Deliberation 2020-106 of October 29, 2020Commission Nationale de l'Informatique et des LibertésNature of the deliberation: OpinionLegal status: In force Date of publication on Légifrance: Thursday July 01, 2021NOR: CNIX2118934VDeliberation n° 2020-106 of October 29, 2020 providing an opinion on a draft decree relating to the national health data system (request for opinion no. 20011090)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 national health data 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;

Having regard to the Public Health Code (CSP), in particular its articles L. 1461-1 et seq.;

Considering the law n° 78-17 of January 6, 1978 modified relating to data processing, files and freedoms, in particular its article 8;

Having regard to Law No. 2019-774 of July 24, 2019 relating to the organization and transformation of the health system;

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

Having regard to the decree of October 9, 2020 modifying the decree of July 10, 2020 prescribing the general measures necessary to deal with the covid-19 epidemic in the territories emerging from the state of health emergency and in those where it has been extended;

On the proposal of Ms. Valérie PEUGEOT, commissioner, and after having heard the observations of Mr. Benjamin TOUZANNE, government commissioner, in his observations, Issues the following opinion: The draft decree referred to the Commission is adopted pursuant to Law No. 2019-774 of July 24, 2019 on the organization and transformation of the health system, which extended the scope of the national health data system (SNDS) and created the Health Data Platform (PDS ), responsible for collecting, organizing and making this data available. Firstly, the Commission wishes to make three observations on the draft decree. On the one hand, it deeply regrets, in view of the essential issue s attaching to the protection

of health data of millions of French people, the lack of readability and clarity of the provisions governing the SNDS which, beyond the legal insecurity thus created, reserve its understanding - and the important issues involved therein attached - only to experts in the field. On the other hand, it considers, for the reasons which are detailed below, that the draft decree only partially meets the objectives set for it by Article L. 1461-7 of the Public Health Code (CSP), in particular in that it does not sufficiently clearly fulfill the objective of fixing the list of categories of data gathered within the national health data system as well as the categories of data controllers of the SNDS and the data controllers and set their respective roles. Finally, and above all, the Commission considers it essential that the guarantee provided for by the decree of October 9, 2020 for the benefit of data from the Covid warehouse be extended to all data making up the centralized SNDS and, thus, that all of this data be prohibited from being transferred outside the European Union, regardless of the hosting methods (portal CNAM; technical solution of the PDS, child system, etc.). It takes note of the ministry's commitment to modify the draft decree on this point. On the scope of the SNDSWhile the SNDS - the historical SNDS - was until then limited to data from medico-administrative databases hosted or likely to be be hosted by the National Health Insurance Fund (CNAM), the law of July 24, 2019 added new categories of data, such as data from medical care when the procedures are reimbursed by social security, data from school medical visits, maternal or child health services, occupational health visits or matched surveys, etc. All of this data falls within the scope of the extended SNDS. When they are used for one of the purposes referred to in Article L. 1461-1 III of the CSP, they are subject to compliance with all the provisions of this code, in particular compliance with the security reference system, the prohibition of pursuit of prohibited purposes, the conditions of access to data via permanent access or the completion of a formality as well as the methods of transparency. This legal attachment to the extended SNDS does not, however, in itself lead to the migration of data within a centralized database. main database (to date comprising the historical SNDS and which may be enriched in the future) and a catalog database including other databases considered relevant for research actors. This integration will involve data migration. Initially envisaged as a decentralized system, the Commission notes that the ministry's choice is ultimately directed towards centralization of SNDS data. It notes that this draft decree aims to initiate this centralization of data with the CNAM and the PDS and to regulate only the implementation of this centralized SNDS. The Commission also notes that, according to the details provided by the Ministry, the PDS will have a copy of the main database, currently hosted by the CNAM and that the catalog database will only be hosted by the PDS. Finally, the Commission draws the attention of the Ministry to the lack of clarity of the perimeter of the expanded SNDS, which is

detrimental to a good understanding of the system provided for by the draft decree. On the scope of the expanded SNDS The Commission considers that certain categories of data listed in Article L. 1461-1 of the CSP would need to be specified.

With regard to the data referred to in 6° of Article L. 1461-1 of the CSP, the Ministry specified that data from medical records, as well as data from hospital warehouses, are not considered to be data from the SNDS ab initio. The Commission understands that these data will be included in the extended SNDS provided they are used for one of the purposes set out in III of this same article (for research, study or evaluation purposes, for example). These data are then likely to integrate the centralized SNDS following a text authorizing their availability.

In addition, according to the details provided by the Ministry, when the producer of the database reuses its own data for research purposes, the criterion of availability will not be met.

The Commission therefore asks the Ministry to clarify the legal regime applicable to the reuse of this data and in particular the concept of making it available.

Furthermore, the Ministry also specified that all data, once matched with SNDS data, would be part of the wider SNDS. While the Commission understands that such processing is effectively subject to the provisions of the CSP (compliance with the SNDS security reference system, transparency, etc.), this should not lead to the conclusion that the base thus matched is de facto part of the scope of the expanded SNDS . To fall within this scope, the base thus matched should only contain data referred to in Article L. 1461-1 of the CSP.

Among the data covered by this article, the Commission notes that the extended SNDS includes personal data from surveys in the field of health, when these data are matched with the data mentioned in 1° to 6°. The Commission notes that, according to the details provided by the Ministry, this terminology refers to the surveys defined by Law No. 51-711 of 7 June 1951 on the obligation, coordination and secrecy in the field of statistics. It takes note of the ministry's commitment to specify the term investigation in the draft decree.

It also takes note of the Ministry's desire to include the cohorts matched with the historical SNDS in the expanded SNDS, but wonders, however, about the purpose of the cohorts matched with the historical SNDS or other databases, created for of research and not falling under the law of June 7, 1951, to be part of the extended SNDS perimeter.

The Commission therefore invites the Ministry to clarify the scope of the extended SNDS, so as not to extend it beyond the sole data mentioned in the law. On the scope of the centralized SNDS (main database and catalog database)The Commission

notes that the draft decree provides that an order of the Minister responsible for health lists the data from 1° to 11° of I of article L. 1461-1 of this code which feed the main database and lists the databases of the catalog . It is periodically updated according to the availability of data.

It notes that the draft decree refers to an order, relating solely to the centralized SNDS, to provide details concerning the categories of data referred to in Article L. 1461-1 of the CSP. It regrets that these categories of data are not specified before registration in the main database and in the catalog database so as to determine beforehand the scope of the extended SNDS.

With regard to the main database

According to the draft text, the main database is intended to cover the entire population and brings together the data mentioned in 1° to 4° of I of Article L. 1461-1. To date, data from the national health insurance inter-scheme information system (SNIIRAM), the information systems medicalization program (PMSI), the epidemiology center on the medical causes of Deaths (CepiDC) and data from departmental centers for people with disabilities. It is also planned that this main database will be gradually supplemented with the data mentioned in 5° to 11° of the aforementioned article.

The Commission notes that, according to the details provided by the Ministry, the main database will be supplied with exhaustive data covering the entire population. It asks the ministry to specify the criteria taken into account to determine that a base will feed the main base, so that the decree specifies, as provided for by law, the methods of feeding the SNDS.

It also wonders about the criteria leading to the integration, by ministerial decree, of the data listed in 5° to 11° of article L. 1461-1 in the centralized SNDS.

Draft article R. 1461-2 of the CSP provides that the catalog databases include data mentioned in 1° to 11° of the aforementioned article.

The Commission notes that, according to the details provided by the Ministry, the catalog will only include data referred to in Article L. 1461-1 of the CSP.

It notes however, also according to the clarifications provided by the Ministry, that when a database partly contains data belonging to the categories referred to in the provisions of Article L. 1461-1 of the CSP and partly other data, only this first part of the database can be integrated into the catalogue.

It draws the Ministry's attention to the difficulties that may arise, from a practical and scientific point of view, such preparation of the bases with a view to their inclusion in the catalogue.

Finally, the Commission notes that the order of the Minister responsible for health will be updated periodically, depending on the availability of data.

It takes note of the ministry's commitment to modify the draft decree so that it specifies that the decree is intended to include the bases in the catalog and not to list those that have already been included in it.

It notes, moreover, that the draft decree returns the responsibility to the PDS to verify the conformity of the databases intended to appear in the catalog, with regard to the GDPR and the Data Protection Act. It takes note of the Ministry's commitment, on the one hand, to modify the project so that this role is no longer assigned to the PDS and, on the other hand, the fact that the Commission will be seized for the prior opinion of the decree referred to in I of article R. 1461-2 of the CSP.On the information of persons and the procedures for exercising the right of opposition, and other rightsThe draft article R. 1461-9 of the CSP provides the procedures for informing the persons concerned and exercising their rights. With regard to information relating to the constitution of the SNDSL, the draft article R. 1461-9 of the CSP distinguishes between the information procedures implemented, on the one hand, by the PDS and, on the other hand, by the CNAM, the PDS being responsible for implementing information on its website, the content of which is specified by the draft decree. The CNAM is, for its part, responsible for providing information on the implementation of the national health data system making it possible to bring the main characteristics of this system directly to the attention of the persons concerned and to make this information available on its website, which will refer to that of the PDS.

The Commission notes that, according to the details provided by the Ministry, the CNAM will make available on its website information relating to the evolution of the scope of the SNDS as well as to the processing and that the persons concerned will be invited to consult the PDS website in order to access more detailed information. It also notes that information recalling the creation of the SNDS and its operation will be made accessible via the Ameli account of the insured and will appear on the reimbursement statements sent by post.

The Commission notes that, despite the extent of the processing, both in terms of sensitivity and volume of data, the draft decree does not provide for individual information of the persons concerned. Furthermore, noting that the information will be produced almost exclusively in a dematerialized way (websites, Ameli account), the Commission asks the Ministry to think about alternative additional information methods (poster or information campaigns in the media, provision of information notices in the primary health insurance funds, transmission of a complete information note if requested by the persons

concerned, etc.). As for the 30% of policyholders who do not have an Ameli account, the Commission requests that complete individual information be sent to them by post, for example, when sending a reimbursement statement.

The Commission recalls that the information disseminated by the CNAM via its website and the Ameli account of policyholders must be supplemented in order to include information concerning the databases feeding the SNDS and the procedures for exercising rights (statements provided for in R. 1461-9 I 1° and 2° of the Public Health Code).

It also insists on the need for the information delivered to the persons concerned to be, whatever the medium used, clear, easily accessible and in accordance with the provisions of Article 14 of the GDPR. Supports that do not include all of the necessary information must refer to a support that includes all of the information provided for by the provisions of the GDPR.

Finally, it considers that a complete information note should be sent by post to any person who requests it. As regards information relating to the reuse of SNDSL data, the draft article R. 1461- 9 of the CSP provides that the PDS will make available on its website the list and characteristics of the projects involving SNDS data. The Commission welcomes the implementation of this transparency portal centralizing, in accordance with the provisions of Article 14 of the GDPR, information relating to all the projects carried out within the framework of permanent access or following the completion of a formality with the Commission.

The Commission recalls that the provisions of Article 69 of the Data Protection Act remain fully applicable to all processing carried out using SNDS data, including in the context of permanent access. In accordance with the provisions of Article 14 of the GDPR, in the event that the provision of individual information proves impossible, requires disproportionate effort or seriously compromises the achievement of the processing objectives, appropriate measures must be implemented by each data controller in order to protect the rights and freedoms, as well as the legitimate interests of the data subject, including by making the information publicly available. The Commission recalls that it will be up to each data controller wishing to process SNDS data to implement appropriate measures to make the information publicly available, which cannot be limited to recording its processing within of the transparency portal of the Health Data Platform.As regards the procedures for exercising the rights of individualsThe Commission notes the lack of clarity of the mechanism provided for in the draft decree and the fact that it only applies to the centralized SNDS. It fears that this system will constitute an obstacle to the exercise of the rights of individuals, especially since the organizations to which requests must be addressed vary according to the database and the right concerned.

The draft decree provides that the right provided for in Article 21 of the GDPR and Article 74 of the Data Protection Act cannot be exercised within the framework of the constitution of the SNDS.

The Commission notes that, according to the details provided by the Ministry, the inapplicability of the right of opposition concerns both the creation of the main database and the catalog database. However, it notes that the ministry also indicated that if a person objected to the reuse of their data in a source database listed in the catalogue, their data will not be fed into the SNDS .

The Commission considers that the opposition to the reuse of data from a source database should prevent the uploading of data to the catalogue. It also considers it necessary to provide for a right to erase data, in the event that they have been uploaded to the catalog prior to the exercise of the right of opposition. It takes note of the ministry's commitment to modify the draft decree on this point.

In addition, it recalls that the right of opposition exercised on each of the databases likely to supply the centralized SNDS before the entry into force of the decree must be taken into account, whether it has been carried out with the bodies managing the compulsory health insurance scheme with regard to the provision of data or with a data-producing organization whose database has been listed in the catalogue.

The Commission notes that the draft decree provides that, in order to exercise their right to object, the data subject must send their request: to the director of the Health Data Platform when the latter is responsible for the processing concerned; to the director the organization managing the compulsory health insurance scheme when the CNAM is responsible for the processing concerned. The Commission notes that the draft decree does not specify the alternative or cumulative nature of the procedures for exercising the rights. It takes note of the ministry's commitment to specify in the draft decree that the persons concerned may address their request to either of these bodies, in accordance with the provisions of Article 26-3° of the GDPR. , and that, in this case, it will be considered that the data subject has opposed any provision of his data (excluding permanent access) in the centralized SNDS .

It also notes that when a request is made to the PDS, the latter implements a circuit for processing the registration number in the directory of natural persons (NIR) in order to remove the pseudonymity of the data and to identify the data relating to the applicant. In this respect, the Commission recalls that one of the fundamental principles of SNDS security is based on the pseudonymisation of its data and strict partitioning between identifying data and pseudonymised data, excluding in principle

that the same entity has simultaneous access to NIR and SNDS data. Therefore, it considers contrary to this principle that the PDS processes the NIR of the person exercising his rights to operate the re-identification of his data. It asks that the draft decree be modified on this point.

With regard to the rights of access and rectification, the Commission notes that the procedures for exercising these rights differ according to the database concerned: thus, the rights are exercised with the organization managing the health insurance scheme for the main database, and with the bodies responsible for each database supplying the SNDS for the data catalogue. The Commission considers that such procedures for exercising the rights of opposition, access and rectification, which require data subjects to contact several data controllers even though they will not always be individually informed of the processing of data concerning them, are not, as they stand, such as to allow the effective exercise of rights. However, it takes note of the Ministry's commitment to clarify the relationship between the procedures for exercising the rights of individuals directly with the managers of the source databases and the procedures for exercising these rights within the framework of the SNDS.

In addition, it notes that, according to the terms of the draft decree, the exercise of a right of access delegated to the managers of the databases supplying the catalog will not allow the person to have knowledge of the consolidated and matched data which are attached to the centralized catalog on the PDS. It takes note of the ministry's commitment to modify the draft text on this point in order to provide for the application of the right of access to the data held by the PDS or the CNAM when the data is subject to matching.

The Commission therefore considers that the management of requests for the exercise of rights should take place at the level of the bodies managing the compulsory health insurance scheme. Indeed, these organizations are custodians of the secrecy allowing the first level of pseudonymization of the NIR to be carried out, and are likely to constitute an effective one-stop shop for all requests to exercise a person's rights.

In this case, the CNAM - as at present - and the PDS would then only receive a pseudonym derived from the NIR allowing them to select the data corresponding to the applicant and to carry out the operations necessary for the proper exercise of their rights (deletion or extraction for transmission). Furthermore, this scheme would allow the data subject, through a single request, to exercise their rights for all the databases of the centralized SNDS, thus making it possible to comply with both the security principles of the SNDS and the provisions of the GDPR.

In addition, performing matches between data from different sources on the basis of identifiers derived from the NIR

constitutes one of the main foundations of the technical architecture of the PDS. Consequently, it seems quite capable of carrying out this type of operation under the necessary safety conditions.

In addition, and in the event that a specific teleservice is put in place to simplify the exercise of rights, the Commission insists on the fact that it must comply with the principles set out above and strongly recommends that the project be submitted prior to its implementation so that it can assess in particular the procedures for verifying the applicant's identity and the security measures implemented in order to limit the risks inherent in re-identifying SNDS data.

Finally, the Commission notes that the above procedures concerning the centralized SNDS do not exclude the ability of individuals to exercise their rights directly with the managers of the other SNDS databases for the data processed by them, whether these databases are in the expanded SNDS or that they feed the centralized SNDS, and requests that the draft decree be supplemented in this sense. On the respective responsibilities of the CNAM, the PDS and the various actors (article R. 1461-3 of the 6° of Article L. 1461-7) Article L. 1461-7 of the CSP provides that the decree must define the categories of SNDS processing managers and processing managers and set their respective roles.

On this point, the Commission takes note of the Ministry's choice not to increase the number of processing managers in the centralized SNDS and not to designate any data-producing organization as processing manager.

The Ministry specified that the CNAM and the PDS were joint data controllers of the centralized SNDS, within the meaning of the GDPR and provided details on the specific missions of each of these organizations in the context of the implementation of the processing, such as the provision of data from the main database or the integration of the catalog. The Commission suggests that the draft text be supplemented, in the light of the clarifications provided.

The Commission notes, however, that an organization responsible for processing a source database feeding the main database or the catalog database may continue to make data from the source database available to other data controllers (for example, the information technology on hospitalization making PMSI data available to other data controllers or a university hospital center making data from a hospital warehouse available to a company specializing in artificial intelligence) . It notes that this provision will be governed by the provisions of the CSP (prohibition of the pursuit of prohibited purposes, compliance with the SNDS security reference system, etc.). It takes note of the clarifications provided by the Ministry according to which the body is responsible for processing its source database as long as it processes the data and until the data is processed to feed the centralized SNDS.

In addition, in its deliberation No. 2019-008 of January 31, 2019, the Commission had called for the implementing texts to provide, as permitted by Article 4 of the GDPR, the specific criteria applicable to the designation of the PDS as controller, co-controller or subcontractor when implementing research projects.

Thus, in the interests of clarity and legal certainty, it considers it necessary to indicate in the decree the qualification of the PDS or the CNAM as well as of the applicant, in the event that the data will be made available to a holder of project, within the framework of an authorized access or when the PDS will carry out operations on behalf of an applicant. It therefore calls for the draft decree to be clarified on these points. On the permanent access of certain public services to the national health data system The Commission notes that the provisions governing permanent access to SNDS data held by public bodies or responsible for a public service mission are largely modified within the framework of this draft decree, both with regard to the beneficiaries of this access and with regard to the nature of the data that may be processed. implemented within the framework of this permanent access The Commission takes note of the clarifications provided by the Ministry according to which this legislative and regulatory authorization concerns only the main database of the centralized SNDS and requests that the draft decree expressly specify this.

It also recalls that these organizations can only carry out, in accordance with the provisions of Article L. 1461-3 of the CSP, matches with the data of the SNDS insofar as these actions are made strictly necessary by the purposes of the processing or by [their] missions. The Commission notes that the draft decree does not provide any details on these pairings, the draft article R. 1461-15 of the CSP only mentioning the need to comply with the procedures defined by section 3 of chapter III of the II of the Data Protection Act when the processing needs exceed the scope of the authorization from which [the body] benefits. The Commission asks the Ministry to specify these terms in the draft decree and to expressly mention that in the event of matching, the provisions of section 3 of chapter III of title II of the Data Protection Act must be respected. concerning organizations benefiting from permanent access and the scope of the data processedThe Commission recalls that the benefit of permanent access should be justified by the need for the organization to carry out a large volume of processing or urgent processing of SNDS data for the purposes of its missions. It also recalls that permanent access is strictly personal to the organizations that benefit from it and that the data thus obtained cannot be made available to other organizations responsible for processing.

The Commission notes that the draft article R. 1461-12 of the CSP substantially extends the list of public bodies or bodies charged with a public service mission for which the new regulations would provide for permanent access. The number of these

organizations would, in fact, be increased to thirty-two, instead of twenty-five previously. It notes that a form was sent by most of these organizations in support of their request. However, the Commission is surprised by the incompleteness of some of the supporting documents submitted and recalls the importance of assessing the needs of these bodies on the basis of objective criteria and detailed arguments.

It notes that several of the new organizations wishing to benefit from permanent access have never submitted an authorization request to the Commission in order to access SNDS data. It also considers that the historical depth requested (9 years or 19 years plus the current year) by some of these organizations is not sufficiently justified in the files sent to it.

With regard to organizations which already had permanent access, the Commission also notes that the historical depth of access and the typology of the data concerned have been substantially modified in order to considerably increase this access, without any justification specific, for certain organizations, have been provided to change the scope of their access.

Finally, it notes that several organizations omitted, in the supporting form they sent, to specify the number of users concerned and/or to describe the procedures for managing their authorisations.

Given the statutory missions of the bodies in question, the Commission does not question the fact that the regulations may authorize them to have permanent access to the SNDS. However, it is appropriate that when this materializes, the administration ensures that it is really necessary and that the organization justifies having deployed the security, information or organizational measures adapted to the risks that represents this provision. To take account of the observations set out above, the Commission therefore asks the Ministry to provide, by amending the draft decree, for a prior check to be carried out before the seven new bodies benefit from this permanent access to the SNDS or before the existing accesses are extended. This control should make it possible to verify that the organization fulfills the required conditions. The commission insists in particular on the need to set up a formal governance of access to the SNDS, a procedure for managing individual authorizations as well as a permanent and reinforced program of training, awareness and support for authorized users. .On the report evaluating the scope of the authorizationThe Commission notes that the draft decree provides that each organization with permanent access must draw up an evaluation report on the scope within a maximum period of three years. of the authorization with regard to its missions and communicate it to the Commission.

It notes that, according to the details provided by the Ministry, the starting point of the three-year period for the establishment of this report runs from the date of publication of this decree. It takes note of the ministry's commitment to modify the draft

decree on this point.

It also insists on the need to comply with the regulatory obligation to transmit the evaluation report, which allows the organization to draw up an internal report on the processing carried out, this approach being part of a process of accountability and transparency vis-à-vis the Commission.

It notes that more than half of the organizations that already had permanent access did not send a report or list of studies and processing characteristics, even though this is a regulatory obligation. Given the stakes attached to the benefit of permanent access (lack of formality vis-à-vis the Commission, inapplicability of the right of opposition, etc.), the Commission considers that the absence of transmission of a complete report should be accompanied by a sanction (non-renewal of permanent access, suspension of access by the CNAM and the PDS). The Commission takes note of the ministry's commitment to modify the draft decree on this point.

Finally, without disregarding the interest of the use of SNDS data by bodies entrusted with a mission of public interest, the Commission draws the attention of the Ministry to the need for it to reassess, at the end of this deadline, the relevance of the permanent access granted.Other pointsThe Commission also wishes to share its observations on the following points:On the conditions for designating and authorizing persons authorized to access the national health data system (article L. 1461 -3 and 4° of Article L. 1461-7) The Commission notes that these conditions are defined for access to data by the CNAM and the PDS; on the other hand, they are not specified for the other cases (direct access to the source databases of the SNDS, for example).

On the role of the local scientific committees With regard to the extension of the SNDS and the role devolved to the CESREES, the Commission asks about the role of local committees, formed for example by organizations with a health data warehouse. This local governance, which is essential for data producers, should in particular be articulated with the opinion given by CESREEE when the data is made available by the PDS following the registration of the database in the catalogue. The role of these committees must also be specified when the data is made available without prior opinion from CESREEE (research involving humans, reference methodology, for example).

The Commission therefore welcomes the ministry's proposal to launch, jointly with the ministry in charge of research, a reflection on the scientific bodies and committees of warehouses and databases, as well as on their governance. On the constitution of data sets The Commission takes act of the ministry's desire to broaden the types of samples that can be created, by no longer limiting them to a generalist sample (for example, a sample on a given pathology). It also notes that

these can be compiled from data from, in addition to the main database, also from the catalogue.

It recalls that the constitution of a data set requiring the processing of personal data will have to be the subject of appropriate formalities with it. It also recalls that formalities will also have to be carried out with it by data controllers wishing to have access to it, in the event that these data sets are not anonymous. On this point, it specifies that repositories may be established, in accordance with Article 66-II of the Data Protection Act. On filing the file with the PDS or the CNAM The Commission notes that the draft Article R 1461-2 - III provides that, with the exception of the organizations referred to in 2° of I of Article L. 1461-3 which benefit from permanent access to the national health data system pursuant to section 2 of this chapter, they [data controllers] file with the Health Data Platform or the National Health Insurance Fund a request file for access to data from the national health data system, the composition of which appears on their websites.

The Commission considers that such wording could imply that the CNAM intervenes in the same way as the PDS as a one-stop shop, in the context of the processing of authorization application files, as provided for in the provisions of Article 76. of the Data Protection Act. On this point, the Ministry clarified that it was referring to the step of expressing the applicant's needs for effective access to SNDS data, regardless of the formality carried out upstream. The Commission takes note of the Ministry's commitment to clarify the draft decree on this point.On the option for the PDS to carry out transactions on behalf of a third partyThe Commission notes that Article L. 1462-1 of the CSP assigns a new role to the PDS, which can carry out, on behalf of a third party and at the latter's request, the operations necessary to process data from the SNDS.

The Commission recalls that if, according to the response of the Ministry, the PDS will have a role of processor within the meaning of the GDPR, it will only be able to process[r] personal data on documented instruction from the controller according to Article 28 of the GDPR.Data from the Covid warehouse and the Contact Covid and SIDEPL filesThe Commission notes that Article 8 of the draft decree provides that the data, processed on the basis of the decree of April 21, 2020 and matched with the data of the national health data system, are stored in the national health data system.

The Commission draws the Ministry's attention to the use of the data matching criterion, even though the data kept under Article 30 of the amended decree of July 10, 2020, which replaced the decree of April 21, 2020, have not been matched with data from the main SNDS database.

In addition, it recalls that Law No. 2020-546 of May 11, 2020 extending the state of health emergency and supplementing its provisions and Decree No. 2020-1018 of August 7, 2020 have provided for a retention period for epidemiological surveillance

and research on the virus six months after the end of the state of health emergency, with regard to data from Contact Covid and SIDEP.

Since the retention period for SNDS data is twenty years pursuant to Article L. 1461-1-IV-4° of the CSP, the Commission is wondering about the possibility of extending by decree the retention period set by the law. On the technical architecture The Ministry has confirmed that the PDS will have a copy of the main database, to respond effectively to requests and in particular for carrying out ad hoc pairings between the main database and the catalogue.

Without questioning this operational necessity, the Commission is nevertheless concerned about the duplication of a database containing, by nature, sensitive data covering the entire population. Indeed, this duplication involves regularly transferring a large volume of data between the CNAM and the PDS, as well as sharing pseudonymised identifiers; moreover, the Commission recalls that the PDS does not have - unlike the CNAM - its own data centers and uses a service provider in a shared data center with several customers.

It recalls that these various operations mechanically increase the attack surface and the risk of breaches of this data. On security measures The Commission notes that draft article R. 1461-5 of the CSP provides that the number of authorized persons is limited to what is strictly necessary. In addition to their regular review, it recommends that these authorizations be issued ab initio for a limited period and that their renewal engages the same authorization circuit.

With regard to draft article R. 1461-6 of the CSP, the Commission takes note of the Ministry's clarification that the list of authorized persons will mention the duration of each person's authorization. On pseudonymization The Commission insists on the fact that pseudonymisation is one of the original pillars of SNDS security. In the context of the use of the technical solution of the PDS, which aims in particular to allow numerous pairings of data, its role will be all the more crucial: the robustness of the pseudonymisation must therefore be ensured over the long term by all the actors required to provide data to the PDS or to carry out projects there.

In this respect, the Commission will remain extremely vigilant on this point in the context of the authorization requests that will be sent to it, particularly with regard to the constitution of the PDS warehouse as well as the projects carried out on the technical solution of the PDS.

Furthermore, the Commission takes note of the forthcoming update of the SNDS security reference system, in particular concerning the pseudonymisation rules, with a target publication date set at the beginning of 2021. In this respect, it

recommends that derivative matches of the NIR are not implemented on the technical solution of the PDS before the Commission has been able to issue an opinion on this reference system.

Finally, the Commission takes note of the clarifications provided by the Ministry concerning the draft article R. 1461-14 of the CSP which mentions aggregated data presenting a residual risk of re-identification in that they correspond to data marts of non-anonymised but presenting a low risk of re-identification due to their aggregation. In this regard, it recommends that the risks of re-identification of these data marts be reassessed regularly.

The president,

M. L. Denis