

[doc. web n. 9722265]

Injunction order against the Company for the Protection of Health (ATS) of Sardinia - 14 October 2021

Record of measures

n. 370 of 14 October 2021

THE GUARANTOR FOR THE PROTECTION OF PERSONAL DATA

IN today's meeting, which was attended by prof. Pasquale Stanzione, president, Professor Ginevra Cerrina Feroni, vice president, dr. Agostino Ghiglia, the lawyer Guido Scorza, members and the cons. Fabio Mattei;

GIVEN the Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, concerning the protection of individuals with regard to the processing of personal data, as well as the free circulation of such data and which repeals Directive 95/46 / EC, "General Data Protection Regulation" (hereinafter the "Regulation");

GIVEN the legislative decree 30 June 2003, n. 196 containing the "Code regarding the protection of personal data, containing provisions for the adaptation of the national system to Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, relating to the protection of individuals with regard to the processing of personal data, as well as to the free circulation of such data and which repeals Directive 95/46 / EC (hereinafter the "Code");

GIVEN the Regulation n. 1/2019 concerning internal procedures with external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor for the protection of personal data, approved by resolution no. 98 of 4/4/2019, published in the Official Gazette n. 106 of 8/5/2019 and in www.gpdp.it, doc. web n. 9107633 (hereinafter "Regulation of the Guarantor no. 1/2019");

GIVEN the documentation in the deeds;

GIVEN the observations made by the Secretary General pursuant to art. 15 of the Guarantor Regulation n. 1/2000 on the organization and operation of the office of the Guarantor for the protection of personal data, in www.gpdp.it, doc. web n. 1098801;

Speaker Dr. Agostino Ghiglia;

WHEREAS

1. The application

With a note dated XX, Ms XX complained about a violation of the rules on the protection of personal data by the Assemini

Mental Health Center, belonging to the Company for the Protection of Health (ATS) of Sardinia, following the " insertion of some sheets that make up the lady's clinical diary, within other documentation relating to a third party and delivered to the same.

As a consequence of this, the aforementioned third party, belonging to the same city community as Ms XX, would have warned her of what happened, also informing her that in the aforementioned documents, parts of psychological interviews had by the reporting party with the operators were reported. of the Middle.

2. The preliminary activity

Following the request for information from this Office (note of the XX, prot.n.XX), with which it was asked to make known the legal basis that would have allowed the communication of personal data relating to Ms XX third parties, ATS Sardinia provided feedback, with a note of the twentieth.

In particular, the extraordinary Commissioner of the Company, in relation to the disputed fact, represented that:

- "the event complained about (communication to a third user of two clinical diary sheets contained in a paper medical record) took place on the basis of an innocent human error, evidently committed not on an intentional basis, but exclusively as a fortuitous event, fatally implicated by the paper keeping of such documentation, moreover, supervised by methods which, according to consolidated operating practices, have so far always adequately ensured their protection ";
- "the event - however unique at the moment - did not involve the dissemination of data, given that the possession of the documentation by a third person lasted very short (...)";
- "the documentation in question has been promptly returned to the interested party, who, however, appears not to have returned it for the purpose of reintegration into the specific medical record, but rather to have filed the documentation with a trusted lawyer, in order to proceed with compensation action against this ATS Sardinia ".

The same Company also forwarded a note / report produced by XX, Manager of the Mental Health Department C.S.M.-Assemini, from which it appears that:

- "On the XXth day Mrs. XX contacts us to report the discovery in the copy of her folder of two sheets of clinical diary belonging to Mrs. XX. The nurse (...) invites the lady to return the documents to the CSM but Mrs XX reported that she had already informed Mrs XX and that she was on her way to her home for collection ";
- "on the same day Ms. XX phoned and talked to the nurse (...) complaining about the incident, expressing her husband's

intention to file a complaint";

- contacted by a nurse and the same manager and set an appointment, "the lady did not show up for the meeting" and visited the next day "she did not bring the documentation with her, claiming to have handed it over to the lawyer".

With reference to what emerged from the examination of the documentation examined and from the declarations made, taking into account that the described conduct did not comply with the relevant legislation on the protection of personal data, the Office, with deed of XX (prot. XX), notified ATS Sardegna, pursuant to art. 166, paragraph 5, of the Code, the initiation of the procedure for the adoption of the measures referred to in art. 58, par. 2, of the Regulations, inviting her to produce defensive writings or documents to the Guarantor or to ask to be heard by the Authority (art.166, paragraphs 6 and 7, of the Code, as well as art.18, paragraph 1, l. N.689 of 24 November 1981).

In particular, the Office represented that:

- the rules on the protection of personal data provide that information on the state of health can be communicated to third parties only on the basis of a suitable legal basis or on the indication of the interested party himself, subject to the latter's written delegation (art.9 Regulation and art.84 of the Code in conjunction with art.22, paragraph 11, legislative decree 10 August 2018, n.101; see also general provision of 9 November 2005, available at www.gpdt.it , web doc. n. 1191411, deemed compatible with the aforementioned Regulation and with the provisions of decree n. 101/2018; see art. 22, paragraph 4, of the aforementioned legislative decree n. 101/2018);

- the data controller is required to comply with the principles of data protection, including that of "integrity and confidentiality", according to which personal data must be "processed in such a way as to guarantee adequate security (...) , including the protection, by means of adequate technical and organizational measures, from unauthorized or unlawful processing and from accidental loss, destruction or damage "(Article 5, paragraph 1, letter f) of the Regulation).

That said, on the basis of the elements acquired, with the aforementioned act of the XXth, the Office found that ATS Sardinia made a communication of health data in the absence of the legal conditions provided for by art. 9 of the Regulation and, therefore, in violation of the basic principles of the processing referred to in art. 5 and 9 of the Regulations.

With a note of the XX (prot. XX), ATS Sardinia sent its defense briefs, in which, in particular, after describing the general context of reorganization of the Regional Health System, it represented that:

a) "in the general (..) context of the reorganization of the Regional Health System, the well-known epidemiological framework is

inserted, which in the recent period is increasingly serious, continuing to induce operational inconveniences and complications in relations between company structures, 'other variously located in the regional territory and therefore forced to relate mainly not in presence ';

b) "in relation to the nature of the violation, it will necessarily be highlighted how, at present, the violation in the processing of their personal data that the interested party claims to have been committed by ATS Sardinia, could be considered" presumed ".

In fact, following an on-site verification carried out by the D.P.O. of the Company at the Assemini Mental Health Center, showing the documents referred to in the same D.P.O. requested ostension and copy as well as from the interviews with the Director of the C.S.M. and its staff, it was found that the person concerned had requested a copy of her medical record, a copy duly made by the staff of the C.S.M. but never withdrawn by the interested party; the documentation of which a copy was requested by the interested party is, therefore, present in its entirety "(ergo, without any missing page) at the C.S.M. At present, therefore, it is not possible to understand how the alleged violation may have occurred, also considered as the generic nature of the request for compensation for damage formulated by the interested party (in the context of which it would seem that there is not even certainty of the contents of the documents object of the violation as it reads "it seems that, on the page inserted by mistake in the copies delivered to another person, even traces of interviews had by our client appeared") does not allow us to trace which pages of the patient's clinical diary were inserted in the file of another patient but still not known to this Company as they are neither returned nor, much less, exhibited to the same so as to allow an exact reconstruction of the facts ";

c) "with regard to the seriousness of the violation, it is impossible not to consider how the parties involved were only two: the interested party (who immediately made her lawyer aware of the fact) and the XX who communicated to the interested in having found among her documents, of which she too had requested copies two days before, the two pages relating to the clinical diary of the latter. Both the subjects involved attended / do attend the C.S.M. of Assemini (a very small center that consists of about 3,700 inhabitants who base their community on mutual knowledge, as usually happens in small centers), evidently knew their telephone numbers and, as a result, there is no was the communication or dissemination of health data to subjects who were not already aware of the therapeutic needs of the interested party. As for the duration, however, the alleged violation would have developed in an extremely limited period of time as the episode itself ended when the XX, after having collected its copies in the afternoon of the XX day, warned the interested party. on the morning of day XX of the presence of

the two sheets in their medical records ";

d) "the conduct that would have determined the violation" can "be described with absolute certainty as negligent: no element of the affair induces, in fact, to think of an intentional gesture by the staff of the C.S.M";

e) "in support of the absence of willful misconduct, but also of gross negligence, it must be observed that the staff in the C.S.M. of Assemini a very precise and consolidated procedure is respected for the satisfaction of requests for the extraction of copies of health records by users: a) having received the request to extract copies of documents, the nursing staff of the C.S.M. it provides for this b) by delivering the copies to the administrative staff who are responsible for numbering the pages, authenticating them and transmitting them c) to the Head of the C.S.M. for the affixing of the final signature. Within the procedure, therefore, three moments of control can be identified: the first when the copies are made by the nursing staff (competent in evaluating the accuracy of the copies with respect to the request), the second in the phase of endorsement by the administrative staff and, finally, the third check preceding the affixing of the signature by the Manager. The intentionality or the behavioral manifestations typical of gross negligence should be distributed equally among three subjects who, often, are not even the same since, as in the case in particular, the nursing staff who receive the request for extraction / copy do not it is the same that materially provides for the extraction itself. If anything, without admitting anything on the merits, the story could be traced back to possible slight negligence of the staff who, however, cannot fail to be considered as being subject to particular pressure due to the pandemic in progress and forced by it to carry out ultraneous operations compared to normal everyday life, such as for example those of triage at the entrance to the C.S.M., even perhaps forcing him to temporarily suspend operations in which he was previously engaged. Last but not least, it must be considered as the actual staff is always, in general, undersized compared to the organic forecast, in the particular current historical moment also considering the impossibility of carrying out public competitions that would allow the turnover of retired staff with new hires . This results in greater pressure in the performance of their duties and functions and, consequently, an increase in the probability of incurring innocent errors ";

f) "the staff of the C.S.M. immediately contacted the interested party to view and ask for the return of the pages of which the loss was complained (in the possession of the interested party as they were delivered to her by the XX in the immediacy of the facts) and to be aware of any responsibilities and, as a result, to contain the consequences of the violation: the interested party, however, refused the return of the copies as they were already in the possession of their lawyer, who forwarded a

request for compensation for damage to ATS Sardinia and proceeded to report to the Guarantor Authority for the alleged violation ";

g) "the general conditions of the C.S.M. of Assemini and a state of affairs has been found that allows adequate protection of the folders contained therein, protected by a locked access door and equipped with appropriate signals of restricted area and access prohibition. Inside, the archive is made up of metal cabinets with drawers equipped with key locks for each of them and without names but simply initial and final letters to identify the patient's surname (...) It is not possible to enter clandestine or force access to the C.S.M. as the entrance is constantly manned by personnel engaged in pre-entry triage and the archives are located near the access but still distant from it and protected by the locked door, owned by authorized personnel ";

h) "when planning its interventions for the strategic evolution of the ICT application and infrastructural park, the activation of a single company Electronic Medical Record (CCE) solution is envisaged (...) currently in the executive design phase";

i) "at the ASSL of Cagliari, in whose territorial scope the CSM of Assemini falls, as of 2017 an outsourced service for archiving, storage and handling of medical records and radiographic files has been operating, with the assignment procedure launched in 2015 at the pre-existing ASL of Cagliari. Furthermore, with Resolution no. 163/2020 "Update of the company regulations on access to documents, simple civic and generalized civic documents", (...) the company regulations on access to documents were updated, providing for a specific discipline on the subject of more detailed health documentation than the previous "and" with Resolution no. 319/2019 (...), ATS Sardinia has adopted specific "Guidelines for the management of current and deposit archives" ";

j) "ATS Sardinia promptly checked the Guarantor Authority in response to the request for information relating to the matter in question and hereby provides further information resulting from inspections, hearings of the subjects involved and acquisition of related documentation in compliance with the maximum collaboration possible albeit in the uncertainty of a situation whose existence remains unclear but simply supported with statements of part and without ever having been allowed to view the pages that are the subject of the story in order to allow a precise reconstruction of the facts ";

k) "ATS Sardinia adheres to the work group Art. 40 of the G.D.P.R. for the study and drafting of codes of conduct in the health sector ".

On the XXth, the hearing requested by the data controller was held before the Authority, during which, in relation to the notified violation, what had already been stated was reiterated and, in any case, it was specified that:

- "in Ms. XX's file, which has not been withdrawn and is still in our possession, there are no psychological updates (interviews between psychologist and patient), but only psychiatric updates; this clarification is aimed at refuting what was declared by the lawyers of the counterpart in the request for compensation of the XX, where it is stated that in the pages inserted in the documentation delivered to the other person, traces of interviews held by our client with psychologists would have appeared; in reality, Dr. XX was able to specify that the psychological updates are not included in the "psychiatric" medical record but constitute a separate medical record from the properly "psychiatric" one precisely for greater confidentiality and protection of the patient herself ; only when the person concerned expressly requests access to the "psychological" file are the recordings of the interviews provided ";

- "the copy of the folder requested by the reporting party is in an integral and non-missing state of the sheets covered by the request ... the report is not supported by documentation; the accused facts are not substantiated and proven and are statements of the reporting party; it was not possible to ascertain what was reported; the ladies involved were promptly contacted by the Company but neither of them came to the same to provide the required documentation, one saying that the same documentation had been delivered to the lawyer, and the other declaring to have delivered the two sheets to the interested party ";

- "the statements made in the XXth note are corrected here; in particular (...) the reference to the 3700 inhabitants is to be referred not to the Mental Health Center but to the country of origin and residence of the ladies involved ".

Subsequently, following a specific request by the Office against Ms XX, to exhibit the documentation relating to the aforementioned sheets that would have been delivered to the same by another patient, the documents issued to another citizen were acquired, on file, transmitted by Ms XX, with a note of the XX.

The annex to the aforementioned note consists of three sheets (two of which reproduce the same page) bearing "Clinical / client diaries (...) medical / psychiatric diaries", in which the content of the interviews held from 2016 to 2019 is summarized and are the therapies administered are indicated, sometimes, also with the indication of the diagnosis.

3. Outcome of the preliminary investigation

Given that, unless the fact constitutes a more serious crime, whoever, in a proceeding before the Guarantor, falsely declares or certifies news or circumstances or produces false documents or documents, is liable pursuant to art. 168 of the Code ("False statements to the Guarantor and interruption of the execution of the tasks or the exercise of the powers of the

Guarantor"), following the examination of the documentation acquired, certifying the validity of the request, as well as the declarations made to the 'Authority during the procedure, it appears that ATS Sardinia has carried out a processing of personal data in violation of the basic principles of the processing referred to in Articles 5 and 9 of the Regulations.

4. Conclusions

In light of the aforementioned assessments, taking into account the statements made by the data controller during the investigation and the documentation transmitted by the interested party, it is represented that the elements provided by the data controller in the defense briefs and during the hearing, even if worthy of consideration - considering the detail and appropriateness of the explanations provided, in relation to each element indicated in art. 83, par. 2, of the Regulation - do not allow the findings notified by the Office to be overcome with the act of initiating the procedure, however, none of the cases provided for by art. 11 of the Guarantor Regulation n. 1/2019.

For these reasons, the unlawfulness of the processing of personal data carried out by ATS Sardegna is noted, in the terms set out in the motivation, in violation of Articles 5 and 9 of the Regulations.

In this context, considering, in any case, that the conduct has exhausted its effects and that assurances have been provided regarding the checks carried out and the initiatives, including organizational ones, aimed at avoiding the repetition of the error that occurred, the conditions are not met. for the adoption by the Authority of the corrective measures pursuant to art. 58, par. 2, of the Regulation.

5. Adoption of the injunction order for the application of the pecuniary administrative sanction and ancillary sanctions (articles 58, par. 2, lett. I and 83 of the Regulation; art. 166, paragraph 7, of the Code).

The violation of articles 5 and 9 of the Regulations, determined by the processing of personal data, the subject of this provision, carried out by the Company, is subject to the application of the pecuniary administrative sanction pursuant to art. 83, par. 5, lett. a) of the Regulations.

Consider that the Guarantor, pursuant to art. 58, par. 2, lett. i) and 83 of the Regulations, as well as art. 166 of the Code, has the power to "inflict an administrative pecuniary sanction pursuant to Article 83, in addition to the [other] [corrective] measures referred to in this paragraph, or instead of such measures, depending on the circumstances of each single case "and, in this context," the College [of the Guarantor] adopts the injunction order, with which it also disposes with regard to the application of the ancillary administrative sanction of its publication, in whole or in excerpt, on the website of the Guarantor pursuant to

Article 166, paragraph 7, of the Code "(Article 16, paragraph 1, of the Guarantor Regulation no. 1/2019).

The aforementioned administrative fine imposed, depending on the circumstances of each individual case, must be determined in the amount taking into account the principles of effectiveness, proportionality and dissuasiveness, indicated in art. 83, par. 1, of the Regulation, in light of the elements provided for in art. 83, par. 2, of the Regulation in relation to which it is noted that:

- the data processing carried out by the Company concerns data suitable for detecting information on the health of only two persons concerned and the violation concerned an extremely short period of time (Article 83, paragraph 2, letters a) and g) of the Regulation) ;
- the episode was accidental and caused by a carelessness of the staff who served at the Company; the conduct matured in the context of the particular working context characterized by particular tension of health workers due to the ongoing emergency context deriving from the Covid-19 epidemic, which affected the Company concerned (Article 83, paragraph 2, lett. b) and k) of the Regulations);
- the Authority became aware of the violation following the request by Ms XX to the Guarantor on the incident (Article 83, paragraph 2, letter h) of the Regulations);
- the Company cooperated fully with the Authority during the investigation and this proceeding, also by producing particularly complex defense briefs (Article 83, paragraph 2, letter f) of the Regulations);
- the data controller promptly took action to remedy the incident and provided for a review of multiple procedures, with particular reference to the management of health documentation (Article 83, paragraph 2, letter c) and d) of the Regulation) .

Due to the aforementioned elements, assessed as a whole, it is believed to determine the amount of the pecuniary sanction provided for by art. 83, par. 5, lett. a) of the Regulations, to the extent of € 8,000.00 for the violation of Articles 5 and 9 of the Regulation as a pecuniary administrative sanction, pursuant to art. 83, par. 1, of the Regulation, effective, proportionate and dissuasive.

It is also believed that the ancillary sanction of the publication on the website of the Guarantor of this provision, provided for by art. 166, paragraph 7, of the Code and art. 16 of the Guarantor Regulation n. 1/2019.

Finally, it is noted that the conditions set out in art. 17 of Regulation no. 1/2019 concerning internal procedures with external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor.

WHEREAS, THE GUARANTOR

the violation of articles 5 and 9 of the Regulations, declares the unlawfulness of the processing of personal data carried out by ATS Sardinia in the terms set out in the motivation;

ORDER

to the Company for the Protection of Health (ATS) of Sardinia, with registered office in Via E. Costa, 57 07100 Sassari VAT number: 00935650903 Tax Code: 92005870909, in the person of the pro-tempore legal representative, pursuant to Articles 58, par. 2, lett. i) and 83 of the Regulations, as well as art. 166 of the Code, to pay the sum of € 8,000.00 (eight thousand) as a pecuniary administrative sanction for the violation referred to in this provision, according to the methods indicated in the annex, within 30 days from the notification of motivation; it is represented that the offender, pursuant to art. 166, paragraph 8, of the Code, has the right to settle the dispute by paying, within 30 days, an amount equal to half of the sanction imposed;

INJUNCES

to the aforementioned Company, in the event of failure to settle the dispute pursuant to art. 166, paragraph 8, of the Code, to pay the sum of € 8,000.00 (eight thousand), according to the methods indicated in the annex, within 30 days of notification of this provision, under penalty of the adoption of the consequent executive acts pursuant to art. . 27 of the law n. 689/1981.

HAS

- the publication of this provision on the website of the Guarantor, pursuant to art. 166, paragraph 7, of the Code;
- the annotation of this provision in the internal register of the Authority - provided for by art. 57, par. 1, lett. u), of the Regulations, as well as by art. 17 of Regulation no. 1/2019 concerning internal procedures with external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor - relating to violations and measures adopted in accordance with art. 58, par. 2, of the same Regulation.

Pursuant to art. 78 of the Regulation, of art. 152 of the Code and 10 of Legislative Decree no. 150/2011, against this provision, it is possible to appeal before the ordinary judicial authority, under penalty of inadmissibility, within thirty days from the date of communication of the provision itself or within sixty days if the applicant resides abroad.

Rome, October 14, 2021

PRESIDENT

Stanzione

THE RAPPORTEUR

Ghiglia

THE SECRETARY GENERAL

Mattei