

DELIBERATION n°2019-048 of APRIL 11, 2019 National Commission for Computing and Liberties Nature of the deliberation:

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April 11, 2019 on a single decision and authorizing PMSI Strategies to implement automated processing for research, study and evaluation purposes requiring access to national data from the information systems medicalization program (PMSI) and to data from passing summaries aux urgences (RPU) The National Commission for Computing and Liberties, Seizure by the company PMSI Strategies of a request for authorization of automated processing for research, study and evaluation purposes requiring access to data information systems medicalization program, as well as data from emergency room summaries;

Having regard to convention No. 108 of the Council of Europe for on the protection of individuals with regard to the 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 natural persons with regard to the processing personal data and the free movement of such data, and repealing Directive 95/46/EC; Having regard to the Public Health Code, in particular its articles L.6113-7 and L.6113-8; Having regard to the law n° 78-17 of January 6, 1978 modified relating to data processing, files and freedoms, in particular its articles 8-II-8°, 54, 61 and following; Considering the law n°2016-41 of January 26, 2016 modernization of our health system, in particular its article 193; Having regard to Decree No. 2005-1309 of October 20, 2005 as amended, taken for the application of Law No. 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 "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 health establishments or private individuals engaged in emergency medicine and the transmission of information resulting from this treatment under the conditions defined in Article L. 6113-8 of the Public Health Code and for the purpose of monitoring and health security; Having regard to the decree of March 22, 2017 relating to the security reference system applicable to the National Health Data System; Having regard to the opinion of the Expert Committee for research, studies and assessments in the field of health of December 18, 2018; Having regard to the file and its supplements; On the proposal of Mrs Valérie PEUGEOT, commissioner, and after having heard the observations of Ms. Nacima BELKACEM, Government Commissioner, Makes the following observations: Responsible for processing Specialized in the processing and mapping of PMSI data, the company PMSI Strategies offers hospital activity analysis services for health establishments. health. It has developed a tool to study the evolution of the activity of an establishment over several years. On the advisability of using the single decision The

activities of the data controller involve the implementation of several data processing operations of the information systems medicalization program (PMSI) as well as data from emergency room summaries (RPU) intended for the development of hospital activity indicators. for research, study or evaluation purposes. The Commission considered it appropriate, in view of the elements presented in the application file, to authorize the implementation of this processing on the basis of the provisions of Articles 54 IV and 61 et seq. of Law No. 78-17 of 6 January 1978 as amended (hereinafter the "Informatique et Libertés" law), within the framework of a single decision. Health (hereinafter "SNDS"), the Commission recalls that all the legislative and regulatory provisions relating to the SNDS are applicable in this case and in particular the prohibition on using this data for the purposes described in Article L 1461-1 V of the public health code. On the legality of the processing The processing implemented by the company PMSI Strategies is part of its commercial activity. They are necessary for the purposes of the legitimate interests pursued by the data controller, with regard to the very indirectly identifying nature of the data and the guarantees, particularly in terms of the rights of individuals, provided for by the texts governing the provision of SNDS data. This processing is, as such, lawful under Article 6, paragraph 1 point f) of the General Data Protection Regulation (hereinafter "GDPR"). On the purpose of the processing and its nature of interest publicThe purpose of processing requiring access to PMSI and RPU data is to carry out studies intended to analyze, over a period ranging from two to five years, the activity of healthcare establishments, regional hospital groups or groupings of establishments and to enable the comparative evaluation of patient care practices with a view to optimizing and adapting the supply of care (helping with strategic decisions). The Commission considers that the purpose of the processing is determined, explicit and legitimate, in accordance with article 5 paragraph 1 point b) of the GDPR. and li bertés". On the categories of data processedThe Commission recalls that the data controller must only process, for each of the processing operations implemented within the framework of this single decision, the data that is strictly necessary and relevant to the purposes of the processing. In addition to the specific file allowing to link all the PMSI data concerning the same patient ("ANO" file), the data concerning the following activity are necessary to carry out these studies: medicine, surgery, obstetrics and odontology (MCO). In addition, RPU data made available by ATIH may be processed as part of these studies. provided that they are disseminated by ATIH. The Commission recalls that, in accordance with Article 30 of the GDPR, the data controller must keep up to date, within the list of processing activities, the list of processing operations implemented within the framework of this single decision. In addition, the adequacy, relevance and limited nature to what is necessary with regard to the purposes for which the data are processed, the geographical area

concerned and the historical depth of the data consulted must be justified in this register for each processing implemented in the framework for this single decision.

On the data retention period The personal data of the PMSI and the RPU's cannot be stored outside the platform of the Secure Data Access Center (hereinafter "CASD") 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, which cannot be more than three years, from the date of access.

On the publication of the results The Commission recalls that, when the result of the data processing is made public, the direct or indirect identification of the persons concerned must be impossible, in accordance with article 56 of the law "Informatique et Libertés". The results of the studies carried out within the framework of this single decision may be sent to public and private health establishments.

On the categories of data recipients Only the data controller and the persons authorized by him have access to the data in the framework of this single decision. 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 authorizations. 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 methods described in the authorization procedure established by the data controller.

On the information and rights of the persons The information of the persons concerned, as to the possible reuse of their data and the methods of exercise of their rights, is ensured under the conditions provided for in Article R. 1461-9 of the Public Health Code, as well as by a statement appearing on the website of the data controller, health insurance organizations and on media allowing it to be brought to the attention of individuals, in particular posters in premises open to the public or documents given to them. Access rights, 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 Public Health Code.

On data security and traceability of actions The implementation of personal data processing within the framework of the study is carried out under the responsibility of the data controller, including 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. The data will be made available to the data controller via the secure access provider designated by ATIH, namely CASD. Only data resulting from anonymization processes, such that the direct or indirect

identification of persons is impossible, may be subject to extraction. by opinion no. 05/2014 on anonymization techniques adopted by the Article 29 group (G29) on April 10, 2014. Failing this, if these three criteria cannot be met, a study of the risks of re-identification must be carried out. On the principle of transparency 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, Article L. 1461-3 of the CSP makes access to data from the SNDS and its components subject to the communication to the National Institute of Health Data (INDS) of several elements by the data controller, before and after the studies. Thus, the data controller undertakes to register with the public directory kept by the INDS all the studies carried out within the framework of this single decision. This registration, to be carried out by the data controller or the person acting on his behalf, before the start of the processing, is accompanied by the transmission to the INDS of a file comprising: the protocol, including the justification of the interest public, as well as a summary, according to the model made available by the INDS; the declaration of interests of the controller, in relation to the purpose of the processing. At the end of the studies, the method and the results obtained must be communicated to the INDS for publication. The recording of the processing and the transmission of the results are carried out in accordance with the procedures defined by the INDS. In addition, the Commission takes note of the commitment of the company PMSI Strategies to transmit annually to the ATIH the list of the processing carried out at based on PMSI and RPU data. On external audits The data controller must carry out an independent external audit at the end of the three-year period in order to ensure compliance with the principles laid down by law, in particular compliance with prohibited purposes. This audit must cover the purposes pursued and the use by the data controller of the results of the studies carried out. An audit report must be sent to the chairman of the SNDS audit committee provided for by the Data Protection Act. Authorizes, in accordance with this deliberation, the company PMSI Strategies to implement the processing operations described above for a period three years, with the obligation, on the one hand, to submit a report to the Commission at the end of this period and, on the other hand, to carry out an independent external audit. For the President The Vice- Deputy ChairmanSophie LAMBREMON