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Patient's Medical Records in Brazil: Legal and Regulatory Considerations

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Abstract. This work aimed to research medical records' legal and regulatory definitions as found in force not only in the Brazilian normative systems but also at the Federal and Regional Councils of Medicine (*Conselho Federal e Conselhos Regionais de Medicina*), particularly their completeness to be accepted by the judicious system. This empirical retrospective documentary research recovered norms, legislations, resolutions, and professional opinions about medical records and some of its parameters, such as content, legibility, and accountability using official legal and regulatory digital platforms. No period limitation was set for document recovery; however, only current ones (still in force) were analyzed in full. Documents that dealt with the content of the medical record per se were included; those that dealt with custody, confidentiality, digitization, and access to third parties were excluded. The Brazilian legislation does not provide a clear definition of medical records or their core content. Nonetheless, its collective nature is recognized. The Federal and Regional Councils of Medicine have issued numerous resolutions and opinions on the matter, clarifying its completeness in nature. Medical Records are a collection of health documents of a patient, which should be readily available upon court request as a complete medical dossier, and must contain legible and signed copies, including all the procedures a person underwent while under care.

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1. Introduction

A patient's medical record is vital from a forensic point of view, as it compiles all the data collected over a patient's life. The Consumer's Code (1), a Brazilian Federal Law, made records more accessible to patients in Brazil during the ninety-nineties. Information, in general, became more accessible to consumers during that time, the same being true to other countries such as the United States[2], United Kingdom[3], Ireland[4], South Africa[5], Canada[6], and Australia[7].

Easing the patient's access to medical records without any need for subpoenas or court rulings ended up leveling up the equilibrium in the power of a malpractice suit. By having the documents, the patient can lay the foundations of the case upfront. As a response, there has been a significant increase in professional malpractice tort cases in Brazil.

Even though in the country, various laws apply for those not willing to provide the medical record to the court or to a patient, such as the Penal or Civil Codes[8,9], the Code of Criminal Procedures[10], the Criminal Misdemeanor Law[11] and the Civil Procedure Code[12], most regulations regarding medical documents come from the Brazilian Councils of Health Professionals (Conselho Federal and Regionais of Medicine, CFM e CRMs; Conselho Federal and Regionais of Dentistry, CFO and CROs, and Conselho Federal and Regionais of Nursing Professionals; Cofens and Corens). The Councils converge their rulings in the matter, creating a regulatory system with inviolable principles regarding the patient's intimacy, privacy, honor, and image, as determined by the Brazilian Constitution[13].

However, even with the noteworthy horizontalization of the hierarchical relationship between doctors and patients in Brazil, and the significant improvement in access to information in general, many still have to petition their medical documents through injunctions or lengthy lawsuits. The excuses vary for not giving a patient his or her records; among those, there are claims of copyright infringement[14] or the professional lack of time to search for the documents[15].

In a recent court ruling of the São Paulo State Court System, where a sepsis patient sought judicial access to her medical records, the judge did not grant access, alleging that as the petition used the generic term, “medical records,” whatever papers were brought to court should suffice to fulfill the court order. The judge believed that if particular parts of the medical records were being sought, they should have been named individually, such as, for example, operation reports[16]. The decision was annulled by the State Appellate Court, as the Justice determined that if the court order was to present the medical record as a whole, the hospital’s obligation was to give the complete medical record of that patient as validated by an expert witness.

But is there a definition of medical records other than the written ***collection*** of information about a patient’s health and treatment[17]? There are, in fact, many definitions, but they all point out that the term is a collective noun, denoting a group of documents containing patients' health information. Some define it as a collection of complete, accurate, and timely data on health[17] or that it "must contain sufficient data to identify the patient, support the diagnosis or reason for attendance at the health care facility, justify the treatment and accurately document the results of that treatment"[18]. Professor Genival Veloso França[19] has a similar definition:

> A medical record is a record of the patient's anamnesis and the complete, standardized, orderly, and concise collection of documents, referring to the record of the medical care provided to that patient with its attached documents. It consists of the patient's clinical examinations, reports of occurrences and prescription forms, nursing reports, anesthesia and surgery reports, registration forms of complementary exam results, and even copies of certificate and exam requisitions. **They constitute an accurate dossier** that serves both for analyzing the evolution of the disease and for statistical purposes that feed the medical service's database. It provides a legal defense for any professional involved if that person is held responsible for any atypical or unwanted results.

As privileged information, other aspects of the records are usually in the center of legal discussions, not its definition or core content. The literature is prolific on articles that deal with safekeeping, confidentiality, and information "ownership," emphasizing the impacts of digitalization in recent years. For its

content, the Brazilian legislator determined that it would be up to the professional councils, such as the Federal Council of Medicine (CFM), Dentistry (CFO), or Nursing (Cofen), among others, to legally deliberate on the pertinent ethical matters and to promote the perfect technical and moral conduct of the healthcare professionals[20-25].

In medicine, the Code of Medical Ethics[26-28] defines, in Chapter X, some precepts about medical records:

> Art. 87 Failure to provide a readable medical history for each patient.
> §1 The medical record must contain the clinical data necessary to manage the case properly. Each evaluation must be filled in chronological order with the date, time, signature, and the physician's registration number at the Regional Council of Medicine.
> §2 The medical record will be under the custody of the physician or institution that assists the patient.
> §3 It is incumbent upon the assistant physician or their substitute to prepare and deliver the discharge summary to the patient, or if this is not possible, to their legal representative.

Although this definition is intelligible for those working in the field, for others, its extent or coherence may not be so evident. The Nursing and Dentistry Codes of Ethics follow the same directives[20, 30]:

> **Code of Ethics of Nursing Professionals**
> Chapter II. Duties. [...] Art. 36 To register in the medical record and other documents the inherent and essential information of the process of patient care in a clear, objective, chronological, legible, and complete manner, without deletions.
> Art. 37 To properly document the stages of the nursing process, aligned with its legal competence.
> Art. 38 To provide complete and reliable written and/or verbal information necessary for patient care and safety continuity.
>
> **Dental Code of Ethics**
> Article 9. The following are the fundamental duties of the registered members, and their violation characterizes an ethical breach:
> X - to provide and keep medical records up to date according to the normative in force, including the digital records; [...]

> Art. 17. It is mandatory to file and keep medical records in a legible and up-to-date form and keep it in its file, whether in physical or digital format. Paragraph 1. Dental professionals must keep all the clinical data necessary for the proper management of the case in the medical record, which has to be filled in for each visit, in chronological order, with the date, time, name, signature, and the dentist's Regional Council of Dentistry registration number.

The aim of this study was to elucidate the meaning of medical records when the document must be presented in court by researching the fundamental regulatory and legal references that regulate the matter in Brazil, mainly (a) the patient's right to access the record as a unit of all available medical information regarding own care; (b) the requirement for all medical procedures to be registered, signed and made readily available; (c) its legibility, and (d) the need to have whatever material or drug prescribed, disclosed on the records. A more detailed description of the Brazilian judicious system is found elsewhere[31]. In short, Brazil follows the civil law, which means that court decisions are based on the Constitution, and all the norms emanated by the legislative body, specialized laws taking precedent over general ones. A main constitutional principle that applies to the present study is that of legality: "No one shall be obliged to do or refrain from doing something except by virtue of law." But laws, decrees, and rulings are regulated and instructed by norms emanated from the executive branch, or designated entities, such as the Ministry of Health or the Brazilian Agency of Supplementary Health. So, in researching the patient's right to access his or hers complete medical record, not only the applicable laws must be analyzed, but the regulatory norms that regulates the subject, including those of Professional Councils, as the Brazilian legislator gave legitimacy to them, Federal Independent Autarchies, to supervise the professional ethical conduct, and, at the same time, to discipline and ethically judge physicians', dentists', and nurses' misconducts. The Councils vote and publish frequent updates of their Deontological Codes, and issue resolutions, advisory opinions, recommendations, and technical notes on pertinent matters that are taken into consideration in civil cases.

2. Materials and methods

Initially, the term “medical record”* was searched on the Brazilian Federal legislation portal (https://legislacao.presidencia.gov.br/#) in decrees, laws, provisional measures, and the Constitution. Norms that have the word “prontuários” but without the medical meaning, such as the Brazilian traffic code, criminal laws, and labor documents, were excluded from the sample. The same portal offers links to recover legislation from all Brazilian states, so “medical record” in Portuguese was also researched at the São Paulo State Legislative system portal (http://www.legislacao.sp.gov.br/legislacao/ index.htm).

Next, a survey was carried out using the term “medical records”* within the Federal Council of Medicine (CFM) Transparency and Accountability Portal (https://transparencia.cfm.org.br/). The following filters were used during the search: Resolutions, Opinions, Recommendations, Technical Notes, and others. The investigation covered all available years (1957-2021) and all Regional Councils. Only documents that dealt with the content of the medical record per se were included; texts that dealt with custody, confidentiality, digitization, and access to third parties were excluded. The scope of each document was discussed separately in the subsequent chapter.

3. Results and discussion

Within the federal regulations recovered, there was no precise definition of a medical record. Therefore, the term was searched in a Portuguese etymological dictionary that revealed its Latin origins, *prōmptuārĭum*, which means ready or “handbook of useful recommendations” (32). It was mentioned for the first time in 1987, in a Decree[24] that regulates nursing practice, and was referred as the professional’s responsibility for taking notes when providing care. In 1990, though not mentioning medical records directly, the Consumer's Protection Code[1] established that Brazilian consumers had the right to be informed regarding a product or service being provided (Art. 6, III) and recognized that the relationship among health professionals, health services, and patients in the private sphere was governed by this norm. It also established that a service provider who refused or hindered access to information and records, in this

* ”Prontuário”, in Portuguese.

case, medical records, would be subject to a penalty of six months to one year of detention or a fine (Art. 72).

The medical record was again cited in Law n. 9,434[33], which regulates procedures of organ removal and transplants. It established that medical records should contain exam reports of the brain death diagnosis and details of the related surgical procedures in such cases.

Military personnel's duty to carefully make notations on patients' progress and prescriptions in their medical or dental records was determined in 2001[34]. In 2009, the Decree n. 6,856[35] mentioned electronic medical records, establishing that periodic examinations of public workers must use such media. Its coherence was mentioned in Law n. 12,732[36] when the government launched a timeframe for the administration of treatment for malignant neoplasms by the Unified Health System (SUS) after a diagnosis was included in the medical record.

> Art. 2nd A patient with malignant neoplasia has the right to receive the first treatment at the Unified Health System, up to 60 (sixty days) starting from the day the diagnosis has been established with a pathological report or in less time, according to the therapeutic need registered on the **sole** medical record.

In 2013, in Decree n. 7,958[37], which deals with guidelines for victims of sexual violence in the SUS, a minimum core content was detailed:

> Art. 4 Assistance to sexual violence victims by professionals of the SUS network will comprise the following procedures: [...]
> II - filling out the medical record with the following information:
> a) the date and time of medical care;
> b) a detailed clinical history, with data regarding the suffered violence;
> c) A complete physical examination, including gynecological examination, if necessary;
> d) A detailed description of the lesions, indicating their temporality and specific location;
> e) A detailed description of trace evidence and other exam findings; and
> f) The identification of professionals who assisted the victim.

In the Decree that regulated the Law of Transplants[38], a chapter is

dedicated to medical records, emphasizing the need to complement the usual information with information from the deceased or living donor and the transplant recipient's consent. In 2018, a milestone in the standardization of medical records, Law n. 13,787[39] provided guidelines for digitalized systems to be used for the safekeeping, storage, and handling of patient records. In the following year, it was established that the patient electronic medical record would be replicated by the National Register of Social Information[40]. With the implementation of the Federal Development Strategy for Brazil (2020-2031) policy during the next years, it is expected that public and private information from health networks will be integrated by creating a single standard electronic medical record platform by the SUS to meet equity and efficiency demands[41].

Within the scope of the Federal Council of Medicine, 579 documents were recovered in total, but, considering the exclusion criteria, only 29 dealt with the content of the record per se, and were discussed in the sequence. The oldest resolution that mentions medical records refers to them as a "***set of standardized and ordered documents, intended for recording professional care provided to the patient by public or private health services***"; this resolution is from 1989[42]. In 2002, Resolution n. 1,638 unequivocally defined the collective nature of the medical record and created the Medical Record Review Commission with the specific task of inspecting the items that should be part of the document[43]:

> Art. 1. To **define medical records as a single document** consisting of a set of recorded information, signs, and images originating from facts, events, and situations related to the patient's health and medical care, within its legal, confidential, and scientific nature, which enables communication among members of the multidisciplinary supporting care team and the continuity of care provided to the individual. [...]
>
> Art. 5. It is mandatory for the Medical Record Review Committee: I. To observe the items that must be included in medical records of any supported media, electronic or paper documents: a. Patient identification - full name, date of birth (day, month, and year with four digits), sex, mother's name, place of birth (indicating the city and state), complete address (public street name, number, apartment, neighborhood/district, municipality, state, and zip code); b. Anamnesis, physical examination, requested laboratory exams and their respective results, diagnostic hypotheses, definitive diagnoses, and treatment carried out; c. Notes on

the patient's daily progress, with dates and times, and a breakdown of all procedures to which the patient has been submitted.

In 2007, Resolution n. 1,821, on technical standards concerning the digitization and use of computerized systems to store and handle documents of patients' medical records, established that support, diagnosis, and therapeutic units' documents are also an integral part of any patient's records[44]. The organization of patients' medical records in a private work environment was defined by CFM Resolution n. 2,056 of November 12, 2013[45], modified by recent resolutions[46-47].

CHAPTER X

THE ORGANIZATION OF PATIENT RECORDS

Art. 45. Any treatment administered to a patient must be justified by clinical observations and should be written in the medical record, which must be organized in such a way as to:

a) allow for easy reading and interpretation by doctors and other professionals who handle it;

b) enable the easy handling and interpretation by auditors and authorities related to the control of medicine;

c) follow the order: anamnesis and physical examinations, exclusive prescriptions and progress sheets for doctors and nurses, and standard progress sheets for other professionals who also intervene during care.

Art. 46. The assistant physician must make routine progress notes and prescriptions notes at least once a day.

§1. In geriatric establishments, psychiatric prescription notes must also be taken daily when dealing with acute patients or those under clinical observation in palliative care.

§2. It should be done at least three times a week with stabilized patients in these same establishments.

Art. 47. The medication sheet must have three columns: the one on the left will contain the date and time of the prescription; the middle one will contain what was prescribed, and the one on the right will be reserved for nurses for recording and checking the time of the procedure.

Art. 48. The progress sheet must have two columns: the one on the left will contain the progress notes dates and times; the one on the right will contain assistant physicians, consultant physicians called to provide support, on-call physicians, resident physicians, or internists under supervised interventions.

CHAPTER XI

REGISTRATION IN THE ANAMNESIS AND PHYSICAL EXAMINATION, PRESCRIPTIONS AND MEDICAL DEVELOPMENTS

Art. 49. The anamnesis is an exclusive instrument for medical propaedeutic evaluation.

Art. 50. Anamnesis is mandatory in any medical environment, including outpatient care and offices.

Art. 51. To comply with the provisions of Art. 87 of the Code of Medical Ethics and its paragraphs, the medical record must, at least, contain the following data:

1- Anamnesis, which must include:

a) Patient identification: name, age, date of birth, parentage, marital status, race, sex, religion, profession, place of birth, address, and telephone number;

b) Main complaint: a brief description of the reason for the consultation;

c) History of the current disease: an illness report.

In several advisory opinions from the Federal or Regional Medical Councils, explanations on the content of the medical record were given in response to the consultation by its members. Regarding operation reports, for example, three opinions were found, which clarified the responsibility of the medical team in providing a detailed description of the procedure:

Regional Council of Medicine - State of Paraná (CRM-PR)

Advisory Opinion n. 1,716/2006[48]

The description of an operation is a mandatory part of the medical record of patients treated by surgical specialists. Its primary purpose is to record information regarding pathological and technical aspects that were verified and which occurred during the operation, which may, in the future, guide the case investigation and the patient's treatment. Of great importance is the legal purpose of the medical records in clarifying any questions in the future. You must, therefore, comply with these requirements be rigorous and complete in the information recorded. This document must contain: - Identification of the patient; - Name of the hospital or clinic; - Date of the operation; - Surgical team; - Type of anesthesia; · Name of the anesthesiologist; - Preoperative diagnosis; - Scheduled procedure; - Operation performed: - Access route; - Description of injuries and other findings; - Pre-operative diagnostic exams; - Surgical techniques and tactics; - Possible surgical accidents; -

Estimated blood loss; -Employed drains; - Summary of plans; - Suture material; and - Postoperative diagnosis. [...] Considering that the description of the operation must include, in detail, the pathological surgical findings and other findings, such as confirmation of the lesion that motivated the procedure, the extension of the pathological process, associated lesions, techniques, and tactics used, the description obviously cannot be done, entirely and rigorously, before the operation. [...] Since this is a medical act, it must be performed in the hospital immediately after the end of the surgical procedure. 3. Can it be printed? As long as it is typed by the surgical team doctor or dictated to the service secretary. We emphasize the need to specify the description of each procedure, especially the pathological aspects, which may be of great value to the patient in the short or long term, a significant reason for the scientific and medical arts.

Regional Council of Medicine - State of Mato Grosso do Sul (CRM-MS)

Advisory Opinion n. 1/2012[49]

The operative and surgical procedures report must describe the lesions and other findings, the surgical techniques and strategies, accidents if any, and the materials used. The description can be made by any surgical team member and must be signed by the attending physician.

Regional Council of Medicine – State of Paraná (CRM-PR)

Opinion CRM-PR n. 2,623/2017[50]

The description of a surgical procedure must contain, in addition to the primary patient data, a summary description of each surgical procedure, including the material used. It must be performed by the attending physician or a surgical team member. The other documents in the operative report are an integral part of the medical record.

[...] The description of a surgical procedure must contain the patient's identification data, the name of the surgical procedure, the patient's diagnosis, the name of the surgeon and their assistants, the start and end time of the operation, and, mainly, the summary description of the surgical times. The description of each surgical procedure must include a detailed dissertation of the surgical tactics and techniques used, the position of the patient, the access route, the surgical accidents, the technical difficulties, the aspect of the condition in question, what was seen and performed from the beginning to end of the procedure, and all the materials used, including drains, wires, prostheses, and orthotics that

> may have been used. Other procedures performed during the surgery should be described, such as transoperative radiological examinations and obtaining surgical specimens or secretions for anatomopathological or bacteriological analysis. [...] This description must be done by the assistant physician or by a physician member of the surgical team. Other operating room documents, such as those for discharging patients, are also an integral part of the medical record; therefore, the insurance operator cannot deny valuable documents to the patient by allegations such as that they are a mere declaration of the materials used. These materials must be included in the operative report.

The same is required from the "*médicos reguladores*", physicians who work for the Pre-Hospital Emergency Medicine System. These professionals are responsible for evaluating emergency calls (e.g., by radio or telephone), providing technical assistance during transportation, and also, making triage and destination decisions. As these are physicians' decisions, under the "Medical Act"[51], they are required to fulfill individual medical records for each patient receiving care by the dispatched unit: the form must contain all the data available to provide a good understanding of the case, as well as the record of all decisions made by the supervising physician and the participating team[52].

During surgery, the registration of OPMEs (orthotics, prostheses, and special materials) falls under the primary surgeon's responsibility. However, the operative report can be done by any physician on the surgical team[53-54]. In that aspect, the following opinions were issued:

> **Regional Council of Medicine - State of Minas Gerais (CRM-MG)**
> **Opinion n. 166/2018[53]**
> [...] The document, which the consultant called the expense report, is actually the operating room report, which includes the materials and medicines used during surgery, as established in the Resolution mentioned above. CFM 1,638/2002, therefore constituting a document of the medical record. However, there is no ethical requirement that a physician must sign such a document.
> The opinion:
> The decision as to whether or not a physician should sign the abovementioned document falls within the norms of each institution. These decisions must be made with the participation of the technical or

clinical director and the head of the specific services, such as anesthesiology or other surgical clinics.

Federal Council of Medicine

Opinion n. 31/2019[54]

[...] The Ministry of Health, through its Manual of Good Practices in the Management of Orthotics, Prostheses and Special Materials (OPME), advises that any OPME used must be registered by the physicians involved in the surgery in the room expenditure record, in the operation report, and the patient's chart. The quantity and size of the materials must be specified. It is also mandatory to attach the traceability labels in each product's packaging to each mentioned document […]. Filling in the surgery report is the responsibility of the professional who performed the procedure and must contain a detailed record of the surgical act and a list of the OPME used and, in specific cases, the justification for the use of surplus or incompatible materials [...].

[...] Given the above, I consider that the traceability and assessment of special materials, including the OPME used in surgical procedures, are of interest to both the institution and the patient. The description of the material used and the recording of its quantity by the surgeon in the operation report, as required by health plans and operators, do not harm the ethics of medical practice since the *pacta sunt servanda* (the agreements must be complied with) lies within the limits of law and medical ethics.

Another conduct, often minimized but extremely important for legal purposes, is that of medical discharge. In this sense, three opinions of the Medical Councils help to clarify the matter[55-57]:

Federal Council of Medicine

CFM Consultation Process n. 36/2018[54]

Summary: The hospital discharge summary is a mandatory document of the medical record, and filling it out is the assistant physician's responsibility, respecting the professional hierarchy description provided in CFM Resolution n. 1,638/2002.

[...] First, the responsibility is that of the assistant physician, but the following physicians are co-responsible, in this order: the head of the service, the clinical director, and the technical director.

Regional Council of Medicine - State of Bahia (Cremeb)
Opinion n. 40/2009[56]

Summary: The Hospital Discharge Report or Information format must be elaborated by the medical directors of the institution and the clinical staff to meet the demand and specificity of the unit.

[...] However, as a suggestion, we recommend that the report, also named HOSPITAL discharge informative, includes the following: 1. Logo and administrative level; 2. Name of the health institution; 3. Registration data (patient identification, age, sex, height, and weight); 4. Hospital registry, bed, and inpatient unit; 5. Date of admission and discharge date; 6. Reason for admission and ICD code; 7. Associated diseases and ICD code; 8. Procedures performed; 9. Diagnosis of discharge and ICD code. 10. Prescriptions and post-discharge instructions; 11. Exam results; 12. Return date and location; 13. Physician's signature; 14. Signature of the patient/guardian. 15. Document in two copies: 1st copy for the patient and 2nd copy for the medical record. [...] It does not replace the Medical Report, a detailed description of the disease and its progress, but succinctly expresses the provided care.

Regional Council of Medicine - State of Pará (CRM-PA)
Opinion Consultation n. 7/2015[57]

Summary: The discharge summary is an integral part of the medical record, and the physician must complete it.

Regarding the possibility of including documents from other health-related areas, CFM Resolution n. 1,821[44] determines that supporting therapeutic and diagnostic documents should be kept together with the medical record. This position was ratified by CRM-SC Opinion n. 100[58] and CRM-MG Opinion n. 48[59], that mentions the need to include nursing progress notes and laboratory and imaging tests/results with the medical records. In fact, CFM Resolution n. 1,638[43] and CRM-DF opinion n. 56[60] recognizes that not only the assisting physician, but all those who provide care for the patient should write and have access to the recorded notes. The Hospital Admission Authorization is another document that has to be included[(61-62)]. Regarding the legibility and legality of the use of acronyms, it has been established that the latter is excusable unless the Medical Records Review Committee has determined otherwise[63]. Any damage resulting from poorly filling out or not completing the

medical record exposes the physician to disciplinary and legal sanctions[64], due to the declaratory legal nature of the document[65] in ensuring patients' rights[66-69].

Regional Council of Medicine – State of Santa Catarina (CRM-SC)
Consultation Process n. 100/2020[58]

Summary: Nursing evolution, laboratory, and imaging exams are part of the medical record, and in the absence of digital certification with an adequate level of security, they must be printed and filed in a good and safe place under the responsibility of the institution and its technical director.

Regional Council of Medicine - State of Minas Gerais (CRM-MG)
Opinion n. 48/2017[59]

Summary: Medical Records - Exam reports are documents that are part of the medical record and can be sent to the division responsible for scanning, storing, and handling the electronic records using proper protocols and ensuring security and confidentiality.

Regional Council of Medicine - State of Federal District (CRM-DF)
Opinion n. 56/2016[60]

Summary: All professionals in the multidisciplinary team (physicians, dentists, social workers, psychologists, nurses, and others) can handle or complete the medical records on servers, and it should be remembered that all those who are part of this team are also required to maintain professional confidentiality.

Regional Council of Medicine - State of Rio de Janeiro (Cremerj)
Consultation Opinion n. 2/2021[63]

Summary: Due to a lack of legal provisions, there will be no ethical infraction related to the use of acronyms and abbreviations in the patient's medical record in a health unit, except if there is a systematization of acronyms and abbreviations that can be used and attached to the patients' medical records by the Review Committee of the Medical Records of that Unit and this is not complied with.

Regional Council of Medicine – State of Santa Catarina (CRM-SC)
Consultation n. 2,075/2011[64]

[...] By not preparing or filling out the medical record adequately or if it is illegible, the physician is not practicing good medicine, as the absence of

documents or the illegible filling of data on the clinical evolution and medical prescription, the results of exams, reports or reports of procedures can put the physician's integrity and even the life of the patient at risk. In addition to being able to infringe on Article 2 of CFM Resolution n. 1,638/2002 and Articles 1 and 87 of CEM of CFM Resolution n. 1,931/09, if there is any damage resulting from poorly filling out or not completing the medical record, the physician may suffer other disciplinary sanctions at the Regional Council of Medicine and be indicted by the judiciary.

For the medical report, the document is usually requested by the patient to take to a new service, either at discharge or even during hospitalization when they are referred to another service; this, as an integral part of the medical record, must follow certain precepts, always in the intention to contain a concise but comprehensive report on the case. Likewise, the medical report must present the entire progress of the issue so that the new professional assistant can have the necessary information to proceed with treatment. When it is impossible to reach the patient or the attending physician, the report can be done by another professional who can report each consultation observed in the medical record from the first to the last examination.

Federal Council of Medicine

Opinion n. 5/2020[65]

Therefore, the medical report expresses a summary of all the medical care provided, with a description of the care, propaedeutics, diagnosis, prognosis, exams, etc., and must undoubtedly be given to the patient when requested, always mirroring their actual clinical situation.

[...] the legal nature of the medical report is declaratory, a descriptive narrative of the care provided to the patient, in its entirety or part, at their family's request. Therefore, when the doctor prepares a medical care report, the legal effect is the same as a certificate, and its falsity is considered a crime (art. 302 of the Penal Code).

Regional Council of Medicine - State of Mato Grosso (CRM-MT)

Opinion n. 5/2019[66]

Summary: The physician cannot deny giving their patient a copy of the medical report or chart.

A Medical Expert Opinion is a document containing the opinion of an expert or arbitrator. The opinion is issued in response to questions proposed by a judge or the interested parties.

A medical report is a detailed description of the facts that have occurred; that is, it translates into words the occurrence and progress of facts related to the treatment of a patient. It is understood that the professional must always provide, when summoned by the assisted person, as much information as possible to favor their interests, unless, in their judgment, this information may bring them discomfort or harm. The physician must understand that the provision of such documents is not a mere courtesy or favor but a right of the patient to request them, as this is an integral part of the medical act. The situation becomes more evident when this request is intended to pass information to another colleague, complement the treatment, or ensure the patient's rights.

Regional Council of Medicine – Federal District (CRM-DF)
Opinion n. 27/2018[67]

Summary: When there is no direct examination of the patient, the physician must issue a report with the data contained in the medical record up to the last examination date, explaining what happened on this date.

Regional Council of Medicine - State of Minas Gerais (CRM-MG)
Opinion n. 161/201[68]

Summary: It is not the responsibility of the hospital supervisor to issue a report based on a medical record for legal purposes. It is up to the medical assistant designated by the institution to prepare such a report for this purpose.

Regional Council of Medicine - State of Minas Gerais (CRM-MG)
Opinion n. 10/2020[69]

Summary: The medical record belongs to the patient and is under the doctor's care or the health care institution that assists them. A detailed report must be provided when transferring or referring a patient for treatment or discharge.

[...] The report is an obligation of the physician who refers the patient, which contains all the data of interest to the patient's treatment by the receiving unit.

Good record keeping must include copies of the medication prescription forms, either given to outpatients or of those prescriptions administered during inpatient care. In two different opinions of Regional Councils of Medicine, the rapporteurs address the possibility of delegating the act of prescribing to a

patient to a third party or indicating what to do when the patient needs the prescription but is not physically present.

Regional Council of Medicine - State of Paraiba (CRM-PB)
Consultation Process n. 1/2005[70]

Summary: Medication prescription is a medical procedure that cannot be delegated to other professionals. Its preparation must comply with the health legislation and the Code of Medical Ethics specifications.

Regional Council of Medicine – Federal District (CRM-DF)
Opinion Consultation n. 24/2018[71]

Summary: The prescriptions for special controlled drugs must be made in the patient's presence, registered in the medical record, and must be by ANVISA Resolution n. 344/1998.

[...] Legislation: Code of Medical Ethics. Art. 3 - It is forbidden for the physician to fail to assume responsibility for the medical procedure they indicated or participated in, even when several physicians have assisted the patient. Article 37 - It is forbidden for the physician to prescribe treatment or other procedures without a direct examination of the patient, except in cases of urgency and proven impossibility of performing it, in which case, they must do so immediately when the impediment is ceased.

Art. 87 - The physician is prohibited from failing to prepare a readable medical record for each patient. Providing or transcribing a prescription is a medical procedure. Thus, as established in Art. 3, they must assume responsibility for the procedure, even if other doctors have already assisted the patient. Art. 37 prohibits you from prescribing treatment without direct examination of the patient, except in urgent cases. Art. 87 prevents a physician from not making a readable medical record for each patient. The medical record has to provide information on the case history and all its laboratory/image exams, contributing to the assertive medical assistance that needs to be provided. In case of patient absence, the prescription will be registered in a separate sheet to be later incorporated in the medical record. The repetition of the prescription, or its adjustment, must be made in the patient's presence and noted in the medical history.

4. Conclusion

Patient's medical records are well defined within the scope of the Brazilian Federal Council of Medicine (CFM) as a sole document that is collective in nature and which contains all useful and necessary records that reveal the health status of an individual and his or hers diagnoses, prognoses, and treatments, including prescriptions and exam results. The records have to be signed by the agents responsible for each note and must be legible. The CFM establishes that its minimum content must include:

- anamnesis,
- physical examinations,
- mental status examinations,
- diagnostic hypotheses,
- laboratory exams,
- possible diagnoses (using the International Statistical Classification of Diseases and Related Health Problems - ICD),
- therapeutic approaches,
- surgical descriptions,
- expense reports,
- registration of any implanted materials (OPMEs) and apposition of their tracking tags on records,
- copies of medication forms and referrals,
- registries of the prognoses, sequelae (if present), and causes of death.

The Brazilian legislation recognizes the coherent and collective nature of the medical record, but in specific situations, such as exams of violence cases, it describes a minimum core content. When patients are transferred to another physician's care or service, or when they receive an external referral or are discharged, a detailed, understandable report must be provided. The discharge summary must contain, in addition to the patient's identification data and place of care, dates of admission and discharge; the reason for hospitalization (ICD code); associated diseases (ICD codes); performed procedures; discharge diagnosis (ICD code); prescription and post-discharge instructions; test results; and return date and location.

Finally, it is clear that noncompliance with the current standards, which means not providing the courts with the complete medical record when requested, besides being an ethical violation of professional conduct (26), might constitute a liable civil offense (9,12) and a crime typified by the Consumer's Code (1), with a penalty of six months to one year of detention or a fine.

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registro de todas as decisões tomadas pelo Regulador e pela equipe participante. O preenchimento do prontuário médico é obrigação e responsabilidade intransferíveis do médico. [The Pre-Hospitalization Emergency Medical System care configures a medical act, thus characterizing the need to having medical records of each service provided. The service form must contain all available data for a good understanding of the case, as well as a record of all decisions made by the physician and the participating team. The completion of the medical record is a non-transferable obligation and it is responsibility of the physician]. Relator: Carlos Roberto Naufel Júnior. [cited 2021 Jan 5]. Available from: at: https://sistemas.cfm.org.br/normas/visualizar/pareceres/PR/2018/2714

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secrecy]. Relator: Maria Natividade Santos Costa Lopes. [cited 2021 Jan 5]. Available from: https://sistemas.cfm.org.br/normas/visualizar/pareceres/DF/2016/56

61. CRM-MS. Opinion n. 24, 17/6/2015. O laudo para a Autorização de Internação Hospitalar (AIH) é um documento de caráter sigiloso, que deve obrigatoriamente ser arquivado no prontuário; sua autorização, pelo médico auditor, ocorrerá nas dependências do hospital; do ponto de vista administrativo, deve-se encaminhar cópia para a Unidade Gestora, inclusive por meio eletrônico [The Hospitalization Authorization report (AIH) is a confidential document, which must be filed in the medical record; its authorization, by the medical auditor, will take place on the hospital's premises; from an administrative point of view, a copy must be forwarded to the Management Unit, including by electronic means]. Relator: Hermann A. V. von Tiesenhausen. [cited 2021 Jan 5]. Available from: https://sistemas.cfm.org.br/normas/visualizar/pareceres/BR/2015/24
62. Conselho Regional de Medicina do Tocantins. CRM-TO. Opinion n. 5, 24/06/2015. Prontuário é o todo, do qual fazem parte as autorizações de internação hospitalar, solicitação de diárias, solicitação de acompanhante, boletins médicos, folhas de observações clínicas, exames, fichas de evolução, prescrições, descrições cirúrgicas, fichas de anestesia, relatório de alta, declaração de óbito (se for o caso). Deixar de preencher o prontuário médico constitui ilícito ético [The medical record is whole, includes authorizations for hospitalization, request for accommodations, request for a companion, medical bulletins, clinical observation sheets, exams, evolution sheets, prescriptions, surgical descriptions, anesthesia sheets, discharge report, death certificate (if applicable). Failure to complete the medical record constitutes an ethical illicit]. Relator: Eduardo Francisco de Assis Braga. [cited 2021 Jan 5]. Available from: https://sistemas.cfm.org.br/normas/visualizar/pareceres/TO/2015/5
63. Conselho Regional de Medicina do Rio de Janeiro. Cremerj. Opinion n. 2, 4/01/2021. Por falta de previsão legal, não haverá infração ética relacionada à utilização de siglas e abreviaturas no prontuário do paciente em unidade de saúde, exceto se houver sistematização das siglas e abreviaturas que poderão ser usadas e anexadas aos prontuários dos pacientes pela Comissão de Revisão de Prontuários daquela Unidade e esta for descumprida [Due to lack of legal provision, there will be no ethical violation related to the use of acronyms and abbreviations in the patient's medical record in a health unit, unless there is a systematization of the acronyms and abbreviations that can be used and attached to the patients' records by the Medical Record Review Commission of that Unit and it is not complied with]. Relator: Marcelo Peixoto. [cited 2022 Aug 8]. Available from: https://www.cremerj.org.br/resolucoes/exibe/pareceres/1090

64. CRM-SC. Opinion n. 2,075, 2011. Relator: José Eduardo Coutinho Góes. [cited 2021 Jan 5]. Available from: https://sistemas.cfm.org.br/normas/visualizar/pareceres/SC/2011/2075

65. CFM. Opinion n. 5, 7/05/2020. Informações médicas são sigilosas e privativas do paciente, sendo que sua divulgação somente ocorre com seu consentimento formal, exceto em cumprimento de determinação judicial, quando, nesse caso, o sigilo ficará sob a guarda do Juízo solicitante. [Medical information is confidential and proprietary to the patient, and its disclosure only occurs with its formal consent, except in compliance with a court determination, when, in this case, the confidentiality will be under the custody of the requesting Court]. Relator: Jeancarlo Fernandes Cavalcante. [cited 2021 Jan 5]. Available from: https://amb.org.br/wp-content/uploads/2020/05/Parecer-CFM-5-2020-relatorio-e-atestado-medico-publicidade-e-seus-efeitos-1.pdf

66. Conselho Regional de Medicina do Mato Grosso. CRM-MT. Opinion n. 5, 8/01/2019. O médico não pode negar o fornecimento de copia de relatório médico ou prontuário ao paciente. [The physician cannot deny to provide a copy of the medical report or record to the patient]. Relator: Hildenete Monteiro Fontes. [cited 2021 Jan 5]. Available from: https://sistemas.cfm.org.br/normas/visualizar/pareceres/MT/2019/5

67. CRM-DF. Opinion n. 27, 28/06/2018. Quando não houver o exame direto do paciente, o médico deverá emitir relatório com os dados contidos no prontuário até a data do último exame, explicitando essa data. [When there is no direct examination of the patient, the physician must issue a report with the data contained in the medical record up to the date of the last examination, specifying this date]. Relator: Rodrigo Machado Cruz. [cited 2021 Jan 5]. Available from: https://sistemas.cfm.org.br/normas/visualizar/pareceres/DF/2018/27

68. CRM-MG. Opinion n. 161, 30/11/2018. Não é atribuição do supervisor hospitalar a emissão de relatório obtido do prontuário para fins judiciais. Cabe ao assistente técnico médico, designado pela instituição, a elaboração de relatório para esse fim. [It is not the responsibility of the hospital supervisor to issue a report obtained from the patient's medical record for legal purposes. It is up to the assisting physician, designated by the institution, to prepare a report for this purpose]. Relator: Jose Afonso Soares. [cited 2021 Jan 5]. Available from: https://sistemas.cfm.org.br/normas/visualizar/pareceres/MG/2018/161

69. CRM-MG. Opinion n. 10, 16/01/2020. O prontuário médico pertence ao paciente e fica sob a guarda do médico ou da instituição de saúde que o assiste. Na transferência ou encaminhamento de paciente para fins de tratamento, ou alta, deve ser fornecido laudo ou relatório circunstanciado. [The medical record belongs to the patient and it is under the custody of the doctor or health institution that assists him. When transferring

or referring a patient for treatment or discharge, a detailed report or report must be provided]. Relator: Martius Adélio Gomes. [cited 2021 Jan 5]. Available from: https://sistemas.cfm.org.br/normas/visualizar/pareceres/MG/2020/10

70. Conselho Regional de Medicina do Estado da Paraíba. CRM-PB. Opinion n. 1/2005, 25/01/2005. A prescrição médica é um ato médico que não pode ser delegado a outros profissionais e a sua elaboração deve obedecer à legislação sanitária e aos ditames do Código de Ética Médica. [Prescription of drugs is a medical act that cannot be delegated to other professionals and its preparation must comply with the health legislation and the rules of the Code of Medical Ethics] Relator: Eurípedes Mendonça. [cited 2021 Jan 5]. Available from: <https://sistemas.cfm.org.br/normas/arquivos/pareceres/PB/2005/1_2005.pdf>
71. CRM-DF. Opinion n. 24, 2/06/2018. O fornecimento de receitas de controle especial deverá ser feito na presença do paciente, com registro em prontuário e de acordo com a Resolução n. 344/98 da ANVISA. [The provision of special control prescriptions must be done in the presence of the patient, registering it in the medical records and it should be done in accordance with Resolution n. 344/98 of ANVISA] Relator: Luiz Fernando Salinas. [cited 2021 Jan 5]. Available from: https://sistemas.cfm.org.br/normas/visualizar/pareceres/DF/2018/24