Deliberation 2018-256 of June 7, 2018 National Commission for Computing and Liberties Legal status: In force Date of publication on Légifrance: Tuesday July 17, 2018 the processing of data requiring access by health establishments and federations to data from the PMSI and summaries of passage to emergencies (RPU) centralized and made available on the secure platform of ATIH (MR 005)The National Commission information technology and freedoms,

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;

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

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 July 24, 2013 relating to the collection and processing of medical activity data produced by public or private health establishments with an activity of emergency medicine and the transmission of information resulting from this processing in the conditions defined in article L. 6113-8 of the public health code and for the purpose of monitoring and health safety;

Having regard to the decree of March 22, 2017 relating to the security reference system applicable to the National Health Data System,

After having heard Mrs. Marie-France MAZARS, commissioner, in her report, and Mrs. Nacima BELKACEM, government commissioner, in her observations,

Makes the following observations:

Regulation (EU) No 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 (hereinafter the GDPR) and in particular its article 5, point 2, provides that the data controller must be able to demonstrate that the principles of the regulation are respected.

Article 9, paragraph 4 of the GDPR specifies that Member States may maintain or introduce additional conditions, including limitations, with regard to the processing of genetic data or data concerning health.

Thus, pursuant to the amended law of 6 January 1978 (hereinafter the Data Protection Act), the processing of personal data for the purposes of research, study or evaluation in the field of health, is authorized by the Commission National Computing and Liberties (hereinafter the Commission).

The Commission may approve and publish reference methodologies, under the reference systems mentioned in II of Article 54 of the Data Protection Act, established in consultation with the National Institute for Health Data (hereafter INDS), as well as only with public and private organizations representing the players concerned.

Among the most common treatments is access by healthcare establishments to data centralized by the Technical Agency for Hospitalization Information (hereinafter ATIH) and made available on the ATIH secure platform, that is, data from the Information Systems Medicalization Program (hereafter PMSI) and data from Emergency Department Passage Summaries (hereafter RPU).

The PMSI consists of a synthetic and standardized collection of administrative and medical information within health establishments, public or private, for-profit or non-profit, whose main objectives are to organize hospital care on French territory. (planning) and to finance establishments according to their activity (activity-based pricing). It is increasingly used in hospital epidemiology to understand the factors of variation in care, the supply of care and its adequacy to the needs of populations.

Governed by Articles L. 6113-7 and L. 6113-8 of the Public Health Code (hereinafter CSP), the PMSI was generalized in the 1990s and is now applied regardless of the hospital sector, but with different collection methods depending on the care categories. It includes data on the following activities:

- medicine, surgery, obstetrics and odontology (MCO);
- follow-up and rehabilitation care (SSR);
- collection of medical information in psychiatry (RIM-P);

- hospitalization at home (HAD).

A specific file is used to link all the PMSI data concerning the same patient (ANO file).

PMSI data make it possible to analyze and understand the activity of healthcare establishments in all their dimensions (volume, attractiveness, leakage rate, value, etc.) and to establish comparisons between establishments throughout the country. They thus allow establishments to develop their medical project and territorial projects taking into account their environment, in terms of care and cost, and to meet their legal obligation to analyze their activity (art. L. 6113-7 of the CSP).

The summary of passage to emergencies (RPU) is a standardized collection of medico-administrative data of patients treated by hospital emergency services. It was made compulsory by an order of July 24, 2013. The purpose of this collection is to improve knowledge of the activity of emergency structures and to allow the establishment of a national database on emergencies.

The RPUs are not linked either with the PMSI (which constitutes a separate database), nor between them, so that the different passages of the same patient will not be grouped together in the ATIH national database.

Although of more recent use than the PMSI, the RPUs represent an important source of information on emergencies, which allows analyzes complementary to those carried out from the PMSI.

Facilitating the access of health establishments to this data is also part of the will of the public authorities to improve access to care and the quality of medical care within a framework of control of general expenditure which leads to strengthening hospital reorganizations and to rationalize their financing with regard to their contribution to improving the overall performance of the healthcare offer.

Directly concerned by this objective, the hospital federations which inform, advise, assist and represent health establishments with the public authorities, also need to use ATIH data on a recurring and iterative basis to meet the needs of their members. , whether common or individual.

In view of all these needs, the Commission considered that the framework of a reference methodology was appropriate to facilitate and supervise the numerous data processing operations carried out by healthcare establishments and hospital federations from data held by ATIH .

Given their missions, the federations and establishments carry out a large number of studies that fit into a set of determined purposes corresponding to their missions (for example: evaluation of health pathways or the quality of care, medical-

economic, responses to requests from public authorities, actions with the general public, advice to members, etc.). Data controllers who send a commitment to comply with this reference methodology are authorized to implement processing as long as it meets the conditions provided for by these provisions.

Decides: Title I: DEFINITIONS, DATA CONTROLLERS CONCERNED, SCOPE AND PUBLIC INTEREST

1.1. Definitions

For the purposes of this methodology, the following terms are thus defined:

- personal data: any information relating to an identified or identifiable natural person (hereinafter referred to as the data subject); an identifiable natural person is deemed to be a natural person who can be identified, directly or indirectly, in particular by reference to an identifier, such as a name, an identification number, location data, an online identifier, or to one or more specific elements specific to his physical, physiological, genetic, psychological, economic, cultural or social identity;
- processing: any operation or set of operations carried out or not using automated processes and applied to data or sets of personal data, such as the collection, recording, organization, structuring , storage, adaptation or modification, extraction, consultation, use, communication by transmission, dissemination or any other form of making available, reconciliation or interconnection, limitation, erasure or destruction;
- data controller: the natural or legal person who, alone or jointly with others, is responsible for research, study or evaluation not involving the human person, manages it, checks that its financing is planned and who determines the purposes and means of the processing necessary for it;
- processor: the natural or legal person, public authority, service or other body which processes personal data on behalf of the controller.
- persons responsible for carrying out the study: the natural person or persons who work on the individual data of the PMSI and the RPUs;
- study: research not involving the human person, study or evaluation in the field of health; a study may require the performance of several queries in the database made available on ATIH's secure platform;
- protocol: document indicating in particular the methodology of the study, the purpose of the processing of personal data, the categories of persons concerned by the processing, the origin, the nature and the list of the personal data used and the list of justifications for the use of these, the duration and organizational methods of the study, the method of data analysis, as well

as, when the characteristics of the study so require, the justification for the number of people and the method of observation chosen;

- operational research: data analysis with the aim of optimizing organizations or producing decision-making aids for new organisations.

1.2. Data controllers concerned

Only the following can make a commitment to comply with this reference methodology:

- health establishments (whether public or private, for-profit or non-profit) governed in particular by the provisions of Titles IV and VI of Book I of Part Six of the CSP;

The following federations:

- the French Hospital Federation (FHF);

- the Private Hospital Federation (FHP);

- the Federation of non-profit private hospitals and personal assistance establishments (FEHAP);

- the Unicancer Federation;

- the National Federation of Home Hospitalization Establishments (FNEHAD).

1.3. Processing of personal data included in the scope of this methodology

Only the processing of personal data for the purpose of carrying out studies of a public interest nature and respecting the security, organizational and transparency:

- Data processing can only be carried out on ATIH's secure platform, after the processing manager has signed a data access agreement with ATIH and the individual commitment of each person authorized to comply with the conditions. of use defined by ATIH. No export of personal data is possible outside the ATIH platform. Only anonymous results can be exported;

- The controller appoints a data protection officer and keeps a record of processing activities. The data controller puts in place an authorization policy for its staff authorized to access the data; a protocol must be validated by the data controller before the start of the implementation of the data processing;

- The data controller undertakes not to pursue one of the prohibited purposes, in particular the promotion of the products mentioned in II of article L. 5311-1 of the CSP towards health professionals or health establishments ;

- The data controller registers all the processing carried out within the framework of the reference methodology in a public

directory kept by the INDS. The method and the results obtained are published by the INDS at the end of the processing, according to the procedures provided for in paragraph 6.2 Principle of transparency .

This reference methodology is not applicable to processing:

- requiring an export of personal data outside the secure platform;

- requiring matching with personal data other than those made available by ATIH.

1.4. Public interest and prohibited purposes

Access to personal data from the National Health Data System (SNDS) and its components, including data from the information systems mentioned in Article L. 6113-7 of the CSP, may be authorized to allow processing for study purposes in the public interest.

The processing carried out within the framework of this reference methodology must respond to a reason of public interest, justified by the data controller to the INDS.

Beyond the ban on re-identification of patients, two purposes are expressly prohibited:

1° The promotion of the products mentioned in II of Article L. 5311-1 towards healthcare professionals or healthcare establishments;

2° The exclusion of guarantees from insurance contracts and the modification of contributions or insurance premiums for an individual or a group of individuals presenting the same risk. Title II: PROCESSING RELATING TO THE DATA OF PERSONS CONCERNED BY STUDIES

2.1. Purpose of processing

Only the purposes of studies in the field of health or planning and promotion of the healthcare offer detailed below are covered by the reference methodology:

- comparative evaluation of the care offer: spatial analyses, strategic analyses;

- evolution of care practices, incidence of certain factors in hospitalizations, temporal analyses;

- comparative analyzes of care activities, patient trajectory studies, recruitment pool, future of patients;

- description and analysis of pathologies and patient care pathways in healthcare establishments;

- analysis of the health territory, regional hospital groups (GHT), collaborative studies between establishments within a defined perimeter;

- continuous analysis of comparative evaluations, better adaptation of the care offer, optimization, valuation of stays, creation of management indicators, strategy;

- modeling, simulation, planning, hospital logistics, operational research;

- epidemiological studies;

- medico-economic studies.

2.2. Origin and nature of the data

2.2.1. Origin of personal data

The data must come exclusively from the databases compiled by ATIH under the PMSI and the RPU.

2.2.2. Nature of personal data

Pursuant to Article 5(1)(c) of the GDPR, the data processed must be relevant, adequate and limited to what is necessary in relation to the purposes for which they are processed (principle of data minimization). In this respect, the data controller undertakes to process only the data that is strictly necessary and relevant to the objectives of the study. Therefore, each of the categories of data can only be processed if their processing is justified in the protocol.

The categories of personal data that may be processed are centralized data made available on the secure platform of the Technical Agency for Hospitalization Information (ATIH), in particular on all files in the fields:

- medicine, surgery, obstetrics and odontology (MCO);

- follow-up and rehabilitation care (SSR);

- collection of medical information in psychiatry (RIM-P);

- hospitalization at home (HAD);

- with the possibility of linking all the PMSI data concerning the same patient by means of the ANO file.

In addition, the data from emergency room summaries (RPU), which are made available by ATIH under the same conditions, are also included in the scope of this methodology.

The processing operations included in the framework of this reference methodology relate to national PMSI and RPU data, the maximum historical depth of which is nine years plus the current year.

The geographical area concerned as well as the historical depth of the data consulted are justified in the protocol.

2.3. Recipients of the personal data processed

ATIH's data is made available to the data controller on a secure platform. No export of personal data can be carried out within the framework of this reference methodology.

The data controller keeps up-to-date documents indicating the competent person(s) within it to issue the authorization to access the data, the list of persons authorized to access this data, their respective access profiles and the procedures for allocation, management and control of authorisations.

Only personnel authorized by the data controller may have access to the data processed with regard to their functions and under conditions that comply with the regulations, in particular those relating to the methods of analysis and the role of the doctor responsible for medical information (art. R. 6113-1 to R. 6113-11 of the CSP).

These categories of persons are subject to professional secrecy under the conditions defined by Articles 226-13 and 226-14 of the Criminal Code.

The qualification of authorized persons and their access rights must be regularly reassessed, in accordance with the procedures described in the authorization procedure established by the data controller.

2.4. Publication of results

In accordance with the provisions of the Data Protection Act, the presentation of the results of the data processing cannot under any circumstances allow the direct or indirect identification of the persons concerned.

2.5. Information and rights of the persons concerned by the study

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 the data controllers, the health insurance organizations and on media to bring it to the attention 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 with the director of the body managing the compulsory health insurance scheme to which the person is attached, in accordance with the provisions of article R. 1461-9 of the CSP .

2.6. The duration of the conversation

The personal data of the PMSI and the RPUs cannot be stored outside the secure platform by the data controller, their export being prohibited. Only anonymous results can be exported.

The duration of access to the data in the secure platform must be limited to the duration necessary for the implementation of the processing. When the data controller justifies it, access to the data may be maintained at the end of the study, within the

limit of two years from the last publication relating to the results.Title III: PROCESSING RELATING TO PERSONAL DATA RESPONSIBLE FOR CARRYING OUT THE STUDY

The data processing of the persons responsible for carrying out the study must have the sole purpose of implementing the study and complying with the legal obligations of the data controller.

In particular, the data processed is intended for the management of declarations of interest, their transmission to the INDS if necessary and the management of internal authorization procedures.

The only categories of personal data relating to data subjects that may be processed are the following:

- surname, first name(s), function, access profiles;

- if relevant: professional telephone, postal and/or electronic contact details, employing body;

- training / qualifications ;

- elements necessary for the evaluation of knowledge in order to carry out the study.

The information of the persons concerned as well as the procedures for exercising their rights comply with the principle of transparency provided for in Chapter III of the GDPR.

The personal data of the persons concerned in charge of carrying out the study cannot be kept beyond a period of five years after the end of the study.Title IV: IMPLEMENTATION AND SECURITY

The implementation of personal data processing occurring within the framework of the study is carried out under the responsibility of the data controller, including with third parties acting on his behalf, in compliance with the provisions of Articles 24, 25 , 28, 32 to 35 of the GDPR as well as the decree of March 22, 2017 relating to the security reference system applicable to the SNDS.

ATIH makes the data available on a secure and approved platform within the meaning of the decree of March 22, 2017 relating to the security reference system applicable to the SNDS.

It is based on a secure internet connection (HTTPS protocol) and strong authentication (one-time password generated by a token). Access traceability is ensured and a computer monitoring mechanism records all actions performed by the user.

A workspace on the platform is provided by ATIH so that users can consult the data. Only statistics aggregated in such a way that the direct or indirect identification of persons is impossible can be extracted from the platform.

A copy of all data output is kept by ATIH, which reserves the right to report to the Commission if it becomes aware of

information likely to reveal serious shortcomings.Title V: SUBCONTRACTORS

When the data controller uses one or more subcontractors, he ensures that they provide sufficient guarantees as to the implementation of appropriate technical and organizational measures so that the processing meets the requirements of the GDPR, the Data Protection Act and guarantees the protection of the rights of the person concerned.

A health establishment or a hospital federation responsible for processing may in particular choose another health establishment or a hospital federation as a subcontractor.

The data controller establishes with the subcontractor a contract or another legal act specifying the obligations of each party and containing the provisions of Article 28 of the GDPR. In particular, the contract must provide that the subcontractor:

- only processes data on documented instructions from the data controller and takes all required security measures;

- does not subcontract without the written authorization of the data controller;

- helps the data controller to guarantee compliance with his various obligations (rights of individuals, security of processing, notification of breach, impact analyses, etc.);

- provides the data controller with all the information necessary to demonstrate compliance with its obligations and to enable audits to be carried out;

- immediately informs the data controller in the event of an instruction which, in his opinion, constitutes a violation of the GDPR or the Data Protection Act.

In addition, the subcontractor:

- appoints, where applicable, a data protection officer in accordance with Article 37 of the GDPR;

- keeps a register of the categories of processing carried out on behalf of the data controller, in accordance with Article 30 of the GDPR. Title VI: IMPLEMENTATION OF THE PRINCIPLE OF RESPONSIBILITY

6.1. Formalities

Each controller appoints a data protection officer, pursuant to Article 37 of the GDPR. This data protection officer will in particular be responsible for verifying compliance with the processing implemented according to this methodology.

Data controllers send the Commission a single commitment to comply with this methodology for all the processing operations they implement provided they are carried out in compliance with all the provisions of the methodology. A request for an opinion from the Expert Committee for research, studies and assessments in the field of health (CEREES) is not required.

In accordance with Article 30 of the GDPR, the data controller keeps up to date, within the register of processing activities, the list of processing operations implemented within the framework of this methodology.

6.2. Principle of transparency

The provision of data from the SNDS and its components is designed to account for their use to civil society. To this end, article L. 1461-3 of the CSP makes access to data from the SNDS and its components subject to the communication to the INDS of several elements by the data controller, before and after the studies.

Thus, the data controller undertakes to register the studies carried out within the framework of this reference methodology with the public directory kept by the INDS. 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 INDS of a file containing:

- the protocol, including the justification of the public interest, as well as a summary, according to the model made available by the INDS;
- 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 must be communicated to the INDS with a view to their publication.

The recording of the processing and the transmission of the results are carried out in accordance with the methods defined by the INDS. Title VII: ENTRY INTO FORCE

This reference methodology comes into force as of its publication in the Official Journal.

This deliberation will be published in the Official Journal of the French Republic.

The president,

I. Falque-Pierrotin