

[doc. web n. 9678001]

Injunction order against the Pisan University Hospital - 29 April 2021

Record of measures

n. 176 of 29 April 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 and the lawyer Guido Scorza, members and the cons. Fabio Mattei, general secretary;

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");

Having seen 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;

Rapporteur the lawyer Guido Scorza;

WHEREAS

1. The violation of personal data.

The Pisan University Hospital (hereinafter "Company") has notified the Guarantor of a violation of personal data pursuant to

art. 33 of the Regulations, in relation to the insertion of a nursing record in a medical record relating to another patient.

In the same communication it was highlighted that the violation concerned identification data (surname, name, residence and tax code), contact details (telephone number), health data (data on the course of hospitalization) and other information such as weight, height, vital parameters and that, following the violation, the patient returned the document that did not contain her personal data, which was then delivered to the interested party.

On the same occasion, the Company, in highlighting that the event was determined by the fact that the digitally signed documents were printed twice and for mere clerical error a copy was inserted in the medical record of another patient, declared, in order to prevent possible future violations, to want to provide an alert that draws the operator's attention in case of a request to print the documents a second time (communication of XX).

2. The preliminary activity.

In relation to what was communicated by the Company, the Office, with deed of the XXth, prot. n. XX, initiated, pursuant to art. 166, paragraph 5, of the Code, with reference to the specific situations of illegality referred to therein, a procedure for the adoption of the measures referred to in art. 58, par. 2 of the Regulation, towards the same Company, inviting it 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 November 24, 1981).

In particular, the Office, in the aforementioned deed, represented that:

- the rules on the protection of personal data provide - in the health field - that information on the state of health can be communicated only to the interested party and can be communicated to third parties only on the basis of a suitable legal basis or on the indication of the interested party same subject to written authorization from the latter (Article 9 of the Regulations and Article 84 of the Code in conjunction with Article 22, paragraph 11, Legislative Decree 10 August 2018, n.101; see also general provision of November 9, 2005, available at www.gpdt.it, web doc. .lgs.n.101 / 2018);
- the data controller is required to comply with the principles of data protection, including that of "lawfulness, correctness and transparency" as well as "integrity and confidentiality", according to which personal data must be "treated in a manner lawful, correct and transparent towards the data subject "and" in order to guarantee adequate security (...), including the protection, by means of adequate technical and organizational measures, from unauthorized or unlawful processing and from loss, destruction or accidental damage "(art. 5, par. 1, lett. a) and f) of the Regulations).

Having said that, with the aforementioned act of the XXth, the Office ascertained that the Company carried out, by delivering a nursing record to a person other than the interested party, a communication of data relating to the health of a patient to another patient in absence of a suitable legal basis and, therefore, in violation of the basic principles of the processing referred to in Articles 5 and 9 of the Regulations.

With a note from the twentieth century, the Company sent its defense briefs, in which, in particular, it was specified that:

a) "on XX the patients concerned were notified, in a separate and distinct way, by registered letter, of the incident and the reporting party was requested to proceed as soon as possible with the return of the documents erroneously delivered to them.

The reporting party followed up the request, providing for it, by registered mail ";

b) "during the audit carried out to identify the cause of the incident and the consequent" violation of personal data "subject to notification, it emerged that this could have been traced back to a double printing of the documents in question; in fact, a first print of the nursing record of another patient was mistakenly stapled at the end of the patient's medical record and, subsequently, a second print was made of the documents that have been correctly inserted in the pertinent record. Therefore, in order to avoid the repetition of similar errors, the competent company structures were requested to make a change to the Electronic Medical Record Software so that a field (written in red) is evident when opening the nursing record. which indicates the operator's data and the date on which the complete nursing record was printed and, by clicking on the printer symbol to request a further copy, the Software automatically opens an "Alert" window indicating that is proceeding to a further printing of those same documents ";

c) "in the year 2018 (the Company) produced about 59,000 medical records and, in the following year, it released over no. 16,000 certified copies of medical records to those directly concerned or in any case to those entitled "highlighting" the exceptional nature of the event that occurred and (...) how it is to be found only in a mere accidental action and the result of a material error of the personnel in charge of composition of medical records ".

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 declarations 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 as well as the declarations made to the Authority during

the procedure, that the Company has made a communication of data relating to health in the absence of a suitable legal condition, in violation of the basic principles of the treatment 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, it is noted that the elements provided by the same owner in the defense briefs, although worthy of consideration, do not allow to overcome the findings notified by the Office with the act of initiation of the procedure and are insufficient to allow the filing of the procedure, however, none of the cases provided for by art. 11 of the Guarantor Regulation n. 1/2019. Therefore, the preliminary assessments of the Office are confirmed and the unlawfulness of the processing of personal health data carried out by the Company is noted, in violation of Articles 5 and 9 of the Regulations.

In this context, considering, in any case, that the conduct has exhausted its effects, given that the person who had erroneously received the health documentation of another person proceeded to return the documents, and that assurances were provided regarding the implementation of the procedures for printing the electronic medical record through an "Alert" aimed at indicating that the printing that is about to be carried out is not the first, the conditions for the adoption of the corrective measures referred to in 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, by the Pisan University Hospital, is subject to the application of a pecuniary administrative sanction pursuant to art. 83, par. 5, of the Regulation.

It should be considered 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 Authority became aware of the violation following the notification made by the data controller who informed the interested party of the incident and no complaints or reports were received to the Guarantor on the incident (Article 83, paragraph 2, letter a) and h) of the Regulation);

the violation, concerning health data, is attributable to a single and isolated episode and determined by a human error of the staff responsible for the composition of the file in service at the Company (Article 83, paragraph 2, letter b) , g);

there are no previous relevant violations committed by the data controller nor have any measures previously been ordered pursuant to art. 58 of the Regulations (Article 83, par. 2, lett. E) and i) of the Regulations);

the Company collaborated with the Authority during the investigation and this proceeding (Article 83, paragraph 2, letter f) of the Regulations).

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 € 4,000.00 (four thousand) 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, also in consideration of the type of personal data being processed.

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

declares the unlawfulness of the processing of personal data carried out by the Pisan University Hospital, for the violation of Articles 5 and 9 of the Regulation in the terms set out in the motivation.

ORDER

pursuant to art. 58, par. 2, lett. i) and 83 of the Regulations, as well as art. 166 of the Code, to the Pisan University Hospital with registered office in Pisa, in via Roma n. 67 - VAT and Tax Code 01310860505, in the person of the pro-tempore legal representative, to pay the sum of € 4,000.00 (four thousand) as a pecuniary administrative sanction for the violations indicated

in this provision, according to the methods indicated in the annex, within 30 days of notification in 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 € 4,000.00 (four 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.

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, April 29, 2021

PRESIDENT

Stanzione

THE RAPPORTEUR

Peel

THE SECRETARY GENERAL

Mattei