Ref: CNS 7/2018

Opinion in relation to the inquiry made by an entity in the field of health on whether the provision of medical data to judicial processes without the consent of the patient or prior judicial request infringes the regulations on the protection of personal data.

A letter from the entity's representative is presented to the Catalan Data Protection Authority in which it is requested that the Authority issue an opinion to assess whether the provision of medical data to judicial processes without the patient's consent or prior judicial request infringes the regulations on the protection of personal data.

The letter refers to the regulations according to which the entity is competent to claim from the insurance companies the amount of the health care provided in its centers to their insureds, and explains that in the face of the refusal of a insurance company to cover the expenses arising from the aforementioned health care provided by the ICS to one of its insured, the entity must file a legal claim for the amount of the invoice generated by the care.

In particular, it asks whether, in this case, it would infringe the regulations governing the protection of personal data if it were to attach the medical data contained in the patient's clinical history to the lawsuits, without the explicit consent of the insured patient, or the prior request of the judicial authority, for the purposes of being able to certify the effective and real provision of the health care claimed, as well as the adequacy of this and the amount of the corresponding invoice, to the set public prices.

It raises whether this action would be protected by the right to effective judicial protection contained in article 24.1 of the Spanish Constitution or whether it could constitute an infringement of article 16 of Law 41/2002, of November 14, basic regulatory the autonomy of the patient and the rights and obligations in terms of information and clinical documentation in relation to article 11 of Organic Law 15/1999, of December 13 on the protection of personal data (LPOD) and the article 10 of General Health Law 14/1986.

Analyzed the request, and the current applicable regulations, and in accordance with the report of the Advisory I issue the following legal opinion:

I

(...)

II

The consultation refers to a communication of personal data included in the patients' clinical history.

Clinical records contain personal health-related data, which constitute what the LOPD, in its article 7, calls specially protected data, indicating in its third section that personal data that reference to racial origin, health and sexual life can only be collected, processed and transferred when, for reasons of general interest, a law so provides or the affected party expressly consents.

Likewise, the sixth section of this article 7 provides that health data may be the subject of treatment when this is necessary for prevention or medical diagnosis, the provision of health care or medical treatments or the management of health services, provided that the data processing is carried out by a health professional subject to professional secrecy or another person subject to an equivalent obligation of secrecy, as well as when the processing is necessary to safeguard the vital interest of the affected or of another person, in case the affected person is physically or legally unable to give consent.

Also article 8 of the LOPD authorizes institutions and public and private health centers and corresponding professionals to process personal data relating to the health of the people they care for in accordance with state or regional health legislation .

Therefore, the LOPD is conclusive with regard to the treatment of health data, since either there is a law that authorizes the treatment and communication, or the express consent of the affected person is obtained, unless the data is treat for the provision of health care or management of health services by health personnel or in those situations in which the vital interest of the affected person is safeguarded.

The LOPD provides in article 3.i) that any disclosure of data made to a person other than the interested party is a transfer or communication and, therefore, remains regulated in article 11 of the LOPD with a general character .

The transfer or communication of personal data is subject to the provisions of articles 11 and 21 of the LOPD, with the particularities mentioned relating to the transfer of health data.

Article 11.1 of the LOPD provides, as a general rule, that:

> "The personal data subject to treatment may only be communicated to a third party for the fulfillment of purposes directly related to the legitimate functions of the assignor and the assignee with the prior consent of the interested party."

This same article, however, in its second section, establishes certain exceptions to this general rule, among which we find the legitimacy of transfers that are provided for by a rule with the rank of law or those that are provided to solve an emergency or the carrying out epidemiological studies in the terms established by the legislation on state or regional health, cases in which the consent of those affected will not be necessary.

Consequently, the analysis of the legal framework is necessary to determine the legality and protection of the transfer of the personal data of patients and/or users.

III

According to what was stated by the entity, it is competent to claim from the insurance companies the amount of the health care provided in its centers to the insured of these. In order to make this claim, the entity will have to communicate patient data for the purposes of being able to certify the effective and real provision of the health care claimed. These data, which form part of the patient's clinical history, are considered health data.

It should be borne in mind that Law 41/2002, of November 14, basic regulation of patient autonomy and rights and obligations in matters of information and clinical documentation, which regulates in its article 3 the right to privacy of the patient, establishes:

> "Every person has the right to respect the confidential nature of the data relating to their health, since no one can access them without prior authorization covered by the Law."

This rule dedicates its chapter V to the regulation of the clinical history and article 14.1 establishes that it is understood as such: "...the set of documents relating to the care processes of each patient, with the identification of the doctors and the other professionals who have intervened in them, in order to obtain the maximum possible integration of the clinical documentation of each patient, at least, in the scope of each center."

In the area of Catalonia, it is also necessary to take into account Law 21/2000, of 29 December, on the rights of information concerning the patient's health and autonomy, and clinical documentation.
Both laws contain provisions that define the uses that can be made of the data contained in the clinical history, specifically, article 16 of Law 41/2002 states that:

> "1. The clinical history is an instrument primarily intended to guarantee adequate assistance to the patient. The healthcare professionals of the center who carry out the diagnosis or treatment of the patient have access to the patient's clinical history as a fundamental tool for their adequate assistance.
> ...
> 4. The administration and management staff of the health centers can only access the clinical history data related to their own functions."

On the other hand, as we have seen, in accordance with the LOPD, this type of data can only be collected, processed and transferred with the express consent of the affected person or when so provided by law, it is therefore necessary to analyze whether there is a rule with the rank of law that enables the communication of data between the Territorial Management of the ICS and the insurance entities.

Article 16.3 of Law 14/1986, of April 25, General of Health (LGS) provides that

> "the invoicing for the attention of these patients will be carried out by the respective administrations of the Centers, taking as a basis the effective costs. These revenues will have the status of the Health Services. In no case will these revenues revert directly to those that they intervene in the care of these patients".

In turn, article 83 of the same LGS adds that

> "The income from health care in the cases of special mandatory insurance and in all cases, insured or not, in which a third party is required to pay, will have the status of income of the corresponding Health Service. The expenses inherent in the provision of such services will not be financed with Social Security income. In no case will these incomes be able to revert to those who intervened in the care of these patients."

In particular, the second paragraph of this precept establishes that "To this end, the Public Administrations that had provided sanitary care to users in such cases will have the right to claim from the responsible third party the cost of the services rendered".

On the other hand, the tenth Additional Provision of the Consolidated Text of the General Security Law Social, approved by Royal Legislative Decree 1/1994, of June 20, establishes, in section 1, that:

> "They will not have the nature of Social Security resources that result from the following services, benefits or services: 1) Income referred to in articles 16.3 and 83 of Law 14/1986, of April 25, General of Health, from the health care provided by the National Institute of Health, in direct management to users without the right to Social Security health care, as well as in the cases of private compulsory insurance and in all such cases, insured or not, in which a third party appears obliged to pay".

Likewise, article 15.1 of Law 8/2007, of July 30, of the Catalan Health Institute (LICS), establishes:

> "The Catalan Health Institute must claim, under article 83 of the General Health Law, the payment of the relevant public fee or price, by virtue of the legal or regulatory rules, of the 'public or private insurance or liability insurance for injury or illness caused to people assisted by the Catalan Health Institute, as long as there is a third party obliged to pay. In the case of agreements or concerts with third parties obliged to pay, they must be claimed for the amount of assistance provided in accordance with the terms of the corresponding agreement or concert."

From what is available in the precepts transcribed so far, it follows that when there is a third party that has to answer for the cost of the medical act performed by a public health center, it will proceed

repercuss to the same, by imperative of what is available in the mentioned Laws, the cost of the sanitary action.

Consequently, the rules contained in the Health and Social Security legislation and the ICS itself would constitute the enabling rules, in terms of article 7.3 of the LOPD, for the transfer of patient health data to whom health care has been provided by the entity, for the claim to the insurance companies or third parties obliged to pay for this care.

However, it is necessary to bear in mind the application of the principle of proportionality in the processing of data provided for in article 4.1 of the LOPD, according to which, in the event of a transfer of data, these must be adequate , relevant and not excessive in relation to the purpose that justifies the transfer.

In such a way that they will have to communicate to the insurance company, or to the third party obliged to pay, only those data that are essential for the invoicing of the healthcare expenditure actually carried out.

IV

Faced with the refusal of an insurance company to cover the expenses arising from the health care provided by the ICS to one of its insured, the entity must file a lawsuit claiming the amount of the invoice generated by the assistance

In this case, the recipient of the health data working in the patient's clinical history, in principle, would no longer be the insurance company or the third party obliged to pay, but the Courts competent to deal with the demands in claim of the invoices generated by the assistance

The legal authorization that allows the communication of personal data relating to health contained in the medical history to the judicial bodies is contained, specifically, in article 16.3 of the aforementioned Law 41/2002, of November 14, basic regulatory the patient's autonomy and rights and obligations regarding information and clinical documentation, which establishes:

> "access to clinical history for judicial, epidemiological, public health, research or teaching purposes is governed by the provisions of Organic Law 15/1999, of December 13, on the Protection of Personal Data, and in Law 14/1986, of April 25, General of Health), and other applicable rules in each case. Access to the clinical history for these purposes requires the preservation of the personal identification data of the patient, separate from those of a clinical and healthcare nature, so that, as a general rule, anonymity is ensured, unless the patient himself has given his consent to don't separate them.
>
> Exceptions are made in cases of investigation by the judicial authority in which it is considered essential to unify the identifying data with the

> medical care, in which it will be what the judges and courts have in the corresponding process. Access to the data and documents of the clinical history is strictly limited to the specific purposes of each case."

However, this legal authorization would be valid only and exclusively in relation to the data expressly required by the judicial body in the framework of a judicial investigation and limited to the specific purposes of each case.

In this context it is necessary to take into account, as the jurisprudence has said that, "the right to reserve the data contained in the clinical history is not, well, absolute and unlimited, but it can be rebelled for the sake of an interest preferred, which can be the resolution of a judicial conflict if it requires the knowledge of those and only respect for the information necessary for the decision of the case" (Provincial Court of Madrid, Order of January 18, 2005, (Rec. 559 /2004)).

A collision between two fundamental rights occurs in these cases. On the one hand, the right to the protection of personal data, derived from article 18 of the Constitution and enshrined as an autonomous right and informer of the constitutional text by the Constitutional Court Judgment 292/2000, of November 30 , and, for another, the right to effective judicial protection of judges and courts, contained in article 24 of the Constitution.

As we have seen, the LOPD itself allows the limits for the requirement of consent to be established, given that its article 6.1 requires, as a general rule, consent for the processing of data "unless the Law provides otherwise" , a system is thus established in which the right to the protection of personal data is waived in those cases in which the legislator himself (constitutional or ordinary) has considered the existence of reasoned and well-founded reasons that justify the need for the treatment of the data, incorporating these assumptions into rules of, at least, the same rank as that which regulates the protected matter.

As the Constitutional Court's repeated jurisprudence maintains (for all, Sentence 186/2000, of July 10) "the right to privacy is not absolute, as none of the fundamental rights are, being able to yield to constitutionally relevant interests, always that the cut that he has to experience is revealed as necessary to achieve the intended legitimate end, proportionate to achieve it and, in any case, be respectful of the essential content of the right".

Well, applying this doctrine to the specific case, the right enshrined in article 24 of the Spanish Constitution must prevail, which guarantees the effective judicial protection of judges and courts and legitimizes the use of all the necessary means of proof in defense of their interests in a judicial process, in the terms set forth.

In short, article 24 of the Spanish Constitution constitutes sufficient authorization for the entity to provide health data in claims for expenses incurred by health care to insurance companies.

This authorization is not, however, unlimited if not that, as we have seen, in accordance with the principle of proportionality in the treatment of personal data, provided for in article 4.1 of the LOPD, the data object of the assignment must be adequate, relevant and not excessive in

relation to the purpose that justifies the assignment. In this, the authorization would be limited to the data strictly necessary to justify the effective health care provided to the insured of the insurance companies, or third parties obliged to pay.

v

It should be borne in mind that Regulation (EU) 2016/679, of the Parliament and of the European Council, of April 27, 2016, General Data Protection (hereinafter, RGPD), applicable from the next 25 May 2018, introduces significant novelties with respect to the regulation of the current LOPD regarding the treatment of health data.

Article 4 of the RGPD establishes that “treatment” is considered: “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 Regulation is based on the criterion that all data processing must be lawful and fair. In order for the processing to be lawful, the data must be processed with the consent of the interested party or "on some other legitimate basis established in accordance with the Law, either in the present Regulation or in virtue of another Law of the Union or of the Member States referred to in this Regulation, including the need to comply with the legal obligation applicable to the person responsible for the treatment or the need to execute a contract to which the interested party is a party or in order to take measures at the request of the interested party prior to the conclusion of a contract" (Considerand 40 RGPD).

The RGPD, apart from the specially protected data already foreseen by the LOPD, which are now called "special categories of data", includes in article 9 two new special categories of data, genetic data and biometric data. For all these categories of data, section 1 of article 9 establishes:

> "the processing of data that reveals ethnic or racial origin, political opinions, religious or philosophical convictions, or trade union affiliation is prohibited, and the processing of genetic data, biometric data aimed at uniquely identifying a natural person, data relating to the health or data relating to the sexual life or sexual orientation of a natural person.”

This article does not use the concept of communication or transfer of data contained in the LOPD, but this concept is included in the definition of treatment which, as we have seen, is included in article 4. And with regard to the categories special data regulations, generally establishes the prohibition of treatments that reveal personal data except in the specific situations provided for in the same regulation.

Section 2 of article 9 lists the circumstances that, if they occur, would allow this treatment, therefore establishing a "numerus clausus" of treatment possibilities. Among these exceptions we do not find, in the same terms as the current LOPD, the possibility of transferring data when, for reasons of general interest, a law provides for it.

Thus, in the case at hand, health data could only be subjected to treatments that reveal them if the object of the treatment is within the assumptions provided for in article 9.2.

In the first of the cases analyzed in this report, that is to say the communication of health data by the entity to the insurance companies or third parties obliged to pay, letter h) of the mentioned article 9.2 of the RGPD, provides that it is possible to treat special categories of personal data if "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 the systems and health and social care services, on the basis of the Law of the Union or of the Member States or by virtue of a contract with a health professional and without prejudice to the conditions and guarantees contemplated in section 3.

Recitals 52, 53 and 54 of the RGPD clarify these precepts by establishing that:

"(52) Likewise, exceptions to the prohibition of processing special categories of personal data must be authorized when established by the Law of the Union or of the Member States and, subject to the appropriate guarantees, in order to protect personal data and other fundamental rights , when it is in the public interest, in particular the processing of personal data in the field of labor legislation, legislation on social protection, including pensions and for security purposes, supervision and health alert, the prevention or control of communicable diseases and other serious threats to health. Such an exception is possible for purposes in the field of health, including public health and the management of health care services, especially in order to guarantee the quality and profitability of the procedures used to resolve claims for benefits and services in the health insurance regime, or for archival purposes in the public interest, scientific and historical research purposes or statistical purposes. The treatment of said personal data must also be authorized on an exceptional basis when it is necessary for the formulation, exercise or defense of claims, either for a judicial procedure or an administrative or extrajudicial procedure."

(53) The special categories of personal data that deserve greater protection must only be treated with health-related purposes when necessary to achieve said purposes for the benefit of individuals and society as a whole, in particular in the context of the management of health or social protection services and systems, including the processing of these data by the health management authorities and the central national health authorities for the purposes of quality control, information management and general national and local supervision of the system health or social protection, and guarantee of the continuity of health care or social protection and cross-border health care or security, supervision and health alert purposes, or for archival purposes in the public interest, scientific or historical research purposes or statistical purposes, based on the Law of the

Union or Member State that must fulfill an objective of public interest, as well as for studies carried out in public interest in the field of public health. Therefore, this Regulation must establish harmonized conditions for the treatment of special categories of personal data related to health, in relation to specific needs, in particular if the treatment of these data is carried out, with health-related purposes, by persons subject to the legal obligation of professional secrecy. The Law of the Union or Member States must establish specific and adequate measures to protect the fundamental rights and personal data of individuals. Member States must be empowered to maintain or introduce other conditions, including limitations, with respect to the treatment of genetic data, biometric data or health-related data. However, this should not be an obstacle to the free circulation of personal data within the Union when such conditions apply to the cross-border processing of these data.

"(54) The treatment of special categories of personal data, without the consent of the interested party, may be necessary for reasons of public interest in the field of public health. This treatment must be subject to appropriate and specific measures in order to protect the rights and freedoms of individuals. In this context, "public health" must be interpreted in the definition of Regulation (EC) No. 1338/2008 of the European Parliament and of the Council, that is to say, all elements related to health, specifically the state of health, including of morbidity and disability, the determinants that influence said state of health, the needs for health care, the resources allocated to health care, the provision of health care and universal access to it, as well as the costs and the financing of health care, and the causes of mortality. This treatment of health-related data for reasons of public interest must not result in third parties, such as employers, insurance companies or banking entities, processing personal data for other purposes."

This criterion has been included in the Draft Organic Law for the Protection of Personal Data, approved by the Council of Ministers on November 10, 2017, and published in BOCG, Congress of Deputies Series A Núm. 13-1 of November 24, 2017.

Article 9 of this project provides:

"Article 9. Special categories of data.

1. For the purposes of article 9.2 a) of Regulation (EU) 2016/679, in order to avoid discriminatory situations, the consent of the affected person alone will not be sufficient to lift the prohibition of data processing whose main purpose is to identify their ideology, affiliation union, religion, sexual orientation, beliefs or racial or ethnic origin. The provisions of the previous paragraph will not prevent the processing of said data under the remaining assumptions contemplated in article 9.2 of Regulation (EU) 2016/679, when applicable.

> 2. The data processing contemplated in letters g), h) ei) of article 9.2 of Regulation (EU) 2016/679 based on Spanish law must be covered by a law, which may establish additional requirements relative to its security and confidentiality In particular, the law will be able to protect the treatment of data in the field of health when this is required by the management of public and private healthcare and social systems and services, or the execution of an insurance contract of which the affected be part

Thus, as we have seen, in accordance with article 9.2.h) in relation to the rules contained in the Health and Social Security legislation and the ICS Law itself, they would enable the treatment that entails the disclosure of data from health by the public health centers to the insurance companies to claim the collection of the health care provided to those insured.

In turn, when the recipients of the health data are judges or courts, letter f) of paragraph 2 of article 9 authorizes the treatment when "it is necessary for the formulation, the exercise or the defense of the claims or when the courts act in the exercise of their judicial function".

As we have already seen, in this regard recital 52 of the RGPD specifies that "the processing of said personal data must also be authorized on an exceptional basis when it is necessary for the formulation, exercise or defense of claims, whether by a judicial procedure or an administrative or extrajudicial procedure."

Therefore, from the application of the RGPD, there will be a legal basis for the treatment of health data and its disclosure when they have to be included in lawsuits against insurance companies, as documentary evidence, without the consent of the interested party and without the prior request of the judicial authority, protected by the provisions of article 9.2.f).

It cannot be forgotten, however, that the Regulation has given a letter of nature to the principle of data minimization and has included it in article 5.1.c), which establishes that in all data processing these must be adequate, relevant and limited in relation to the purpose for which they are treated.

In short, as already foreseen by the LOPD, the requirement remains that the data are only processed to the extent that they are essential for the fulfillment of the intended purpose.

Therefore, there being authorization for the treatment of health data that entails its disclosure in the two cases analyzed, this authorization will be limited to those minimum data essential for the fulfillment of the intended purposes, which as we have seen have as their object the billing and effective collection of healthcare expenses for healthcare services provided by public healthcare administrations, which must be borne by insurance companies or third parties obliged to pay.

VI

In accordance with the considerations made in these legal foundations in relation to the query raised by the entity in relation to whether the provision of medical data to judicial processes without the patient's consent or prior judicial request infringes the data protection regulations of a personal nature. the following are done,

Conclusions

From the perspective of the personal data communication regime provided for in the LOPD, there is sufficient legal authorization in article 11.2.a) of the LOPD in relation to the rules contained in the Health legislation (art. 16.3 and art. 83 LGS), Social Security (DA tenth LGSS) and the LICS (art. 15.1 LICS), as well as with article 24 of the EC for the communication of adequate, relevant and non-excessive personal health data, which must be included in the judicial claims for the amounts of the assistance services provided by the public health centers to the insurance companies, without the consent of the interested party or the requirement of the judicial authority.

Once the RGPD is applicable, the legal basis for these treatments is provided for in article 9.2.h) and 9.2.f) of the RGPD with the limits established by article 5 of the RGPD, specifically the principle data minimization. Therefore, this authorization must be limited to the minimum data essential for the fulfillment of the intended purposes for those treatments.

Barcelona, March 7, 2018