Deliberation 2020-071 of July 16, 2020Commission Nationale de l'Informatique et des LibertésNature of the deliberation: OpinionLegal status: In force Date of publication on Légifrance: Tuesday September 07, 2021NOR: CNIX2126778VDeliberation n° 2020-071 of July 16, 2020 providing an opinion on a draft decree issued in application of article 52 of law n° 2019-774 of July 24, 2019 relating to the organization and transformation of the health system (request for opinion n° 20004964)The National Commission for the computing and freedoms,

Seizure by the Minister for Solidarity and Health of a request for an opinion on a draft decree issued pursuant to Article 52 of Law No. 2019-774 of July 24, 2019 relating to the organization and transformation of the health system,

Having regard to Convention No. 108 of the Council of Europe for the protection of individuals with regard to automatic processing of personal data;

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 (General Data Protection Regulation or GDPR);

Having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 relating to the application of patients' rights in cross-border healthcare, in particular in its article 14 relating to online health;

Having regard to the Public Health Code, in particular in its articles L. 1111-14 to L. 1111-22;

Having regard to the social security code;

Considering the law n° 78-17 of January 6, 1978 modified relating to data processing, files and freedoms;

Considering the decree n° 2019-536 of May 29, 2019 taken for the application of the law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms;

Having regard to the opinion of the Article 29 Group of the data protection authorities dated April 11, 2018;

Having regard to the multilateral agreement reached between the national authorities or the heads of the national contact points for e-health, signed on February 10, 2020 by the Digital Health Agency; On the proposal of Mrs Valérie PEUGEOT, commissioner, and after having heard the observations of Mrs. Nacima BELKACEM, Government Commissioner, Issues the following opinion: Article 52 of Law No. 2019-774 of July 24, 2019 on the organization and transformation of the health system (hereinafter the draft). Article 52 introduces into the Public Health Code (CSP) Article L. 1111-22 which provides that the collection, exchange or sharing of personal health data necessary for the care of the patient during treatment delivered during

his presence on the territory of another Member State of the European Union can be carried out by means of the shared medical file made accessible to the professionals involved in the context of this care. This article refers to a decree on the terms of application of these provisions. The purpose of the draft decree is therefore to define the conditions allowing the exchange of personal health data, from the shared medical file (DMP), between France and certain Member States of the European Union, within the framework of the care of a patient holding a DMP present on the territory of one of these Member States, the list of which will be fixed by decree. case of use retained is that of the cross-border exchange of the summary of the patient's file, corresponding for France to the medical summary section integrated into the DMP, with health professionals established in one of the Member States signatory to a multilateral agreement governing these data exchanges. On the terms of access by the ANS to health data The draft article D. 1111-46 of the CSP provides that the ANS has access to the personal health data contained in the summary section DMP medical service, for the time necessary for their translation and formatting. The file specifies that the ANS, at the request of a European contact point and subject to the consent obtained from the French patient, recovers the medical summary section from his DMP , translates it into English and formats it if necessary, then sends it to the contact point of the European State. The latter is in charge of communicating this document to the health professional at the origin of the request, taking charge of the French patient. The ministry indicated that the translation and formatting operations are carried out automatically, without intervention. human, in particular by coding information from the medical summary section, by means of the use of health terminologies making it possible to ensure the semantic interoperability of the document. However, the Commission does not have any details on this point, the technical methods remaining to be defined by the Ministry. Asked about the guarantees provided with regard to the confidentiality of the personal health data contained in the medical summary section from the DMP, the ministry specified that the ANS does not have access to the medical summary section, nor to any patient health data, all of the formatting and translation operations being automated. The Commission takes note of this and requests that draft article D. 1111-46 be reformulated in such a way as to remove any ambiguity as to the access of the ANS to personal health data. medical, in its translated version Draft article D. 1111-50 of the CSP refers to the procedures for exercising the rights provided for the DMP. It also provides for consultation of the medical summary section by the European healthcare professional to be reported in the DMP, so that its holder can have visibility of the accesses made. The Commission notes that the file transmitted not the Ministry specifies that, in the context of the processing referred to in Article L. 1111-22 of the CSP, patients will be able to exercise their rights: with regard to the traces of operations carried out

within the NCPeH with the ANS; with regard to the data contained in their medical summary section and transmitted to the European health professional, to the said professional. In order to facilitate the exercise of rights, in particular the exercise of the right of access or rectification in the event of translation error, the Commission requests that the translated version of the medical summary section be included in the DMP so as to avoid the holder of the DMP having to make this request to the healthcare professional ult in another Member State. It also asks that these methods be described in the project.On the reuse of data from the medical synthesis sectionIn principle, the data is used by the healthcare professional in the context of the provision of healthcare as defined by the Directive 2011/24/EU: health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensing and supply of medicinal products and medical devices. multilateral signed by the ANS on February 11, 2020 nevertheless considers the possibility of reusing patient data for archival purposes in the public interest, for scientific or historical research purposes or for statistical purposes in compliance with the GDPR and in particular its Articles 6, 9 and 89. The Commission recalls in this respect that with regard to personal health data of French patients, the reuse of s data from the medical synthesis component for the purposes of research, study or evaluation in the field of health will be subject to the provisions of articles 72 and following of the data protection act, in accordance with article 3- II of this same law. On security measures The draft decree provides that the transfer methods as well as the format of the data transmitted are defined by a multilateral agreement signed by each national authority or responsible for the national e-health contact points. However, the Commission notes that this agreement only mentions general security requirements applicable to all processing of personal data. Health data is particularly sensitive and must benefit from special protection. following and R. 1111-8 and following of the Public Health Code. These provisions provide in particular for the obligation, in the event of outsourcing of the hosting of health data, to entrust them to a service provider approved or certified for this purpose. The Commission notes that it follows from the information in the file that the French NCPeH allows the transmission of the medical summary section from the DMP to the NCPeH without it being stored there. It recalls that the obligation to use an approved or certified host applies in the event of storage of health data. It also asks the Ministry for the decree to clearly specify whether these obligations apply in the event of outsourcing of the hosting of health data outside the national territory, in the event of storage of health data. , in any case, that the processing of personal health data must take place under security conditions at least equivalent to those provided for by national legislation, so as not to lower the general level of protection. The Commission notes that the processing must be the subject of a data protection

impact assessment (DPIA) prior to any implementation. The draft does not call for any other observations from the Commission. President Marie-Laure DENIS