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National Data Protection Commission

OPINION/2021/146

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. 966/XIV/3.a, which “allows access to a set of personal data by medical students and scientific researchers, for academic purposes, public interest archival purposes, scientific or historical research purposes or statistical purposes (1, amendment to Law No. 58/2019, of [8 August])», presented by the Left Bloc Parliamentary Group.

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 no. 4 of article 18 of Law no. 43/2004, of 18 August, last amended by Law no. 58/2019, of 8 August.

II. Analysis

4. The Bill under analysis, according to its Explanatory Memorandum, «has two concrete objectives», as follows:

“Firstly, it is necessary to guarantee access to a set of clinical data by the scientific community and, for this, we propose a regime of access to a set of data held by the General Directorate of Health, the Shared Services of the Ministry of Health , E.P.E. (SPMS) and the Central Administration of the Health System, IP., in a model that guarantees its encryption and

anonymity. This measure aims to improve scientific research and bring the various realities of health administration in Portugal closer to the various centers for the production of scientific knowledge that the country has.

Second, in order to eliminate the bureaucratic obstacles that prevent medical students from accessing medical students' clinical data, we propose an amendment to Law No.

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of August 8, which ensures the execution of the General Data Protection Regulation, in order to allow this access.»

5. And the Bill, when defining its scope of application, delimits the universe of persons entitled to access personal data contained in clinical processes under the terms provided for in article 2. Thus, it allows access to such data to “medical students attending medical courses in university hospitals” and to “researchers belonging to Laboratories and Research Centers belonging to the legal and administrative perimeter of Public Higher Education Institutions.”

i. The universe of people entitled to access clinical processes

6. Firstly, it is important to emphasize that, in accordance with the principle of proportionality, in terms of necessity, the recognition of the possibility for medical students to access clinical files seems to be limited to those who are enrolled in clinical years.

7. In fact, if, according to the curricular program of each Medical School, the student still does not follow the medical consultations or other types of medical acts, it is not necessary for the student to access and know the personal data contained in the clinical processes of the users of that university hospital. For the purpose of learning the information system that supports medical activity and learning the ways of recording and consulting clinical information, as well as all the ethical and legal issues that they raise, it is sufficient to make available databases that are not real (or anonymized), which, incidentally, is

already carried out at least in a university hospital center.

8. For the above reasons, it is understood that the universe of medical students is, in fact, too broad for the intended purpose, and therefore, under penalty of violating the principle of proportionality, in terms of necessity, this universe to students enrolled in the clinical years (according to the criteria of each educational institution).

9. The delimitation of researchers who are recognized as having legitimate access to personal data contained in clinical files also appears to inscribe a differentiation between the universe of researchers that does not fit into the current legal regime applicable to Laboratories and Research Centers in the Portuguese legal system.

10. In fact, laboratories and research centers recognized and evaluated by the Fundação para a Ciência e Tecnologia are not restricted to those “belonging to the legal and administrative scope of Public Higher Education Institutions” (cf. point b) of article 2. of the Bill). Bearing in mind that, thus, the law differentiates, where there seems to be no reason to differentiate, the conditions of investigation with regard to

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processing of personal data, affecting the researchers' right to equality, the CNPD takes the liberty of pointing out this inconsistency not explained in the Explanatory Memorandum.

ii. Access by scientific researchers

11. Considering now the purpose of the Bill indicated in the first place in the Explanatory Memorandum, it should be noted, first of all, that the amendment introduced by Article 3 of the Bill in Article 31(5) of Law No. 58/2019, of August 8, does not correspond to the proposal described in the Explanatory Memorandum.

12. Indeed, not only is access by the scientific community not limited to databases or a set of data under the responsibility of the General Directorate of Health, Shared Services of the Ministry of Health, E.P.E. (SPMS) and the Central Administration of the Health System, IP., since in the new no. 6 introduced in the same article 31, regarding the need for the access model to guarantee the encryption and anonymity of information. In fact, the reference to government regulation, in the aforementioned

paragraph 6, is empty of any link with regard to these or other measures to guarantee the rights of users of the National Health Service (SNS).

13. It is difficult to understand that this is the case, not only in view of the announcement in the Explanatory Memorandum of a proposal for a more precise regime on this access, but also in view of the requirement imposed by subparagraph j) of paragraph 2 of article 9 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 for its treatment.

14. It is insisted that it is at the legislative level, in accordance with the norms contained in the Constitution of the Portuguese Republic (CRP), that the minimum provision for adequate and specific measures for the defense of fundamental rights and the interests of holders of data, referred to in that GDPR rule (cf. Article 18(2) and Article 165(1)(b) of the CRP). In fact, access to personal data relating to the health and private life of SNS users by the scientific community necessarily implies the restriction and conformation of rights, freedoms and guarantees, in particular, the rights to reserve the privacy of private life and family and the protection of personal data, enshrined in articles 26 and 35 of the CRP.

15. It is evident that access to clinical information with identification of the respective holders, for the purpose of scientific research (or even, as determined by this Project, for archiving purposes of public interest, historical research purposes or statistical purposes), is manifestly excessive. , if not unnecessary, due to the exposure it entails of the private life of citizens and the risk of discriminatory treatment.

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16. This appears to be the reason why the Explanatory Memorandum refers to the information encryption security measure and, specifically, it also refers to the prior anonymization of this highly sensitive information.

17. In fact, it can only be like this, with the provision and implementation of specific measures aimed at protecting privacy and ensuring non-discrimination, that it is possible, in the name of the interest of scientific research, to promote the availability of 'big data and metadata for analysis by data scientists' (expression taken from the Explanatory Memorandum). In fact, the movement to create open databases for the purpose of global scientific research can only be taken into account if it is accompanied by solutions that protect the private life of citizens and the impacts that such widespread access to clinical information is likely to have. create.

18. It would therefore be imperative, in the first line and before making a legal provision of this generalized access to directly identified clinical information, i.e., to personal data with identification of the respective holder, that the risk assessment had been carried out resulting therefrom for the rights, freedoms and guarantees and interests of the data subjects. And, it should be noted that in the provision of the new paragraph 5 of article 31 of Law no. with identification of the respective holder, because there is no condition, limit or measure that guarantees that access only concerns data already anonymized.

19. In view of the absence of a risk assessment, which apparently has not been carried out, and the absence of any measures to guarantee the fundamental rights to the privacy of private and family life and the protection of personal data, it can only be concluded that the new provisions introduced by Article 3 Bill of Law in Article 31 of Law no. Article 9 of the GDPR, read in the light of Article 18(2) and Article 165(1)(b) of the CRP.

20. Furthermore, and as mentioned, it has not been demonstrated that access by the scientific community to clinical personal data is effectively necessary for archiving purposes of public interest, scientific or historical research or statistical purposes, since it appears , prima facie, access to anonymized clinical information is sufficient for the pursuit of such purposes¹, given that, due to the risks that it poses to privacy, especially risks of discrimination, access to that personal data always proves to be excessive. In these terms, the CNPD understands that the provisions of the new paragraph 5 of article 31 of Law no.

¹ We say prima facie, as we cannot rule out the hypothesis that, when justified by the need to correlate clinical information, access to pseudonymized personal data is admissible.

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August 8, introduced by Article 3 of the Bill, violates the principle of proportionality, in disregard of Article 18(2) of the CRP.

iii. 0 access by medical students

21. With regard to the second objective of the Bill, concerning the «elimination of bureaucratic obstacles to access by medical students to clinical processes» (cf. Explanatory Memorandum), the CNPD begins by pointing out that the alleged bureaucratic obstacles do not they are a manifestation or reflection of administrative bureaucracy, rather they are related to the guarantee of fundamental rights. And yet, such a guarantee is not strictly speaking an obstacle, as it is evident the suitability and need for access to clinical processes for medical students in clinical years, as well as for other students in the health area (e.g., nursing students ; clinical psychology students), and why an access solution that safeguards the fundamental rights of patients is feasible.

22. Indeed, the protection ensured to personal data relating to health and privacy - contained in clinical processes - has at its genesis the recognition (in the legal-constitutional plan and in the plan of European Union Law) of the risks arising from access to such information by anyone.

23. To that extent, access to clinical files is based on the recognition of a space of autonomy or free will for citizens regarding information relating to their private life, where that relating to their health is subsumed. subparagraphs h) and i) of paragraph 1 of article 9 of the RGPD, only with the consent of the data subjects can this take place.

24. The CNPD has already sufficiently explained all this in its Opinion on Bill No. 666/XIV/2.a2.

25. Therefore, the option contained in the Bill (in the new number 3 that the Bill introduces in article 29 of Law No. 58/2019, of 8 August) to extend access to information systems that support the provision of health care and treatment or diagnostic services by doctors to medical students.

26. It can easily be seen that the purpose of this access thus defined is not, as far as medical students are concerned, to provide health care and treatment or diagnostic services, as they are not yet entitled to perform medical acts. The purpose will be, as follows - only implicitly - 2

2 Cf. Opinion/2021/31, of March 16, accessible at

<https://www.cnpd.pt/decisooes/historico-de-decisooes/?vear=2021&tvpe=4&ent=&pnri=?>

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of the final part of this paragraph 3, support the training of students, therefore, the purpose of learning or academic training formality.

27. It is therefore a different purpose and, it is insisted, not covered by Article 9(1)(h) of the GDPR. Nor is it covered by any of the other purposes recognized by Article 9(2) of the GDPR, with the exception of the hypothesis of an explicit (and informed, free, specific and unambiguous) consent of the data subject - cf. Article 9(2)(a) of the GDPR.

28. 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.

29. 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.

30. Thus, the CNPD understands that the new paragraph 3 of article 29 of law no. 58/2019, of 8 August, confuses two distinct purposes, seeking to subsume the purpose that legitimizes access by doctors to processes clinics of their patients for the purpose of learning or academic training, which, per se, without any other reason, is not legitimized in the light of subparagraph h) of paragraph 2 of article 9 of the RGD.

31. Even if it were intended by law to directly and autonomously provide for this access by students, which would always depend on qualifying as an important public interest purpose the one related to student training - which, from the outset, would require that such purpose be explicitly identified and thus qualified in the articles of law -, in order to support subparagraph g)

of no. interests of data subjects.

32. However, paragraph 4 only refers to the creation of a specific profile for students that guarantees the same degree of security applicable to the other profiles.

33. First of all, it is important to point out that security is not (it cannot be) related to profiles, but to operations on personal data - it is in relation to these operations that security measures must be applied.

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34. Furthermore, if it is considered that health professionals (maximum, doctors and nurses) can only access the clinical files of patients who are under their direct responsibility, it is at least worrying that there is no requirement for contextualization access by students, thus allowing undifferentiated or generic access to any clinical personal data (e.g., colleagues or professors, or any others, who are monitored or processed in that establishment or in other establishments).

35. Furthermore, nowadays, the SNS user is recognized, on the respective portal³, 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 SNS information systems, 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. And the current paragraph 3 of article 29 of Law no. 58/2019, of 8 August, reinforces the informational self-determination of data subjects, when it recognizes their right to oppose access to data your data is done through electronic means.

38. Now, when in the new paragraph 5 of article 29 of that law the version still in force of paragraph 3 is repeated but with the reference only to paragraph 2 of the same article, thus not covering, in these guarantees, access by students, we arrive at the absurd solution that the Bill is more demanding with access by health professionals in their activity of providing care than with access by students for their training.

39. In fact, it is not just a matter of excluding the data subject's right to oppose access when it is carried out by students, thus

ruling out a right of opposition currently recognized in the Portuguese legal regime, but also the electronic registration (logs) of access by students, in breach of the provisions of article 32 of the RGD.

40. 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.

3 Accessible at <https://servicos.min-saude.pt/utente/>

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41. 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 patient's will, 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 concretely justified need, provided for and regulated by law).

42. Thus, the CNPD considers that the changes introduced in Article 29, specifically in the new paragraphs 3 to 5, represent a setback in the protection of patients' personal data and, specifically, in the guarantee of respect for the autonomy of their will and in the control of their personal data, in clear contradiction with the underlying ratio both to the RGD and to articles 26 and 35 of the CRP, the latter enshrining the right to informative or informational self-determination as a guarantee of other fundamental dimensions of citizens.

43. Thus, the CNPD insists that this legislative amendment to article 29 of Law No. 58/2019, of 8 August, which, as presented in the Bill, is not capable of constituting a legal basis for access to personal data contained in clinical processes by medical students for the purpose of academic training in view of the limits and conditions imposed by the RGD, in particular in

paragraphs 1 and 2 of article 9.

44. It insists that, strictly speaking, the consent of SNS users is the basis that best safeguards the autonomy of these data subjects, which the current legislative framework allows, given that the model for the realization of such a access based on consent.

45. In fact, the working group created this year following a meeting between the CNPD, the Council of Medical Schools and the Council of Rectors of Portuguese Universities, designed an access mechanism that also guarantees respect for the autonomy of will of the Portuguese Universities. patients, in parallel terms to what is required in our legal system in relation to the presence of students in medical consultations or during the provision of health care, according to which a system is created that integrates the access profile of a medical student and also includes the provision of informed, free, explicit and specific consent for the purpose of training. Only the implementation of the system has not yet been carried out by the Shared Services of the Ministry of Health, EPE, and this entity has now guaranteed that this will happen, in the part that depends on it, until the end of this calendar year.

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III. Conclusion

46. On the grounds set out above, the CNPD, reiterating that it recognizes the adequacy and need for access to health information by students of Medicine (and other areas of training in the health sector), considers, however, that the Bill here in question represents a setback in the protection of patients' personal data and, specifically, in guaranteeing respect for their autonomy of will and in the control of their personal data, in clear contradiction with the underlying ratio both of the RGPD and the Constitution of the Republic Portuguese.

47. In particular, the CNPD understands that:

The. Article 2 of the Draft Law delimits the universe of persons entitled to access clinical processes, sometimes in too broad

terms, in terms of medical students, as access is only necessary for students enrolled in the clinical years, sometimes in discriminatory terms regarding researchers by limiting access to those who integrate laboratories and research centers that belong to public higher education institutions;

B. As for the access of scientific researchers to clinical processes, the new paragraphs 5 and 6 introduced in article 31 of Law No. 58/2019, by article 3 of the Bill,

i. do not provide adequate measures to protect the fundamental rights of privacy and the protection of patients' personal data, not complying with the requirements of point j) of paragraph 2 of article 9 of the RGPD (read in the light of constitutional norms that require such regulation to be made by law); and

ii. refer to access to personal data that is not necessary for the pursuit of archiving purposes of public interest, scientific or historical research or statistical purposes, since prima facie access to anonymized clinical information is sufficient, and that, due to the risks involved, in particular the risks of discrimination, it always proves to be excessive, in violation of the principle of proportionality;

ç. Regarding the access of medical students to clinical information about patients, the amendments to article 29 of Law no. in paragraphs 1 and 2 of article 9, and specifically:

i. The new paragraph 3 of article 29 of Law no. 58/2019 is incongruous when it subsumes the purpose of training medical students in subparagraph h) of paragraph 2 of article 9, when this aims to

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encompass processing of personal health data that are carried out directly in the interest of the data subject; and

ii. The same new paragraph 3 and also the new paragraph 5 translate the elimination of any space of autonomy of will of

patients regarding access to their health data by students, autonomy that today national law recognizes and that the SNS ensures in practice, when it comes to access to data by health professionals, which is incomprehensible.

48. 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, an agile, effective and secure mechanism for access to health data by students is possible and is being developed of Medicine 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.

Lisbon, November 11, 2021

Filipa Calvão (President, who reported)