

Deliberation 2020-023 of February 6, 2020 National Commission for Computing and Liberties Nature of the deliberation: Single decision Legal status: In force Date of publication on Légifrance: Saturday July 11, 2020 Deliberation n° 2020-023 of February 6, 2020 bearing single decision and authorizing the company PIERRE KARAM CONSEIL SANTÉ to implement automated processing for research, study and evaluation purposes requiring access to national data from the information systems medicalization program (PMSI)

(Request No. 918249 v1)

The National Commission for Computing and Liberties, Seizure by the company PIERRE KARAM CONSEIL SANTÉ of a request for authorization of automated processing for research, study and evaluation purposes requiring access to the national data of the program of medicalization of information systems; 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 April 27, 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 Health Code public, in particular its articles L. 6113-7 and L. 6113-8; Considering the law n° 78-17 of January 6, 1978 modified relating to data processing, files and freedoms, in particular its articles 66, 72 and following ; Considering the law n° 2016-41 of January 26, 2016 of modernization of our health system, in particular its article 193; Having regard to decree n° 2016-1871 of December 26, 2016 relating to the processing of personal data called National health data system; Having regard to decree n° 2019-536 of 29 May 2019 taken for the application of law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms; Having regard to the decree of March 22, 2017 relating to the security reference system applicable to the National Data System of health; Having regard to the opinion of the Expert Committee for research, studies and evaluations in the field of health of December 23, 2019; Having regard to decision DU-2018-001 authorizing the company PIERRE KARAM CONSEIL SANTÉ to implement implementation of automated data processing aimed at carrying out studies allowing the construction of indicators of activity, positioning and efficiency of health establishments, requiring access to data from the PMSI, a component of the National Data System (SNDS), for the years 2012 to 2018, with ATIH (authorization request no. 918249); Considering the file and its supplements; On the proposal of Mrs. Sophie LAMBREMON, commissioner, and after hearing the observations of Mrs. Nacima BELKACEM, Government Commissioner, Makes the following observations: Responsible for processing Created in 2011, the company Pierre Karam Conseil Santé (the company PKCS) is

a company specializing in the analysis of medico-economic data. In particular, it has developed a tool intended to analyze the activity, performance and positioning of establishments based on data from the program for the medicalization of information systems (hereinafter PMSI). On the appropriateness of recourse to the single decision The activities of the PKCS company involve the annual implementation of around one hundred and thirty PMSI data processing operations. The processing operations described come under the processing authorization regime 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 66 IV, 72 et seq. of Law No. 78-17 of 6 January 1978 amended (hereinafter the Data Protection Act), within the framework of a single decision. On the application of the provisions relating to the SNDSL The PMSI data being taken from one of the databases making up the National Health Data System (below s 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 processing and the conditions for processing data concerning health The processing carried out by the company PKCS is part of its commercial activity. They are necessary for the purposes of the legitimate interests pursued by the data controller, taking into account the very indirectly identifying nature of the data and the guarantees, particularly in terms of personal rights, provided for by the texts governing the provision of SNDS data. lawful under Article 6(1)(f) of the General Data Protection Regulation (hereinafter GDPR). ts, necessary for scientific research purposes, fulfill the condition provided for in Article 9 paragraph 2 point j) of the GDPR allowing the processing of data concerning health. On the purpose of the processing and its nature in the public interest Processing requiring a access to PMSI data are intended to carry out studies for the construction of indicators of activity, positioning, course, efficiency, relevance and activity projection of health establishments. These indicators have aims to enable establishments to meet health needs, improve their performance, develop their practices, describe their organization and their activity, understand the cooperation between the different establishments and anticipate future developments. 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. theirs, it considers that the processing has a purpose of public interest, in accordance with Article 66 I of the Data Protection Act. Finally, the Commission notes that the users of the tool developed by the company PKCS undertake , via the general conditions of use, not to pursue prohibited purposes based on the aggregated PMSI data indicators made available to them. On the categories of data processed The

Commission recalls that the data controller must not process, for each of the processing implemented within the framework of this single decision, only the data strictly necessary and relevant to the objectives of the processing. The data concerning the following activities are necessary for the performance of these studies: medicine, surgery, obstetrics and odontology (MCO); follow-up and rehabilitation care (SSR). The treatments included in the framework of the single decision relate to the national data of the PM IS for the years 2013 to 2021, provided that they are disseminated by ATIH. , the list of processing implemented in the context 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 PMSI personal data 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. effective data. On the publication of results The Commission recalls that, when the result of data processing is made public, the direct or indirect identification of the persons concerned must be impossible, in accordance with Article 68 of the Data Protection Act. The results of the studies carried out within the framework of this single decision may in particular be sent to the regional health agencies, to the Interministerial Committee for performance and modernization of the care offer, to public and private health establishments, to hospital groups territory as well as consulting firms. On the categories of data recipients Only the controller and the persons s authorized by him have access to the data within 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 ion with the data controller via the secure access provider designated by ATIH, namely the CASD. or indirect, of persons is impossible, may be subject to extraction. the three criteria defined by Opinion No. 05/2014 on anonymization techniques adopted by the Article 29 group (G29) on April 10, 2014. Failing that, if these three criteria cannot be met, a study re-identification risks must be carried out. In this respect, the Commission notes that the results concerning fewer than ten stays are systematically excluded and will not be made accessible. However, it draws the data controller's attention to the fact that the deletion of results containing small numbers may not be sufficient to meet the three criteria defined by the above-mentioned opinion no. 05/2014 and that a complete analysis of its anonymisation processes must be carried out, accompanied by a regular reassessment of the risks of re-identification. 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 society civil. 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 Health Data Platform of several elements by the data controller, before and after the studies. .Thus, the data controller undertakes to register with the public directory maintained by the Health Data Platform 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 processing, is accompanied by the transmission to the Health Data Platform of a file comprising: the protocol, including the justification for 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 processing. At the end of the studies, the method and the results obtained must be communicated to the Health Data Platform for publication. Recording of processing and transmission of results are carried out in accordance with the procedures defined by the Health Data Platform. vis-à-vis civil society through the annual publication on its website of the list of processing implemented within the framework of the single decision as well as the list of communications and publications produced. The

Commission also recalls that at the At the end of the three-year period, a report containing in particular the list of analyzes carried out within the framework of the single decision as well as the methodology followed within the framework of the analyzes must be sent to the Commission. On external audits The 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 particular respect for 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 PKCS to implement the processing operations described above for a period of 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, the external audit report. For the President

Deputy Vice-President Sophie LAMBREMON