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National Data Protection Commission

OPINION/2021/31

I. Order

1. The Committee on Constitutional Affairs, Rights, Freedoms and Guarantees asked the National Data Protection Commission (CNPD) to issue an opinion on Bill No. 666/XIV/2.a, which "[proceeds to 1 , the amendment to Law No. 58/2019, of 8 August, which ensures the implementation of the General Data Protection Regulation, ensuring access by medical students to information systems and platforms on which health data are recorded. users of health services», presented by the Parliamentary Group of the Socialist Party.

2. The CNPD issues an opinion within the scope of its attributions and competences as an independent administrative authority with powers of authority to control the processing of personal data, conferred by subparagraph c) of paragraph 1 of article 57, in conjunction with subparagraph b) of paragraph 3 of article 58, and with paragraph 4 of article 36, all of Regulation (EU) 2016/679, of 27 April 2016 - General Regulation on Data Protection (hereinafter GDPR), in conjunction with the provisions of article 3, paragraph 2 of article 4, and paragraph a) of paragraph 1 of article 6, all of Law n° 58 /2019, of 8 August, which enforces the GDPR in the domestic legal order.

3. It should be noted that this Bill, which introduces new relevant rules for the processing of personal data and regulates a new operation for the processing of personal data, is not accompanied by the impact study on the protection of personal data required by the paragraph 4 of article 18 of Law no. 43/2004, of 18 August, last amended by Law no. 58/2019, of 8 August.

II. Analysis

i. Preliminary point: clarifications regarding the explanatory memorandum

4. The Bill under analysis here, according to the respective explanatory memorandum, is based on Deliberation/2020/262 of the CNPD, which considered that, in the current regulatory framework, there is no other legal basis for the new processing of personal data which means access by medical students to the clinical process of patients at university hospitals, other than the consent of each patient.

5. In the explanatory memorandum, it is stated that Law No. 58/2019, of 8 August, in article 29, when it provides for the duty of secrecy of students and researchers in the health area who have access to data concerning to health, «he did not take care to expressly establish the conditions under which students can access the data about which they must keep confidential, and it could even be argued that such a desideratum resulted implicitly from the establishment

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general access conditions resulting from the RGPD, which a systematic interpretation oriented towards balancing with other constitutionally enshrined rights would allow to conclude", concluding that the interpretative option of such a rule "would lead to the creation of a bureaucratic, impractical and unbalanced circuit, which would make training impossible. And, he continues, arguing that this solution is based “on a misunderstanding: the restrictions on the processing of sensitive data under the GDPR and the law apply to those who have that responsibility. What is at stake in the case of students is the mere access with a specific profile and adequate security rules, respecting the rules of the RGPD».

6. It is therefore important, before proceeding to the analysis of the projected legislative changes, to clarify the content of the aforementioned CNPD deliberation, demonstrating, now more clearly, that the underlying concerns of this Bill are based on a manifest misunderstanding. Let's see.

7. The argument that the conditions of access by medical students to health data «result[m] implicitly from the general establishment of access conditions resulting from the GDPR, which a systematic interpretation and oriented towards balancing with other constitutionally enshrined rights would allow to conclude»1 deserves the full acceptance by the CNPD: this was precisely the conclusion of the CNPD in the aforementioned Deliberation, when it stated that such access can only be supported by the consent of each patient, under the terms of subparagraph a) of no. 2 of article 9 of the GDPR.

8. In fact, no other provision of Article 9(2) of the RGPD - it being indisputable that, as specially protected personal data are involved, it is essential that one of the grounds provided for in this article is verified - allows to legitimize the intended access, since point h) of the same number delimits the set of purposes for the processing of personal data that, from the perspective of the European legislator, justify the processing of personal health data. And in this set, objectively, neither scientific or clinical

research nor the training of future health professionals fit.

9. In this sense, it appears that the CNPD, in its deliberation, was not clear enough to explain why, in the light of that same precept - Article 9(2)(h) of the GDPR does not there is a need for student access. Contrary to what seems to result from the explanatory memorandum of this Bill, the CNPD did not question the need or convenience of medical students' access to personal health data, it only underlined what is all too evident: subparagraph h) of n. 2 of article 9 of the GDPR only legitimizes access to health-related data when they are necessary for the purposes of preventive medicine or work, for the assessment of the employee's work capacity,

Interestingly, rights not mentioned in the explanatory memorandum.

medical diagnosis, the provision of health care or treatment or social action or the management of health or social action systems and services, so that such a need does not exist when the access for the purpose of training students of medicine.

10. In this regard, it is also important to deconstruct the judgment underlying the statement, contained in the explanatory memorandum, that “the restrictions on the processing of sensitive data under the GDPR and the law apply to those who have this responsibility. What is at stake in the case of students is mere access with a specific profile and adequate security rules, respecting the rules of the RGPD».

11. While it is evident that the restrictions on the processing of sensitive data under the GDPR and the law apply to those who have [the] responsibility for such processing, it is no less evident that any access to personal data constitutes a data processing operation that, for it, the person responsible for the processing of personal data is responsible, under the terms of Article 4, points 2) and 7), of the RGPD, and precisely any access - regardless of the status or activity of whoever accesses - must respect the restrictions of Article 9 of the GDPR.

12. In other words, university hospital centers are responsible for the clinical processes of patients and, to that extent, for any and all access to the personal data contained therein, therefore also by medical students, it being essential that this access also respects the restrictions provided for in the GDPR, in particular in Article 9. Another interpretation would legitimize access

by hackers to sensitive information, such as that listed in Article 9(1) of the GDPR, which clearly does not correspond to the ratio of the Union's legal regime.

13. The reason why, in the explanatory memorandum, access by students is classified as "mere" is not achieved and it is specified that it is carried out through a specific profile and adequate security rules, continuing for clarify how this “mere access” complies with the rules of the GDPR if it does not respect the restrictions of article 9 of the same diploma.

14. Finally, still referring to the explanatory memorandum, the CNPD cannot fail to refute the assertion that the interpretation that the CNPD advocates of the RGPD and Law No. 58/2019 "would lead to the creation of a bureaucratic circuit, impractical and unbalanced, which would make training impossible'. The demonstration that such an interpretation does not lead to the described result resides in the circumstance that it is possible to create, for medical students who are attending the clinical years, a profile of access to the personal data of the patients included in the clinical file in respect of the principles and rules for the protection of personal data, in particular, with respect for patients' autonomy of will, as required by the most basic principles within the scope of clinical activity.

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15. In fact, shortly after the issuance of Deliberation/2020/262, as the CNPD understood the need to expedite the access of medical students enrolled in the clinical years to clinical processes, it was created, following a meeting between the CNPD, the Council of Medical Schools and the Council of Rectors of Portuguese Universities, which took place in January of this year, a working group that devised an access mechanism that also guaranteed respect for the autonomy of will of patients, in parallel terms to what is required in our legal system in relation to the presence of students at medical appointments or during the provision of health care.

16. The referred working group of specialists, which also includes representatives of the Shared Services of the Ministry of Health, EPE, to guarantee the feasibility of the solution to be presented.

17. Thus, on the present date, it can be announced that a system has already been designed that, integrating the access profile of a medical student, also includes the provision of informed, free, explicit and specific consent for the purpose of training.

18. In this way, compliance with Articles 4(11), 7 and 9(2)(a) of the GDPR is guaranteed, thus proving to be inaccurate the statement that, within the framework of the current data protection legal regime, the interpretation that the CNPD makes of it, regarding the access of medical students, creates a bureaucratic, impractical and unbalanced circuit, which would make training impossible.

19. Having made these clarifications, the articles of the Bill are now considered.

ii. Analysis of Articles 2 and 3 of the Bill

20. Article 2 of the Draft Law provides that "Medical students' access to patients' clinical information, in the establishments where their training takes place, under adequate technical supervision, is considered to be part of the process of providing of health care and treatment or diagnostic services, and authorized as such'.

21. The precept, written in this way, causes the greatest perplexity: how can students' access to patients' clinical information be considered as part of the process of providing health care and treatment or diagnostic services? When it is certain that:

i. The provision of such care and diagnosis cannot be the responsibility of students, since the law reserves the practice of acts to doctors, as results from article 9 of Decree-Law no. 9 of Decree-Law No. 177/2009, of 4 August, and No. 2 of Article 3 and Articles 6 and 7 of Regulation No. 698/2019, of 5th of September, given that the exercise of the activity of medicine depends on prior registration with the Medical Association, which at least assumes the

degree in Medicine (see Article 1(2) and Article 98 of the Statute of the Medical Association, approved by Decree-Law No. 282/77, of 5 July, last amended by Law No. 117/2015, of 31 August);

ii. The presence of students in medical consultations or during the provision of health care is not, at all, necessary for the provision of health care and treatment or diagnostic services, arising rather from the need to pursue a different purpose, which is the of training for those.

22. Such a legal provision would lead to the need to review the legal framework for the professional activity of a doctor, since it would mean recognizing the faculty of practicing medical acts to those who are not registered with the Medical Association and, therefore, are not doctors.

23. Thus, the authorization of students' access to patients' clinical information resulting from article 2, in fine, because it is based on a manifestly wrong assumption and, above all, not in accordance with the legal regime of medical activity, is tainted from the start.

24. In addition, with regard specifically to the legal regime of data protection, this rule confuses purposes quite different from the processing of personal data and which are presented in autonomous plans: the diagnosis and provision of medical care, on the one hand, and the training of medical students, on the other hand.

25. The processing of personal data carried out for the pursuit of the first purpose has a direct (and sufficient) legal basis in point h) of no. of the framework in subparagraph a) of paragraph 2 of the same article or, alternatively, it may be expressly provided for in national law, in which case it must enshrine adequate guarantees of patients' rights.

26. In fact, if one considers the ratio of subparagraph h) of paragraph 2 of article 9 of the GDPR, it is easy to conclude that it is incongruous and even paradoxical to seek to include a processing of personal data that, objectively, is not intended to a direct and immediate advantage for the patient in a normative hypothesis that presupposes this direct and immediate advantage for the patient, and which, for that very reason, dispenses with the patient's consent.

27. From this point of view, the solution of referring to the patient's consent the legitimacy of the processing of his data is more in line with the principle of respect for his autonomy of will whenever the data are processed for a purpose that does not correspond to the satisfaction direct and immediate concern of their interests and rights, as is the case with the purpose of training medical students.

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28. Therefore, it is the CNPD's understanding that access by medical students to patients' clinical information cannot be considered, by law, as part of the process of providing health care and treatments, nor of the process of providing diagnostic services and cannot, therefore, be authorized by law on that basis.

29. With regard to the amendments to article 29 of Law no. 58/2019, and starting with considering the introduction of a new paragraph 3, it is important to clarify that medical students, strictly speaking, do not provide care and health treatments or diagnostic services. It is insisted: such acts assume, under the terms of the current law, the professional quality of doctor and, therefore, the enrollment in the Order of Physicians, and it is very strange to intend, through this provision, to change the current legal regime. Hence, the first assumption that allows that service to be equated with that provided by doctors is missing.

30. In addition, it appears to be a circular legislative technique and, therefore, inappropriate, to provide for data processing in the terms in which it is provided for in the conjunction of article 2 with article 3 of this Bill: first, the student access to patients' personal data is considered an integral part of the healthcare and diagnostic process; second, such provision by students is equivalent to that provided by doctors for the purposes of access to clinical files.

31. The same is to say: first, it is fictionalized that access by students to patients' personal data corresponds to a medical act (providing health care and diagnosis), and then it is concluded that, for the purpose of that same fictionalized medical act (/.and„ access to data), the fictionalized medical act (ie, access to data) is equated with the medical act of providing care and diagnosis.

32. Such a normative construction in a circle departs from the traditional syllogism underlying legislative norms, harming the understanding and acceptance of the legal effects resulting from it.

33. Finally, it is important to consider the amendment of the provisions of the current paragraph 3 of article 29 of Law No. 58/2019 (corresponding to paragraph 4, in the projected version), which limits the provisions of that paragraph to access personal health data provided for in paragraph 2 of the same article, thus excluding access by students.

34. It so happens that the regime currently provided for in paragraph 3 of article 29 of Law no. 58/2019 aims to establish guarantees for the rights of holders of personal health data, determining that access to data "is done exclusively by electronically, unless technically impossible or otherwise expressly indicated by the data subject [...]», and the Bill, strangely,

eliminates not only the right of the data subject to oppose access to health data when he is is carried out by students, thus removing a right of opposition currently recognized in the Portuguese legal regime, as well as the electronic registration (logs) of access by students, in breach of the provisions of article 32 of the RGPD.

35. In fact, nowadays, users of the National Health Service are recognized, on the respective portal2, the ability to control who accesses their health data, being able to limit the access of health professionals through the Electronic Health Record.

36. In addition, a large part of the information systems of the National Health Service, in respect of the right to informational self-determination and for the control by the holders of the observance of the confidentiality of health professionals, presents a mechanism for automatic notification of the user whenever there is access to the Electronic Health Record.

37. The amendment now introduced eliminates the guarantee regime for the rights of data subjects regarding access by students and, therefore, reduces the data subject's power of control over their own data, in clear contravention of the logic underlying the regime national law and also the GDPR.

38. There seems to be an intention here to block any space of autonomy of will of patients regarding access by students, as if the interest of training should always and in any circumstance override the will of the patient, when the availability of their data, even where, today, the interest of providing health care does not override such a will (except in cases of specifically justified need).

39. In fact, it is not clear what the underlying rationale might be for a legislative option to establish a guaranteeing regime for the rights of data subjects when access is made by health professionals and to exclude it in terms of access by medical students.

40. The CNPD considers that the changes introduced in article 29, specifically in the new paragraphs 3 and 4, represent a setback in the protection of patients' personal data and, specifically, in the guarantee of respect for the autonomy of will. of them and in the control of their personal data, in clear contradiction with the ratio underlying both the RGPD and Article 35 of the Constitution of the Portuguese Republic, which enshrines the right to informational or informational self-determination as a

guarantee of other fundamental dimensions of citizens.

41. As for the new paragraph 9 of article 29, its provision has a tautological character, adding little regarding the duty of secrecy already provided for in the same article and, above all, regarding the rules regarding the lawfulness of data processing provided for in the RGPD .

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42. In short, the setback in the protection of the fundamental rights of patients that this Bill implies, on the pretext of providing for access by medical students to personal health data, deserves the most vehement repudiation by the CNPD. The public and private interests in the training of medical students do not and cannot justify their prevalence, at any cost, over the rights of citizens, especially in a context that weakens and conditions the data subject, such as the disease, forgetting the constitutional and European framework for the protection of personal data and citizens' autonomy of will.

III. Conclusion

43. On the grounds set out above, the CNPD understands that the Bill under consideration here, on the pretext of providing for access by medical students to personal health data, represents a setback in the protection of patients' personal data and, specifically, in guaranteeing respect for their autonomy of will and in controlling their personal data, in clear contradiction with the underlying ratio both to the RGPD and to article 35 of the Constitution of the Portuguese Republic, which enshrines the right to informational self-determination as a guarantee of other fundamental dimensions of citizens.

44. In particular, the CNPD understands that:

i. Article 2 of the Bill, by fictionalizing that medical students' access to patients' clinical information is part of the process of

providing health care and treatment and diagnostic services, confuses two purposes for the processing of personal data. of patients, a law that subsumes the purpose of training medical students in subparagraph h) of no. Dice;

ii. Article 3 of the Project, by introducing the new paragraph 3 of article 29 of Law no. 58/2019, in conjunction with the provisions of article 2 of the Project, reveals a normative construction in a circle, which, in addition to being incongruous and paradoxical, departs from the traditional syllogism underlying legal norms, harming the understanding and acceptance of the legal effects arising therefrom, an objective that any legal norm must seek to achieve;

iii. The changes introduced in the current paragraph 3 of article 29 of the same legal diploma (nº 4 in the Project version) translate the elimination of any space of autonomy of will of patients regarding access to their health data by students , which national law recognizes today and which the

In practice, the National Health System ensures access to data by health professionals, which is incomprehensible.

45. Finally, the CNPD emphasizes that, within the framework of the current legal regime for the protection of personal data and with respect for the conditions imposed therein, it is possible and feasible to create an agile and effective mechanism for accessing health data by medical students enrolled in clinical years, which is based on informed, free, explicit and specific consent for the purpose of training, fully guaranteeing the rights of data subjects.

Approved at the meeting of March 16, 2021

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