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Injunction order against the University Hospital of Parma - 27 January 2021

Register of measures

no. 30 of 27 January 2021

THE GUARANTOR FOR THE PROTECTION OF PERSONAL DATA

IN today's meeting, which was attended by prof. Pasquale Stanzione, president, prof.ssa Ginevra Cerrina Feroni, vice president, dr. Agostino Ghiglia and the lawyer Guido Scorza, members 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 on the protection of natural persons with regard to the processing of personal data, as well as on the free circulation 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 regard to the processing of personal data, as well as to the free movement of such data and which repeals 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 Secretary General 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, in www.gpdp.it, doc. web no. 1098801;

Speaker the lawyer Guido Scorza;

WHEREAS

1. The personal data breach.

The University Hospital of Parma (hereinafter the Company) has sent the Authority two communications relating to two distinct violations of personal data pursuant to art. 33 of the Regulation, in relation to the delivery of health documentation to subjects other than the interested party (communications of 5 July 2018, prot. n. 26398 and of 25.1.2019- prot. n. 3726, integrated with note 7.2.2019) .

In the communication of 5 July 2018, the Company declared that it had become aware of the presence "in the copy of a medical record issued to the parents (...) (of a) minor patient, a microbiological examination report belonging to other subject". "The data subject to violation belong to the category of personal data (name, surname, tax code, residence, date of birth) and health data (request department, type of microbiological examination, specifically bacteria research, and result, among 'other negative)". The Company also declared that, following the affair, it "proceded to recover the copy of the medical record containing the report represented above", to "contact the insurance company to which the copy of the medical record was sent requesting the immediate destruction, thus avoiding any hypothesis of further communication of personal data and the occurrence of a high risk of injury to the rights of the data subject", to "communicate all employees of the department concerned (Pediatric Surgery) to increase controls at the time of training of copies of the medical record" and to "communicate to all employees of the various structures of the hospital to increase controls when making copies of the medical record".

In the communication of 25 January 2019, supplemented on 7 February 2019, the Company stated that, in another case, "a copy of a medical record was delivered to the heir of the holder of the record, containing a report from a different patient. This report contains personal data personal data: surname, name, date of birth; data relating to revealing the state of health: blood chemistry test report referring to a hospitalized patient". In this regard, the Hospital declared that it had "proceded for: contacting, through the contact person of the Medical Records Office, the heir to whom a copy of the medical record containing the report of another patient was delivered to retrieve the medical record containing the report and deliver a copy without the same and acquire the declaration that the copy has not been disclosed to third parties; in the face of a non-cooperative attitude" proceeded to "formally request the return of the copy of the medical record to the heir of the holder of the file itself, distrusting him from using the data of the holder of the report (Interested), and requesting to give communication to any third parties in possession of a copy of the documentation to destroy it and in any case not to use the data;" to "forward a communication to the Director of the Operating Unit involved, aimed at reminding the importance of keeping the health records, as well as with the indication to carry out the self-assessment of the medical records, also for the purpose of avoiding

the accidental insertion of documents containing personal data of subjects other than the holder and requesting clarifications on the incident;" to schedule an audit relating to the management of health records to be held within three weeks to which the structures affected by the episode will be subject".

2. The preliminary investigation.

2.1. Violation Notice dated July 5, 2018

In relation to the aforementioned communication of violation of 5 July 2018, the Office requested information from the Company (note of 30.1.2019, prot. no. 3196), which provided elements with a note of 1 March 2019 (prot. 9373), representing that:

- provided for "the immediate restoration of the correctness of the documentation of both parties involved, the recovery and delivery of a copy without the report in question";
- "in the present case, the numerous outcomes of checks that arrive daily from the reporting structures and must find a place in the respective health documentation, the rapid succession of patients for so-called hospitalizations "fast" that from Pediatric Surgery are hospitalized in the various hospitalization wards located in the same structure, the small number of personnel that can be employed in these activities, may have determined, by mere clerical error, the incorrect positioning of the report in the incorrect medical records";
- with reference to the documentation sent to the insurance company, which the same "provided confirmation of the destruction" of the sent documentation.

Following the acquisition of the elements provided with the aforementioned note of 1 March 2019, the Office, with deed no. 8769 of 12 March 2019, with reference to the specific situations of illegality referred to therein, notified the Company, pursuant to art. 166, paragraph 5, of the Code, the initiation of the procedure for the adoption of the measures referred to in article 58, paragraph 2, of the Regulation, inviting the aforesaid holder to produce defense writings or documents to the Guarantor or to ask to be heard by the Authority.

In particular, the Office, in the aforementioned deed, considered that the violation of personal data notified to the Guarantor pursuant to art. 33 of the Regulation, has detected the existence of elements suitable for configuring by the Company the violation of art. 9 of the Regulation, also in the light of the principles of integrity and confidentiality referred to in the deed (art. 5, par. 1, letter f) of the Regulation), representing that the conduct described in the notice of violation (insertion in copy of a

medical record issued to the parents of a patient who is minor than a microbiological examination report belonging to another subject) has integrated a communication of data relating to the health of a patient in the Pediatric Surgery department to another patient in the same department in the absence of a suitable legal prerequisite.

With a note dated 10 April 2019 (prot. n. 15796), the Company sent its defense briefs, in which, in particular, it was represented that:

- "as regards the duration of the violation, it can reasonably be affirmed that the same occurred from the moment of delivery to the applicant holder of the health documentation containing personal data of another subject (14/06/2018) until the verification of the violation (02/07/2018)";
- "the assessment is in fact followed promptly by the recovery of the documentation (the same 02/07/2018) kept with the parents of the applicant as well as the sending (05/07/2018) of communication to the insurance company of the holder of the documentation, requesting the destruction of the copy that the holder's parents had sent for accident prevention purposes";
- "the violation event was promptly managed, but also (...) the integrity of the documentation of the interested party was promptly restored, with the immediate delivery (02/07/2018) to the applicant of a copy of documentation after removal of the report containing personal data of others";
- "no consequence can reasonably be assumed for the interested party, not only for the interventions promptly put in place by the Company, but also in the light of the fact that those exercising parental responsibility over the holder of the file, demonstrating a strong sense civic and not demonstrating any interest in the report of others, immediately proved to be collaborative, making themselves available to return the documentation";
- a "Check list" was sent to the Department Directors, the Directors/Heads of Complex Structures, Simple Departmental Structures and Simple Structures of Operating Units and equivalent Programs (note prot. n. 28375 of 20/07/2018) for the self-assessment regarding the compilation of the medical record (hereinafter Checklist), a practical tool that has been used for years by this Company to carry out the assessments relating to the completeness of the health documentation, envisaged by the Regional Council Resolution 1706/2009 " ;
- considering "the importance of providing for the control, limited to what is of interest for the correct processing of personal data, of the individual phases that make up the health documentation management process, the opportunity was also evaluated to make changes or revisions to existing procedures and instructions, aimed at reducing the risk associated with the

occurrence or recurrence of security incidents” and a specific training activity was carried out for the personnel involved in this activity.

2.2 Notice of infringement dated January 25, 2019

With reference to the aforementioned communication of violation of 25 January 2019, supplemented on 7 February 2019, the Office, with deed no. 9776 of 21 March 2019, ordered the meeting of the investigative proceedings relating to the aforementioned communications made by the Company, with reference to the specific situations of illegality referred to therein and notified the Company, pursuant to art. 166, paragraph 5, of the Code, the initiation of the procedure for the adoption of the measures referred to in article 58, paragraph 2, of the Regulation, inviting the aforesaid holder to produce defense writings or documents to the Guarantor or to ask to be heard by the Authority.

In particular, the Office, in the aforementioned deed, considered that even the violation of personal data, notified on 25 January 2019 to the Guarantor pursuant to art. 33 of the Regulation, has detected the existence of elements suitable for configuring, by the Company, the violation of art. 9 of the Regulation, also in the light of the principles of integrity and confidentiality referred to in the deed (art. 5, par. 1, letter f) of the Regulation), representing that the conduct described in the notification of violation (delivery of a copy of a medical file to the heir of the holder of the file, containing a report of a different patient) has integrated a communication of data relating to the health of a patient to another subject in the absence of a suitable legal prerequisite.

With a subsequent note of 19 April 2019 (prot. n. 17308), the Company, also in the light of the aforementioned meeting of the proceedings, sent its defense briefs in which, in summary, it was represented that:

- "on 23/012019, on the occasion of the photoreproduction of the health documentation referring to a single episode of hospitalization (and consisting of three volumes corresponding to the stay in three different Operating Units), during the coroner's investigation following a report from part of the family member of the same, a microbiological examination report of another subject was found in the file of the U.O. Pneumological Clinic”;
- following the checks carried out by the Company regarding the facts which are the subject of the notification of violation of 25 January 2019, supplemented on 7 February 2019, it emerged that "in relation to the event which is the subject of the notification made (...) (on) 25/01 /2019, personal data (name, tax code) and health data (negative result of a microbiological test and hospitalization ward of the subject to whom the diagnostic test refers) were processed for treatment purposes by the staff of the facility U.O. Pneumological, where the interested party was hospitalized, and erroneously entered in other people's

health records. As regards the duration of the violation, it can reasonably be affirmed that it occurred from the moment of delivery to the requesting holder of the health documentation containing the personal data of another (18/06/2018) until the day in which the staff at the of photoreproduction was aware of the other's report (23/01/2019). The interested party, or legitimate subjects, had never asked for a copy of the corresponding file";

- the medical record of the aforesaid subject "was characterized by high complexity both in terms of duration (...), and for the various transfers that took place (...), and for the copious documentation (431 pages, reproduced photos);

- "in relation to the integration carried out (...) (on) 07/02/2019, the personal data (name, surname, date of and health (haematochemical test report of hospitalized patient) were always processed for treatment purposes, from part of the staff of the Pneumology and Thoracic Endoscopy Unit UTIR, where the interested party was hospitalized, and had been erroneously entered in other people's health records. As regards the duration of the breach of confidentiality, it can reasonably be stated that it occurred from the moment of delivery, to the requesting holder, of the health documentation containing personal data of another subject (18/06/2018) until the day in which the staff became aware of the other person's medical report (28/01/2019). the clinical report was therefore missing from the moment of transmission to the requesting interested party (08/05/2018), until it was sent to the interested party following the verification (12/02/2019);

- "the verification of the first finding of violation is promptly followed by a telephone communication to the recipient's heir to whom the copy of the health documentation had been delivered, in order to provide for the recovery of the same";

- the documentation relating to third parties was requested to be returned to the heir of the holder of the medical record, but "in the face of a non-cooperative attitude (...), a formal note followed (our prot. no. 4084 of 29 /01/2019), delivered by registered mail, in which it was requested to return the copy of the file in your possession by agreeing with the Medical Records Representative, also providing the telephone contacts, furthermore steps were taken to distrust (...) from using the data of the holder of the documentation as well as to deliver to anyone the copy of the documentation currently in your possession". "Having received no response (...) the return of the documentation was requested (note our prot. n. 5780 of 07/02/2019)";

- "on 02/20/2019 (our prot. n. 7576 of 02/20/2019) the lawyer of the holder's joint (...) also communicated that (...) (the) documentation in possession of his client was was forwarded on 16/01/2019 to the Public Prosecutor's Office at the Court of Parma and for this reason the "medical records of Mr. (omissis) are no longer in the material availability of my client";

- "a specific note was sent to the Public Prosecutor's Office at the Court of Parma (note our prot n; 13329 of 03/26/2019),

communicating that the Company had initiated the procedures pursuant to art. 33 of EU Regulation 2016/679 relating to documentation filed as an attachment to a complaint".

3. Outcome of the preliminary investigation.

Having taken note of what is represented by the Company in the documentation in the deeds and in the defense briefs, it is noted that:

- the regulation on the protection of personal data provides - in the health sector - 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 prerequisite or on the indication of the interested party same subject to written authorization from the latter (Article 9 of the Regulation and Article 83 of the Code in conjunction with Article 22, paragraph 11, Legislative Decree No. 101 of 10 August 2018; see also general provision of 9 November 2005, which can be consulted on 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 d .lgs. n. 101//2018).

- the Regulation also establishes that personal data must be "processed in such a way as to guarantee adequate security (...), including protection, through appropriate technical and organizational measures, against unauthorized or unlawful processing and against loss, destruction or from accidental damage («integrity and confidentiality»)" (Article 5, paragraph 1, letter f) of the Regulation);

- the inclusion in two medical records of medical documentation of subjects other than the holders of the same resulted in the communication of health data to non-legitimized subjects in the absence of a suitable legal prerequisite.

4. Conclusions.

In the light of the assessments referred to above, taking into account the statements made by the data controller during the preliminary investigation and considering that, unless the fact constitutes a more serious crime, whoever, in a proceeding before the Guarantor, falsely declares or certifies news or circumstances o produces false deeds or documents and 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" the elements provided by the data controller in the defense briefs do not allow to overcome the findings notified by the Office with the deed of initiation of the proceeding, since none of the cases envisaged by art. 11 of the Regulation of the Guarantor n. 1/2019.

For these reasons, the unlawfulness of the processing of personal data carried out by the University Hospital of Parma is noted, in the terms set out in the justification, in violation of articles 5 par. 1, letter f) and 9 of the Regulation.

In this context, considering, in any case, that the conduct has exhausted its effects, given that the Company has declared that the documents erroneously delivered to third parties have been returned and that it has planned the further technical and organizational measures deemed necessary to reduce human error to a minimum, the conditions for the adoption 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 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, par. 2, lit. f) and 9 of the Regulation, caused by the conduct of the University Hospital of Parma, is subject to the application of the administrative fine pursuant to art. 83, paragraph 5, of the Regulation.

Consider 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. 85, par. 2, of the Regulation in relation to which it is observed that:

the Authority became aware of the event following the personal data breach notifications made by the same controller and no complaints or reports were received to the Guarantor regarding the events covered by the aforementioned notifications (art. 83, paragraph 2, lett. a) and h) of the Regulation);

the data processing carried out by the Company concerns data suitable for detecting information on the health of a small number of interested parties including a minor (art. 4, paragraph 1, n. 15 of the Regulation and art. 83, paragraph 2 , letters a) and g) of the Regulation);

the episodes are isolated and characterized by the absence of voluntary elements on the part of the Company in causing the events (Article 83, paragraph 2, letter b) of the Regulation);

the Company immediately demonstrated a high degree of cooperation (Article 83, paragraph 2, letters c), d) and f) of the Regulation).

Based on the aforementioned elements, evaluated as a whole, also taking into account the phase of first application of the sanctioning provisions pursuant to art. 22, paragraph 13, of Legislative Decree lgs. 10/08/2018, no. 101, it is decided to determine the amount of the pecuniary sanction provided for by art. 83, par. 5, letter. a) of the Regulation, to the extent of 10,000 (ten thousand) euros for the violation of articles 5, par. 1, lit. f) and 9 of the Regulation as a pecuniary administrative sanction deemed, pursuant to art. 83, par. 1, of the Regulation, effective, proportionate and dissuasive.

It is also believed that the ancillary sanction of publication on the Guarantor's website of this provision 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, also in consideration of the type of personal data subject to unlawful processing.

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

declares the illegality of the processing of personal data carried out by the University Hospital of Parma, for the violation of the art. 5, par. 1, lit. f) and 9 of the Regulation in the terms referred to in the justification.

ORDER

pursuant to articles 58, par. 2, lit. i) and 83 of the Regulation, as well as art. 166 of the Code, to the University Hospital of Parma with registered office in Parma, Via Gramsci 14 – Tax Code/VAT Number 01874240342, in the person of its pro-tempore legal representative, to pay the sum of 10,000 (ten thousand) euros by way of pecuniary administrative sanction for the violations indicated 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 Company, in the event of failure to settle the dispute pursuant to art. 166, paragraph 8, of the Code, to

pay the sum of 10,000 (ten thousand) euros according to the methods indicated in the annex, within 30 days of notification of this provision, under penalty of adopting 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 entire publication of this provision on the website of the Guarantor and believes that the conditions set forth in 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.

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, 27 January 2021

PRESIDENT

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THE SPEAKER

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THE SECRETARY GENERAL

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