Deliberation 2019-008 of January 31, 2019 National Commission for Computing and Liberties Nature of the deliberation: Opinion Legal status: In force Date of publication on Légifrance: Wednesday February 20, 2019 Deliberation No. 2019-008 of January 31, 2019 providing an opinion on a draft law relating to the organization and transformation of the health system (request for opinion no. 19001144) The National Commission for Information Technology and Liberties, Seizure by the Ministry of Solidarity and Health of a request for opinion concerning a bill 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; Having regard to the Public Health Code; Having regard to Law No. 78-17 of 6 January 1978 as amended relating to data processing, files and freedoms, in particular its article 11-I -4-a; Having regard to Law No. 2017-55 of January 20, 2017 on the general status of independent administrative authorities and independent public authorities, in particular its article 22; Having regard to Decree No. 2005-1309 of October 20, 2005 as amended taken for the application of law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms; After having heard Mrs. Valérie PEUGEOT, Commissioner, in her report, and Mrs. Nacima BELKACEM, Government Commissioner, in its observations, Issues the following opinion: Pursuant to Article 11-4-a) of the law of 6 January 1978 as amended, the Commission has been informed by the Ministry of Solidarity and Health of certain provisions of the bill on the organization and transformation of the health system. The Commission is thus seizure of the main provisions of its title III (Developing digital ambition in health), namely those relating to the expansion and transformation of the national health data system (SNDS) (article 11), the abolition of a trusted third party responsible for re-identifying data subjects in the SNDS (article 15), creating a digital health space (ENS) (article 12) and the new system called telecare (article 13). Finally, by amending referral, the Commission is referred to the provisions of Article 20 of the draft law relating to the extension of the unique identification system for victims provided for by Article L. 3131-9-1 of the Code of public health (CSP). As a preliminary point, the Commission considers it necessary, in view of the strong issues related to data protection, that the impact study of the bill contain appropriate elements on the specific impact of the processing of personal data envisaged, given their extent and the nature of the data.Concerning article 11 of the draft law (SNDS)On the enlargement and change of nature of the SNDS In order, as specified in the explanatory memorandum, to promote the use and multiply the possibilities for exploiting data, both in clinical research and in terms of new

uses, in particular those linked to the development of artificial intelligence methods, the public authorities consider it necessary to extend the scope of the data included in the SNDS – i.e. data made available to third parties under the conditions set by article L. 1461-1 of the CSP – to all the data collected during the acts covered by the 'Health Insurance. Concretely, it is a question of expanding the SNDS, which already brings together all the major files under the law of January 26, 2016 (the SNIIRAM, the PMSI, the BCMD, the medico-social data of the departmental houses of the disabled and the representative sample of reimbursement data by beneficiary transmitted by mutual insurance companies) to now include all clinical data collected by healthcare professionals as part of their activities and related to the acts or services reimbursed; ; data processed in the professional software of doctors or in the prescription software of pharmacists, those contained in the warehouses created by certain hospital establishments, etc. would thus be concerned. Beyond a simple enlargement, this evolution changes the very dimension of the SNDS, which would aim to contain all the medical data giving rise to reimbursement collected by healthcare professionals in France. If the extension provided for in the bill can be justified by objectives of aid for research and innovation in the field of health, and if the evaluation of the conformity of the entire system supposes the intervention of implementing regulatory acts, in the absence of any precision in the draft law on the precise architecture of the system, the Commission now draws attention to the major problem of compliance, in practice, with the principles of limitation of purposes and minimization of data by these new processing operations, evolving in a context of data accumulation to feed artificial intelligence algorithms. In addition, in view of the extremely sensitive nature of the data processed, it alerts the public authorities to the concrete conditions for implementing this change, in particular with regard to patient information and the security of the information systems concerned, which must be provided for when regulatory texts and achieve the level of guarantee required, pursuant to the General Data Protection Regulation (GDPR), for processing of this nature. application provided for in draft 6° of Article L. 1461-1 of the CSP. At this stage, concerning the new scope of the SNDS, the Commission understands that the data collected in cohort studies outside the coverage medical (for example through patient questionnaires) or outside of reimbursed procedures would not be included in this scope. The Commission takes note of the Ministry's clarifications that the data processed in the warehouses set up by certain private operators will not fall within the scope of the extended SNDS. On the creation of the Health Data Technology Platform The Commission notes that the draft law does not include any description or framework of the technical architecture of the health data technology platform, given the options currently under discussion. In this respect, the Commission considers it essential that the decree, issued after

consulting the CNIL and to which it will pay particular attention, specifies the overall and technical architecture, the framing of which will be carried out in collaboration with the National Agency for Information Systems Security (ANSSI). As of now, the Commission warns of the risks inherent in the possible concentration of sensitive data on the technological platform, which will require the implementation of appropriate security measures adapted to the risks. On the creation of the Health Data Platform in as a Public Interest Group (GIP) Unlike the choice made by the law on the modernization of our health system, the implementation of the modified SNDS would not be based on a single data controller. The bill refers to a decree in the Council of State, taken after consulting the CNIL, the task of determining the managers or categories of managers of the processing of the SNDS, and their respective roles. In addition, the bill provides for the creation of the Health Data Platform, a public interest group (GIP), which would replace the National Institute for Health Data (INDS). The Health Data Platform would take over, in part, the current missions of the INDS, in particular the single secretariat for research not involving the human person. Among its new missions would be the one, essential with regard to the choice of a decentralized architecture of the SNDS, to collect, organize and make available the data of the SNDS (…) . The Commission considers that this GIP would be likely, depending on the case, to be qualified as controller (for example, for the processing operations carried out before exporting the data to the applicants), or as co-responsible for processing (for example, those intended to be exploited by the applicants within the framework of the technical platform that the GIP will be intended to offer). The Commission considers that the texts could usefully provide, as permitted by Article 4 of the GDPR, the specific criteria applicable to its designation as controller or co-controller. The Health Data Platform could also be considered to be under -processor within the meaning of Article 4 of the GDPR when it carries out operations on behalf of an applicant. In any event, the role of the Health Data Platform as provided for by the bill – without commensurate with the current role of the INDS – will require the provision of significant human and technical resources so that the principles of the GDPR and the law are effectively respected in the context of the provision of data from the SNDS.Finally , given the change in the nature of the SNDS, the Commission considers that the Health Data Platform should be given an additional mission of informing patients and promoting and facilitating their rights, in particular concerning the rights of opposition or, where applicable, portability.On opening access to the SNDS to any processing of health dataThe bill aims to modify article L. 1461 -3 of the CSP in order to allow access to SNDS data for any processing in the public interest, and no longer solely for the purpose of research, study or evaluation. This modification will lead in particular to allowing the matching of SNDS data with databases such as warehouses (private or public) or registers established for long

periods, or even permanently, subject to authorization from the CNIL. The Commission emphasizes the major significance, given the nature of the mechanism in question, of the removal of any express framework of the purposes in the law. It recalls that in any case, in accordance with the principle of purpose limitation resulting from Article 5 of the GDPR, the processing carried out must meet one or more specific, explicit and legitimate purposes. authorization requests that it will be required to receive, the Commission will be particularly vigilant to strict compliance with the principles relating to data protection – namely the principles of minimization, retention periods and data recipients – as well as the data security aspects. In the event that data is duplicated within the technological platform, it will pay particular attention to their retention period and their partitioning. In addition, the Commission considers that this opening leads by itself to extending the cases presentation of requests for the constitution of child systems containing data from the SNDS, including for processing carried out outside of a precise and time-limited search, even though the security reference system relating to the SNDS sets strict requirements for security. The Commission notes, however, the government's desire to reduce the number of child systems. In this regard, it suggests that the decree could regulate the conditions for the creation of these child systems (duration, methods, etc.), in particular in the event that these are constituted outside the technological platform.On the procedure of access to data As a preliminary point, in view in particular of the modifications relating to the nature of the data made available, and this, whatever the status of the applicant, the Commission warns of the need for a solid doctrine on the nature of public interest and, where applicable, on an in-depth examination of this criterion when applying for authorization. of the SNDS Access Commission to health-related processing only. However, some research projects only use data from SNDS health professionals (and not personal health data). The Commission wonders about the choice made to exclude them from the principle of authorization from the moment the SNDS data are used. The Commission notes that the expert committee for research, studies and evaluations in the field of health (CEREES) would be replaced by a new ethical and scientific committee for research, studies and evaluations in the field of health (CES). This committee would take over the missions of the CEREES and could also be seized, or seized, of the public interest character of a research, role previously assigned to the Committee of Expertise for the Public Interest (CEIP) placed at the INDS .The Commission draws attention to the composition of this future committee with extended powers, in particular to ethical questions. She believes that the statutes of the members of the Committees for the Protection of Persons (CPP) as well as those of the CEIP could serve as a reference for the composition of this committee. Finally, the Commission regrets that its missions are not specified at the legislative level, as was the case for the CEREES or as is currently the case

for the CPPs. , article L. 1461-5 of the CSP provides for free access to SNDS data for public authorities and research carried out exclusively for the needs of public administrative services. Conversely, private actors would be required to pay for access to the SNDS. It draws the government's attention to the need to precisely define the status of each applicant and the resulting consequences on this tariff. With regard to public-private partnerships, the Commission takes note of the Ministry's clarification on free access when the processing is requested by the public authority or during research carried out exclusively for the needs of the services As regards the modification of Article 30 of the Data Protection Act on the processing of the NIR, the Commission takes note of the addition of this provision, which clarifies that an authorization is necessary during a processing of the NIR INS within the framework of databases (warehouse type) used for subsequent research purposes. The other provisions of this article do not call for any comments from the Commission. of lawArticle 15 abolishes the trusted third party responsible for re-identifying data subjects in the SNDS.According to the public authorities, the reality of these needs has not been established because the identification mechanisms ication, in particular to alert a person of a serious health risk to which they would be exposed, can be implemented via the source databases of the SNDS, which are nominative. The Commission, insofar as such a mechanism does not undermine the principle of non-re-identification of persons enshrined in article L.1460-1 of the CSP, is in favor of deleting the above-mentioned provision.Concerning article 12 of the bill (digital health space)The purpose of this bill is to purpose of allowing each user of the health system to have free access, by 2022, to a digital health space (ENS) including their personal health data and their healthcare reimbursement data and also enabling them to access digital health services and tools (such as the use of secure messaging, an online appointment booking service or a telemedicine service). These additional tools and services may, where appropriate, be offered by external private players. The Commission notes that this offer constitutes processing of personal data within the meaning of Article 4-2 of the GDPR and that it must therefore be seizure of the decree in Council of State intended to define the conditions and methods of application of the ENS. Consequently, the Commission asks that the draft be supplemented to specify that the conditions and methods of application [of this article] are defined by decree in Council of State taken after opinion of the CNIL. Article L. 1111 -13-1 of the bill provides that the ENS will allow its holder to access in particular his shared medical file (DMP) as well as all the data relating to the reimbursement of his health expenses presented as the two first devices supplying the ENS. The Commission generally wonders about the articulation with these already existing devices in a context where the DMP is in full phase of generalization and technical development. It emphasizes that confusion could arise in the minds of users between these

different devices whose operating methods differ. In this context, it will be particularly vigilant with regard to the content and methods of informing people about the ENS and suggests that these information methods be specified by the Conseil d'Etat decree. and more specifically, on the interest and the need to allow healthcare professionals access to all ENS information beyond the information contained in the DMP. It suggests that access be restricted to certain content in the digital space and that the conditions according to which this access is permitted be specified. The Commission also notes that the bill provides that the ENS is open to the initiative of persons, while the provisions governing the DMP provide for the need to obtain the express consent of persons. Insofar as the Ministry has confirmed that the legal basis retained for the ENS would be that of consent, it suggests, to avoid any confusion, that the user's consent to the creation of the ENS should also be mentioned in the draft law. .The bill provides for the possibility for any person or their legal representative to open an ENS. The Commission requests that the procedures for opening an ENS, where applicable when the holder is a minor, be specified in the implementing decree. As regards the personal data collected at the opening of the ENS listed in article L. 1111-13-1 of the draft, the Commission recalls that the data collected must be adequate, relevant and limited to what is necessary with regard to the purpose for which they are processed, in accordance with the provisions of the article 5-1-c of the GDPR. She asks that the nature of the information from the ENS be detailed by the Conseil d'Etat decree which would be taken after consulting the CNIL and wonders about the framework for the cross-referencing of data between the various departments of the ENS and on the conditions for secure data portability. The Commission draws attention to the fact that the referencing of services and tools must also lead to the fact that only relevant data can be entered into them in order to remedy any bad practices in the feeding of the ENS by the users. It asks to be associated with the work relating to the development of the repositories, labels and standards imposed in the ENS and to be consulted prior to their validation. Concerning the safety aspects , the Commission emphasizes that the ENS, as an aggregator of services and data, must comply with the authentication rules, the authorization matrices and the traceability principles defined for each of the services. different services that it will aggregate. The Commission also notes that the ENS, as a processing operation in its own right – offering, moreover, specific functionalities for sharing access and extracting data – will have to have its own privacy risk management. Finally, the Commission observes that the ENS must be hosted by an approved/certified health data host in compliance with Article L. 1111-8 of the CSP.Concerning Article 13 of the billThe bill introduces, following the provisions relating to telemedicine which allows remote medical management of a patient by a doctor, a new practice of remote care between a patient and one or more pharmacists(

s) or one or more medical auxiliaries, entitled telecare. The bill provides that only the conditions for taking charge of telecare activities are set by decree. Telecare activities are authorized by order of the Minister of Health, issued after consulting the Haute Autorité de Santé, which will relate to the conditions of performance guaranteeing quality, safety and relevance. The Commission notes that the activity of telemedicine , of which telecare is the counterpart for health professionals outside the medical professions stricto sensu, was the subject of a decree relating to the conditions of implementation and coverage of which the CNIL had been seized for an opinion.Account given the significant issues raised by the use of new information and communication technologies in terms of the protection of personal data and insofar as telehealth constitutes processing of personal data within the meaning of Article 4- 2 of the GDPR, the Commission considers that the decree adopted for the application of telecare must also expressly relate to the conditions of implementation.Concerning article 20 of the bill (dispo systems put in place to deal with exceptional health situations) The bill extends the possibility of collecting the information strictly necessary for the identification of victims and their follow-up in the event of an exceptional health situation or for any event likely to involve many victims, in particular collective accidents. In any case, it will be particularly vigilant to the guarantees provided by the Ministry of Solidarity and Health with regard to this device subject to authorization by the CNIL. The other provisions do not call for any comments on the part of the Commission. in article 22 of the law of January 20, 2017, this opinion will be made public. The President I. FALQUE-PIERROTIN