

Deliberation 2021-050 of April 15, 2021 Commission Nationale de l'Informatique et des Libertés Nature of the deliberation:

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CNIX2126768V Deliberation n° 2021-050 of April 15, 2021 providing an opinion on a draft decree relating to the shared medical file (request for opinion no. 21001149) 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 the shared medical file,

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);

Having regard to Articles L. 1111-14 and L. 1111-21 of the Public Health Code;

Considering the modified law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms; Issues the following opinion: The draft decree aims to modify the regulatory provisions applicable to the shared medical file (DMP) in order to harmonize them with the operating rules relating to the digital health space (ENS). The DMP being a component of the ENS, the two systems will be, when the regulatory texts come into force, inseparable. The regulatory provisions relating to the DMP are therefore based on those relating to the ENS. On the maintenance of a pre-existing DMP in the event of opposition to the opening of the ENS during a transitional period Draft article R. 1111 -40 of the Public Health Code (CSP) provides that the DMP will be automatically created when opening an ENS. In the event that a person already has a DMP and does not object to the opening of his ENS, the DMP will be automatically integrated into it. Article L. 1111-14 of the CSP also provides that the opposition to the opening of the ENS does not lead to the closure of the existing DMP during a transitional period, the terms of which are defined by decree. Article 2 of the draft decree thus provides that the DMP will remain open for three years from of January 1, 2022. The Commission notes, however, that the draft provides that during this period, the holder will not be able to directly access his DMP and that only duly authorized professionals will retain the possibility of integrating data and consult. According to the Ministry, the inaccessibility of the DMP by the holder during the transitional period is justified by budgetary reasons which do not make it possible to maintain an interface allowing this holder to directly access his DMP. The holder will nevertheless be able to access the content of the DMP through the intermediary of a healthcare professional. The Commission considers, however, that such operation, which will not allow the holder to directly access the content of his DMP,

nor to consult the list of professionals who have access to it or to modify it, or to read the access traces, is contrary to the provisions of article L. 1111-19 of the CSP. It therefore asks the Ministry to modify the draft decree in order to maintain direct access by the holder to the content of the DMP for the duration of the transitional period. In this respect, it takes note of its commitment to examine the possibility of reducing the transitional period and maintaining minimum access for the holder during this period. On the closure of a pre-existing DMP at the end of the transitional period, after opposition to the opening of the ENS According to article 2 of the draft decree, within two months preceding the end of the transitional period, and no later than December 31, 2024, the holder of the DMP who s Anyone opposed to the creation of their ENS will be informed that their opposition to the creation of their ENS will lead to the closure of their DMP. The draft decree provides that, unless the holder wishes otherwise expressed in the month following the sending of the information letter, the closure of his DMP is notified to him and is effective from this notification. The Commission understands that the initial opposition to the opening of the ENS and the silence kept by the holder after the transitional period would make it possible to close a pre-existing DMP. The Commission notes, however, that this system does not comply with the provisions of the Article L. 1111-14 of the CSP which provides that at the end of this transitional period, the digital health space is automatically opened, unless confirmation of the opposition of the person or his legal representative. This new opposition leads to the closure of the shared medical file. As a result, in the absence of confirmation of the opposition to the opening of the ENS, it will be automatically opened, thus resulting in the maintenance of the pre-existing DMP. The Commission therefore requests that the draft decree be modified in order to provide that the closure of the DMP will only take place in the event of new opposition to the opening of the ENS. concerned of these procedures for exercising the right of opposition and to provide for a mechanism allowing them to be reminded of them within a sufficient period of time before the end of the transitional period. On the information of persons relating to the creation of the DMP-ENS According to the draft d he article R. 1111-40 of the CSP the holder is informed of the creation of his medical file and its articulation with his digital health space on the occasion of the individual information provided for in article R. 1111-28. The Commission therefore notes that a single piece of information will be communicated to the persons concerned, covering both the DMP and the ENS. The Commission understands that, if all the components of the ENS will be opened automatically, the holder will not will not be required to use all of its services. In this regard, it notes that the DMP and secure messaging are the only automatically activated services that can be used at the initiative of healthcare professionals or ENS holders. The Commission recalls that it is the responsibility of the data controller to send, before the creation of the ENS, the

necessary information to the holders of pre-existing DMPs so that they can configure it and benefit from functionalities almost similar to the existing DMP. The Commission also asks that people be informed very clearly of the operating methods and configuration possibilities of the ENS so that it only gives access to the services which the holder intends to benefit from, in addition to the DMP and the secure messaging. The draft decree removes article R. 1111-32 of the CSP relating to the procedures for informing holders of the DMP which provided in particular that the holder was informed of the access procedures by himself and by the professionals of health, as well as his rights to the data contained and the specific rights enjoyed by the attending physician. In this respect, the draft article R. 1111-40 of the CSP refers to the individual information provided for in the context of the ENS, which will be detailed in a new article R. 1111-28 not modified by this draft. The Commission, as it specified in its deliberation no. 2016-147 of 12 May 2016, considers that all beneficiaries must be clearly informed of the role and prerogatives of their attending physician within the framework of the DMP. The Commission notes that the Ministry has undertaken to modify the draft decree on this point.

On the masking of data at the request of minors

The draft article R. 1111-45 of the CSP provides, for minors holding of a DMP, the possibility of asking the professional supplying it to hide the data concerning him so that they are not accessible by his legal representative(s). The Board draws the Ministry's attention to the fact that this masking should not be limited to the DMP and should be possible for other ENS departments likely to reveal information relating to elements hidden in the DMP (secure messaging, diary, etc.). The Commission recalls that access by holders of parental authority to information covered by secrecy must also comply with the conditions provided for in Article L. 1111-7 of the CSP.

On the DMP's responsibility for processing

The Commission notes that the draft decree does not mention the data controller of the DMP. Indeed, the content of article R. 1111-27 of the CSP which designates the National Health Insurance Fund (CNAM) as data controller of the DMP no longer appears in the provisions amended by the draft. The Commission considers it necessary that it be supplemented in order to indicate that the CNAM is responsible for processing the DMP or that it refers to the provisions applicable to the ENS specifying this point.

On access to and closure of the DMP

According to the draft of article R. 1111-48 of the CSP, the holder accesses his DMP electronically from his ENS. The Commission invites the Ministry to add a reference to the article relating to access to the ENS in order to facilitate the reading of the additional provisions of the decrees respectively relating to the DMP and the ENS. The DMP being inseparable from the ENS, the closure of the DMP results in the closure of the ENS. Draft article R. 1111-48 of the CSP specifies that the procedures for closing the medical file are those of the ENS. The Commission invites the Ministry to modify the draft decree so

that it specifies the nature of the medical file to which reference is made and that it recalls that the DMP can be, like the ENS, closed at any time. .On security measuresThe Commission notes that as the DMP becomes a component of the ENS, the procedures for accessing the DMP and the means of securing them will mainly be transferred to the ENS. implementation of the planned processing and the security of the data processed, the Commission is not in a position to verify the compliance of the processing with the GDPR, and notes that the Ministry has planned to send it requests for advice on these issues. The Commission takes note that the DPIA which will be sent to it will be updated as the project progresses, and wishes to receive it before each deployment milestone. President Marie-Laure DENIS