for purposes of advertising products or services, except in cases exempted by law.



5. VETERINARY TELEHEALTH

HIGHLIGHTS OF THE NEW REGULATIONS

CONCEITO

It is the exercise of Veterinary Medicine through the use of Information and Communication Technologies (ICTs), with the objective of assistance, observing technical and ethical standards, including the modalities of teleconsultation, telemonitoring, teleorientation, teleinterconsultation and telediagnosis.



FIND OUT MORE ABOUT THE REGULATION

MODALITIES OF VETERINARY TELEHEALTH

Veterinary telehealth can be carried out in the following modalities:



Veterinary teleconsultation: veterinary consultation carried out remotely, via ICTs, in cases where the veterinary physician and the patient are not located in the same geographical area, except in cases of urgency and emergency;



Veterinary Teleorientation: veterinary assistance provided remotely, sans any type of diagnostic practice or therapeutic conduct or request for veterinary exams or prescription of medication;



Veterinary screening: modality aimed at allocating patients, at the discretion of the veterinary physician, regarding the possibility of carrying out teleconsultation or the need for immediate or scheduled in-person care;



Veterinary Interconsultation: practice carried out among veterinary physicians in order to exchange information and opinions and for the purpose of providing diagnostic or therapeutic assistance;



Veterinary telediagnosis: transmission of data and images to be remotely interpreted and evaluated among veterinary doctors with the purpose of issuing a report or opinion;



Veterinary Telemonitoring: continuous monitoring of physiological parameters, carried out under guidance and supervision of a veterinary physician for remote monitoring or surveillance of health conditions and/or disease;

AUTONOMY OF THE VETERINARIAN

The veterinarian is entitled to decide whether veterinary telehealth can be carried out and is entirely liable for such decision, in accordance with the principles of beneficence and nonmaleficence.

DEVELOPMENT OF SPECIFIC APPLICATIONS AND PLATFORMS

The professional may develop a specific application for telehealth care or integrate existing platforms with their practices, provided that they comply with the criteria and guarantees established in the respective rules, and record information on the technology employed in a medical record.

SPECIFIC REQUIREMENTS FOR THE MODALITIES



a. veterinary physicians must have an active registration in the CFMV/ CRMVs system;



b. The responsible individual must have a prior Veterinary-Animal-Individual relationship, established in person, and duly registered – exempted in the case of disaster scenarios;



c. Protect the set of information, signals and imaging registered in the report of veterinary medical assistance provided;



d. Inform the individual responsible for the patient of all limitations inherent to the use of Veterinary Telehealth, including its infeasibility, if that is the case.

REQUIREMENTS FOR LEGAL PERSONS

Legal persons who wish to carry out their practices via veterinary telehealth must comply with the following requirements:

- a.** active registration with the respective Local Veterinary Medicine Council where they are located; and
- b.** technical responsibility annotation (ART) of a veterinary physician regularly registered with the same Council.



PROHIBITIONS

Veterinary telehealth practices are prohibited in the event of emergency or urgency cases.

In the event of a disaster situation, the professional must record and clarify that the situation is exceptional and fits as an exception to provide care.

INFORMATION SHARING CONSENT

Veterinary physicians must submit for the signature of the person responsible for the patient a Consent Form for Veterinary Telehealth (Annex I of the Resolution), whenever there is a need to share information for teleinterconsultation and telediagnosis.

REMOTELY ISSUED MEDICAL PRESCRIPTION

Medical prescriptions issued remotely must include:

- a.** identification of the veterinary physician, including name, CRMV (registration number in the Local Veterinary Council), telephone number and business and/or electronic address;
- b.** Identification data of the patient;
- c.** date and time the service was provided;
- d.** valid digitally certified signature for the issuance of prescriptions and other documents;
- e.** prescription of controlled medications will only be valid when issued with a valid digitally certified signature, in addition to complying with the rules issued by specific regulatory bodies and agencies.



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A large, white, triangular sign with the word "DEMAREST" in raised, brown, 3D letters. The sign is set against a background of a modern building with a glass facade and palm trees under a clear blue sky.

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