

Deliberation 2021-051 of April 15, 2021 Commission Nationale de l'Informatique et des Libertés Nature of the deliberation:

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n° 2021-051 of April 15, 2021 providing an opinion on a draft decree relating to the implementation of the digital health space

(request for opinion no. 21001144) The National Commission for Computing and Liberties,

Seizure by the Minister for Solidarity and Health of a request for an opinion concerning a draft decree relating to the implementation of the digital health space;

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;

Having regard to the public health code, in particular its article L. 1111-13-1;

Considering the modified law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms; Issues the following opinion: The main purpose of the draft text submitted for opinion to the Commission is the implementation of the digital health space (ENS) provided for in Article L. 1111-13-1 of the Code of public health (CSP). It also extends the categories of professionals likely to exchange or share information relating to the same person covered mentioned in article R. 1110-2 of the CSP. The ENS will be implemented in stages according to the following schedule : a test phase from April to June 30, 2021 relating to data and fictitious ENS; a pilot phase from July 1 to December 31, 2021 consisting of an experiment in three departments (Haute-Garonne, Somme and Loire Atlantique) which will concern insured persons, adults or minors, covered by a compulsory health insurance scheme; a generalization phase from January 1, 2022 which will concern all French people and people residing in France, which represents more than 67 million people . Certain functional bricks of the ENS will not be implemented on January 1, 2022, namely: the collection of data relating to the reception and support provided by establishments and social services x and medico-social; the directory of access authorizations for services and digital tools not referenced within the ENS; the procedures for permanent access of a professional or a health establishment to the ENS d a person; the terms of access for professionals and staff of an establishment providing care for the holder of an ENS. On the categories of data The Commission notes that the data contained within the ENS, in particular those contained in the shared medical file (DMP), are likely to come under the categories of data making up the national health data system (SNDS) mentioned in article L. 1461-1 of the CSP, in particular 6° of this article. The ministry specified that the use of these data for

one of the purposes mentioned in III of article L. 1461-1 of the CSP leading to their integration within the SNDS is not envisaged for the moment. In the event that this data is incorporated into the SNDS, the ministry has undertaken to inform people before any reuse in order to allow them to exercise their right of opposition under the conditions defined by the legal and regulatory provisions governing the NSDS. The Commission takes note of this. In addition, it asks the Ministry to carry out an information campaign explaining to the people concerned by the creation of an ENS, the articulation between the various existing systems, including the SNDS and the DMP. conditions for informing people About the reuse of data collected by health insurance organizations The Ministry has indicated that, for the sending of information letters on the enrollment process mentioned in draft article R. 1111-28, the National Health Insurance Fund (CNAM) will reuse the data collected by the various health insurance organizations in order to identify the persons concerned. He also specified that the identity of the person will be collected, as well as their electronic or postal contact details. The Commission understands exchanges with the Ministry that the identity of minors linked to the person concerned will also be collected. It takes note of the ministry's commitment to supplement the draft decree with a provision relating to this reuse of data. Concerning the retention period of the data: the data will be transferred to a notification center dependent on the CNAM in charge of the sending of letters; the data will be deleted as soon as the operations of sending letters are carried out. In this respect, the ministry specified that this communication operation relating to the launch of the ENS would be completed at the beginning of 2022. On information prior to the creation of the ENS The information letter refers to the notion of French citizen for determine the persons concerned by the opening of an ENS. However, it appears from discussions with the ministry that an ENS will be open to anyone affiliated with a health insurance scheme or beneficiary of state medical aid, which does not correspond to the status of French citizen. does not mention the right that each person has to request the closure of their ENS and the erasure of the data it contains, requests that can be made at any time. The Commission considers it necessary to mention these rights in the letter in order to guarantee perfect information for the persons concerned and the transparency of the system, and therefore invites the Ministry to modify the letter accordingly. The individual information of the persons, provided for by the draft of article R. 1111-28 of the CSP, relates to the enrollment process to proceed with the activation of an ENS or to oppose it, and does not constitute information within the meaning of the GDPR. The ministry specified that information under the GDPR and the Data Protection Act will be provided by: a reference to a dedicated website mentioned in the information letter, and during the enrollment process of the ENS account holder; the provision posters or flyers within health insurance funds. The Commission recommends that

individual and collective information campaigns as part of the enrollment process highlight the possibility for people to request transmission of a complete information note and the terms of this request, which must not refer exclusively to electronic means. The persons concerned must be informed under the conditions provided for by the GDPR; the information cannot be limited to the posting of the general conditions of use (CGU) of the ENS and should be the subject of a specific notification. With regard to minors, the ministry specified that the letter of individual information will be sent to the person registered as the principal beneficiary of a health insurance plan for a minor. This principal entitlement holder will have delegated access to the minor's ENS. The Commission takes note of this. The Commission notes that the minor will not be the recipient of the individual information letter, regardless of their age. It asks that any minor with a vital card be the recipient of an individual information letter describing the procedures for creating their ENS, in particular the fact that their right of opposition is exercised by their legal representative, as well as the the existence of delegated access to his ENS by his legal representative. Consequently, it invites the Ministry to specify that the individual information is carried out directly with the person concerned and his legal representative, if applicable. In addition, it requires that each of the holders of parental authority be informed, prior to the implementation of the processing of personal data concerning a minor, of the existence of this processing as well as the procedures for exercising the rights . The ministry indicated that the CNAM was not able to identify the second holder of parental authority since the minor is not attached to it. It nevertheless considers that the information of each holder of parental authority should be provided for from the start of the pilot phase. On the exercise of rights On the right to object Article L. 1111-13-1 of the CSP provides for the automatic opening of an ENS, unless opposed by the person concerned or his legal representative. The draft article R. 1111-30 provides that this right will be exercised electronically by activating a code provided when sending the information mail. The ministry indicated that this opposition could also be carried out via the France Connect teleservice or by telephone via the support set up by the CNAM. The Commission welcomes the existence of an alternative procedure to those provided for electronically. It acknowledges that the person who opposed the creation of his ENS can reconsider his choice by deciding to create his ENS at any time. In this case, the person can either contact the support set up by the CNAM, or request a new enrollment code on the electronic enrollment platform. Concerning the exercise of the right of opposition by the holders of the parental authority of a minor, the Ministry has indicated that only the holder of parental authority registered as the main right-holder may express, on behalf of the minor, his opposition to the creation of an ENS. The Commission recalls that the rights of minors can be exercised by each holder of parental authority. Consequently, it

recommends that the Ministry provide, from the start of the pilot phase, the possibility for each holder of parental authority to exercise the right to oppose the creation of the ENS of the minor whose are responsible. The ministry specified that in the event of notification of a disagreement between the two holders of parental authority, it will invite them to settle their dispute amicably or by legal means. The Commission nevertheless considers that, pending the settlement of this dispute, the right of opposition must take precedence. On the right to erasure The draft article R. 1111-39 provides that the holder may request the deletion of the data contained in its ENS without indicating the procedures for exercising this right. The Commission notes that this draft article will be amended in order to specify that the right to erasure will be exercised via the CNAM's telephone support. It invites the Ministry to implement alternative methods for the exercise of this right. On the directives relating to the storage, erasure and communication of a person's personal data after his death The draft Article R. 1111-39 provides that the death of the holder entails the closure of his ENS and that the data are kept for ten years after this. role of the person in the protection and improvement of their health as well as the management of their health data. With regard to the objectives pursued by the ENS and the duration for which the data are kept in the event of the death of the person , the Commission invites the Ministry to reflect on the integration of a component enabling individuals to draft directives relating to the retention and erasure of their data after their death, as mentioned in article 85 of the Data Protection Act. On the referenced services and tools The Commission understands that in addition to the referenced services and tools, it is envisaged that non-referenced services and tools may be able to access the ENS. On the one hand, it questions the purposes, functionalities and operating methods of these services and tools. On the other hand, it considers that the integration into the ENS of non-referenced tools and services constitutes, in view of the particularly sensitive nature of the data it contains and in that it implies a lack of evaluation of the purposes pursued and the level of security, a risk of infringement of the rights and freedoms of the persons concerned. Article 2 of the draft decree provides that the provisions of III of article L. 1111-13-11 of the CSP will come in force on September 1, 2021. Consequently, digital services and tools cannot be offered to ENS users when the pilot phase starts.

The Commission notes that thirty service and tool publishers have been selected in order to co-construct the different use cases for access to ENS data in reading and writing, which will make it possible to determine the categories of data whose a service or tool would need to operate. It also acknowledges that a referencing agreement, currently being drawn up, will be concluded with the publishers of these services and tools to determine their responsibilities and obligations. Commission

welcomes the ministry's forthcoming request for advice on determining the criteria for referencing tools and services. On the criteria for referencing digital health services and tools these criteria, currently being developed, will make it possible to verify the compliance of these services and tools, in particular with regard to: the technical doctrine of digital health; ethical criteria, such as the transparency of algorithmic processing, the environmental impact of the processing implemented, actions in favor of digital inclusion; content quality criteria in consideration of the best practices defined by the Haute Autorité de santé. Draft article R. 1111-35 provides that a data protection impact analysis (AIPD) may be requested in support of a referral request. The ministry specified that the publishers of services and tools wishing to be referenced and to access ENS data must have carried out an AIPD. The Commission takes note of this and considers that a DPIA, concluding that there is no high residual risk for the rights and freedoms of the persons concerned, should be systematically required in support of a referral request. It invites it to modify the draft article R. 1111-35, paragraph 2, in this sense. The provisions of III of article L. 1111-13-1 of the CSP do not authorize access to tools and ENS data services only for the purposes of prevention, diagnosis, care or social and medico-social monitoring. Thus, it considers that a particular justification on the interest of accessing the data of the ENS and the other services it contains, such as the DMP, and the compatibility of the purposes of the tool or service with the provisions aforementioned, will have to be provided by the services and tools, in particular with regard to well-being applications for which such compatibility cannot be presumed. The Commission notes that these services and tools will never have access to the content secure messaging in application of the principle of secrecy of correspondence. In any event, it recalls that these services and tools will not be able to access ENS data for promotional purposes. not pursuing the purposes mentioned in III of article L. 1111-13-1 of the CSP may be referenced if they do not access ENS data. The Commission wonders about the possibility for these services and tools to fully or partially pursue promotional purposes, in particular by collecting additional data which would not be synchronized with the person's ENS and, therefore, would not come under the notion of ENS data. The Commission invites the Ministry to be particularly vigilant when referencing services and tools in order to ensure that such use is not planned. Most of the data contained in the ENS will be covered by the medical secrecy mentioned in Article L. 1110-4 of the CSP and constitute information that can only be shared and exchanged under the conditions provided for in this same article. The Commission considers that particular attention should be paid to the conditions in which people will be informed of the processing implemented by these services and tools, as well as the procedures for exercising their rights. It recommends that the ENS interface list the procedures for exercising rights concerning each tool and service and offer a

simplified access path, for example by means of a dashboard. ENS

On the directory of access authorizations Draft article R. 1111-26 provides that the ENS is composed in particular of a directory of access authorizations that the holder is required to give or withdraw. The ministry specified that this directory would group the authorizations granted by the holder for access to the data contained in his ENS by: professionals intervening for his care; services and tools referenced within the ENS; the staff of establishments in the health, medical and -social and social. The Commission notes that it will be asked for an opinion on the text determining the conditions of access for this category of professionals; services and tools not referenced within the ENS. In general, the Commission invites the Ministry to provide: a regular system of alerting the person in order to invite him to check that the access authorizations issued are still relevant and adapted to his situation and his need for support; a suspension of the access authorization in the event of modification of connection identifiers to a referenced service or tool, in particular in the case of the ENS of a minor. all access as long as the person has not expressly consented thereto. With regard to access authorizations granted for services and tools: these access authorizations are based on the free and informed consent of the person, who must be fully informed of the consequences of their consent with regard to access to their health data; consent can be modified or withdrawn at any time; any access authorization presupposes positive action on the part of the holder; the categories of data to which the services and tools could have access will be determined by purpose during the referencing procedure and the person will be specifically informed before consenting. the person, the draft article R. 1111-36 conditions the access of professionals or health, social or medico-social establishments to the prior agreement of the person and refers to the conditions provided for in 1° of IV of the Article L. 1111-13-1 of the CSP. Only temporary access authorizations for professionals, i.e. access whose duration is determined by the person, will be implemented during the phase of generalization. This access duration will be determined with a fine granularity which can correspond to a period of a few hours or several days. access whose validity period will be limited. This access code will be generated by the person via their ENS. The Commission invites the Ministry to provide an alternative way of generating the access code insofar as not all of the target population has frequent access to digital tools; access and the identity of the professional concerned will be notified to the person; concerning access to the DMP only, the access rules and the authorization matrix for professionals, natural or legal persons, currently in place, will be retained. On access to the ENS for a minor and the secrecy of information concerning them The ministry specified that only one of the holders of parental authority will be able to access the ENS of a minor and that the minor will not have access to his ENS. Reflections are underway to allow access to each of the holders of parental

authority. In any event, it recalls the need to provide access for each of the holders of parental authority from the start of the pilot phase of the ENS insofar as, under Article 372 of the Civil Code, parental authority is exercised jointly. Concerning the minor's lack of access, the Ministry justified this by the fact that it is the responsibility of the holders of parental authority to associate their child to the decisions which concern him, according to his age and his degree of maturity, pursuant to article 371-1 of the civil code.

The Commission regrets that no access for minors, whatever their age, to their ENS is provided for and recalls that under article L. 1111-2 of the CSP, minors have the right to have information relating to their health and to participate in decision-making concerning them in a manner appropriate to their degree of maturity. In addition, the GDPR and the Data Protection Act strengthen information and the rights of minors with regard to the processing of personal data concerning them and, more particularly, on their right to consent to such processing with regard to the direct offer of services. In particular, the Commission points out that, according to Article 45 of the Data Protection Act, a minor may, from the age of fifteen, consent alone to the processing of their data. Consequently, the Commission considers that the minors with their own Vitale card must be able to access their ENS directly and consent to access services, tools or professionals. She asks that this access and its necessary implications in terms of access authorization be provided for when the pilot phase of the ENS starts. In addition, she wonders about the consequences of this lack of access in the hypotheses where the minor requests the secrecy of the information concerning him, under the conditions provided for in articles L. 1111-5, L. 1111-5-1, L. 2212-7 and L. 6211-3-1 of the CSP. of article R. 1111-30 provides that minors may request the secrecy of information concerning one of the acts referred to in articles L. 1111-5, L. 1111-5-1, L. 2212-7 and L. 6211-3-1 of the CSP in one or more elements of its ENS. 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.

It appears, however, from exchanges with the Ministry that the masking of data will only concern DMP data and reimbursement data related to these procedures. The Commission alerts the Ministry to the fact that information relating to health data covered by the minor's request for secrecy could be present in other components of the ENS (secure messaging, calendar, etc.) and invites it to provide a similar masking mechanism for all the components of the ENS. On the notifications of access traces The draft article R. 1111-37 provides that the holder is informed of each access by a professional to his ENS. It appears from the exchanges with the ministry that the person will also be informed of any addition to their DMP or of the receipt of a

message via secure messaging. The Commission notes that the Ministry has undertaken to: notify any access, addition, modification or deletion of the data stored on the person's ENS, for persons who have activated their ENS or do not being not opposed to this creation having a recognized electronic address; sending, by post, a summary of the events which have occurred during the last twelve months to people who have not proceeded to the activation of their ENS. Consequently, the Commission invites the Ministry to modify the draft article R. 1111-37 of the CSP in order to specify, on the one hand, that the person is informed on a regular basis of the events occurring on his space and, on the other hand, that a summary of the events that have taken place during the last twelve months is communicated to it. On the addition of categories of professionals referred to in Article R. 1110-2 of the Public Health Code The draft Article 3 aims to complete article R. 1110-2 of the CSP of several categories categories of professionals authorized to exchange or share information relating to the same person in charge. The Commission nevertheless wonders about the possibility for this draft decree issued pursuant to the provisions of V of Article L. 1111-13-1 of the CSP to extend the categories of professionals authorized to share and exchange information covered by secrecy. These categories of professionals are involved in the care of the person for the purposes of prevention, coordination or continuity of care. The Commission recalls that the exchange or sharing of information covered by medical secrecy must, in any event, be carried out subject to compliance with the conditions provided for in Articles L. 1110-4, L. 1110-12 and R. 1110-1 et seq. of the CSP. does not provide any details concerning the categories of professionals likely to be authorized to exchange or share information relating to a person in charge, in particular with regard to categories other than those referred to in Article D. 541-2 of the Education Code, and which may refer to non-health professionals. The Commission considers that only the health professionals mentioned in the fourth part of the CSP practicing within a school medical service may be authorized to exchange or share information relating to the health of pupils. The Commission takes note of the Ministry's commitment to modify the project accordingly. On risk management and security measures The Commission considers that the ENS is a structuring project concerning the methods of access to health data from the all persons affiliated to a compulsory health insurance scheme or residing in France; as such, security is a major and inseparable component, both technically and functionally. In the absence of information concerning the implementation of the planned processing and the security of the data processed, the Commission is not able to verify the compliance of the processing with the GDPR. It notes that the Ministry has planned to send it requests for advice on these questions. The Commission also notes that the DPIA which will be sent to it will be updated as the work progresses. project, and wishes to receive it before each deployment



milestone. In particular, she stresses that the DPIA will have to reach her before the implementation of the first pilot phase involving real data, scheduled for summer 2021. The President,

M. L. Denis