Carrer Rosselló, 214, Esc. A, 1r 1a
08008 Barcelona

In this resolution, the mentions of the affected population have been hidden in order to comply with art. 17.2 of Law 32/2010, given that in case of revealing the name of the affected population, the physical persons affected could also be identified.

File identification

Resolution of the rights protection procedure no. PT 129/2021, petition against the Catalan Health Institute.

Background

1. On 02/11/2021, the Catalan Data Protection Authority received a letter from Mrs. (...) (hereinafter, the person making the claim), for which he made a claim for the alleged neglect of the right of access to his clinical history and traceability, which he had previously exercised before the Catalan Health Institute (hereafter, ICS).

The claimant provided a copy of a burofax that he sent on 08/17/2021 to the Primary Care Center of (...) (hereafter, CAP (...)), managed by the ICS, through which formulated an access request in the following terms:

> "...as it has already been requested previously and today the delivery of the clinical history and its traceability has not yet been made effective, I request EXERCISE THE RIGHT OF ACCESS TO THE CLINICAL HISTORY AND ITS TRACABILITY of the identified patient - in reference to the claimant-, whose copy of the DNI is attached, with special mention of the professionals who performed the care, with number, surnames and number of colleagues, interventions performed, diagnostic imaging tests, informed consents and other documents that contain data, evaluations of information of any kind on the patient's situation and clinical evolution in accordance with what is established in article 3 of Law 41/2002 of November 14, the basic regulatory framework for patient autonomy and rights and obligations in the field of information and clinical documentation."

2. On 11/25/2022, the claim was transferred to the ICS so that within 15 days it could formulate the allegations it deemed relevant.

3. The ICS made allegations by means of a letter dated 17/12/2021, in which it set out, in summary, the following:

> "In the month of August:
> - He sent a Burofax to the CAP (...), nominal to his general practitioner , requesting clinical documentation .
> - The doctor attended to her, by telephone, the day after receiving the burofax (...). From this visit, the doctor works on the case in a network, both

Carrer Rosselló, 214, Esc. A, 1r 1a
08008 Barcelona

with the T.Social of the CAP and the City Council, and also coordinates with the PSP Mental Health service .

In the month of September:

- He complained to the CAP administrators about his request made by Burofax. They informed her of the documentation request procedure , and explained the procedure she had to do, and the documentation she had to present.

  On 09/09/2021 she was summoned to the CAP, so that she would come in person to sign the official application already prepared to process the management.

- On 09/09/21, she was attended by the GiS Referent of the CAP, and when explaining to her the documentation she had to sign for the request to be activated, Ms. (...) it was refused, as no official procedure could be activated."

Fundamentals of Law

1. The director of the Catalan Data Protection Authority is competent to resolve this procedure, in accordance with articles 5.b) and 8.2.b) of Law 32/2010, of October 1, of the Catalan Data Protection Authority.

2. Article 15 of Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, relating to the protection of natural persons with regard to the processing of personal data and the free movement of such data (hereafter, RGPD), regarding the right of access of the interested person, provides that:

"1. The interested party will have the right to obtain from the controller confirmation of whether or not personal data concerning him or her are being processed and, in such case, the right to access personal data and the following information:

a) the purposes of the treatment;
b) the categories of personal data in question;
c) the recipients or the categories of recipients to whom the personal data was communicated or will be communicated, in particular recipients in third countries or international organizations;

d) if possible, the expected period of personal data conservation or, if not possible, the criteria used to determine this period;
e) the existence of the right to request from the person in charge the rectification or suppression of personal data or the limitation of the treatment of personal data relating to the interested party, or to oppose said treatment;
f) the right to present a claim before a control authority;
g) when the personal data has not been obtained from the interested party, any available information about its origin;
h) the existence of automated decisions, including the creation of profiles (...).

Carrer Rosselló, 214, Esc. A, 1r 1a
08008 Barcelona

> 2. (…)
> 3. The person responsible for the treatment will provide a copy of the personal data subject to treatment. The person in charge may charge a reasonable fee based on administrative costs for any other copy requested by the interested party. When the interested party presents the request by electronic means, and unless he requests that it be provided in another way, the information will be provided in a commonly used electronic format.
> 4. The right to obtain a copy mentioned in section 3 will not negatively affect the rights and freedoms of others."

In relation to the rights contemplated in articles 15 to 22 of the RGPD, sections 3 and 4 of article 12 of the RGPD establish the following:

> "3. The person in charge of the treatment will provide the interested party with information related to their actions on the basis of a request in accordance with articles 15 to 22, and, in any case, within one month from the receipt of the request. This period can be extended another two months if necessary, taking into account the complexity and the number of applications. The person in charge will inform the interested party of any such extension within one month of receipt of the request, indicating the reasons for the delay. When the interested party submits the request by electronic means, the information will be provided by electronic means whenever possible, unless the interested party requests that it be provided in another way.
> 4. If the person in charge of the treatment does not comply with the request of the interested party, he will inform him without delay, and no later than one month after receiving the request, of the reasons for his non-action and of the possibility of submitting a claim before a control authority and exercise judicial actions."

Apart from the previous regulation, in the case analyzed here, it is also necessary to take into account the applicable health regulations. Specifically, on the one hand, Basic State Law 41/2002, of November 14, basic regulatory framework for patient autonomy and rights and obligations in the field of clinical information and documentation (hereinafter, Law 41/2002) establishes in its article 18 the right of access to the clinical history in the following terms:

> "Rights of access to the clinical
> history 1. The patient has the right of access, with the reservations indicated in section 3 of this article, to the documentation of the clinical history and to obtain a copy of the data contained therein . Health centers must regulate the procedure that guarantees the observance of these rights.
> 2. The patient's right of access to the clinical history can also be exercised by duly accredited representation.
> 3. The patient's right of access to the clinical history documentation cannot be exercised to the detriment of the right of third parties to the confidentiality of the data contained therein collected in the patient's therapeutic interest, nor to the detriment of the right of professionals who participate in its preparation, who can object to the right of access to the reservation of their subjective annotations.

4.(...)"

Regarding the content of the clinical history, article 15 of this legal body establishes the following:

"1. The medical history must incorporate the information that is considered important for truthful and up-to-date knowledge of the patient's state of health. Any patient or user has the right to record, in writing or in the most appropriate technical support, the information obtained in all their care processes, carried out by the health service both in the field of primary care and specialized care.

2. The main purpose of the medical history is to facilitate health care, recording all the data that, under medical criteria, allow truthful and up-to-date knowledge of the state of health. The minimum content of the clinical history must be the following:

a) The documentation relating to the clinical statistics sheet.
b) Entry authorization.
c) The emergency report.
d) History and physical examination.
e) Evolution.
f) Medical orders.
g) The interconsultation sheet.
h) The reports of complementary explorations.
i) Informed consent.
j) The anesthesia report.
k) The operating room or birth registration report.
l) The pathological anatomy report.
m) The evolution and planning of nursing care.
n) The therapeutic application of nursing.
ñ) The graph of constants.
o) The clinical discharge report.
Paragraphs b), c), i), j), k), l), ñ) io) are only required in the formalization of the clinical history when it is about hospitalization processes or it is arranged in this way. "

On the other hand, the Catalan Law 21/2000, of December 29, on the rights of information concerning the patient's health and autonomy, and clinical documentation
(hereinafter, Law 21/2000) determines the following in article 13:

"Rights of access to the clinical history

1. With the reservations noted in section 2 of this article, the patient has the right to access the documentation of the clinical history described by article 10, and to obtain a copy of the data contained therein. It is up to the health centers to regulate the procedure to guarantee access to the clinical history.
2. The patient's right of access to the documentation of the clinical history can never be to the detriment of the right of third parties to the confidentiality of their data appearing in said documentation, nor the right of the

Carrer Rosselló, 214, Esc. A, 1r 1a
08008 Barcelona

professionals who have intervened in the preparation of this, who can invoke the reservation of their observations, appreciations or subjective annotations.
3. The patient's right of access to the clinical history can also be exercised by representation, as long as it is duly accredited."

Article 10 of Law 21/2000, relating to the content of the medical history, establishes the following:

"1. The medical history must have an identification number and must include the following data:
a) Identification data of the patient and of the assistance:
Name and surname of the patient.
Date of birth.
sex
Usual address and telephone number, in order to locate you.
Date of attendance and admission, if applicable.
Indication of origin, in case of referral from another care center.

Service or unit in which assistance is provided, if applicable.
Room and bed number, in case of admission.
Doctor responsible for the patient.
Likewise, when it comes to users of the Catalan Health Service and care is provided on behalf of this entity, the personal identification code contained in the individual health card must also be recorded.
b) Clinical care data:
Physiological and pathological family and personal history.
Description of the disease or current health problem and successive reasons for consultation.

Clinical procedures used and their results, with the corresponding opinions issued in case of specialized procedures or examinations, and also the interconsultation sheets.
Clinical course sheets, in case of admission.
Medical treatment sheets.
Informed consent form if applicable.
Information sheet provided to the patient in relation to the diagnosis and the prescribed therapeutic plan, if applicable.
Epicrisis or discharge reports, if applicable.
Voluntary discharge document, if applicable.
Necropsy report, if available.
In the case of surgical intervention, the operating sheet and anesthesia report must be included, and in the case of childbirth, the registration data.
c) Social data:
Social report, if applicable.
2. In hospital clinical histories, in which more than one doctor or healthcare team often participates, the actions, interventions and prescriptions made by each professional must be recorded individually.

Finally, article 16.1 of Law 32/2010, of the Catalan Data Protection Authority, regarding the protection of the rights provided for by the regulations on personal data protection, provides the following:

> "1. Interested persons who are denied, in part or in full, the exercise of their rights of access, rectification, cancellation or opposition, or who may understand that their request has been rejected due to the fact that it has not been resolved within the established deadline, they can submit a claim to the Catalan Data Protection Authority."

3. Having explained the applicable regulatory framework, it is then necessary to analyze whether the ICS resolved and notified, within the period provided for by the applicable regulations, the right of access exercised by the person making the claim, since precisely the reason for his complaint that initiated the present rights protection procedure, was the fact of not having obtained a response within the period provided for the purpose.

In this regard, it is certified that on 17/08/2021 a burofax was entered in the CAP (...), through which the claimant exercised the right of access to his personal data, specifically, to the clinical history and its traceability.

In accordance with article 12.3 of the RGPD, the ICS had to resolve and notify the request to exercise the requested right within a maximum period of one month from the date of receipt of the request legality Well, the ICS has not proven to have responded to the request for access made by the person making the claim, neither within the one-month period (extendable for two more months) provided for the purpose, nor subsequently .

From the statements made by the ICS (precedent 3), it appears that the reason why the ICS did not process the access request was that the person concerned did not
he followed the procedure provided for the purpose, according to which it was necessary to fill out a certain form and sign it.

In this regard, it should be noted that article 12 of Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights (hereinafter, LOPDGDD), establishes that "the exercise of the right (of 'access) cannot be denied for the sole reason that the person concerned opts for another means" different from that provided by the person in charge of the treatment. So that the use by the interested person of a burofax to formulate the access request - instead of filling in the ad hoc form - was not a reason not to process it and neglect their right to access

In this assessment that is made, it is also taken into account that the access request made was clear in the identification of the person requesting access, in the content of the request, it was duly signed, and -according it was indicated on the request itself -, it was accompanied by a copy of the DNI of the person requesting access (the claimant). So, once it was entered in the CAP (...), the ICS was obliged to give an answer within one month, which ended on 08/16/2021.

Carrer Rosselló, 214, Esc. A, 1r 1a
08008 Barcelona

Consequently, given that the claim was based on the lack of response to the request to exercise the right of access, it must be declared that the ICS did not resolve and notify in form and time the said request submitted by the affected person

4. Regarding the content of the access request, the part referring to the content of the clinical history (4.1) will be analyzed first, and secondly, the part referring to traceability (4.2).

4.1. About the request for access to the content of the clinical history.

The claimant has requested access to his medical history, noting the information in which he has a special interest.

The right of access includes the right to obtain a copy of all the documents included in the claimant's medical record where their data appear (art. 15.3 RGPD).
Therefore, it must not be limited to the minimum mandatory content indicated by articles 15 of Law 41/2002 and 10 Law 21/2000 (transcribed in the 2nd legal basis), but the available documentation must be provided. In the same way, the documentation indicated in these precepts should be provided if it is available. Thus, in the event that, for example, the medical history of the claimant does not include the "medical treatment sheet", despite being a mandatory document of a medical history, this should not be issued afterwards, from the access request made by the person making the claim, as this exceeds the scope of the right of access provided for in Article 15 of the RGPD.

On the other hand, it should be borne in mind that articles 18.3 of Law 41/2002 and 13.2 of Law 21/2000 foresee limits to the right of access, referring, on the one hand, to the right to data protection of third parties regarding the data of these third parties that may appear in the clinical history in the therapeutic interest of the patient (here claimant). And on the other hand, the right of professionals to the confidentiality of their observations, assessments or subjective notes that they may have made
to consign In the two cases indicated, access to this data could be limited
that may appear in the documentation to be delivered, noting the exceptional circumstances that apply and the reservation expressed by the professional or another third party.

Since it is not known that there is any exceptional case of denial of the right of access provided for in Article 23.1 RGPD, nor has the ICS invoked any, the claimant's right of access to the content of the your medical history.

With regard to the documentation of the medical history that the claimant noted in his request for access, the following should be stated:

- Name and surname and number. of a member of "the professionals who will carry out the attention" to the person claiming:

Carrer Rosselló, 214, Esc. A, 1r 1a
08008 Barcelona

In accordance with article 10.1.a) of Law 21/2000, access to information on the identity of the doctor assigned to the claimant ("doctor responsible for the patient") should be facilitated, although it is considered that the information that must be provided is only the name and surname of the doctor in charge, since with regard to the membership number, although it is public data, it is considered excessive for identification purposes.

With regard to the rest of the professionals who have intervened in some care process for the claimant, in accordance with what is provided for in article 9.1 of the same rule ("the medical history includes the set of documents relating to the care process of each patient while identifying the doctors and other healthcare professionals who intervened"), it will also be necessary to provide the identification data of these professionals, if this information is included in their medical history, although for identification purposes it is enough with the first and last name.

- Documents showing the provision of informed consent:

Pursuant to the provisions of article 15.2.i) of Law 41/2002 and article 10.1.b) of Law 21/2000, access to said documentation should be facilitated in the event that it exists.
It should be clarified that the indicated precepts only require the inclusion of informed consent in the clinical history when "...it is about hospitalization processes or it is provided in this way" (art. 15.2.j law 41/2000), or or "...if relevant" (art. 10.1.b law 21/2000).

- Interventions carried out:

In the event that there is, it is necessary to facilitate access to said documentation, which in any case should include the operating room report or reports, the operating sheet or sheets and the anesthesia report or reports, in by virtue of what is provided for in article 15.2.k) of Law 41/2002 and in article 10.1.b) of Law 21/2000.

- Diagnostic imaging tests:

In the event that there is, access to said documentation should be facilitated, in accordance with the provisions of article 10.1.b of Law 21/2000.

- Data, assessments and information about the patient's situation and clinical evolution:

It is appropriate to facilitate access to said documentation, under the provisions of article 15.2.e) of Law 41/2002, among others.

4.2. About the request for access to the traceability of the clinical history.

First of all, the term "traceability" should be clarified. Royal Decree 3/2010, of January 8, which regulates the National Security Scheme in the field of

the Electronic Administration, defines it as the "property or characteristic consistent in that the actions of an entity can be imputed exclusively to said entity". For its part, the ICT Security Guide CCN-STIC 803.
ENS [National Security Scheme]. Valuation of the systems prepared by the National Cryptological Center, refers to "traceability" as "being able to verify a posteriori who has accessed, or modified, certain information".

Understanding traceability in these terms, it can be noted that the traceability of accesses to a patient's clinical history includes information on the identity, position and/or category of staff of the person responsible for the treatment who accesses it, the date and time of access, and the center and module or unit from which it is accessed.

However, this term does not coincide with the material aspect of the right of access regulated in article 15 of the RGPD, the neglect of which constitutes the object of the present guardianship procedure. Specifically, of all the information corresponding to the traceability of access to the clinical history, the only one that must be provided when exercising the right of access in Article 15 of the RGPD, is that relating to recipients or categories of recipients to whom the clinical information would have been provided, that is to say, the identification of the entities or persons outside the organization to whom the clinical data was communicated. Therefore, in the opposite sense, it can be affirmed that the identity of the staff attached to the person in charge of the treatment (in this case, the ICS) who has accessed is not part of the right of access in Article 15 of the RGPD in the clinical history.

On the other hand, the health regulations that have been transcribed in the 2nd legal basis, also do not recognize the patient's right to know the identity of the professionals who have accessed their clinical history.

Therefore, with regard to the request for access referring to the traceability of the clinical history, the right of the person claiming to access the information about the recipients or categories of recipients to whom they have been communicated or it is foreseen to communicate data, and dismiss the claim regarding the request for access to the rest of the information on traceability, for exceeding the material scope of the right of access provided for in art. 15 of the GDPR.

5. In accordance with what is established in articles 16.3 of Law 32/2010 and 119 of the RLOPD, in cases of estimation of the claim for protection of rights, the manager of the file must be required so that within the term of 10 days to make the exercise of the right effective. In accordance with this, it is necessary to require the ICS so that, within 10 counting days from the day after the notification of this resolution, it makes effective the exercise of the claimant's right of access, in the terms and with the limits indicated in the preceding legal basis. Once the right of access has taken effect
in the terms set forth and the person making the claim is notified, in the following 10 days the claimed entity must report to the Authority.

For all this, I resolve:

1. Partially estimate the guardianship claim made by Ms. (...)against the Catalan Institute of Health, and recognize his right of access to the documents of his clinical history, with the limits indicated in the 4th legal basis. And in terms of traceability

Carrer Rosselló, 214, Esc. A, 1r 1a
08008 Barcelona

of the medical history, recognize the right of access to information about the recipients or categories of recipients to whom data has been communicated or is expected to be communicated, and reject the claim regarding the rest of the information on traceability.

2. Request the Catalan Institute of Health so that, within 10 counting days from the day after the notification of this resolution, it makes the right of access effective exercised by the claimant, in the form and with the scope indicated in the fundamentals of law 4th and 5th. Once the right of access has taken effect, in the following 10 days the Catalan Institute of Health will have to report to the Authority.

3. Notify this resolution to the Catalan Health Institute and the person making the claim.

4. Order the publication of the resolution on the Authority's website (apdcat.gencat.cat), in accordance with article 17 of Law 32/2010, of October 1.

Against this resolution, which puts an end to the administrative process in accordance with articles 26.2 of Law 32/2010, of October 1, of the Catalan Data Protection Authority and 14.3 of Decree 48/2003, of 20 February, by which the Statute of the Catalan Data Protection Agency is approved, the interested parties can file, as an option, an appeal for reinstatement before the director of the Catalan Data Protection Authority, in the period of one month from the day after its notification, in accordance with the provisions of article 123 et seq. of the LPAC or to directly file an administrative contentious appeal before the administrative contentious courts of Barcelona, in the period of two months from the day after its notification, in accordance with articles 8, 14 and 46 of Law 29/1998, of July 13, regulating administrative contentious jurisdiction.

Likewise, the interested parties may file any other appeal they deem appropriate for the defense of their interests.

The director,