

Health / Intellectual Property, Media and IT

Legal Flash | Portugal

January 20, 2020



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Supervisory and Physician's Bar warning related to the processing of health data.



I. Supervisory and Physicians Bar Association warnings on the processing of personal data necessary for providing healthcare services.

Supervisory Alert No. 01/2019 of the Health Regulatory Authority on the processing of personal data necessary for providing healthcare services

The Portuguese Health Regulatory Authority ("ERS") has issued a Supervisory Alert on the implementation of personal data protection legislation. However, the ERS highlights that this alert does not overrule the authority of the Data Protection Supervisory Authority to interpret and monitor compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC ("GDPR").

As "the incorrect application of personal data protection legislation in this context is likely to lead to restrictions on access to health care," the ERS warns healthcare providers of the following:

- Healthcare providers must use different lawful means of processing personal data, depending on whether they are processing the data needed to provide healthcare or other personal data.
- The processing of personal data is lawful where it is necessary for the following purposes: medical diagnosis and provision of care or therapeutic treatments, under article 9(2)(h) and (3) of the GDPR.
- > Healthcare providers must seek data subjects' prior consent where the purpose of the data processing is to send marketing communications.
- Healthcare providers must ensure that health data is processed only for the purposes mentioned above and that it is done by professionals subject to the obligation of professional secrecy or the duty of confidentiality, in compliance with article 9(3) of the GDPR.
- > The data controller must take appropriate measures to provide the data subject with the information required under articles 13 and 14 of the GDPR:
 - In this context, the provider can ask the user to sign a declaration to prove compliance with the duty to provide information, provided the declaration is (i) independent of any declaration of consent to the processing of personal data; and (ii) not a condition for access to healthcare.

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The ERS concludes by stating that refusal to provide healthcare to beneficiaries of the national health system or public health subsystems constitutes an administrative offense, punishable by a fine of EUR 1,000.00 to EUR 3,740.98, or EUR 1,500.00 to EUR 44,891.81, depending on whether the beneficiary is a natural or legal person.

On January 3, 2020, the Physicians Bar Association has published its own alert, regarding the same topic, informing doctors about the Supervisory Alert No. 01/2019 of ERS and emphasizing the need to comply with other GDPR obligations.

The Physicians Bar Association ("OM") emphasizes that the processing of personal data does not rely on the need to seek an explicit and written consent by the patient, when the purposes of the processing are the fulfillment of medical diagnosis and provision of care or therapeutic treatments, under article 9(2)(h) and (3) of the GDPR.

OM reminds all healthcare patients have the right to obtain information regarding the identity of the data controller and its data protection officer (DPO) and health care providers may ask patients for written confirmation that they have received such information.

While recognizing the usefulness of the ERS warning in clarifying healthcare facilities regarding the need for patients to give their prior consent for personal data processing, we must note that the regulator could have gone a little further in this matter.

Medicine and medical-scientific research have evolved significantly and will continue to do so, resulting from technological developments and the use of artificial intelligence based on health data. These uses may have direct application in healthcare delivery, but also in improving health services, assessing the impact on public health spending, increasing patient safety, among others.

Given this changing outlook, understanding the regulator's position on the use of health data for these purposes, the so called <u>"secondary uses," is important</u>.

Under article 9 (2) 2nd, al. (h), does the GDPR allow the processing of health data without consent in the context of secondary uses, provided these secondary uses are a step for a specific healthcare delivery?

What secondary or ancillary uses of health data by the healthcare establishment would be permissible under this policy? Is it permissible for improving your customer service system? Can a healthcare facility qualify as a digital application for a more accurate diagnosis in a hospital environment?

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It may be difficult to draw a clear distinction between the actual provision of healthcare to a user, for whom prior consent is not required for the processing of their health data according to the ERS alert, and other purposes related to the provision of healthcare or diagnosis, or involving treatment, including the communication of health data to third parties.

Until guidance is issued from the competent authorities, this assessment will have to be carried out by the healthcare providers on a case-by-case basis.

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