

Injunction order against the Rhodense Territorial Social Healthcare Company - 21 July 2022

Record of measures

n. 263 of 21 July 2022

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 national law 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 the free circulation of such data and which repeals Directive 95/46 / EC (hereinafter the "Code");

GIVEN the legislative decree 10 August 2018, n. 101 on "Provisions for the adaptation of national legislation to the provisions of 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 repealing Directive 95/46 / EC ";

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 functioning of the office of the Guarantor for the protection of personal data, Doc. web n. 1098801;

Speaker prof. Pasquale Stanzone;

WHEREAS

1. Violations of personal data

The Rhodense Territorial Social Healthcare Company based in Garbagnate Milanese (MI), Viale Forlanini 95, zip code 20024 - Tax Code: 09323530965 (hereinafter the "Company") notified the Authority of two personal data violations, pursuant to art. 33 of the Regulation, dated XX and XX, concerning, respectively:

a) the "partial loss of medical records relating to a patient hospitalized since the 20th century at the Garbagnate Milanese Hospital. (...) Specifically (...) the paper medical allowance was lost, showing the description of the daily clinical conditions and the consent sheet for the execution of the diagnostic procedure (paracentesis) ".

In relation to this event, the Company announced that:

"Having been lost a part of the paper medical record not (...) (you have) the availability of some documents of which you do not have copies" and that "the communication of loss was sent to the Data Protection Officer on day XX and forwarded by him to the Data Controller on the same day, or the XX ";

in the notification it was stated: that the violation relates to "health data; personal data (name, surname, sex, date and place of birth, tax code, residence, contact telephone numbers) "of the interested party; to believe that "the violation (...) (presents a) high risk (for the rights and freedoms of the interested party) given the partial loss of the medical record" and to have communicated the violation to the interested party, on XX date, to by means of paper mail, representing the incident to the latter and offering the relative apologies.

In this regard, the Company, after having illustrated the technical and organizational measures in place at the time of the violation, adopted to guarantee the security of the personal data involved, also represented that it had filed a complaint with the local Carabinieri Command of Garbagnate Milanese. on XX, through the Head of UOC Medicina 1 of the Garbagnate Milanese Hospital, assuring, that "it will carry out internal audits of the company Operating Units (...) (giving) once again maximum dissemination of the company protocol XX" Documentation Management Healthcare and Medical Record Keeping ", to all operators, reaffirming their availability and permanent consultation on the company intranet. (...) (In addition) it will continue to issue operating instructions to newly hired personnel, also published on the company intranet site, in the appropriate section that can be consulted by all Appointees, as well as to promote a new self-training course for all its Appointees " .

b) the "loss of a patient's clinical documentation, at the Surgery Department of the P.O. di Garbagnate Milanese, (...) at the closing of the folder on the XXth ".

In relation to this violation, the Company declared that it became aware of it on the XXth date and that the delay in communication by the competent department was determined by the "search for the lost documentation and found to be unsuccessful", also considering serious the potential impact for those concerned, as "some documents of which copies are not available are no longer available, other than the digital documentation that allowed the partial reconstruction of the lost file. Given the failure to check the lost part of the paper medical record, it is no longer possible to guarantee the confidentiality of the personal data contained therein ".

Also in this case, after having illustrated the technical and organizational measures in place at the time of the violation to guarantee the security of personal data, the Company, with reference to the measures adopted following the violation, communicated to "carry out internal audits to the Company operations ", to want to give" once again maximum dissemination of the corporate protocol XX "Management of Health Documentation and Keeping of Medical Records", to all operators, reaffirming their availability and permanent consultation on the company intranet "and, finally, to have scheduled training courses for personnel concerning the correct compilation and custody of the medical record.

2. The preliminary activity

The Office, with regard to the cases described above, on the basis of what is represented by the data controller in the respective acts of notification of violation, as well as subsequent assessments, notified the Company, pursuant to art. 166, paragraph 5, of the Code, the initiation of proceedings for the adoption of the measures referred to in art. 58, par. 2, of the Regulations, inviting the aforementioned owner to produce defensive writings or documents to the Guarantor or to ask to be heard by the Authority (Article 166, paragraphs 6 and 7, of the Code; as well as Article 18, paragraph 1, of Law no. . 689 of 11/24/1981).

In particular, the deed prot. n. XX of the XX and the deed prot. n. XX of the XX, with which the Authority communicated to the Company that it had detected - on the basis of what was declared with the notifications of violation of personal data made, respectively on XX and XX, pursuant to art. 33 of the Regulations, as well as the related assessments of the Department - the existence of elements suitable for configuring, by the Company itself, the breach of the security obligation pursuant to art. 32 of the Regulation and the basic principles of processing referred to in art. 5, par. 1, lett. f) of the same Regulation.

Furthermore, with the deed prot. n. XX of the XX, the Office, pursuant to art. 10, paragraph 4, 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, arranged for the merger of the two proceedings launched, respectively, following the aforementioned notifications of violation of the XX and the XX, since these are similar cases originating from the conduct of the same data controller.

Following the aforementioned communications of violations made by the Authority pursuant to art. 166, paragraph 5, of the Code, the Company has sent its defense briefs. In particular:

a) with reference to the first case described above (see point 1, letter a)), with a note of the XX (prot. no. XX), without making a specific request for a hearing pursuant to art. 166, paragraph 6 of the Code, the Company, in addition to what has already been represented in the notification of the violation of personal data pursuant to art. 33 of the Regulation, stated that:

- "The partial loss in question would seem to be attributable to mere human error, having a negligent character, given that, as stated in the note from the Director of the OU of Internal Medicine of the twentieth (...) a precise path of the medical record in the period following discharge at the OU has been traced for some time. of Internal Medicine of ASST Rhodense ";
- "The medical record, before being archived, observes three levels of control: it is checked by the Doctor following the patient's discharge and, consequently to the verification, the Doctor delivers the file to the Secretariat of the OU. where further control is carried out. Once the routine checks have been carried out at the Department, the Medical Record is finally delivered to the Medical Department of the Presidium where it is further examined, for completeness, by the S.D.O. In the present case, the partial loss of Clinical Record n.5093, referring to the hospitalization of the (patient) (...), was detected when the necessary checks were carried out to check the completeness of the documentation by the resigning Doctor who, detected the partial lack of documentation, he alerted the Secretariat of the U.O. of Internal Medicine ";
- "The Director of the OU of Internal Medicine with a note of the twentieth (...), reports: "In relation to the loss of part of the clinical documentation, I would like to point out the possibility that this is a completely unpredictable event in the context of an extremely organized path. In the U.O an average of over 1,800 patients per year are managed and in the recent pandemic period which has seen over 3,000 patients treated by the medical departments, there have never been, to our knowledge, dissynergies on the conservation of health documents "";
- "(...) in the periodic organizational meeting at the ward where the (...) (patient) was hospitalized, the episode that occurred

with analysis of improvement processes was reviewed, and with the assumption of reaffirming the commitment to improvement processes also in the meeting of the U.O. of Internal Medicine scheduled on the 20th ";

- "With specific reference to the measures adopted by ASST Rhodense to the detriment of possible future actions of loss and loss of data, we inform you that two courses have already been scheduled: a course concerning the correct compilation and custody of the medical record, that the Medical Direction of the Garbagnate Milanese Hospital had already planned in the month of XX (...). In the first evaluation phase, the course had as its object the correct compilation of the medical record and, subsequently implemented in the month of XX with a part specifically dedicated to the custody of the file: the course will start in the month of XX and will be aimed at all Healthcare Staff ";

- "Finally, it should be noted that on XX part of the Information Systems Personnel of ASST Rhodense was involved in the first meeting referred to in the tender (...) relating to the assignment of the service for the introduction and evolution of the Electronic Medical Record (CCE) at health authorities. (...) Finally, we inform you that with respect to the case outlined above, no corrective measures have been imposed by the Guarantor and therefore, on this point, no relevant documentation can be produced regarding the implementation of the provisions, limitations or prohibitions set by the Authority ".

b) in relation to the second case represented above (see point 1, letter b)), the Company, with a note and attachments sent via PEC on XX, in addition to reiterating what has already been communicated in the notification of violation made pursuant to 'art. 33 of the Regulation, highlighted, among other things, that:

- "With a note of the XXth the Medical Direction of the P.O. of Garbagnate forwarded the complaint filed to the Carabinieri Command of Garbagnate Milanese (...) to the Privacy Office for prompt evidence from the Authority, and in order to allow any subsequent action to be carried out ";

- "The loss in question would seem to be attributable to mere human error, having a negligent character, given that (...) a precise path of the medical record has been traced for some time in the period following the patient's discharge at the OU. of Surgery of the ASST Rhodense ";

- "The internal procedure (...) indicated in the Protocol for the management of the medical record of patients discharged from the OU General Surgery, a precise series of checks follows: the doctor who discharges the patient delivers the medical record to the Coordinator of the ward or to his substitute, who will then take care of delivering the file to the Department Secretariat.

The Department Secretariat, as the last step inside the Department, delivers the medical record to the Director of the OU. The

taking over of the medical record is traced with the signatures of the subjects involved in the process. Once the routine checks have been carried out at the Department, the Medical Record is finally delivered to the Medical Department of the Presidium where it is further examined, for completeness, by the S.D.O Office ";

- "In the present case, the loss of the Medical Record (...), referring to the hospitalization of the (...) (patient), was detected when the necessary checks were carried out to check the completeness of the documentation by the resigning Doctor who , having detected the lack of documentation, he alerted the Nursing Coordinator ";

- "In order to find the lost file, several searches were carried out also outside the ward where the patient was admitted, even if prolonged and insistent searches were then unsuccessful";

- "The event was also the subject of analysis within an extraordinary meeting held at the ward where the (...) (patient) meeting was admitted further than those of ordinary planning and during which the need was also reiterated in precise compliance with the existing procedure in force since the twentieth century and referring to the traceability chain ";

- "For the year the (...) (Company)" - in addition to other illustrated measures, adopted before the event occurred - "has activated a FAD course called" Traveling with the medical record ", (...) intended for everything the Healthcare Personnel and having as object the compilation, management and correct keeping of the medical record ". This "course (has been) proposed again with the company training plan approved by provision no. XX (...) ";

- "(...) the so-called organizational performance for the current year XX will see all the staff of ASST Rhodense engaged in privacy matters, with the specific aim of further raising awareness of the 2016/679 European Regulation for the specific aspects of competence. The path (...) has already started with the transmission of a communication in everyone mode to company employees. (...) (This activity, to be carried out) in the course of the XX year, will be preparatory to the subsequent revision (after the XX) of the Data Controller's register of processing activities, so as to create continuity of work on the subject also for the year to come, XX, and in order to point out, to all Staff, the importance and delicacy of the aspects involved in data processing ";

3. Outcome of the preliminary investigation

Having acknowledged what is represented and documented by the Company during the two investigative proceedings referred to in point 1, lett. a) and b), first with the acts of notification of violation and, subsequently, with the related defense briefs, the following is observed.

The processing of personal data must take place in compliance with the applicable legislation on the protection of personal data and, in particular, with the provisions of the Regulation and the Code.

With reference to the cases of violation covered by this provision, it is represented that "data relating to health" means "personal data relating to the physical or mental health of a natural person, including the provision of health care, which reveal information relating to his state of health "(art. 4, par. 1, n. 15 of the Regulations); such data deserve greater protection since the context of their processing could create significant risks for fundamental rights and freedoms (Cons. n. 51).

The Regulation provides that 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 (principle of "integrity and confidentiality") "(Article 5, paragraph 1, letter f) of the Regulation). The adequacy of these measures must be assessed by the data controller in order to "guarantee a level of security appropriate to the risk", taking into account, among other things, "the nature, object, context and purpose of the processing, as well as the risk of varying probability and gravity for the rights and freedoms of natural persons "(Article 32 of the Regulation).

3. Conclusions.

In light of the aforementioned assessments, taking into account the statements made by the data controller during the investigation and considering that, unless the fact constitutes a more serious crime, anyone, 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 tasks or the exercise of the powers of the Guarantor" notified by the Office with the aforementioned acts of initiation of proceedings, however, none of the cases provided for by art. 11 of the Guarantor Regulation n. 1/2019.

For these reasons, the preliminary assessments of the Office are confirmed and the unlawfulness of the processing of personal data carried out by the Azienda Socio Sanitaria Territoriale Rhodense based in Garbagnate Milanese is confirmed, in the terms set out in the motivation, in violation of Articles 5, par. 1, lett. f) and 32 of the Regulations.

In this context, considering that the Company has adopted, following the events that occurred, further technical and organizational measures deemed necessary to prevent future similar events and, in any case, to minimize human error, the conditions for the " adoption of measures, of a prescriptive or inhibitory nature, pursuant to art. 58, par. 2, of the Regulation.

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

The violation of articles 5, par. 1, lett. f) and 32 of the Regulations caused by the conduct put in place by the Company, is subject to the application of a pecuniary administrative sanction pursuant to art. 83, par. 4, lett. a) and par. 5, lett. a) of the Regulations.

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, for the present case, it is noted that:

the Authority has taken note of the events that occurred following the notifications of violation of personal data made by the owner and no complaints or reports have been received to the Guarantor on what happened (Article 83, paragraph 2, letter h) and k) of the Regulation);

the processing of data carried out by the Company concerns data suitable for detecting information on the health of a single interested party for each of the two cases of violation (Article 4, paragraph 1, No. 15 of the Regulation and Article 83, paragraph 2, letters a) and g) of the Regulation);

from the point of view of the subjective element, no intentional attitude emerges on the part of the data controller given that the latter has highlighted in both cases that the violations occurred accidentally (Article 83, paragraph 2, letter b) of the Regulation);

the Company promptly took care to take charge of the problem by introducing corrective solutions aimed at minimizing human error and therefore the replicability of the same events that occurred (Article 83, paragraph 2, letter c of the Regulation);

the owner has demonstrated a good degree of cooperation with the Authority in order to remedy the violations and mitigate their possible negative effects (Article 83, paragraph 2, letter f) of the Regulation);

against the Company itself, no provision has previously been adopted for pertinent violations (Article 83, paragraph 2, letter e) 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. 4, lett. a) and par. 5, lett. a) of the Regulations, to the extent of € 3,000.00 (three thousand) for the violation of Articles 5, par. 1, lett. f) and 32 of the Regulations 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 subject to unlawful processing.

Finally, it is noted that the conditions set out in art. 17 of the regulation of the Guarantor n. 1/2019 concerning internal procedures with external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Authority.

WHEREAS, THE GUARANTOR

declares the unlawfulness of the processing of personal data carried out by the Rhodense Territorial Healthcare Company with headquarters in Garbagnate Milanese (MI), Viale Forlanini 95, c.a.p. 20024 - Tax Code: 09323530965, for the violation of articles 5, par. 1, lett. f) and 32 of the Regulations 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 Azienda Socio Sanitaria Territoriale Rhodense, in the person of the pro-tempore legal representative, to pay the sum of € 3,000.00 (three thousand) as a pecuniary administrative sanction for the violations indicated in this provision; 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 € 3,000.00 (three 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

pursuant to art. 166, paragraph 7, of the Code, the full publication of this provision on the website of the Guarantor and believes 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.

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 lodge a judicial 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, 21 July 2022

PRESIDENT

Stanzione

THE RAPPORTEUR

Stanzione

THE SECRETARY GENERAL

Mattei