

## File identification

Resolution of sanctioning procedure no. PS 85/2022, referring to the Catalan Institute of Health (University Hospital of Bellvitge).

## Background

1. On 10/11/2021, the Catalan Data Protection Authority received a letter from a person for which he filed a complaint against the Bellvitge University Hospital - dependent of the Catalan Institute of Health (ICS)- (henceforth the HUB), due to an alleged breach of the regulations on the protection of personal data .

In particular, the complainant stated that on 06/25/2021 he submitted a request for access to the traceability of his medical history and that the HUB, in response to his request, sent him a letter in which he was informed that accesses to his clinical history had been detected that could not be justified, and that this fact would be brought to the attention of the Directorate of Personnel of the ICS for the appropriate purposes.

In order to substantiate his complaint, the person making the complaint provided a copy of the letter dated 16/09/2021 that the HUB had sent informing him of the unauthorized access. In this office, the dates on which these would have occurred, or even the time interval, were not specified.

2. The Authority opened a preliminary information phase (no. IP 457/2021), in accordance with the provisions of article 7 of Decree 278/1993, of November 9, on the sanctioning procedure applied to areas of competence of the Generalitat, and article 55.2 of Law 39/2015, of October 1, on the common administrative procedure of public administrations (henceforth, LPAC), to determine whether the facts were susceptible to motivate the initiation of a sanctioning procedure.

3. In this information phase, on 01/26/2022, the complainant was requested to provide a copy of the letter of 06/25/2021 presented to the HUB, in which he requested access to the traceability of your medical history, in order to place the allegedly improper accesses in time.

4. On 01/26/2022, the person reporting here provided a copy of the requested document, in which it is stated that the person reporting here had requested traceability in his medical history, from "December 2020 , 1 December " (sic) .

5. On 1/02/2022, this Authority required the ICS to provide the record of access to the medical history of the reporting person, in the period between 1/12/2020 and 31/12/2021 . Likewise, it was requested that he report in detail on the reason that justified each of the accesses, and that he clearly indicate those that he considered were not justified by any assistance action. And, on the other hand, to indicate whether, in relation to unwarranted access, the ICS had instituted reserved information or disciplinary proceedings against the person or persons who had improperly accessed.

6. By means of a letter dated 8/02/2022, the ICS requested that it be provided with a copy of the official document that the complainant submitted together with his complaint, and that the deadline of 10 days to respond be extended to the request for prior information. This request

was resolved by agreement of the same date, notified on the same day 8/02/2022, and through which the deadline to respond to the request was extended and a copy of the requested document was provided.

7. On 2/03/2022, given that the deadline had been exceeded without the ICS having provided the required information, this Authority reiterated the requirement that it respond within 5 days.

8. On 3/03/2022, the ICS responded to the request by providing a report of 28/02/2022 drawn up by the head of the Unit for Attention to Citizenship and Participation and the Southern Metropolitan Territorial Management of the ICS, in which the following was stated:

- That the ARSOPOL Rights Commission of the HUB, meeting on 07/27/2021 and 02/28/2022 (the first date following the request for traceability of the herein complainant of 06/25/2021 and the second following the request received by the Authority), analyzed the accesses to the medical history of the complainant here and determined that the following unjustified accesses had occurred: two accesses on 12/22/2020 and 01/26/2021 by part of a person with a nursing profile; and, a third access on 01/26/2021 by a person with a technician profile.
- That on 10/22/2021 the South Metropolitan Territorial Management sent a report to the competent body of the ICS, bringing to its attention the alleged unwarranted access to the medical history of the complainant here, and that no they had no information regarding whether *"reserved information or disciplinary proceedings have been initiated"*

Together with this report, the minutes of the ARSOPOL Rights Commission of the HUB dated 27/07/2021 and 28/02/2022 which were alluded to in the report were attached; and the record of accesses to the medical history of the complainant here, which contains the details of the accesses that the Commission had considered unjustified, which are as follows:

*"(...) Technician 12/22/2020 18:33:55 12/22/2020 18:35:03 (...)"* in the "Clinical Research" module

*"(...) Nurse 12/22/2020 18:36:06 12/22/2020 18:47:25 (...)"* in the "Clinical Research" module

*"(...) Nurse 01/26/2021 16:26:36 01/26/2021 17:24:03 (...)"* in the "Clinical Research" module

9. On 24/11/2022, the director of the Catalan Data Protection Authority agreed to initiate a sanctioning procedure against the ICS for an alleged infringement provided for in article 83.5.a), in relation to article 5.1.f); both 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 thereof (hereinafter, RGPD).

10. On 12/01/2023, the person instructing this procedure formulated a resolution proposal, by which he proposed that the director of the Catalan Data Protection Authority admonish the ICS as responsible for an infringement provided for in article 83.5.a) in relation to article 5.1.f), both of the RGPD.

This resolution proposal was notified on the same date, 12/01/2023, and a period of 10 days was granted to formulate allegations.

11. The deadline has been exceeded and no objections have been submitted.

### proven facts

On 22/12/2020 and 26/01/2021, with the details indicated in the preceding 8th *in fine*, two people, one with a technician profile and the other with a nurse profile, who provided services to the Bellvitge University Hospital - dependent on the Catalan Institute of Health - accessed the historic clinic of the person making the complaint here, without his consent, and without these accesses being related to any assistance or diagnostic action.

### Fundamentals of law

1. The provisions of the LPAC, and article 15 of Decree 278/1993, according to the provisions of DT 2a of Law 32/2010, of October 1, of Catalan Data Protection Authority. In accordance with articles 5 and 8 of Law 32/2010, the resolution of the sanctioning procedure corresponds to the director of the Catalan Data Protection Authority.

2. The accused entity has not made allegations in the resolution proposal, but it did so in the initiation agreement. Regarding this, it is considered appropriate to reiterate below the most relevant part of the motivated response of the instructing person to these allegations.

In its letter of objections to the initiation agreement, the ICS refers to the demonstrations made during the prior information phase and adds that actions have been taken to prevent new ones from being carried out illicit accesses but which has not been able to take disciplinary action given that the events were carried out by professionals other than the holders of the credentials. Of particular note is the letter submitted on 03/03/2022, in which it acknowledges that three unjustified accesses to the complainant's medical history were carried out.

In this regard, it is necessary to take into account article 5.1.f) of the RGPD, which regulates the principle of confidentiality of personal data, and which provides:

*"1. The personal data will be:*

*(...)*

*f) processed in such a way as to guarantee adequate security for personal data, including protection against unauthorized or illegal processing and against accidental loss, destruction or damage, through the application of appropriate technical and organizational measures ("integrity and confidentiality")."*

The previous precept must be put in relation to the health regulations that regulate the use of the medical history. Specifically, article 11 of Law 21/2000, of December 29, on the rights of information concerning the patient's health and autonomy, and clinical documentation and article 16 of Law 41/2002, of November 14, "*basic regulation of patient autonomy and rights and obligations in the field of clinical information and documentation*". Both precepts, reproduced in the following section, establish the prohibition of access to patients' clinical history unless it is for a justified reason.

On the basis of the aforementioned regulations, and given that the ICS has recognized that its staff has carried out improper access to the medical history of the person reporting, the ultimate responsibility for this treatment is the imputed entity that, in accordance with article

24.1 RGPD, has the obligation to apply the appropriate technical and organizational measures in order to guarantee the confidentiality of the data subject to treatment and that it complies with the data protection regulations.

In the present case, the ICS has stated that it has taken actions aimed at preventing further improper access. In this regard, it is worth saying that, although any measure tending to improve the traceability and control of access to clinical histories must be evaluated very positively, this fact does not detract from the imputed fact or its legal qualification, consisting in the violation of the principle of data confidentiality.

For all of the above, it must be concluded that the ICS, as the entity responsible for the reported treatment, breached the duty of confidentiality of personal data by having produced three unjustified accesses to the medical history of the reporting person.

2. In relation to the conduct described in the section on proven facts, relating to the principle of integrity and confidentiality, it is necessary to refer to article 5.1.f) RGPD, which provides for the following:

*"1. The personal data will be:*

*(...)*

*f) processed in such a way as to guarantee adequate security for personal data, including protection against unauthorized or illegal processing and against accidental loss, destruction or damage, through the application of appropriate technical and organizational measures ("integrity and confidentiality")."*

This principle of integrity and confidentiality provided for by the RGPD must be supplemented with the duty of confidentiality contained in Article 5 of Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of rights digital (hereinafter, LOPDGDD), which establishes the following:

*"Article 5. Duty of confidentiality*

- 1. Those responsible and in charge of data processing as well as all the people who intervene in any phase thereof are subject to the duty of confidentiality referred to in article 5.1.f) of Regulation (EU) 2016/679.*
- 2. The general obligation indicated in the previous section is complementary to the duties of professional secrecy in accordance with the applicable regulations.*
- 3. The obligations established in the previous sections remain even if the obligee's relationship with the person in charge or person in charge of the treatment has ended."*

The health legislation, applicable to the case, regulates the use of the clinical history in the following terms:

Article 11 of Law 21/2000, of 29 December, on the rights of information concerning the patient's health and autonomy, and clinical documentation:

*"1. The clinical history is an instrument primarily intended to help guarantee adequate assistance to the patient. For this purpose, the care professionals of the center who are involved in the diagnosis or treatment of the patient must have access to the clinical history.*

2. Each center must establish the mechanism that makes it possible that, while assistance is provided to a specific patient, the professionals attending to him can, at all times, have access to the corresponding clinical history.

3. 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 the Law of State 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.

4. The staff who take care of the administration and management tasks of the health centers can access only the data of the clinical history related to said functions.

5. The personnel in the service of the Health Administration who perform inspection functions, duly accredited, can access the clinical histories, in order to check the quality of the assistance, the fulfillment of the patient's rights or any other obligation of the center in relation to patients or the Health Administration.

6. All staff who use their powers to access any type of clinical history data remain subject to the duty of confidentiality."

Article 16 of Law 41/2002, of November 14, " basic regulation of patient autonomy and rights and obligations in the field of clinical information and documentation ":

"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.

2. Each center will establish the methods that enable access to the clinical history of each patient at all times by the professionals who assist them.

3. Access to clinical history for judicial, epidemiological, public health, research or teaching purposes is governed by the provisions of current legislation on the protection of personal data, and Law 14/1986, of April 25, General of Health, and other rules of application in each case. Access to the clinical history for these purposes requires the preservation of the patient's personal identification data, 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.

The investigation cases provided for in Section 2 of the Seventeenth Additional Provision of the Organic Law on the Protection of Personal Data and Guarantee of Digital Rights are excluded.

Likewise, cases of investigation by the judicial authority are excluded in which the unification of identifying data with clinical care is considered essential, in which cases the judges and courts in the corresponding process will follow. Access to clinical history data and documents is strictly limited to the specific purposes of each case.



*When it is necessary for the prevention of a serious risk or danger to the health of the population, the health administrations referred to in Law 33/2011, of October 4, General Public Health, will be able to access the identifying data of patients for epidemiological or public health protection reasons. Access must be carried out, in any case, by a healthcare professional subject to professional secrecy or by another person subject, likewise, to an equivalent obligation of secrecy, with prior motivation on the part of the Administration that requested access to the data.*

*4. The administration and management staff of the health centers can only access the clinical history data related to their own functions.*

*5. Duly accredited health personnel who carry out inspection, evaluation, accreditation and planning functions have access to clinical records in the fulfillment of their functions of checking the quality of care, respect for patient rights or any other obligation of the center in relation to patients and users or the health administration itself.*

*6. The personnel who access the clinical history data in the exercise of their functions are subject to the duty of secrecy.*

*7. The Autonomous Communities will regulate the procedure so that there is a record of access to the clinical history and its use".*

During the processing of this procedure, the fact described in the proven facts section, which is considered constitutive of the violation provided for in article 83.5.a) of the RGPD, which typifies the violation of " *principios básicos para el tratamiento* ", among which the principle of confidentiality is at the top.

The conduct addressed here has been included as a very serious infringement in article 72.1.i) of Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights (hereinafter , LOPDGDD), in the following form:

*"i) The violation of the duty of confidentiality established in article 5 of this Organic Law."*

**3.** Article 77.2 LOPDGDD provides that, in the case of infractions committed by those in charge or in charge listed in art. 77.1 LOPDGDD, the competent data protection authority:

*"(...) must issue a resolution that sanctions them with a warning. The resolution must also establish the measures to be adopted so that the conduct ceases or the effects of the offense committed are corrected. The resolution must be notified to the person in charge or in charge of the treatment, to the body to which it depends hierarchically, if applicable, and to those affected who have the status of interested party, if applicable."*

In terms similar to the LOPDGDD, article 21.2 of Law 32/2010 , determines the following:

*"2. In the case of violations committed in relation to publicly owned files, the director of the Catalan Data Protection Authority must issue a resolution declaring the violation and establishing the measures to be taken to correct its effects . (...)".*

In the present case, given that it is a timely and consummated event, and that the ICS has stated that it has proceeded to carry out the necessary actions in order to prevent further improper access from occurring, it is considered unnecessary to require the adoption of corrective measures.

For all this, I resolve:

**1.** Admonish the Catalan Institute of Health as responsible for an infringement provided for in article 83.5.a) in relation to article 5.1.f), both of the RGPD.

It is not necessary to require corrective measures to correct the effects of the infringement, in accordance with what has been set out in the 3rd legal basis.

**2.** Notify this resolution to the Catalan Institute of Health.

**3.** Communicate the resolution to the Ombudsman, in accordance with the provisions of article 77.5 of the LOPDGDD.

**4.** Order that this resolution be published 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 February 20, by which the Statute of the Catalan Data Protection Agency is approved, the imputed entity can file, with discretion, an appeal for reinstatement before the director of the Catalan Data Protection Authority Data, within one month from the day after its notification, in accordance with the provisions of article 123 et seq. of the LPAC. You can also directly file an administrative contentious appeal before the administrative contentious courts, within two months from the day after its notification, in accordance with articles 8, 14 and 46 of Law 29/1998, of July 13, regulating the administrative contentious jurisdiction.

If the imputed entity expresses to the Authority its intention to file an administrative contentious appeal against the final administrative decision, the decision will be provisionally suspended in the terms provided for in article 90.3 of the LPAC.

Likewise, the imputed entity can file any other appeal it deems appropriate to defend its interests.

The director,