

Deliberation 2021-052 of April 29, 2021 Commission Nationale de l'Informatique et des Libertés Nature of the deliberation:

Opinion Legal status: In force Date of publication on Légifrance: Tuesday September 07, 2021 NOR:

CNIX2126775V Deliberation n° 2021-052 of April 29, 2021 providing an opinion on a draft decree relating to telehealth (request for opinion no. 21003752) The National Commission for Computing and Liberties,

Seizure by the Minister of Solidarity and Health of a request for an opinion concerning a draft decree relating to telehealth,

Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 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;

Considering the modified law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms; On the proposal of Mrs. Valérie PEUGEOT, commissioner, and after having heard the observations of Mr. Benjamin TOUZANNE, commissioner of the Government , Issues the following opinion: The draft decree defines the conditions for the implementation and management of telehealth activities, including telemedicine and telecare, as defined in Articles L. 6316-1 and L. 6316 -2 of the Public Health Code (CSP). The decree provides that telehealth activities will be subject to the same requirements for health professionals as those provided for telemedicine acts. On the conditions for implementing data processing related to telehealth Article R. 6316-2 provides that the use of telemedicine or telecare will be determined by the medical professional, pharmacist or medical assistant. The Commission deduces from this that these professionals could therefore be qualified as data controllers. In order to avoid any uncertainty or confusion as to the distribution of responsibilities between the actors involved, it invites the Ministry to specify in the decree the categories of actors likely to be qualified as data controllers, all the more so if this role is likely to be devolved to categories of actors other than medical professionals, pharmacists or medical auxiliaries. purposes of preventive medicine, medical diagnosis, the administration of care or treatment, or the management of health services. Being implemented by a member of a health profession or by another person on whom is imposed, by reason of his functions, the obligation of professional secrecy, the infringement of which is repressed by article 226-13 of the criminal code, they are therefore not subject to authorization by the Commission, pursuant to the provisions of article 65-1° of the data protection act. The Commission notes that draft Article 4 provides for the modification of Article 2.B-6° of Decree No. 2019-341 of 19 April 2019 in order to authorize healthcare professionals and any other person subject to an obligation to professional secrecy carrying out or contributing to a telehealth activity to process the registration number in the national identification

directory of natural persons for operations related to invoicing and financial support for these activities. The Commission takes note of this. On the collection of the person's consent for the performance of a telehealth activity The Commission notes that draft article R. 6316-2 of the CSP no longer refers to the free and informed consent of the person for the performance of a telemedicine act. Since telehealth activities refer to the performance of care or medical acts at a distance, the Ministry specified that the requirements relating to the consent of the person were governed by the provisions of common law of the CSP, in particular by the fourth paragraph of article L. 1111-4. With regard more specifically to telecare, he indicated that the decision to use it was a shared decision of the patient and the professional caring for him. The Committee nevertheless considers that the use of this type of device requires that a particular attention is paid to the procedures for obtaining the consent of the persons concerned. It therefore invites the Ministry to plan an information and awareness campaign for professionals and any other person subject to an obligation of professional secrecy participating in telehealth acts. On the sharing or exchange of information covered by secrecy The draft article R. 6316-2 no longer refers to the prior information of the person for the exchange of information concerning him between professionals participating in a telemedicine act nor to his right to oppose it, the case applicable. The Commission notes that the Ministry has indicated that: these exchanges of information between professionals must take place under the conditions defined in Article L. 1110-4 of the CSP; the professionals who can carry out a telecare activity will be the pharmacists and medical auxiliaries, it being specified that the notion of medical auxiliary authorized to carry out telecare activities refers to the professions regulated by Titles I to VII of Book III of the fourth part of the CSP. The Commission underlines the importance of informing the person of the identity of the professional concerned prior to the implementation of an exchange of information concerning him, in particular within the framework of the provisions of IV of article L. 1110-4 of the CSP and invites the ministry to mention it in the decree. On the registration of data collected during a telemedicine act or a telecare activity in the patient file, the shared medical file or the pharmaceutical file The draft article R. 6316-4 provides that the professional performing a telemedicine act or a telecare activity should enter it in the patient file or possibly in the shared medical file defined in article L. 1111-14 or in the pharmaceutical file defined in article L. 1111-23. The Commission considers that this wording is likely to be a source of ambiguity insofar as it can be interpreted as alternative data collection requirements. does not replace the patient file kept by each establishment and health professional intervening for the care of a person in accordance with article R. 1111-28 of the CSP; the creation of a pharmaceutical file is subject to the consent of the person pursuant to Article L. 1111-23 of the CSP.

The Commission takes note of the Minister's commitment to modify this draft article in order to indicate that the professional is required to record the information relating to the reimbursement of the person in the patient file and, where applicable, in the DMP. On security measures The Commission notes that the amendments made to Article R. 6316-3 lead to the deletion of the current provisions relating to the conditions guaranteeing the authentication of the health professionals involved in the act, the identification of the patient and the access of health professionals to the patient's medical data necessary for the performance of the act. The ministry justified this deletion by the fact that these conditions were governed by the standards referred to in article L. 1110-4-1 of the CSP. The Commission notes, however, that the reference standards referred to have not yet been published and emphasizes that these texts are necessary for the management of tools and practices related to telehealth. President Marie-Laure DENIS