DELIBERATION n°2019-122 of OCTOBER 3, 2019National Commission for Computing and LibertiesNature of the deliberation: AuthorizationLegal status: In force Date of publication on Légifrance: Tuesday, November 05, 2019Deliberation n° 2019-122 of October 3, 2019 on a single decision and authorizing ALTAO to implement automated processing for research, study and evaluation purposes requiring access to national data from the information systems medicalization program (PMSI)(Request No. 918449)The Commission National Data Protection Authority, Entry by the company Altao of an application for authorization of automated processing for research, study and evaluation purposes requiring access to national data from the medical systems medicalization program 'information; 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 the regulation t (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, in particular its articles L. 6113-7 and L. 6113-8; Having regard to law n° 78-17 of January 6, 1978 as amended relating to data processing, files and freedoms, in particular its articles 66, 72 and following; Considering the law n $^\circ$ 2016-41 of January 26, 2016 of modernization of our health system, in particular its article 193; Having regard to the 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 May 29, 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 System of Do Health data; Having regard to the opinions of the Expert Committee for research, studies and assessments in the field of health of October 3, 2018, November 20, 2018 and December 18, 2018; Having regard to the opinion of the Institute national health data of July 8, 2019 on the public interest presented by the processing planned by the company Altao; Having regard to deliberation no. 2019-065 of May 9, 2019 referring to the National Institute of Health Data for an opinion on the character of public interest presented by the processing envisaged by the company Altao: Considering the file and its supplements; On the proposal of Mrs. Sophie LAMBREMON, commissioner, and after having heard the observations of Mrs. Nacima BELKACEM, commissioner of the Government, Formulates the following observations: Responsible for processing Created in 1993, Altao is an audit, consulting and support company for healthcare establishments. In order to be aware of the activity of the establishments it advises, it carries out studies based on data from the program for the medicalization of information systems (hereinafter "PMSI"). On the advisability of using the single decision The activities of

the Altao company involve the implementation of around thirty PMSI data processing operations. The processing operations described fall under the processing authorization regime for research, study or evaluation purposes. of this processing on the basis of the provisions of articles 66 IV, 72 and following of the law n ° 78-17 of January 6, 1978 modified (hereinafter law "data processing and freedoms"), within the framework of a single decision. On the application of the provisions related to the SNDSL Since PMSI data comes from one of the databases making up the National Health Data System (hereinafter "SNDS"), the Commission recalls that all the legislative and regulatory provisions relating to the SNDS is 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 lawfulness of processing and the conditions for processing data concerning healthThe processing implemented by Altao is part of its commercial activity. They are necessary for the purposes of the legitimate interests pursued by the data controller, taking into consideration 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. Article 6, paragraph 1 point f) of the General Data Protection Regulation (hereinafter "GDPR"). Furthermore, the Commission considers that these processing operations, necessary for scientific research purposes, fulfill the condition laid down 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 character of public interestin addition to the creation a repository of practices for coding medical acts and main diagnoses made available to healthcare establishments via the Altadim tool, the processing operations requiring access to PMSI data are intended to carry out studies intended to build establishment activity indicators thanks to: the analysis of their ambulatory activity in order to follow its evolution over several years; the analysis of hospital care needs in order to know their positioning on the territory; analyzing their business for optimization; the analysis of the journey of their patients. 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. Furthermore, subject to compliance with the conditions mentioned in the According to the opinion of the National Institute for Health Data of July 8, 2019, it considers that the processing serves a purpose of public interest, in accordance with Article 66 I of the "Informatique et Libertés" law. On the categories of data processed The 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 objectives of the processing. Data concerning the following activities are necessary in carrying out these studies: medicine, surgery, obstetrics and odontology (MCO); follow-up and rehabilitation care (SSR); home hospitalization (HAD). The

treatments included in the framework of the single decision relate to national PMSI data from the years 2013 to 2020 (with a rolling historical depth of five years), provided that they are disseminated by ATIH. work 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 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. data. 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 68 of the law "Informatique et Libertés The results of the studies carried out within the framework of this single decision." may in particular be sent to the healthcare establishments advised by Altao. On the categories of data recipients Only the data controller and the persons authorized by him have access to given in the context 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 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 methods defined by the INDS. In addition, the Commission takes note of the commitment of the Altao company to implement additional transparency efforts vis-à-vis of civil society through the annual publication on its website of the list of processing carried out within the framework of the single decision as well as the aggregated results of the studies carried out using PMSI data. The Commission also recalls that 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 in the context of the analyzes must be sent to the Commission. 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 "Informatique et Libertés" law.

Authorizes, in accordance with this deliberation, the company Altao 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, to carry out an independent external audit. For the PresidentThe Deputy Vice-PresidentSophie LAMBREMON