[doc. web no. 9574789]

Injunction against the Careggi University Hospital - 25 February 2021

Register of measures

no. 70 of 25 February 2021

THE GUARANTOR FOR THE PROTECTION OF PERSONAL DATA

IN today's meeting, which was attended by Dr. the professor. Pasquale Stanzione, president, prof. Geneva Cerrina Feroni, vice president, dr. Agostino Ghiglia, the lawyer Guido Scorza, components and the cons. Fabio Mattei, general secretary;

HAVING REGARD TO Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, concerning the protection of natural persons with regard to the processing of personal data, as well as the free movement of such data and repealing Directive 95/46/ CE, “General Data Protection Regulation” (hereinafter, “Regulation”);

HAVING REGARD TO Legislative Decree 30 June 2003, n. 196 containing the "Code regarding the protection of personal data", containing provisions for the adaptation of the national legal system to Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, relating to the protection of natural persons with regarding the processing of personal data, as well as the free movement of such data and repealing Directive 95/46/EC (hereinafter the "Code");

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

Given the documentation in the deeds;

Given the observations made by the general secretary pursuant to art. 15 of the Regulation of the Guarantor n. 1/2000 on the organization and functioning of the Office of the Guarantor for the protection of personal data, doc. web no. 1098801;

Supervisor Prof. Geneva Cerrina Feroni;

WHEREAS

1. The personal data breach

The Careggi University Hospital (hereinafter the "Company") has notified the Guarantor of a personal data breach pursuant to art. 33 of the Regulations, with reference to the delivery, in paper format, of health documentation relating to a First Aid

service, of a patient to a person other than the same.

The same Company specified that it was an episode of duplication of documentation and not of exchange of the same, since the interested party, to whom the documents refer, had in any case received the reporting of his competence. On the same occasion, the Company declared that it had contacted the subjects involved by telephone "to ensure that everyone was in possession of only the documentation pertaining to them" and that it had started an analysis process as part of the Company's Clinical Risk activities with the planning of an audit (communication of 25 January 2019).

2. The preliminary investigation.

Following a request for information from the Authority aimed at knowing other elements useful for assessing the case, the Company, in describing the dynamics of the incident and the causes that may have determined it, explained that "the reports are printed (... ) and placed in the patient file". (…) Only two printers are installed in the care area "that housed the patient. It evidently happened that the doctor who followed the patient, when he printed the documentation concerning her, took from the drawer of the printer and inserted in the file, together with it, also the document of a different patient, previously sent to be printed by another doctor and not yet withdrawn". In any case "the whistleblower was made available her own documentation and was assured that she had destroyed the one improperly received".

The Company also took the opportunity to highlight that "as an improvement action resulting from the audit, it was requested that additional printing devices be added" as well as "the modification of the visualization on the software of the P.S. exams" (note of 10 April 2019).

In relation to what has been learned from the Company, the Office, with deed dated 23 May 2019, prot. no. 17383, notified the Company, pursuant to art. 166, paragraph 5, of the Code, the initiation of the procedure for the adoption of the provisions pursuant to art. 58, par. 2 of the Regulation, inviting you to produce defense 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, law n. 689 of 24 November 1981) .

In particular, the Office, in the aforesaid deed, represented that, on the basis of the elements acquired, the Company made a communication of data relating to the health of a patient to another patient in the absence of a suitable legal prerequisite and, therefore, in violation of the basic principles of the treatment referred to in articles 5 and 9 of the Regulation.

With a note dated June 22, 2019, the Company sent its defense briefs, in which, in particular, it highlighted that it was a clerical

error by a professional "in the last of the 11 scheduled service hours, in a day (Monday), of particular commitment for the structure (that day 322 accesses)", in a peculiar operational context, that of the Emergency Department, characterized "by extreme complexity and highly dependent time, in which redundancy and a more dilated timing some actions are not always possible".

The Company therefore asked to acknowledge: "the accidental nature of the event; the particular operational and relational context in which this occurred; that the violation relates to a single interested party and a single document" ("laboratory report in which no particular alteration or condition is highlighted and from which it does not appear objectively possible to obtain any information on the pathology or event that led to the 'interested in benefiting from the services"); "that the Company has taken an active part in the notification and communication of the event" and in minimizing the consequences of the same; "that there have been no previous violations in relation to the processing of personal data".

3. Outcome of the preliminary investigation.

Given that, unless the fact constitutes a more serious offence, whoever, in a proceeding before the Guarantor, falsely declares or certifies news or circumstances or produces false deeds or documents is liable pursuant to art. 168 of the Code ("False statements to the Guarantor and interruption of the execution of the duties or the exercise of the powers of the Guarantor"), following the examination of the acquired documentation as well as the declarations made to the Authority during the proceeding, it emerges that the Company, by delivering health documentation relating to an Emergency Room service, to a third party, not authorized to receive such documentation, has made a communication of data relating to health in the absence of a suitable legal prerequisite, in violation of the principles of basis of the treatment pursuant to articles 5 and 9 of the Regulation.

4. Conclusions.

In the light of the assessments referred to above, taking into account the statements made by the data controller during the investigation, aimed at highlighting that the violation was caused by a material error in a specific operational context, it is stated that the elements provided by the data controller treatment in the defense briefs, although worthy of consideration, do not allow the findings notified by the Office to be overcome with the act of initiation of the procedure and are insufficient to allow the closure of the procedure, since none of the cases envisaged by the art. 11 of the Regulation of the Guarantor n. 1/2019.

Therefore, the preliminary assessments of the Office are confirmed and the illegality of the processing of personal health data

carried out by the Company is noted, in violation of articles 5 and 9 of the Regulation.

In this context, considering, however, that the conduct has exhausted its effects - also expected that the Company has provided assurances regarding the destruction by the patient who had mistakenly received a copy of the laboratory report, of the same health documentation and with regard to the improvement actions undertaken in order to avoid the repetition of the incorrect conduct - the conditions for the adoption of further corrective measures by the Authority, pursuant to art. 58, par. 2, of the Regulation.

5. Adoption of the injunction order for the application of the pecuniary administrative sanction and accessory sanctions (articles 58, paragraph 2, letter i and 83 of the Regulation; article 166, paragraph 7, of the Code).

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

It should be considered that the Guarantor, pursuant to articles 58, par. 2, lit. i) and 83 of the Regulation, as well as art. 166 of the Code, has the power to "impose a pecuniary administrative sanction pursuant to article 83, in addition to the [other] [corrective] measures referred to in this paragraph, or instead of such measures, according to the circumstances of each single case" and, in this context, "the Board [of the Guarantor] adopts the injunction order, with which it also orders the application of the ancillary administrative sanction of its publication, in whole or in part, on the website of the Guarantor pursuant to article 166, paragraph 7, of the Code" (art. 16, paragraph 1, of the Guarantor's Regulation no. 1/2019).

The aforementioned pecuniary administrative sanction 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 the light of the elements provided for in art. 83, par. 2, of the Regulation in relation to which it is observed that:

- the data processing carried out by the Company concerns data suitable for detecting information on the health of a single interested party, a patient of the Company (article 83, paragraph 2, letters a) and g) of the Regulation);
- the episode was accidental and caused by a human error by an operator on duty at the Company, in the complex operational context of the Emergency Department (Article 83, paragraph 2, letter b) of the Regulation);
- the Authority has become 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 have been received to the Guarantor on the incident (Article 83, paragraph 2, lett. h) of the Regulation);

- the Company collaborated with the Authority during the investigation and in the present proceeding (Article 83, paragraph 2, letter f) of the Regulation);

- the data controller promptly took action to remedy the incident through telephone contacts with the subjects involved, as well as intervening on organizational measures in order to improve processes (Article 83, paragraph 2, letters c) and d) of the regulation);

- the Company has been the recipient of a warning order from the Guarantor for the violation of articles 12, par. 3, and 15 of the Regulation, having failed to respond, within the terms, to a request for access to the data of the interested party (Provision of 29 July 2020, n. 146) (Article 83, paragraph 2, letter i) of the Regulation).

Based on the aforementioned elements, evaluated as a whole, it is decided to determine the amount of the pecuniary sanction provided for by art. 83, par. 5, letter. a) of the Regulations, in the amount of 6,000.00 (six thousand) euros 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.

Considering that the unlawful processing involved data relating to health included in the particular categories referred to in art. 9, par. 1 of the Regulation and that the Company has been the recipient of a previous corrective measure, it is also believed that the ancillary sanction of publication on the website of the Guarantor of this measure should be applied, provided for by art. 166, paragraph 7, of the Code and art. 16 of the Regulation of the Guarantor n. 1/2019.

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

ALL THIS CONSIDERING THE GUARANTOR

found the violation of the articles 5 and 9 of the Regulation, declares the unlawfulness of the processing of personal data carried out by the Company in the terms set out in the justification;

ORDER

to the Careggi University Hospital, with registered office in Florence, Largo Brambilla, 3 – VAT no. 04612750481, in the person of the pro-tempore legal representative, pursuant to articles 58, par. 2, lit. i) and 83 of the Regulation, as well as art. 166 of the

Code, to pay the sum of 6,000.00 (six thousand) euros as a pecuniary administrative sanction for the violation referred to in this provision, according to the methods indicated in the attachment, within 30 days of the notification in the 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 fine imposed;

ENJOYS

to the aforementioned health facility, in the event of failure to settle the dispute pursuant to art. 166, paragraph 8, of the Code, to pay the sum of 6,000.00 (six thousand) euros, according to the methods indicated in the attachment, within 30 days of notification of this provision, under penalty of adopting the consequent executive deeds pursuant to art. . 27 of the law n. 689/1981.

HAS

the publication of this provision on the Guarantor's website, pursuant to art. 166, paragraph 7, of the Code;

annotation of this provision in the internal register of the Authority - provided for by art. 57, par. 1, lit. u), of the Regulation, as well as by art. 17 of Regulation no. 1/2019 concerning internal procedures having external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor - relating to violations and measures adopted in compliance with art. 58, par. 2, of the same Regulation.

Pursuant to art. 78 of the Regulation, of the articles 152 of the Code and 10 of Legislative Decree no. 150/2011, against this provision it is possible to lodge an 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 appellant resides abroad.

Rome, 25 February 2021

PRESIDENT

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THE SPEAKER

Cerrina Feroni

THE SECRETARY GENERAL

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