[doc. web n. 9695041]

Injunction order against the local health authority of Chieri, Carmagnola, Moncalieri and Nichelino (Asl To5) - 22 July 2021

Record of measures

n. 279 of 22 July 2021

THE GUARANTOR FOR THE PROTECTION OF PERSONAL DATA

IN today's meeting, which was attended by prof. Giuseppe 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 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;

HAVING REGARD to 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 Attorney Guido Scorza;

WHEREAS

1. The violation of personal data.

The local health authority of Chieri, Carmagnola, Moncalieri and Nichelino (Asl To5) has notified a breach of personal data,

pursuant to art. 33 of the Regulations, in relation to the inclusion, in the clinical documentation of a patient admitted to the Internal Medicine Complex Structure P.O. Carmagnola and, subsequently deceased, of the reports of two other patients containing, respectively, an oncological consultation and an ultrasound of the abdomen. The aforementioned documentation was delivered to the daughter of the hospitalized and subsequently deceased patient, who returned the erroneously included reports.

As stated by the Company, the technical and organizational measures adopted to remedy the violation and reduce its negative effects for the interested parties consisted in the activation of an "internal investigation to identify the exact methods for which the accident occurred . The reports of the 2 patients concerned were included in the files of their respective patients "and in the adoption of" a procedure for managing security incidents and managing violations which "(at the time of notification)" is under review ". In relation, then, to the technical and organizational measures adopted to prevent similar future violations, the intention was communicated to "update the procedure for the management of clinical documentation, with particular regard to the verification of integrity at each change of hands", as well as to "carry out awareness raising and training on the procedures in place" and "repeat in different ways the awareness and training interventions of all personnel in relation to the procedure for managing personal data violations".

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, has preliminarily represented that:

- "The regulations on the protection of personal data provide - in the health field - that information on the state of health can only be communicated 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 interested party itself 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. general 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. Legislative Decree no. 101/2018) ";

- "the data controller is, in any case, 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 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 ) ".

Having said this, on the basis of the elements in the files, with the aforementioned note of 21 October 2020, the Office deemed that the Company, by inserting two reports belonging each to a different patient, in the clinical documentation relating to another patient, delivered to the daughter of the same, has made a communication of data relating to health in the absence of a suitable legal basis and, therefore, in violation of the basic principles of the treatment referred to in Articles 5 and 9 of the Regulations.

With a note dated December 19, 2019, the Company sent its defense briefs, in which, in particular, the story was reconstructed more clearly, highlighting, in particular, that:

- “Following the death of the patient Mr. XX, which occurred in the Medicine Department of the Carmagnola Hospital, the iconographic radiological documentation (as indicated by the company) is returned to the family members, in the person of the daughter. Among this documentation are erroneously included: a) the personal documentation of Mr. YY, hospitalized in the same ward, (reports of oncological outpatient visits prior to access to the ward, which certify the current state of illness whose evolution has led to at hospitalization); b) the original ultrasound report of Mr. ZZ, carried out during hospitalization (also a patient of the same department) ";

- "the above, the result of an unconscious error on the part of the nurse on duty that day for discharge and hospitalization, comes to our knowledge on 20.08, when the daughter of Mr. XX reports to the ward the documentation unrelated to the father's hospitalization , handing it over to one of the doctors of the ward, reporting that he had mentioned it with a doctor and that he had reported it for fear that the treatment of the patients concerned (YY and ZZ) could have been affected by the absence of the aforementioned reports in the medical records ";

- "The dynamics of the incident showed that: Mr. ZZ's personal reports were most likely found in the blue folder of the bed he had previously occupied which subsequently hosted Mr. XX, not individually checked at the time of delivery; the photocopy of Mr. YY's ultrasound, just produced, had been temporarily placed, for a call for assistance in the ward, on the reception desk,

where the resigning nurse was providing for the delivery of personal effects and radiological documentation to his daughter of the deceased patient, accidentally including this photocopy. Although evident by retracing contingencies and facts, one of the elements that certainly represented the premise, especially in relation to the reports of Mr. ZZ's personal oncological visits, was a consequence of the contiguity of the beds in which the patients involved were hospitalized (contiguity replicated by records clinics and blue folders in the examination trolley), further facilitated, in its negative evolution, by the transfer of patients from one bed to another (one for clinical monitoring needs, to facilitate the visits of relatives in safety in the light of restrictions imposed by the Covid Emergency in the terminal phase of the disease, in the other) ";

- "the duration of the violation was limited: from 08.08.2020 (date of delivery of the documentation) to 20.08.2020 (date of delivery) then for 12 days (...) The daughter who received the documentation by mistake stated not to have made copies and not to have used the documentation in any way ".

The Company has amply represented that it has carried out, on several occasions, training activities in relation to data protection in the healthcare context and within the specific department, concerning the issue of management and closure of medical records, also defining specific instructions also on the delivery of clinical documentation at the time of discharge, both to the patient and to the caregiver authorized by the same, in order to prevent data breaches and identifying a specific "path of the medical record traced by a procedure that determines the various steps (closure, delivery to a nurse dedicated to checking the document verification before filling out the SDO, checking the Head Office, delivery to the Hospitality with shared list check and countersigning for acceptance) ".

Among the various initiatives indicated by the Company, the adoption of "new methods of requesting and delivering copies of medical records that no longer involves the physical transport of the file from the filing archive to the Folders Office, but the folder is scanned by the supplier at the warehouse. The employees of the Folders Office access the requested digitized copy via https, print it and deliver it to the external user "as well as specific" logistical measures for the management of the documentation present in the ward during hospitalization episodes ", which also include a redesign of the documentation containers and separators for the documents of the various patients, with clear indication of the number of the bed.

It was also stated that:

- "The company is going through an economically difficult period. Added to these difficulties was the well-known pandemic phenomenon which had heavy repercussions on many countries (collapse of GDP by more than 2 figures), changed the

working habits of all of us, caused the suspension of the terms for the definition of the proceedings, deadlines and payments, but it was particularly strong on Public Health with phenomena that hit the entire structure hard ";

- "The entire strategic management of the body (General Manager, Health Director and Administrative Director) was absent for reasons of health and containment of the infection with the need to appoint an Extraordinary Commissioner from 15/03/2020 to 15 / 04/2020 ";

- it was necessary "to hire new health personnel to be immediately dedicated to the care of patients (between March and August 2020 137 people were hired on a fixed-term basis, mainly from the sector, to which 43 freelancers must be added for a total of 193 people hired with COVID reason , therefore, about 10% of the company workforce and just under 20% of the medical and nursing staff dedicated to the care of patients) "and" reallocating spaces, structures and personnel to cope with the pandemic ";

- "the workloads to protect the very lives of patients and the entire community required to reshape, if not cancel, the planned training activity" which could be carried out "almost exclusively remotely to avoid the risk of contagion";

- "in reference to the violation of art. 9 confirms the absolute non-intentionality of the processing of communication of particular data to third parties. We therefore believe that the communication of personal data is due solely to the inattention of the staff and to the training and supervision skills on which the aforementioned has undoubtedly heavily affected ".

- "with reference to art. 5. P 1 f) the above considerations on the safety measures adopted, the context of the contingent health emergency, the limited number of interested parties constitute evidence of a fortuitous event. Any negligence is mitigated (or in any case not easy to quantify) by the emergency situation. The exceptional nature of the event, in our opinion, completely excludes the culpable nature of the violation ";

- "the interested party Mr. YY was informed and did not express any particular complaints. As described above, the effects for the interested parties are modest. To date, more than 2 months after the incident, no complaints have been received, nor a claim for damages. The integrity of the clinical documentation of the interested parties was also checked and no alterations emerged ";

- “it was considered that some passages useful for identifying organizational and / or structural interventions useful for a further reduction of risk were considered: a. The patient's personal documentation relating to the structure must be summarized as usual during the compilation of the History and returned immediately to the interested party requesting, when necessary or

foreseeable further consultations, that it be kept with their personal effects in the locker or in the bedside table assigned to him; b. The possible introduction of a form showing what was delivered by the patient or his family at the entrance, with details of the documentation acquired, to be included in the medical record and used as a check list at the time of return to the legitimate owners is being studied. discharge (eg value delivery form) with signature for receipt; As far as radiological investigations are concerned, the computerization of the report is close to completion with the relative production of images on disk which, in terms of size, will be kept in the medical record, eliminating the use of the current blue file; the staff was made aware and recalled, sharing the event and its consequences, to intensify the checks on the documentation in the final stages of the health event ";

- "the Company has not made any profit or the violation has avoided costs; (…). The financial situation of the Company is not good: the last financial year closed with a huge loss (..) ".

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 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, since 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, however, that the conduct has exhausted its effects, given that the Company has entered the reports erroneously delivered in the files of the respective patients, and assurances have been provided regarding the many

initiatives implemented in order to train personnel and organizational and structural interventions aimed at avoiding repetition of the erroneous 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 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 interested parties (Article 83, paragraph 2, letter a) and g) of the Regulation);
- the incidents were accidental and determined by the carelessness of the staff who served at the Company (Article 83, paragraph 2, letter b) of the Regulations);
- the Authority has become aware of the violation following the notification made by the data controller and no complaints or reports have been received 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 keeping and delivery 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 € 4,000 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 the Company under the terms set out in the motivation;

ORDER

To the local health authority of Chieri, Carmagnola, Moncalieri and Nichelino (Asl To5), with registered office in Piazza Silvio Pellico 1, Chieri (TO), VAT number 06827170017, 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 4,000.00 (four thousand) euros 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 € 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 - 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, July 22, 2021

PRESIDENT

Stanzione

THE RAPPORTEUR

Peel

THE SECRETARY GENERAL

Mattei