

Deliberation 2020-072 of July 16, 2020 National Commission for Computing and Liberties Legal status: In force Date of publication on Légifrance: Tuesday August 04, 2020 the procedural guarantees allowing the provision for processing of the generalist sample of beneficiaries (EGB) and the thematic databases called "datamarts" of the National Health Insurance Interregime Information System (SNIIRAM), presenting a low risk of impact on privacy and repealing deliberation n° 2019-039 of April 11, 2019 The National Commission for Computing and Liberties,

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;

Considering the law n° 78-17 of January 6, 1978 modified relating to data processing, files and freedoms, in particular its article 66-II;

Having regard to Law No. 98-1194 of 23 December 1998 on the financing of social security (CSS), creating the national health insurance inter-scheme information system (SNIIRAM);

Having regard to law n° 2019-774 of July 24, 2019 relating to the organization and transformation of the health system, in particular its article 41;

Having regard to Decree No. 2016-1871 of December 26, 2016 relating to the processing of personal data called the national health data system;

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

Having regard to the decree of 19 July 2013 as amended relating to the implementation of the national health insurance inter-scheme information system;

Having regard to the decree of March 22, 2017 relating to the security reference system applicable to the national health data system (SNDS);

Having regard to the decree of July 17, 2017 relating to the reference system determining the criteria of confidentiality,

expertise and independence for research laboratories and design offices;

Having regard to deliberation no. 2019-039 of April 11, 2019 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. 2018-134 of April 12, 2018;

Having regard to the referral to the Health Data Platform dated April 28, 2020 for approval of a simplified procedure pursuant to Article 66 of Law No. 78-17 of January 6, 1978 referred to above (hereinafter the Data Protection Act and Freedoms). On the proposal of Mrs Valérie PEUGEOT, commissioner, and after having heard the observations of Mrs Nacima BELKACEM, government commissioner, Makes the following observations: The Commission was seized on April 28, 2020 by the Health Data Platform a request for modification of the reference system relating to the description and the procedural guarantees allowing the provision for their processing of the generalist sample of beneficiaries (hereinafter, EGB) and the thematic databases called datamarts of the national health insurance inter-scheme information system (SNIIRAM), presenting a low risk of impact on privacy, established by deliberation no. 2019-039 of 11 April 2019. This reference tier relates to the description and the procedural guarantees allowing the provision for processing of data from the EGB of SNIIRAM, a component of the national health data system (SNDS). The EGB of SNIIRAM is a sample made up by the National Health Insurance Fund (CNAM) which concerns 1/97th of the population covered by health insurance in France. The EGB contains information on the socio-demographic and medical characteristics of beneficiaries and the care services they received. 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 over a period. Thematic databases of aggregated data called datamarts are also made up from SNIIRAM. oriented towards the monitoring of expenses (Damir) or the analysis of the healthcare offer (Amos), as well as dashboards on biology and pharmacy. These datasets are included in the scope of this reference document. In accordance with the provisions of the third paragraph of article 66-II of the Data Protection Act, health datasets presenting a low risk of impact on privacy may be made available for processing under conditions previously defined by a reference system, without the authorization provided for in Article 76 of the aforementioned law being required. The Commission recalls, as a preliminary point, that the SNIIRAM being a component of the SNDS, all the legislative and regulatory provisions relating to the SNDS are applicable to the processing of data from the EGB and, in particular: the prohibition on using the data of the SNDS for the

purposes described in Article L. 1461-1 V of the Public Health Code (prohibited purposes); compliance with the security baseline applicable to the SNDS, set by the decree of March 22, 2017; the principle of transparency e provided for in Article L. 1461-3 II of the Public Health Code. The Commission recalls on this point that the legal framework allowing the provision of data from the SNDS and its components is designed in such a way as to account for their use to civil society. To this end, the Public Health Code makes access to data from the SNDS and its components subject to the communication to the Platform of health data of several elements by the data controller, before and after the studies have been carried out. Thus, the data controller undertakes to register with the public directory maintained by the Health Data Platform the studies carried out within the framework of this reference system. This registration, to be carried out by the data controller or the person acting on his behalf before the start of the studies, is accompanied by the transmission to the Platform of health data of a file comprising:

- the protocol, including the justification of the public interest, as well as a summary, according to the model made available by the Health Data Platform;
- the declaration of interests of the data controller, in relation to the subject 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 procedures defined by the Health Data Platform.

The information of the persons concerned as to the possible reuse of their data and the procedures for exercising their rights, must comply with the legislative and regulatory provisions applicable to the processing of personal data of the SNDS. Decides: The description and procedural guarantees allowing the provision of personal data from the EGB of the SNDS defined by the Commission are the following: Processing likely to be examined only 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 evaluations in the field of health, justified by the public interest, and for the realization of which only an access to the EGB and/or to the datamarts and table x of the SNIIRAM is necessary. Processing that meets the following cumulative conditions is likely to benefit from a single approval from the Health Data Platform: the processing is carried out within the CNAM's secure portal and does not provide for the constitution of a child system of the SNDS as defined in the decree of 22 March 2017 mentioned above; 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 by a maximum of twenty-four months at the reasoned request of the data controller. The processing meets one of the following purposes:

- comparative evaluation of the healthcare 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 records for discussions and meetings with the competent authorities and committees, or studies for surveillance purposes;
- feasibility studies in the context of research involving or not involving the human person. Terms of access specific to certain categories of data controllers:

In order to benefit from these conditions for making the EGB and datamarts available, in the event that the processing is carried out by persons producing or marketing the products mentioned in II of article L. 5311-1 of the public health or 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, the latter are required to use a research laboratory or a design office mentioned in article L. 1461-3 of the public health code.

**Examination by the Health Data Platform**

The Health Data Platform decides with regard to the following elements: the justification provided by the data controller to demonstrate the scientific relevance of the project; the public interest purpose pursued by the processing; the duration of access to the portal for the intended processing, 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 requirements applicable to the SNDS and the data controller's commitment to compliance with paragraph 5 Access to repository data aforementioned security applicable to the SNDS; where applicable, compliance with the terms of access to data provided for by the reference system determining the criteria of confidentiality, expertise and independence for research laboratories and design offices (use of a research laboratory or a design office for certain categories of actors).

**Access procedure**

The request for access is sent to the Health Data Platform under the same conditions as those provided for the transmission of the request file authorization for research, study or evaluation in the field of health provided for in article 76 of the Data Protection Act. The Health Data Platform notifies its decision to the applicant within fifteen working days of receipt of a complete file. Without a response from the Health Data Platform at the end of the fifteen working day period, the request is deemed approved. The Health Data Platform may contact the applicant for any

additional information if necessary. The approval period is suspended pending additional information. In the event that the Health Data Platform does not consider itself in a position to make a decision in view of the constituent 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 72 to 79 of the amended Data Protection Act and informs the applicant. After the latter's agreement, the Health Data Platform contacts CESREEE for an opinion, then the National Commission for Information Technology and Freedoms for authorisation, in compliance with the provisions of the Data Protection Act. Transparency Without prejudice to the transparency system provided for by the legislative and regulatory provisions applicable to the processing of personal data of the SNDS, the Health Data Platform informs the Commission at least once a year of the approvals issued under the conditions described in the context of this reference system as well as the characteristics of the processing implemented. Deliberation no. 2019-039 of April 11, 2019 adopting a reference system relating to the description and the procedural guarantees allowing the provision for their processing of the EGB and the databases thematic data called SNIIRAM datamarts, presenting a low risk of impact on privacy and abrogating the deliberation n° 2018-134 of April 12, 2018, is repealed. This reference document relating to the description and the guarantees of procedure allowing the provision for their treatment of the EGB and the thematic databases called datamarts of SNIIRAM, presenting a low risk of impact on privacy, comes into force the day after its publication in the Official Journal of the French Republic.

The president,

M. L. Denis