

Injunction order against Piacenza Local Health Unit - 6 June 2018

Register of measures

no. 377 of 6 June 2018

THE GUARANTOR FOR THE PROTECTION OF PERSONAL DATA

IN today's meeting, in the presence of Dr. Antonello Soro, president, of dott.ssa Augusta Iannini, vice president, of dott.ssa Giovanna Bianchi Clerici and of prof.ssa Licia Califano, members and of dott. Giuseppe Busia, general secretary;

NOTING that the Guardia di Finanza, special privacy unit, in execution of the request for information no. 31538/114083 of 3 October 2017 formulated pursuant to art. 157 of the legislative decree lgs. June 30, 2003 no. 196, containing the Code regarding the protection of personal data (hereinafter the "Code") has carried out, formalizing it with the reports of operations carried out dated 12, 13 and 14 December 2017, a control activity against the Healthcare Unit Local in Piacenza VAT number: 01138510332, with headquarters in Piacenza, via Antonio Anguissola n. 15, in the person of the pro-tempore legal representative. This control activity, also in the face of the dissolution of the reservations formulated and finally dissolved with the sending of the notes dated 28 December 2017, made it possible to ascertain that the Local Health Unit has set up the patients' electronic health dossier, putting in logical sharing of the clinical history referred to them, for the benefit of the health personnel of the facility:

1. without having previously informed the data subjects of the specific processing in question pursuant to art. 13 of the Code and contrary to what was clarified by the Guarantor in the "Health dossier guidelines" of 4 June 2015 (in www.garanteprivacy.it, web doc. n. 4084632);
2. without having acquired a specific consent to this purpose pursuant to art. 23 of the Code and contrary to what was clarified by the Guarantor in the "Health dossier guidelines" of 4 June 2015;
3. has failed to designate the persons in charge of processing pursuant to art. 30 of the Code and to give them the prescribed instructions, thus disregarding the provisions of Annex B to the Code, rules nos.rr. 1-10 and 12-15;

HAVING REGARD TO the report drawn up by the Special Privacy Unit of the Guardia di Finanza on 18 January 2018, in which two administrative violations, which can be briefly defined pursuant to art. 16 of the law of 24 November 1981, n. 689, provided for by art. 161 and by the art. 162, paragraph 2-bis of the Code, in relation to art. 13 and art. 23, as well as the administrative

violation, which cannot be briefly defined pursuant to art. 16 of the law of 24 November 1981, n. 689, provided for by art. 162, paragraph 2-bis of the Code, in relation to the measures indicated in art. 33;

CONSIDERING the written defense dated 8 March 2018 sent pursuant to art. 18 of the law n. 689/1981, with which the Local Health Unit of Piacenza, after having observed how in the face of the issue by the Guarantor of the "Guidelines on health dossiers" dated 4 June 2015 "(...)" within the of the Regional Table it was acknowledged that the definitive version of the Interpretative Notes to the Guidelines of the Privacy Guarantor for the correct management of the DSE (electronic health dossier) in the Emilia Romagna Region (...) would therefore have been officially sent to the Authority and will be adopted by the Region within the year. To date, the aforementioned notes with which the Region will indicate the uniform path at regional level to give correct application of the Guidelines of this Authority on the subject of DSE, have not yet been received", he preliminarily highlighted that he had "(...)" taken steps to adopt the resolutions with which, since 2005 (...), it has designated (...) as responsible for the processing of user data, the Heads of Complex Operating Unit and Simple Departmental Operating Unit (...)", to have "(...)" provided (...) through the same resolutions (...) to designate all AUSL employees (...) as persons in charge of processing patient data (...) specifying their duties (...)" and to deem that "(...)" in the light of these considerations , and taking into account that the responsibility in the event of commission of offenses involving the imposition of an administrative sanction is personal, as can be deduced from the articles 2, 3, 7 and 11 l. no. 689/1981, the erroneousness of the contestation report in the epigraph raised and notified against the Local Health Authority emerges (...)" . On the merits, with specific reference to what was contested in relation to the violation of art. 33 of the Code, in explaining in detail how "The designation of the appointees (...) took place and also the security measures pursuant to art. 34, paragraph 1 lett. a), b) and c) legislative decree n. 196/2003 are complied with in the manner indicated in Annex B of the same Code", specifying how "(...)" the designation of the appointees was made in writing, as well as the scope of the processing permitted to them was identified. This also happened with specific reference to the technological aids made available by the Company, and thus, therefore, also to the electronic health dossier", he noted how "(...)" the regulatory provisions regarding the designation of the persons in charge have instead been fully respected by the Local Health Authority of Piacenza (...)" making it infer that "(...)" this in itself excludes the violation of the security measures pursuant to art. 34 lett. a), b) and c) of the Code. In any case and for mere defensive reasons, it should be noted that this specific aspect has already been subject to verification, in the past, by the Guardia di Finanza, during the aforementioned inspections of 2009 (checks formalized by the Guardia di Finanza with reports of operations carried out on

10 November 2009)". With regard to the dispute regarding the violation of art. 13 of the Code, observed how "(...) all users of the Piacenza Local Health Authority have always received, at the company's Operating Units, information on the processing of their personal data, containing all the information prescribed by art. 13 of the Privacy Code, being also informed of the fact that the aforementioned treatment could also have taken place on electronic media, such as the health dossier. In other words, the fact that users' personal data have been processed (...) also through the health dossier, and therefore with electronic and not merely paper-based methods, does not detract from the fact that they were in any case recipients of information (...) already in itself fully compliant with the requirements identified by art. 13 of the Privacy Code". Regarding what was contested for the violation of art. 23 of the Code, "(...) with specific reference to the electronic health dossier, the AUSL (...) has decided to start an experiment independently (...). It is the so-called graphometric signature, which, fully expressing the concept of dematerialisation in the health sector, consists in the preparation (...) of a form to be submitted to the patient (previously informed), for the affixing of a graphometric signature on it using a software of collection of biometric data of the signature itself on graphic devices capable of allowing reading. The aforesaid trial was positively concluded on January 31st of last year. (2018) (...)". Furthermore, "Although the trial period of the graphometric signature (...) was started and underway before the inspections by the Guardia di Finanza at the company premises, the need to have to conclude it (...) prompted the Piacenza Local Health Authority to intervene immediately on their IT systems";

HAVING REGARD TO the minutes of the hearing of the parties drawn up on 4 May 2018, pursuant to art. 18 of the law n. 689/1981, in which the Local Health Unit of Piacenza, in reiterating what was argued in the defense brief, observed that "In relation to finding no. 3 (violation of Article 33 of the Code) no request was made, and then provided, the documentation relating to the designation of several managers/in charge for each operating unit";

CONSIDERING that the arguments put forward do not allow the liability of the Piacenza Local Health Authority to be excluded in relation to the dispute in question.

The circumstance according to which the Table of the Emilia Romagna Region did not provide the interpretative notes of the "Guidelines on health dossiers" of 4 June 2015, does not substantiate any of the constituent elements of the discipline of excusable error pursuant to art. 3 of the law n. 689/1981, also on the basis of what is asserted by the jurisprudence (Cass. Civ. section I of 15 May 2006 n. 11012; Cass. Civ. section II of 13 March 2006, n. 5426).

With reference to what was argued regarding the fact that it "(...) proceeded to adopt the resolutions with which, since 2005

(...), it designated (...) as persons in charge of the treatment of patient data (...) all the employees of the AUSL (...) specifying their duties (...)", it should be noted that both the defense brief and the hearing report pursuant to art. 16 of the law n. 689/1981 do not introduce any additional element to those formalized in the preliminary investigation activity both with the reports of operations carried out drawn up by the Guardia di Finanza on 12, 13 and 14 December 2017 and with note no. 2017/0113448 of 27 December 2017 and evaluated for the purpose of ascertaining the specific finding contested for the violation of art. 33 of the Code. The Local Health Unit of Piacenza has not proved, while taking into account the documentary productions according to which "The designation of the appointees (...) has taken place and also the security measures pursuant to art. 34, paragraph 1 lett. a), b) and c) legislative decree n. 196/2003 are complied with in the manner indicated in Annex B of the same Code", to have provided for a timely designation of the persons in charge of the treatment pursuant to art. 30 of the Code, with specific reference to the processing of personal data relating to the "health dossier". Furthermore, we note the inconsistency of the aforementioned control activity carried out by the Guardia di Finanza in November 2009, given that this activity did not concern the specific processing of personal data relating to the "health dossier".

Furthermore, we note the pretext of what was argued in the minutes of the hearing of 4 May 2018 "In relation to finding no. 3 (violation of Article 33 of the Code) (...)", given that the request for information made to the Company Local Health Unit of Piacenza pursuant to art. 157 of the Code expressly requested account, in point 7), of the "designation of (any) data processors and data processors and instructions given to them, pursuant to articles 29 and 30 of the Code, also with reference to any third parties who participate in the processing (producing, in this case, a copy of the relative stipulated service contracts)".

The Local Health Authority of Piacenza erroneously believes that "(...) the imposition of an administrative sanction is personal, as can be deduced from the articles 2, 3, 7 and 11 l. no. 689/1981 (...)" . With regard to the discipline relating to the principle of personality referred to in Articles 2, 3 and 7 of the law n. 689/1981, it should be noted that the discipline dictated by the Code constitutes *lex specialis* with respect to the provisions of law no. 689/1981 as a source of the same degree that can be invoked, as a result of art. 166 of the Code, only "as applicable". The Code establishes that the fulfillments are implemented, in the first place, by the data controller who, according to the provisions of art. 28 of the Code, when the processing is carried out by a legal person, a public administration or any other body, association or body, the data controller is "the entity as a whole" where, moreover, the data controller can , within the scope of the power to organize data processing, delegate the fulfillment of

certain obligations also to individuals (natural or legal) identified, pursuant to art. 29 of the Code, as data controllers. In the case that concerns us, it is undisputed that the data controller pursuant to art. 28 of the Code, as can be clearly seen from the investigative documents, is the Local Health Authority of Piacenza.

With regard to what was argued regarding the violations of articles 13 and 23 of the Code, it should be noted that both the defense brief and the report of the hearing pursuant to art. 16 of the law n. 689/1981 do not introduce any additional element to those formalized in the preliminary investigation activity both with the reports of operations carried out drawn up by the Guardia di Finanza on 12, 13 and 14 December 2017 and with note no. 2017/0113448 of 27 December 2017. It should therefore be reiterated that, while taking into account the evidence produced in the documents, the Local Health Authority of Piacenza does not consider, with specific reference to the information pursuant to art. 13 of the Code, as punctually asserted in the "Health dossier guidelines" of 4 June 2015 regarding the fact that "The processing of personal data carried out through the dossier differs from that relating to the compilation and keeping of the medical record, understood as the individual information tool aimed at detecting all the significant personal and clinical information relating to a patient and a single hospitalization episode. As such, the processing of personal data carried out through the health dossier requires specific information that contains all the elements required by art. 13 of the Code".

The same observations are also confirmed with specific reference to the discipline of consent pursuant to art. 23 of the Code, given that the same "Guidelines on health dossiers" provide as "(...) the health dossier, constituting the set of personal data generated by present and past clinical events concerning the interested party, constitutes a treatment of specific personal data and additional to that carried out by the healthcare professional with the information acquired during the treatment of the single clinical event. As such, therefore, it is configured as an optional treatment. (...) Given this, any lack of consent to the processing of personal data through the health dossier must not negatively affect the possibility of accessing the requested medical care. (...) In this framework, the consent to the dossier, even if expressed together with that envisaged for the processing of data for treatment purposes, must be autonomous and specific";

NOTING, therefore, that the Local Health Unit of Piacenza has processed personal data (Article 4, paragraph 1, letter a) and b) of the Code) by setting up the patients' electronic health dossier and logically sharing the history clinic referred to them, for the benefit of the health personnel of the facility:

1. without having previously informed the data subjects of the specific processing in question pursuant to art. 13 of the Code

and contrary to what was clarified by the Guarantor in the "Health dossier guidelines" of 4 June 2015 (in www.garanteprivacy.it, web doc. n. 4084632);

2. without having acquired a specific consent to this purpose pursuant to art. 23 of the Code and contrary to what was clarified by the Guarantor in the "Health dossier guidelines" of 4 June 2015;

3. without designating the persons in charge of processing pursuant to art. 30 of the Code and to give them the prescribed instructions, thus disregarding the provisions of Annex B to the Code, rules nos.rr. 1-10 and 12-15;

CONSIDERING the art. 1, paragraph 2, of the law of 24 November 1981, n. 689, pursuant to which the laws that provide for administrative sanctions are applied only in the cases and for the times considered in them;

CONSIDERING the art. 161 of the Code, which punishes the violation of the provisions of art. 13 of the same Code, with the administrative sanction of the payment of a sum from six thousand euros to thirty-six thousand euros;

CONSIDERING the art. 162, paragraph 2-bis, of the Code which punishes the violation of the provisions indicated in art. 23 of the Code with the administrative sanction of the payment of a sum from ten thousand euros to one hundred and twenty thousand euros;

CONSIDERING the art. 162, paragraph 2-bis, of the Code which punishes the violation of the provisions indicated in art. 33 of the Code with the administrative sanction of the payment of a sum from ten thousand euros to one hundred and twenty thousand euros;

CONSIDERING that, for the purposes of determining the amount of the pecuniary sanction, it is necessary to take into account, pursuant to art. 11 of the law of 24 November 1981 n. 689, of the work carried out by the agent to eliminate or mitigate the consequences of the violation, of the seriousness of the violation, of the personality and economic conditions of the offender and that, therefore, the amount of the pecuniary sanction with reference to the violation referred to in art. 161 must be quantified in the amount of 6,000.00 (six thousand) euros, the amount of the pecuniary sanction with reference to the violation pursuant to art. 162, paragraph 2-bis, in relation to art. 23 of the Code, must be quantified in the amount of 10,000.00 (ten thousand) euros and the amount of the pecuniary sanction with reference to the violation pursuant to art. 162, paragraph 2-bis, in relation to art. 33 of the Code, must be quantified in the amount of Euro 20,000.00 (twenty thousand) for a total quantification of Euro 36,000.00 (thirty six thousand);

HAVING REGARD to the documentation in the deeds;

HAVING REGARD to the law of 24 November 1981 n. 689, and subsequent modifications and additions;

HAVING REGARD TO the observations of the Office, formulated by the Secretary General pursuant to art. 15 of the Guarantor's regulation n. 1/2000;

SPEAKER Prof. Licia Califano;

ORDER

to the Local Health Authority of Piacenza VAT number: 01138510332, with headquarters in Piacenza, via Antonio Anguissola n. 15, in the person of the pro-tempore legal representative, to pay the sum of 36,000.00 (thirty-six thousand) euros as a pecuniary administrative sanction for the violations envisaged by articles 161 in relation to the art. 13 of the Code, 162, paragraph 2-bis in relation to art. 23 of the Code and 162, paragraph 2-bis in relation to art. 33 of the Code, as indicated in the motivation;

ENJOYS

to the same subject to pay the sum of 36,000.00 (thirty-six thousand) euros, according to the methods indicated in the attachment, the fractional payments of which will be made by the last day of the month following the one in which the notification of this order will take place, under penalty of adoption of the consequent executive acts pursuant to art. 27 of the law of 24 November 1981, n. 689.

Pursuant to articles 152 of the Code and 10 of Legislative Decree lg. no. 150/2011, opposition to this provision may be lodged with the ordinary judicial authority, with an appeal lodged with the ordinary court of the place where the data controller has his residence, within the term of thirty days from the date of communication of the provision itself or sixty days if the appellant resides abroad.

Rome, 6 June 2018

PRESIDENT

Soro

THE SPEAKER

Califano

THE SECRETARY GENERAL

Busia