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Subjective annotations in the clinical record.
Las anotaciones subjetivas en el expediente clínico.

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Abstract:

In Mexico, the debate about the ownership of clinical records is still relevant. In this article, we will analyse some theories on the subject , but also we will distinguish between the ownership of the document, whatever its archival support, and the ownership of the personal data contained therein and that allows the work of health personnel.

Keywords:

Subjective notes, clinical records, and protection of personal data.

Resumen:

En México aún resulta relevante el debate acerca de la titularidad de la propiedad del expediente clínico. En este artículo analizamos algunas teorías acerca del tema pero también invitamos a hacer la distinción entre la propiedad del documento, cualquiera que sea su soporte archivístico, y la propiedad de los datos personales que en él se contienen y que permiten el quehacer del personal sanitario.

Palabras Clave*:*

.Anotaciones subjetivas, expediente clínico, protección de datos personales.

INTRODUCTION

Management and protection of clinical records constitute a relevant topic regarding the right to health and bioethics environments. Considering as a reference that technological advances have transformed the way documents are registered and guarded. Some questions arise about the ownership and access of the information they have. Principally subjective notes done by health professionals represent an ethical and legal challenge. At the same time, manifestation in the intellectual exercise of the physician and a register that can contain personal sensible data.

This article explores the legal and ethical implications of subjective notes in clinical records, emphasizing the different theories about ownership, patients' rights, health personnel, and regulatory requirements that seek to balance confidentiality with access rights. Throughout this article, diverse national and international regulatory frameworks pretend to answer these questions. Additionally, these notes impact the quality of medical care and the relationship between patients and healthcare providers.

Likewise, tensions arise to guarantee the right of patient access and maintain integrity in the clinical process and confidence in the relationship between the physician and the patient.

LEGAL AND CLINICAL CONSIDERATIONS ABOUT OBSERVATIONS PERFORMED BY THE LEGAL HEALTH PROFESSIONAL

Firstly, it is fundamental to distinguish between the practitioner and the user properties. Whether it was an intellectual work of the first one, it could be arranged without the consent of the second one. The user property has been its information source.

Moreover, what had been described in the medical record, we can find the testimony of the professional activity that could be seen as " intellectual property and worthy of protection related to physician´s right […]; however, all of this focuses on the patient's intimacy. Even when attributed to the physician in his right to intellectual property, it could not be used against or hurt the intimate patient right (Muñoz (1996, pg. 153)

According to Galan (2020, pg. RB-4-14), this document is part of the medical record because the responsible for the treatment is the physical or legal person who decides about his purpose,

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content, and treatment. This fact determines its ownership and compliance with Spanish legislation on personal data protection.

Authors like Cantero (n.d.)stated three theories that answer the question of who has ownership of this document:

a) Once his information source provides his ownership, it is the patient's property. This argument adds to the consideration that the patient pays for medical care (when it happens).

b) When it is related to the private sector and the physician works for an institution that owns the property, it becomes the physician's property. It does not mean patients cannot access information but with certain restrictions. Another side of the theory proposes that because it is a product of the intellectual process of the doctor, it becomes his intellectual property.
c) Integrated positions: claim that the owner's document is the health care facility or the health care practitioner who is the " owner of his intellectual contribution, and the interest manager of third parties registered there".

Regarding the Spanish legal framework, Royal Decree 1093/2010 of September 3rd approves the minimum data set for clinical reports in the National Health System. It is evident in Annex VIII, which establishes the minimum data set for the summarized clinical history, that the physician can make notes of his free subjective observations. Only is it possible when concerning assessments of unproven diagnostic hypotheses, suspicions of non-compliance with treatment, suspicions of undeclared treatments, unrecognized habits, having been the victim of abuse or unusual behavior, with the unique justification of reporting his assessments whenever they are of legitimate interest for the management of health problems by another professional.

On the contrary, the Article 29 Working Group (2007, pg. 8) points out that the information included in the clinical record was there because it was relevant to medical care, so if it were not, it should not have been included. Therefore, unrestricted access should be considered.

The patient has never had a clinical report; however, with technological advancements, he is about to become one of the material suppliers, at least in Mexico. To determine the property of this document, apart from its documentary support. According to Romeo & Castellano (1993, pg. 14), it is so relevant to establish the data discovery procedures and the right to access this document by the user, who turns out to be the owner's data.

To resolve this issue, the authors propose two scenarios. Firstly, physicians do not have intellectual rights to their documents. Secondly, it argues that people who elaborate on these documents have intellectual rights. As far as the information derived from the elements collected is concerned.For instance, diagnosis, prognosis, appraisals, and assessments about the patient's health state.Resulting in a denial of the patient's right to access his medical record.

In this way, the cited authors claimed that if the physician demanded his author's rights, he would not obtain the content. Thus, it only recovers information about the documentary support used but does not mean he is the original creator of the last one. While it is evident that he keeps in mind all the notes and his academic training, it does not have to be confused with the faculty and duty of avoiding giving information about whether the clinical records will be treated or transmitted to a non-authorized person or for illegitimate purposes(Romeo & Castellano, 1993, pg. 14)

Elements of a distinct nature are part of this document, which considers the relevant points of view that might reach in legal science. As stated throughout the article, it includes the relevant subjective notes of the physician concerning directions and patient's attitudes, which are of great importance in some cases. (Romeo & Castellano, 1993, pg. 14)claimed that the only ones that can be objects of consideration are part of scientific creations, so they have intellectual property.

Furthermore, if it is about activities developed in a public or private institution, the ownership corresponds to this. Providing the physician control over the third-party parties' use can give the document transmitting the exploration rights to the workplace to develop the intended activity. Because of that, the patient can not request the original document.

Sanchez & Abellán (2006, pg. 25) proposed that physicians have the faculty to impede access to subjective notes included in the medical record. Notwithstanding, these comments must be noted, provided they have clinical transcendence. For these authors, these are defined as the reflections and impressions cited in the documents of anamnesis and clinical course by the health professionals in charge of attending the patients and whose destinations are the professionals involved in the assistance.

Fajardo (2011, pg. 309, 310) agrees with the previous idea because he claims that the opinions reflected in the physicians' generality are those we share due to work reasons. For this reason, it is imperative to maintain certain information in the clinical record, especially that which could affect third parties or even a patient's health. Additionally, the ideal would be to protect certain information in the medical record since total,

unrestricted, or indiscriminate access to it could lead to distrust and cause defensive medical practice.

Considering this situation, Gomez (2006, pg. 11-12) mentioned that Mexican health professionals were seen as the ancient patrimonialism idea of documents generated or obtained by the government, only having access to the public workers who created them. That means that the physicians who work for the State but that the Mexican government can not uphold the principle that it is its responsibility to safeguard the files have the right to own them, even to the prejudice of the holder of the medical record. It contemplates guaranteeing the right to access clinical records is vitally relevant since “A cornerstone of this (a dignified existence) is [...] free access to his medical files and records”.

Official Mexican Standard NOM-004-SSA3-2012, of June 29, 2012, seems to coincide with this criterion because it only foresees providing verbal information to the patient, exercising parental authority, guardianship, legal guardianship, legal representation to relatives or competent authorities. Similarly, it reflects on contributing a clinical record summary or other clinical record evidence but not giving the whole medical record if requested in writing. Although, it does not establish any other special formality.

Nevertheless, the same Official Mexican Standard explicitly recognizes the patient as the owner of his data. Afterward, he is demanded to give them to the health professionals for his attendance. Besides those allowing their identification and being considered confidential, an issue seen by the creators of this regulation as ratification and consolidation of the ethical principle of professional secrecy.

This proposal coincides with Galan's criteria (2020, R-B4.14). Neither should the access of these notes be impeded, nor should inadequate expressions be used during the given care. Therefore, these notes are considered of interest for the patient’s treatment because they must have clinical transcendence. What is more, not denying the content to the patient, whose objective “is to gain full knowledge about his health state, in addition to the reservation to such subjective annotations must be opposed [...] by the specific physician who made the notes and not by the health center that keeps them".

Braibant (1976, pg. 153) contemplates the main objective of exercising the right to access their private data. Whether necessary, there are two possibilities: employing and rectifying.
First, employing refers to the data intended to be accessed so it is possible to rectify, are incontrovertible facts. Secondly, it is about opinions about the behavior or character: "For this data category, the 1971 U.S. Act offers an appealing solution, which recalls the general principle enshrined in German law; the subject of the file may submit a brief statement containing his objections, which will be attached to his file and communicated to third parties.

Unless these objections are frivolous and irrelevant so that the statement is not too long and consequently costly for the data manager, the last may request that it be limited to one hundred words as long as it helps the subject of the file to draft it with clarity. Hence, the file assumes an "adversarial" manner under the procedural definition of the term, which results in an extra value to its content and guarantees the protection of the citizen."

In this sense, it seems the cited Official Mexican Standard NOM-004-SSA3-2012 from the clinical file of June 29, 2012, clearly states that property of clinical record, the ownership of the clinical record is held by the institution or by the medical service provider that generates it if it does not belong to an institution. What belongs to the patient is the personal data and information given and found in the document as a beneficiary of the medical care received. This ownership recognizes health protection and data confidentiality. Moreover, it precisely ascertains that the information must remain in the hands of its owner for a minimum period of five years from the date of the last medical act due to a set of elaborated documents of interest and patient’s benefit.

Since the legislator's temporality, the clinical record remains to hospitalize sick people. Regulation of the General Health Law regarding the provision of health care services of May 14, 1986, has made a statement on the matter. Additionally, it added mandatory handling of this document to only authorized personnel, even though it does not specify what it is about.

Troncoso (2006, pg. 86) cited the last aspect referring to the clinical record as ” live ”. On the contrary, after the deadline and turning into a “ passive” document, the author suggests that these documents “ must be filed as a general norm, separating the identity data from the clinical documents for safety precaution without damaging genetic, scientific, epidemiological professor research.

With the text of Official Mexican Standard NOM-004-SSA3-2012, we could unequivocally observe how it regulates any health service provider and must integrate and maintain clinical records and are part of the medical center, which will be entirely responsible for fulfilling the described duties, independently of the recruitment of personnel. Electronic, magnetic, electromagnetic media,magneto-optical optics, or any other technological media regarding Official Mexican Standard NOM-004-SSA3-2012 Electronic health record information systems. Health information exchange of November 30, 2011.

Equally, Spanish Law 41/2002, of November 14, 2022, is the regulatory basis of a patient’s autonomy, rights, and obligations

concerning information and clinical documentation. It determines a similar responsibility. Thereby, it mentions that each medical center will file the clinical records of its patients. Even though they are not necessarily the original documentary support, having a minimum of five years taken from the date of discharge from each care process.

About the related date with the patient's birth, biometric, medical, or analytical tests to verify the affiliation with the mother will not be destroyed once the causes of death are known, relocating them to the corresponding files for administration. As soon as they arrive, they will be kept under safety precautions that the legislation protects data disposal. It is considered to preserve and retrieve information, in addition to the authenticity mechanisms of the content and the possible modifications due to its nature and future reproduction. Maintaining technical and organizational measures suitable for its file and protection that avoid its destruction or accidental loss. These dispositions will be applied to all clinical documentaries.

The aforementioned data could only be communicated with previous requests of the court in criminal proceedings or the case of a claim or legal challenge of maternal filiation.

Similarly, it verifies the duties to cooperate in the orderly and sequentially creating and managing the clinic documentary. If it is given an individual service, the responsibility will be the health professional in charge of management and the management and custody of the reference documentation. It is noteworthy that Spanish law establishes as a patient's right those related to the custody of the clinical history.

Nonetheless, Cantero (n.d.) considers it more important to clarify who has access to the medical record than who owns it.

CONCLUSION

The clinical record represents a space of intersection between individual rights and collective responsibilities to manage information with the utmost respect for the patient's privacy and the ethical principles of medical practice. Not only is this document a record of personal data, but it is also a tool for guaranteeing continuity and health care quality. Through the analysis of the normative and doctrinal provisions, it is apparent that the ownership of the personal data belongs to the patient, and the documentary support belongs to the healthcare professional or institution that generates it. This duality poses a complex framework in which transparency, data protection, and appropriate access must coexist harmoniously.

On the other hand, subjective notes in clinical records raise a particular challenge by combining elements of intellectual property with information of a confidential nature. It requires compliance with a regulatory framework that ensures adequate access to the information and protection against misuse, setting clear limits regarding the purpose and relevance of these annotations. Further, promoting a culture of shared responsibility among healthcare professionals, institutions, and patients to ensure safety and respect for all parties' rights.

Consequently, it requires a balance that allows patients to exercise their rights without undermining trust and efficiency in healthcare services provision. Only through a comprehensive and collaborative approach will it be possible to meet the challenges of clinical records management in a constantly evolving technological and regulatory context.

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