Deliberation 2022-124 of October 13, 2022National Commission for Computing and LibertiesNature of the deliberation: Referential/standard regulation/standardLegal status: In force Date of publication on Légifrance: Saturday February 11, 2023NOR: CNIL2302972XDeliberation n° 2022-124 of October 13 2022 adopting a reference system relating to the description and procedural guarantees allowing the provision for processing of the sample of the national health data system (ESND) and thematic databases called "datamarts" of the national health insurance inter-scheme information system (SNIIRAM) presenting a low risk of impact on privacy and repealing deliberation no. 2020-072 of July 16, 2020 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 articles L. 1461-1 et seq. and R. 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 66;

Having regard to deliberation no. 2020-072 of July 16, 2020 adopting a reference system relating to the description and procedural guarantees allowing the provision for processing of the generalist sample of beneficiaries (EGB) and the databases thematic data called datamarts of the national health insurance inter-scheme information system (SNIIRAM), presenting a low risk of impact on privacy and repealing deliberation no. 2019-039 of April 11, 2019; On the proposal to Ms. Valérie PEUGEOT, commissioner, and after having heard the observations of Mr. Benjamin TOUZANNE, government commissioner, Makes the following observations: of the sample of data from the SNDS (hereafter ESND) and the thematic databases called SNIIRAM datamarts is intended to replace the repository governing the provision of data from the EGB and the thematic databases called datamarts of the SNIIRAM established by deliberation n° 2020-072 of July 16, 2020. Constituted by the National Health Insurance Fund (CNAM), the ESND is a random sample comprising two percent of the people whose data appear in the SNIIRAM mentioned in Article L. 161-28-1 of the Social Security Code. The ESND contains the following information from SNIIRAM: the inter-regime consumption data mart (DCIR), also called the individual beneficiary database; the data contained in the program for the medicalization of information systems (PMSI) in the fields of medicine, surgery, obstetrics and odontology (MCO), follow-up care and rehabilitation (SSR), collection of medical information in psychiatry (RIM-P) and hospitalization in (HAD). Thematic databases of aggregated data called datamarts oriented towards monitoring expenditure (DAMIR) or analyzing the supply of care (AMOS) are also created from SNIIRAM, as well as tables of board on biology and

pharmacy. These datasets are included in the scope of this reference document. The use of this sample makes it possible in particular to better know and understand the use of care, the trajectories of care and the health expenditure of the insured. In accordance with the provisions of the third paragraph of Article 66-II of the Data Protection Act, sets of health data with a low risk of impact on privacy may be made available for processing in conditions previously defined by a reference system, without prior authorization being required. laws and regulations relating to the SNDS is applicable to the processing of data from the ESND, in particular: the prohibition on using SNDS data for the purposes described in Article L. 1461-1-V of the public health (CSP) (prohibited purposes); compliance with the safety baseline applicable to the SNDS provided for in article L. 1461-1-IV-3° of the CSP; the principle of transparency provided for in article L. 1461- 3-II of the CSP. Decides: The description and the procedural guarantees allowing the provision of personal data from the ESND and/or the SNIIRAM datamarts and dashboards, defined by the Commission are as follows: Processing subject to a single approval issued by the Health Data Platform The conditions of access defined by this standard apply to processing carried out for the purposes of research, study or evaluation in the field of health, justified by the public interest, and for the realization of which only an access to the data of the ESND and/or to the datamarts and dashboards of the SNIIRAM is necessary. health data (PDS) processing that complies with the following cumulative conditions: the processing is carried out within the CNAM's secure portal; no crossing of several potential identifiers, as defined by the regulatory provisions applicable to the SNDS, is carried out ; the duration of access to the portal does not exceed twenty-four months. This period may be extended for a maximum period of twenty-four months at the reasoned request of the data controller; the processing meets one of the following purposes:

- comparative evaluation of the care offer;

- evolution of care practices; - comparative analyzes of care activities; - description and analysis of pathologies and patient care pathways; - epidemiological and/or medico-economic studies, including studies for the preparation of discussion files - - and meetings with the competent authorities and committees, or studies for monitoring purposes;

- feasibility studies in the context of research involving or not involving the human person. Modalities of access specific to certain categories of data controllers: In order to benefit from these conditions for making datamarts, are required to use a research laboratory or a design office mentioned in article L. 1461-3 of the CSP: persons producing or marketing products mentioned in II of article L. 5311-1 of the CSP; the organizations mentioned in 1° of A and in 1°, 2°, 3°, and 6° of B of Article L. 612-2 of the Monetary and Financial Code as well as the insurance intermediaries mentioned in Article L. 511-1 of the

Insurance Code. Examination by the Platform of health data for a single approval: The request for access to data from the ESND and data marts sent to the PDS includes: the protocol, including the justification of the public interest, as well as a summary, according to the model made available by the PDS; the declarations of interests of the controller and head of the research laboratory or design office, in relation with the purpose of the studies; at the end of the studies, the method and the results obtained with a view to their publication; the compliance of the recording of the processing and the transmission of the results with the methods defined by the PDS. The Data Platform of health decides with regard to the following elements: the justification provided by the data controller to demonstrate the scientific relevance of the project; the justification of the historical depth requested concerning the ESND data (nine years in addition to the year in course or nineteen years in addition to the current year); the justification of the potential identifier retained; the public interest purpose pursued by the processing; the duration of access to the CNAM portal for the processing envisaged, which must be limited to the time necessary to carry out the research, study or evaluation; and, where applicable, the justification for the request for extension of this period sent by the data controller; compliance with the legislative and regulatory requirements applicable to the SNDS; the procedures for informing and exercising the rights of the persons concerned; the where applicable, compliance with the terms of access to the data provided for by the reference system determining the criteria of confidentiality, expertise and independence for research laboratories and design offices. Access procedure: The request for access is sent to the PDS under the same conditions as those provided for the transmission of the application file for authorization of research, study or evaluation in the field of health provided for in Article 76 of the Data Protection Act. The PDS notifies its decision to the applicant within fifteen working days of receipt of a complete file. If there is no response from the PDS at the end of the fifteen working day period, the request is deemed approved. The PDS may contact the applicant for any additional information if necessary. The approval period is suspended pending additional information. In the event that the PDS does not consider itself able to make a decision based on the elements of the file, it may decide that the processing envisaged is subject to the complete procedure, according to the procedures provided for in Articles 66, 72 and following of the Data Protection Act, and informs the applicant. After the latter's agreement, the PDS refers to the CESREEEs for an opinion, then the National Commission for Computing and Liberties for authorisation. Information and procedures for exercising rights: The information of the persons concerned cannot be limited to registration of processing in the public directory of the PDS. Pursuant to the provisions of Article 14-5-b of the GDPR, the controller may claim an exception to the obligation of individual information for the implementation processing involving

exclusively data from the ESND and datamarts. In this case, it must take appropriate measures to protect the rights and freedoms as well as the legitimate interests of the persons concerned, including by making the information publicly available .Thus, collective information relating to the carrying out of the study must appear on the website of the data controller as well as, where applicable, of the research laboratory or design office carrying it out. In addition, other vectors may be used to disseminate this information (communication on social networks, in the regional media, with patient associations, publication of a press release, etc.). processing carries out several studies using data from the ESND and data marts, it must set up a transparency portal containing general information on the SNDS, as well as an information note specific to each study. These documents must include all of the information provided for in Article 14 of the GDPR. Transparency: The legal framework allowing the provision of SNDS data is designed to account for their use to civil society. This principle of transparency is provided for in Article L. 1461-3-II of the Public Health Code (CSP). To this end, access to SNDS data is subject to the communication to the PDS of several elements by the data controller, before and after the studies have been carried out. Thus, the data controller undertakes to register in the public directory kept by the PDS the studies carried out within the framework of this reference system. This registration must be carried out before the start of the studies by the data controller or the person acting on his behalf. The PDS sends the Commission an annual report of the approvals issued under the conditions described in the context of this reference system as well as the characteristics of the processing implemented. Entry into force: Deliberation No. 2020-072 of July 16, 2020 is repealed. Processing implemented pursuant to the aforementioned deliberation may continue in compliance with the provisions of this deliberation. relating to the description and procedural guarantees allowing the provision for processing of data from the ESND and the thematic databases called SNIIRAM datamarts, presenting a low risk of impact on privacy, enters into force the day after its publication in the Official Journal of the French Republic.

The president,

M. L. Denis