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OPINION 2019/25

I. Order

The Health Regulatory Entity (ERS) asked the National Data Protection Commission (CNPD), under article 91 of the Administrative Procedure Code, to issue an opinion within the scope of the ERS' draft deliberations issued in the investigation processes No. ERS/118/2018, ERS/128/2018, ERS/133/2018 and ERS/143/2018.

These processes are concerned with the refusal to provide healthcare by healthcare units to data subjects who have not signed a declaration authorizing the processing of their personal data.

Although the main disputed legal issue is the same in all cases, it is configured differently in each of them, depending on the facts described or the reasoning presented by the data controllers.

In addition, in two of the investigation processes there is still an autonomous question, not to be confused with the requirement of consent for the processing of personal data, which concerns the possibility of obtaining from the holder of the personal data a written declaration proving that he the right to information on data processing has been provided.

For this reason, in this opinion the two issues will be analyzed separately, taking into account the specific aspects of each process.

This opinion, issued under the competence defined in point b) of paragraph 3 of article 58 of Regulation (EU) 2016/679, of 27 April 2016 (General Regulation on Data Protection - RGPD) , in conjunction with the provisions of paragraph 1 of article 21 and paragraph 1 of article 22, both of Law no. 67/98, of 26 October, amended by Law no. 103 /2015, of 24 August (Personal Data Protection Law - LPDP), aims to assess the compliance with the RGPD of the procedures adopted by the health units in question, in the strictest measure of their relevance to the exercise of ERS' powers , not focusing, in particular, on the assessment of the privacy policy of the entities involved in the proceedings.

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II. appreciation

1. The consent of users/clients of health units as a condition for the processing of personal health data

In all the processes mentioned above, access to health care was denied due to the fact that the user/client had not signed a declaration of consent regarding the processing of personal data.

In fact, these entities present themselves as responsible for the processing of personal data and, as such, they required users to sign a document as a condition of providing the scheduled service (eg medical consultation, diagnostic examination).

In the case of Process ERS/128/2018, concerning Centro Hospitalar São Francisco, S.A., in the document presented to the data subject it is stated that the data are only necessary for the provision of health care, having been declared within the scope of the process that, for the purpose of using the information for marketing, an autonomous declaration of consent was presented (cf. §7 of the draft deliberation of the ERS). Not so in the case concerning Somardental Serviços Policlínicos, Lda. (process ERS/133/2018), where, as declared by this entity, according to §6 of the draft deliberation of the ERS, the declaration of consent brings together the processing of data for the purpose of providing health care and the processing for the purpose Of marketing.

In both cases, the CNPD understands that the procedure adopted by the two entities is contrary to the GDPR, as it is based on an error as to the legality of the processing. In fact, the two entities consider that the consent of the data subject is essential for the collection of personal data, invoking the GDPR for this purpose, so that, in the absence of that, they believe they cannot provide health care.

This error implies a violation of the principle of lawfulness of the processing of personal data, enshrined in point a) of paragraph 1 of article 5 of the GDPR, since consent is not the appropriate condition to legitimize the processing of personal data. necessary for the provision of health care. In fact, the GDPR provides an autonomous condition for this purpose of processing personal data in Article 9(2)(h). Furthermore, in such a situation, as the data necessary to

the provision of the service, one cannot see where there is freedom to consent or not to the processing of data - and therefore, one of the attributes of consent established by law for it to have legal relevance would never be fulfilled (cf. paragraph 11) of article 4. ° GDPR).

The processing of personal data for the purpose of marketing may depend on consent (because the legitimate interest, in certain circumstances, is sufficient to legitimize the treatment), but, of course, due to the absence of a direct connection between this purpose and the provision of care. health care, obtaining that specific consent could never serve as a condition for the provision of health care.

It should be added that the allegations made by Grupo Sanfil Medicina (which includes Centro Hospitalar São Francisco, S.A.) in the context of the ERS/128/2018 process (cf. §7 of the ERS draft deliberation), that the companies of this group , as those responsible for the processing of personal data, are not entitled by subparagraph h) of paragraph 2 of article 9 of the RGPD to collect and keep such data for the provision of health care, they work in an error, already highlighted by ERS in the draft resolution, in §§ 148-152.

Indeed, if Centro Hospitalar São Francisco, S.A., did not provide health care (even through an intermediary, the health professional) it would not, under any circumstances, have the legitimacy to collect, store and communicate personal data relating to the health of its customers. In this case, consent for the provision of health care could not be given to this entity, but only to the health professionals who effectively provided that care.

It is therefore clear that the company that operates Centro Hospitalar São Francisco holds a database of its customers with their clinical records because it is legitimized for that purpose by subparagraph h) of paragraph 2 of article 9 of the GDPR And in order to comply with Article 9(3) of the GDPR, you must ensure that only health professionals bound by a duty of professional secrecy can collect and access personal health data.

As for the case ERS/118/2018, concerning Hospital de Esposende - Valentim Ribeiro, it is important to emphasize that the declaration of consent that was intended to be signed did not concern the processing of personal data necessary for the provision of health care (cf. §11 of the draft resolution issued in this process).

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The same happened in relation to Process ERS/143/2018, concerning CLIRIDAL -Clinic of Diagnosis and Radiology, Lda.

Here, too, the declaration of consent that was intended to be signed was related to the processing of data for sending reminders or changing the appointment of exams and promotional information (marketing) (cf. §10 of the project).

It was not, therefore, a question of requiring consent for the provision of the diagnostic or health care service, but for the further processing of personal data for other purposes. Such a declaration of consent is in accordance with the RGPD (with the exception of the use of contact data to change the schedule of exams, which seems to still fit in the management of health services, therefore, within the scope of point h) of no. 2 of article 9 of the GDPR).

What cannot, in any case, be accepted is that the provision of the contracted service depends on the consent of the data subject for a data processing purpose that is not even essential to the realization of such provision.

Here, as in the case ERS/118/2018 (cf. §11), the fact that the declaration that the terms of the processing of personal data has been made known comes immediately before the declaration concerning the authorization of a certain type of processing of personal data impairs the understanding of the exact scope of the declaration of consent, verifying that the representatives of those responsible who interact with the data subjects are not, themselves, sufficiently clarified to clear up any confusion regarding the object of the consent. And in particular in the ERS/118/2018 case, the terms in which the consent declaration is written do not in any way facilitate the understanding of its scope.

2. Proof of the right to information guarantee

As for the inquiry processes ERS/118/2018 and ERS/143/2018, in the document on the processing of personal data that is presented to customers/users for signature, information on the treatment is provided and a signature is requested under the declaration " I took notice".

Here, it is important to consider the claims of data controllers, who claim that the document in question is composed of three separate parts.

The first part concerned the collection of personal data for the purpose of providing the contracted service (e.g. identification and contact data), such as

happened in the ERS/143/2018 process, or confirm ("validate") personal data collected before the application of the GDPR (as happened in the ERS/118/2018 process) - that is, with the intention of updating or guaranteeing the updating of the information conserved personnel.

The second part of the declaration was intended to inform the data subject of the information that was collected about them, the purposes of this collection, as well as other elements listed in article 13 of the RGPD, therefore, to guarantee the right to information. . At the end of this part, a paragraph is presented in which the declarant certifies that he has been aware of this information, with space for the signature of the data subject.

Immediately after, a new paragraph appears in which the declarant authorizes the processing of data for the provision of health care or, in some cases, for other purposes, part of which the CNPD has already commented in the previous point.

As for the collection or updating of personal data, the CNPD has nothing to say within the scope of these processes, since this data processing operation is not under discussion here (and in the ERS projects, as for all those responsible, the categories of personal data being processed). Assuming that there is a set of personal data that are necessary to ensure the provision of health care and that must be updated (cf. point d) of paragraph 1 of article 5 of the RGPD), the CNPD reserves the right to power to comment on such processing of personal data at another location.

Specific attention deserves the second part of the documents here.

It is important to clarify here that those responsible for the processing of personal data are obliged to provide information to the holder of the personal data about the treatment, under the terms provided for in articles 13 and 14 of the RGPD, and that to that extent they can collect evidence that they have complied with this obligation.

However, given that the RGPD requires that the right to information be provided in writing, although it admits the provision orally at the request of the data subject (cf. paragraph 1 of article 12 of the RGPD), the procedure used conforms to the GDPR.

It is also true that it is up to the data controller to prove that he complies with the GDPR - cf. Article 5(2).

Although this piece of legislation does not define the appropriate form of proof of compliance with this obligation, therefore not requiring a written declaration from the holder

of the data, nothing prevents those responsible from providing the information in the way in which Hospital de Esposende - Valentim Ribeiro and CLIRIDAL - Clínica de Diagnóstico e Radiologia, Lda. . In other words, this procedure does not violate the GDPR and, as long as it is clearly explained to the data subject, it can be effective.

In the event that the data subjects refuse to sign such a declaration, the representative of the person in charge can register that the user did not want to sign and, perhaps, make sure that he has testimonial evidence to that effect.

It is a different thing to require this signature from the data subject, presenting it as a condition for the provision of the service object of the contract with him. Here, and to the extent that the entities have effectively presented these declarations and their signature as a condition for the provision of health care, it is that there may be an illicit behavior. In fact, from the allegations of the two responsible, it is not clear that this signature was presented as a condition for the provision of the service, although it is admitted that the fact that this declaration, which attests to the knowledge, is immediately before the declaration concerning the authorization of the treatment may have confused the data subjects, a confusion to which the absence of explanations or the scarce clarification of the representatives of those responsible who presented the documents in question to the data subjects may have contributed.

It is recalled that, according to paragraph 1 of article 12 of the GDPR, the information must be provided in clear and simple language, and that a pre-defined declaration of acknowledgment of the information, for signature of the holder data, must be independent of any declarations of consent for other processing of personal data (cf. Article 7(2) of the GDPR).

III. Conclusion

The CNPD understands that the requirement of consent from the holder of the personal data for the processing of personal data necessary for the provision of health care is based on an error as to the lawfulness of the data processing and, therefore, contradicts the provisions of the GDPR, under the terms of Article 5(1)(a) and Article 9(2)(h) of the GDPR.

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to the NATIONAL COMMISSION . - DATA PROTECTION

It is also his opinion that the obligation to provide information on the processing of personal data to the respective holder, imposed by articles 13 and 14 of the RGPD, can be implemented by means of a written document that is presented to him, nothing preventing which, for the purpose of proof, its signature is requested to certify that it has become aware of that information. However, this signature is not a condition for the provision of the contracted service, so in case of refusal to sign by the data subject, other forms of proof must be found that that right has been guaranteed.

In any case, the information must be provided in clear and simple language, and the pre-defined declaration of acknowledgment of the information must be duly separated from any declarations of consent to the processing of personal data for other purposes.

Lisbon, May 10, 2019

Filipa Calvão (President)