

Deliberation 2019-039 of April 11, 2019 National Commission for Computing and Liberties Legal status: Repealed Date of publication on Légifrance: Wednesday March 10, 2021 NOR: CNIL1914312X and the procedural guarantees allowing the provision for processing of the generalist sample of beneficiaries (EGB) and the thematic databases called "datamarts" of the National Inter Scheme Health Insurance Information System (SNIIRAM), presenting a low risk of impact on privacy and repealing deliberation n°2018-134 of April 12, 2018 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 (general regulation on the data protection), and repealing Directive 95/46/EC;

Considering the law n° 78-17 of January 6, 1978 modified relating to data processing, files and freedoms, in particular its article 54-II;

Having regard to law n° 2016-41 of January 26, 2016 on the modernization of our health system, in particular its article 193;

Having regard to law n° 98-1194 of December 23, 1998 on the financing of social security (CSS), creating the national information system for inter health insurance schemes (SNIIRAM);

Considering the decree n° 2005-1309 of October 20, 2005 modified taken for the application of the law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms;

Having regard to Decree No. 2016-1871 of December 26, 2016 relating to the processing of personal data called the national health data 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 19 July 2013 as amended relating to the implementation of the national health insurance inter-scheme information system;

Having regard to deliberation no. 2018-134 of April 12, 2018 approving the conditions for making available the generalist sample of beneficiaries (EGB) and the thematic databases called datamarts of the national inter-regime insurance information system disease (SNIIRAM);

Considering the referral to the National Institute for Health Data dated January 7, 2019 for approval of a simplified procedure pursuant to Article 54-V of the Data Protection Act;

Having regard to the opinion of the expert committee for research, studies and assessments in the field of health (CEREES) dated December 14, 2017; After having heard Mrs Valérie PEUGEOT, commissioner, in her report, and Mrs Nacima BELKACEM, Government Commissioner, in his observations, Makes the following observations:1. The Commission was seized on January 7, 2019 by the National Institute for Health Data (INDS) with a request for transformation into a reference system of the procedure approved by it in its deliberation No. 2018-134 of April 12, 2018 approving conditions for making available the generalist sample of beneficiaries (EGB) and the thematic databases called datamarts of the national health insurance inter-regime information system (SNIIRAM);

2. This reference document relates to the description and the guarantees of procedure allowing the provision for their processing of the data of the generalist sample of the beneficiaries (hereinafter EGB) of the National inter-regime information system of the health insurance (SNIIRAM), component of the National Health Data System (SNDS).

3. The SNIIRAM EGB is a sample drawn 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.

4. 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 dashboards on the biology and pharmacy. These datasets are included in the scope of this standard.

5. In accordance with the provisions of the third paragraph of Article 54-II of the Data Protection Act, sets of health data presenting a low risk of impact on privacy may be made available with a view to their processing under conditions previously defined by a repository, without the authorization provided for in article 64 of the aforementioned law being required.

6. Since SNIIRAM is a component of the National Health Data System (SNDS), the Commission recalls, as a preliminary point, that 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 SNDS data for the purposes described in Article L. 1461-1 V of the Public Health Code (prohibited purposes);

- the obligation for the persons referred to in Article L. 1461-3 II of the Public Health Code to entrust the processing of data to a design office or research laboratory that has made a commitment to comply with the reference system including the criteria of confidentiality, expertise and independence, set by the decree of July 17, 2017 or to demonstrate that the methods of implementation of the processing make any use of the data for one of the prohibited purposes impossible;
- compliance with the safety baseline applicable to the SNDS, set by the order of 22 March 2017;
- the principle of transparency provided for in Article L. 1461-3, II of the Public Health Code: transmission of the protocol, the declaration of interests and the results to the INDS.⁷ In accordance with the applicable legislative and regulatory provisions, the data concerned being personal health data, not directly identifying, collected on a compulsory basis and intended for the services or establishments of the State, the information of the persons concerned, as to the possible reuse of their data and the procedures for exercising their rights, is ensured by a statement appearing on the website of health or medico-social establishments, health insurance organizations as well as on media allowing it to be brought to knowledge of people, in particular posters in premises open to the public or documents given to them. The rights of access, rectification and opposition are exercised according to the conditions defined in article R. 1461-9 of the public health code with the director of the body managing the compulsory health insurance scheme to which the person concerned is attached.

Resolves:⁸ The description and procedural safeguards allowing the provision of personal data from the EGB of the SNDS defined by the Commission are as follows: Processing likely to be examined only by the INDS.⁹ The conditions of access defined by this standard apply to processing implemented for the purposes of research, study or evaluations in the field of health, presenting a character of public interest, and for the realization of which only access to the EGB and/or to the SNIIRAM datamarts and dashboards is necessary.

10. Processing that meets the following cumulative conditions is likely to benefit from a single INDS approval: - 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 March 22, 2017 mentioned above;

- no crossing of several potential identifiers, as defined by decree n° 2016-1871 of December 26, 2016 relating to the processing of personal data called the national health data system, is carried out;

- the duration of access to the portal does not exceed 24 months.

Examination by the INDS¹¹. The INDS decides with regard to the following elements:- the purpose of public interest of the research, study or evaluation in the field of health;

- the justification provided by the data controller to demonstrate the scientific relevance of the project;
- the duration of access to the portal for the processing envisaged, which must be limited to the duration necessary to carry out the research, study or evaluation;
- compliance with the legislative requirements applicable to the SNDS and in particular the commitment of the data controller to compliance with paragraph 5 Access to data of the aforementioned security baseline applicable to the SNDS. Access procedure¹². The access request is sent directly to the National Institute for Health Data (INDS) under the same conditions as those provided for the transmission of the research, study or evaluation authorization application file in the planned health field. in article 64 of the Data Protection Act.

13. The INDS notifies the applicant of its decision within 15 working days of receipt of a complete file. If there is no response from the INDS at the end of the 15 working day period, the decision is deemed to be favourable.

14. The INDS may contact the applicant for any additional information if necessary. The approval period is suspended pending additional information.

15. In the event that the INDS 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 section II of chapter IX of the Data Protection Act and informs the applicant. After agreement of the latter, the INDS seizes the CEREES for opinion, then the CNIL for authorization in compliance with the provisions of the Data Protection Act.

Transparency¹⁶. The INDS informs the CEREES and the CNIL at least once a year of the approvals issued under the conditions described in this deliberation.

17. Deliberation no. 2018-134 of 12 April 2018 approving the conditions for making available the generalist sample of beneficiaries (EGB) and the thematic databases called datamarts of the National Inter-Regime Information System of the health insurance (SNIIRAM), is repealed.

18. This reference document relating to the description and the guarantees of procedure allowing the provision for their processing of the generalist sample of beneficiaries (EGB) and the thematic databases called datamarts of the National inter-regime information system de l'assurance maladie (SNIIRAM), presenting a low risk of impact on private life, comes into force the day after its publication in the Official Journal of the French Republic. For The President The Deputy Vice-President

Sophie LAMBREMON