CNS 49/2021

Opinion in relation to the query made by a hospital regarding access to clinical histories for teaching purposes

A query from the data protection representative of a hospital regarding access to clinical histories for teaching purposes is presented to the Catalan Data Protection Authority.

The consultation raises a doubt in relation to the interpretation of point 7, and in particular in relation to point 7.2.2 with respect to point 7.2.1, of the Protocol through which basic guidelines are determined to ensure and protect the right to patient privacy for students and residents in Health Sciences, agreed by the Plenary of the Human Resources Commission of the National Health System, of October 25, 2016 and published from Order SSI/81/2017, of January 19 of the Ministry of Health, Social Services and Equality.

Having analyzed the request, which is not accompanied by further information, in view of the current applicable regulations and in accordance with the report of the Legal Counsel, the following is ruled:

I

(...)

II

On the basis of the Protocol through which basic guidelines are determined to ensure and protect the patient's right to privacy for students and residents in Health Sciences (henceforth, protocol), and from the perspective of the access to clinical histories for educational purposes, the data protection delegate raises in his consultation whether the provisions of point 7.2.2 of the protocol can be interpreted as an alternative to what is provided for in point 7.2.1 of the same protocol.

Point 7 of the protocol includes the guarantees of access to clinical data and, in particular, with regard to the guarantees of access to the clinical history for teaching purposes, among others, are included in point 7.2.

Point 7.2 of the protocol provides for the following:

"7.2.1 The LBAP in its article 16.3 establishes that access to the clinical history for judicial, epidemiological, public health, research or teaching purposes obliges to preserve the personal identification data of the patient, separate from those of a clinical nature assistance, so

that, as a general rule, anonymity is guaranteed, unless the patient himself has given his consent not to separate them.

The dissociation of data obliges to separate data of scientific utility (clinical-assistantial in our case) from those others that allow identification of its holder (medical history number, Social Security number, ID, etc.). The dissociation of data must be carried out by a healthcare professional subject to professional secrecy or another person subject to an equivalent obligation of secr

In the field of teaching, students will be able to access the clinical history with dissociated personal data or simulated clinical histories by the head of teaching in order to guarantee that the learning derived from them is carried out respecting the privacy and confidentiality of the health data .

7.2.2 The Center's management will authorize access to the clinical history register. The authorization will be processed by the person in charge of the registry, requiring for this the previous and motivated report of the tutor or those responsible for the research/master's/ proper title/doctorate which will be submitted to a prior opinion of the corresponding Comité de Etica Asistencial/Investigación. Said authorization will have time limits that are appropriate to the specific purpose for which access is authorized".

In relation to these provisions, the consultation raises in particular whether it can be interpreted that the medical center, with the approval of the Ethics Committee, can authorize access to clinical histories for the purpose of teaching, without the need to comply with the requirements provided for in point 7.2.1 of the protocol.

III

Given the consultation in these terms, the analysis must start from the basis that, according to what is established in articles 2.1 and 4.1 of Regulation (EU) 2016/679 of the Parliament and of the Council, of April 27, 2016, relative to the protection of natural persons with regard to the processing of personal data and the free movement of such data and which repeals Directive 95/46/EC (General Data Protection Regulation), hereinafter RGPD, the data protection regulations apply to the treatments that are carried out on any information "on an identified or identifiable natural person ("the interested party"); Any person whose identity can be determined, directly or indirectly, in particular by means of an identifier, such as a number, an identification number, location data, an online identifier or one or more elements of identity, shall be considered an identifiable physical person physical, physiological, genetic, psychological, economic, cultural or social of said person".

And, in relation to the treatment, article 4.2) of the RGPD defines it as "any operation or set of operations carried out on personal data or sets of personal data, either by automated procedures or not, such as collection, registration, organization, structuring, conservation, adaptation or modification, extraction, consultation, use, communication by transmission, diffusion or any other form of enabling access, comparison or interconnection, limitation, deletion or destruction".

The processing of data relating to natural persons who receive assistance in health institutions, such as that formulated by the query, is subject to the principles and guarantees of the personal data protection regulations (RGPD and Organic Law 3/2018, of December 5, of protection of personal data and guarantee of digital rights (from now on, LOPDGDD)).

The RGPD provides that all processing of personal data must be lawful (article 5.1.a) and, in this sense, establishes a system of legitimization of data processing that is based on the need for one of the legal bases established in its article 6.1.

At the same time, to the extent that Law 21/2000, of December 29, on the rights of information concerning the patient's health and autonomy, and the clinical documentation provides that the clinical history "[...] includes the whole of documents relating to the care process of each patient while identifying the doctors and other care professionals who have intervened" (art. 9.1), and which must collect, among other things, the information relating to the identification data of the patient and care (art. 10.1.a), as well as clinical care data, such as the description of the disease or the current health problem and successive reasons for consultation, or the clinical procedures used and their results, etc. (art. 10.1.b), it is clear that the treatment derived from health care involves the treatment of information relating to the health of natural persons (article 4.15) of the RGPD).

In accordance with article 9 of the RGPD, the processing of personal data, among others, that are related to health is prohibited, unless one of the circumstances of article 9.2 of the RGPD is met, such as now, section h), which refers when "the treatment is necessary for the purposes of preventive or occupational medicine, evaluation of the labor capacity of the worker, medical diagnosis, provision of assistance or treatment of a sanitary or social type, or management of health and social care systems and services, on the basis of the Law of the Union or Member States or by virtue of a contract with a health professional [...]".

In accordance with what has been progressed, the definition and regulation of clinical histories is provided for in Law 41/2002, of November 14, basic regulation of patient autonomy and rights and obligations in matters of clinical information and documentation, basic rule in accordance with its first additional provision, and Law 21/2000, of December 29, on the rights of information concerning the health and autonomy of the patient, and the documenta

In relation to the uses of the medical history, article 11.1 of Law 21/2000, and in similar terms article 16 of Law 41/2002, provides that it is an instrument intended primarily to help guarantee adequate assistance to the patient And, on the other hand, section 3 provides the following:

"The clinical history can be accessed for epidemiological, research or teaching purposes, subject to the provisions of Organic Law 15/1999, of December 13, on the protection of personal data, and State Law 14/1986, of April 25, general health, and the corresponding provisions. Access to the clinical history for these purposes obliges the preservation of the patient's personal identification data, separate from those of a clinical care nature, unless the patient has previously given consent.".

It is worth saying that the reference to which article 11.3 of Law 21/2000 refers to Organic Law 15/1999, of December 13, on the protection of personal data, must be understood as made in the RGPD and the LOPDGDD.

In accordance with what has been stated, Law 21/2000 enables the treatment of data relating to patients for healthcare purposes in health centers and, with regard to the use of clinical histories for teaching purposes, among other intended purposes, establishes the obligation that access must be done preserving the patient's personal identification data, separate from those of a clinical care nature, unless the patient gives his consent.

With regard to the teaching purpose, the Protocol was published through Order SSI/81/2017, of January 19, through which basic guidelines are determined to ensure and protect the patient's right to privacy by students and residents in Health Sciences.

In accordance with what is provided for in point 2 of the protocol, this applies to "the health centers of the National Health System (SNS), to the centers/and private entities of a health nature that, by agreement or under any formula of indirect management collaborate with the SNS in assistance, teaching or research, as well as other private health entities accredited for training in Health Sciences".

In the case at hand, and according to the information available, they apply to the institution by consulting the provisions of this protocol.

It should be noted that the object of the proposed consultation focuses on the interpretation of point 7.2 of the protocol, which is related to the guarantees of access to the clinical history of the health service for purposes, among others, of teaching, and in particular if point 7.2.2 of the protocol can be interpreted as an alternative to the requirements of point 7.2.1 - we refer to the previous legal basis in which both points of the protocol have been transcribed.

In relation to point 7.2.1 of the protocol, note that its wording begins by making express mention of the legal basis from which it supports its forecasts, that is to say, article 16.3 of Law 41/ 2002 (coinciding with what is provided for in article 11.3 of Law 21/2000 in accordance with what has been revealed). In this sense, the first paragraph of point 7.2.1 constitutes a partial reproduction of the provision of article 16.3 of Law 41/2002, and in the following paragraphs the requirement relating to the separation of the patient's identifying data is developed of those of an assistance nature, in case the patient's consent is not recorded. Thus the third paragraph makes express mention of the fact that, in the field of teaching, "students will be able to access the clinical history with dissociated personal data or clinical histories simulated by the person in charge of teaching in order to guarantee that the learning derived from the same is done respecting the privacy and confidentiality of health data".

On the other hand, for the purposes we are interested in, point 7.2.2 provides that the management of the center must authorize access to the clinical history register, which must be processed by the person in charge of the register by requesting the prior and reasoned report from the tutor or the person in charge of the master's degree, own title or doctorate which will be submitted to the prior opinion of the corresponding Care Et

On the basis of what has been presented, and in accordance with the reasons that will be presented below, it is considered that point 7.2.2 of the protocol cannot be interpreted in the sense proposed by the consultation, that is to say, it does not constitute an alternative to the requirements required by point 7.2.1 of the proto

At the outset, because based on the principle of regulatory hierarchy (art. 9.3 EC), in any case a ministerial order, with a regulatory nature, cannot contradict a rule of higher rank, as is the case with Law 41/2002. That is to say, in any case, the interpretation that could be given to point 7.2.2 of the protocol, in relation to point 7.2.1, cannot contradict what is provided by a higher-ranking rule, that is, the need to preserve the patient's personal identification data, separate from those of a clinical care nature, unless the patient has previously given consent.

In fact, it must necessarily be so to the extent that, in accordance with what has been explained, point 7.2.1 of the protocol begins its wording by expressly citing the provision of article 16.3 of Law 41/ 2002

On the other hand, according to what can be seen from the foundation of Order SSI/81/2017, or from the heading of the protocol itself, it does not seem that the objective of this is the interpretation proposed by the consultation.

In accordance with the provisions of Order SSI/81/2017, the measures implemented by the protocol are intended for the "[...] control of personnel in training and research in health institutions, as well as the acquisition by this group of skills and habits that guarantee a professional future in which respect for privacy, dignity and confidentiality of health data are integrated and internalized in the daily work of all professionals who act in areas linked to the health sector".

And, in this sense, point 1 of the protocol provides that the object of this is the establishment of basic action guidelines aimed at guaranteeing the patient's right to dignity and privacy when he is treated in the presence of students from qualifications related to the health sciences (students) and when it is attended by professionals who have specialized training in the health sciences (resident in training).

Given its purpose, the goal of the protocol seems to be to establish more specific control mechanisms on the use of patients' health data, to control that their rights and freedoms are respected, when in health care there may be have the presence of students and residents.

Thus, in relation to the provision made in point 7.2.2, it must be understood that the protocol aims to grant health centers, in any case, the possibility of authorizing, or not, the use of clinical histories for the purpose of teaching (without prejudice to the fact that article 16.3 of Law 41/2002, or article 11.3 of Law 21/2000, also applies to other purposes), in accordance with a certain procedure, and with the favorable opinion of a healthcare ethics committee.

And, this should not be understood apart from the need that, once the center has authorized access to the clinical histories for the purpose of teaching, this treatment should not be carried out preserving the data identification of the patients from those of a clinical assistance nature, so that anonymity is ensured, or the patient's consent is provided not to separate this data.

In fact, the third paragraph of point 7.2.1 of the protocol provides that students, in the field of teaching, can access previously dissociated clinical histories, or

clinics simulated by the head of teaching in order to guarantee the students' learning and respecting the privacy and confidentiality of health data.

In short, the provisions of points 7.2.1 and 7.2.2 of the protocol must be interpreted cumulatively and not alternatively, so that in any case the health center must authorize the use of clinical histories with teaching purpose, either by preserving the patient's identifying data from those of a clinical assistance nature, so that anonymity is ensured, or with the patient's consent.

Conclusions

In accordance with the Protocol through which basic guidelines are determined to ensure and protect the patient's right to privacy for students and residents in Health Sciences, published by Order SSI/81/2017, of January 19 , the medical center, can only authorize access to clinical histories for the purpose of teaching, with the approval of the Ethics Committee, if the requirements of section 7.2.2 of the Protocol are met and any of the foreseen cases occur in the patient autonomy legislation and point 7.2.1 of the Protocol.

Barcelona, November 2, 2021