French Republic

SÉNAT

EUROPEAN AFFAIRS COMMITTEE

Paris, 5 July 2023

# POLITICAL OPINION

## POLITICAL OPINION ON THE PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE EUROPEAN HEALTH DATA SPACE

The European Affairs Committee of the French Senate,

Having regard to the Treaty on the Functioning of the European Union, in particular Articles 16, 114, 168 and 290,

Having regard to Regulation (EU) N° 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers,

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 of personal data and on the free movement of such data, and repealing Directive 95/46/EC,

Having regard to Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC,

Having regard to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 19 February 2020, “A European Strategy for Data”, COM(2020) 66 final,

Having regard to Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724,

Having regard to Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148,

Having regard to the Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data, COM(2022) 68 final,

Having regard to Senate European Resolution No 140 (2022-2023) of 16 June 2023 on the Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data,

Having regard to Senate Information Report “Regulation on data, new stage in the single European market for data” (No 597, 2022-2023) - 11 May 2023 - by Florence Blatrix Contat, André Gattolin and Catherine Morin-Desailly, produced in the name of the European Affairs Committee,

Having regard to Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014,

Having regard to Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU,

Having regard to the Communication from the Commission to the European Parliament and the Council, of 3 May 2022, “A

European Health Data Space: harnessing the power of health data for people, patients and innovation", COM(2022) 196 final,

Having regard to the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM(2022) 197 final,

Having regard to the Impact Study accompanying the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, SWD(2022) 131 final,

**Ensuring that the Proposal for a Regulation is advantageous for patients**

- *on the advisability of processing health data for primary use*

Whereas the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (hereafter Proposal for a Regulation) provides that this data may be processed for primary use, i.e. to supply health services intended to assess, maintain or restore the state of health of the natural person to whom the data refers;

Considering the advantage for patients of having their health data available in electronic format to ensure its portability;

Whereas an electronic health record (EHR) that includes patients' health data is useful for their care by a health professional;

Whereas it is desirable that patients from one Member State should be able to provide health professionals in another Member State with access to their health data when necessary;

Whereas this access will be via the MyHealth@EU data-sharing infrastructure;

Whereas Article 13 of the Proposal for a Regulation states that Member States may provide a translation service for this data;

Whereas the use of electronic health records may contribute to a more efficient health system;

Supports the principle of processing health data for primary use in the interest of patients;

Hopes that MyHealth@EU will from now on include a translation service funded by the Union to facilitate access by health professionals from all Member States to their patients' EHRs;

- *on the advisability of processing health data for secondary use*

Whereas secondary use of health data can bring benefits to medical research;

Whereas easier sharing of Europeans' health data would promote the development of treatments for rare diseaeses;

Whereas health data is important for drawing up policies in response to public health emergencies within the meaning of Regulation (EU) 2022/2371, such as the COVID-19 pandemic;

Whereas the Proposal for a Regulation allows for this data to be processed for secondary use, i.e. for purposes listed exhaustively in Article 34 of the Proposal for a Regulation and including in particular scientific research related to the health or care sectors;

Supports the principle of processing health data for secondary uses in the interest of patients and for reasons of public interest in in the area of health;

Considers it necessary to recall that the secondary use of health data should be limited to purposes that have a sufficient link with public health or social security and that this should be specified in points f and g of Article 34(1) of the Proposal for a Regulation;

- *on the funding needed to create a European Health Data Space*

Whereas a significant amount of investment is needed to create a European Heath Data Space;

Whereas the Commission has committed a contribution from the Union budget of €810 million to support the European Health Data Space, funded via the EU4Health Programme, the Horizon

Europe Programme, the Digital Europe Programme and the Connecting Europe Facility;

Whereas patients provide their data free of charge;

Whereas health professionals will have to dedicate time to completing their patients' EHRs and may have to make investments to enhance the security of the health data that they hold;

Whereas health data may be processed for secondary use in order to generate commercial profit or for purposes of public interest;

Whereas under the terms of Article 42 of the Proposal for a Regulation, health data access bodies and data holders will be able to charge fees and compensation respectively for making electronic health data available for secondary use;

Whereas Regulation (EU) 2022/868 provides that these fees are intended to be used to cover the costs of making data available and that public sector bodies may draw up a list of categories of users for whom data can be made available for reuse for a discounted fee or free of charge;

Calls on the European Commission to propose allocating a larger European budget to the creation of the European Health Data Space;

Hopes that part of these funds can be used to help health professionals finance, on the one hand, their investment in digital health data processing tools and in the security of the data processed using these tools, and on the other hand, their training in the use of these tools and completion of EHRs, which should not be to the detriment of care;

Supports the setting up of a fee system to cover the costs incurred when making data available, both for health data access bodies and for data holders;

Recommends that this system should be able to adjust the amount of fees according to whether the purpose of the health data processing is to generate commercial profit or not;

Believes that reflection is needed on the establishment of a mechanism whereby access by pharmaceutical companies to health data for secondary use is conditional on their reinforced commitment to the objectives of the Pharmaceutical Strategy, in particular addressing unmet medical needs and ensuring that medicines are accessible and affordable;

- *on the provision of health care services*

Whereas the Proposal for a Regulation has as its legal basis Articles 16 and 114 of the Treaty on the Functioning of the European Union (TFEU) and these Articles do not address questions of health;

Whereas Article 168(7) of the TFEU states that the organisation and delivery of health services and medical care fall within the competence of the Member States;

Considers that the legal basis adopted for the Proposal for a Regulation does not allow it to address the conditions for the delivery of health services, especially telemedecine;

Requests therefore that Article 8 of the Proposal for a Regulation be deleted;

**Ensuring the primacy of rules to protect personal data**

- *On the nature of health data*

Whereas Regulation (EU) 2016/679 (GDPR) includes a definition of personal health data and the Proposal for a Regulation puts forward a new definition with a broader scope;

Whereas anonymised personal health data would then become non-personal data, and would therefore no longer be protected by the GDPR since non-personal data as defined by the GDPR includes all data that is not personal, including health data;

Whereas it is sometimes difficult, in practice, to differentiate between personal and non-personal data;

Whereas Article 44 of the Proposal for a Regulation recalls the data minimisation principle established by the GDPR;

Whereas, in the terms of the same Article, health data access bodies should provide data in an anonymised format;

Whereas, even when rendered anonymous, some data may nevertheless allow an individual to be reidentified, especially in the case of rare diseases;

Whereas this data may also be provided in pseudonymised format when the user submits a justified request;

Requests that the definition of personal health data that appears in the Proposal for a Regulation be aligned with that of health data;

Calls for further clarification of the definition of non-personal health data;

Requests that, when non-personal health data is inseparable from personal health data, the provisions of the GDPR should apply when it is processed;

Hopes that the provision of pseudonymised health data remains the exception;

Calls for all necessary measures to be taken to ensure that users cannot reidentify individuals from health data provided, whether in anonymised or pseudonymised format;

Hopes that, in the event of an attempt at reidentification, a health data user will be prohibited access to such data for a period of five years;

- *On consent*

Whereas Article 9(1) of the GDPR stipulates that the processing of personal health data shall be prohibited;

Whereas Article 9(2) of the GDPR nevertheless sets out conditions under which this prohibition shall not apply, in particular when the person concerned has given explicit consent (point a) or when the data processing is for reasons of public interest or for scientific research (points i and j);

Whereas, at the same time, Article 6(1) of the GDPR determines the conditions for the lawfulness of processing,

especially when the person concerned has given consent (point a) or again when the processing is necessary for compliance with a legal obligation (point c) or is necessary for the performance of a task carried out in the public interest (point e);

Whereas, under Article 168(7) of the TFEU, the delivery of health services falls within the competence of the Member States;

Believes that the choice of whether or not to use EHR systems falls within the sole competence of the Member States;

Considers therefore that, while the Proposal for a Regulation stipulates that the Member States will have to guarantee the interoperability of health data and EHR systems, responsibility will nevertheless lie with the Member States for deciding whether or not the processing of health data for primary use requires patient consent;

Requests that the consent of the individuals concerned should be necessary to allow the processing of their health data for secondary use;

Recommends that this consent can be considered as granted when the natural persons concerned, after having been duly informed, do not express any objection to the processing of their health data;

*- On the rights of natural persons when their health data is processed*

Whereas the Proposal for a Regulation includes a right to rectification of health data, in accordance with the GDPR;

Whereas the GDPR is aimed at the “further processing” of data and not “processing for secondary use”;

Whereas Article 34 of the Proposal for a Regulation lists the authorised purposes for which health data can be processed for secondary use and Article 35 lists the prohibited purposes;

Whereas Article 38(2) of the Proposal for a Regulation stipulates that health data access bodies are not obliged to provide the specific information required under Article 14 of the GDPR to the persons concerned when their health data is processed for secondary use;

Recommends that it be specified that health professionals will be required to provide a reasoned response to patients' requests for rectification of their health data;

Hopes that it will be specified that processing health data for secondary use should be considered equivalent to further processing, within the meaning of the GDPR;

Considers that, to avoid any confusion, it is necessary to specify that purposes not mentioned in Article 34 of the Proposal for a Regulation are prohibited and to delete Article 35;

Requests that Article 14 of the GDPR be applied in the context of processing health data for secondary use, in order to ensure that data subjects who so wish are provided with individualised information on the use of their data;

**Allowing the flow of data in a secure framework**

- *On the choice of data processed*

Whereas one of the purposes of the Proposal for a Regulation is to facilitate the flow of health data within the European Union;

Whereas the wider the scope of data processed, the higher the cost of processing;

Whereas the efficient processing of health data implies quality data in sufficient quantities;

Whereas Article 5 of the Proposal for a Regulation establishes the priority categories of health data to be processed for primary use, while Article 33 of the Proposal for a Regulation establishes the categories of health data that may be processed for secondary use;

Whereas the flow of health data implies the interoperability of data and of the different EHR systems in the Member States;

Whereas the definition of data holders given in the Proposal for a Regulation does not expressly include social security bodies;

Recommends that the results of medical tests, such as electrocardiograms and lung function tests carried out in a medical setting should be added to the list of priority categories of personal electronic health data that should be processed for primary use;

Hopes that health data from wellness applications is not included in the list of categories of data intended for secondary use because of doubts as to its quality;

Requests that electronic health data from clinical trials be provided only after phase III trials are completed and only on condition that it is protected;

Considers that a data holder may refuse to disclose data from a clinical trial if they demonstrate that this may violate trade secrets and the confidentiality of intellectual property rights;

Recommends that social security bodies be included in the list of data holders that should make available the data that they hold in the context of processing for secondary use;

- *On access to data for primary use*

Whereas Article 4 of the Proposal for a Regulation provides for health professionals to have access to the electronic health data of their patients in the context of processing for primary use;

Whereas patients will be informed when a health professional accesses their data;

Whereas the Proposal for a Regulation provides for the possibility of patients restricting access by health professionals to some of their data but these health professionals will be informed of the existence of this data and may get access to it when this is necessary in order to protect the vital interests of the person concerned or of another natural person;

Recommends that health professionals only access their patient’s health data when they need it in order to establish their diagnosis or propose treatment, without prejudice to cases where this is necessary in order to protect the vital interests of the person concerned or of another natural person;

Calls for clarification of the conditions under which patients will be informed when health professionals get access to their data;

Welcomes the possibilities offered to patients to restrict access to data;

Recalls that the shared medical record is in no way intended to replace communication between health professionals and their patients in the context of a consultation;

- *On access to data for secondary use*

Whereas Article 36 of the Proposal for a Regulation states that Member States should designate a body responsible for granting access to electronic health data for secondary use and authorising its processing;

Whereas Article 46 of the Proposal for a Regulation states that, if permission is not expressly given within four months, the data permit is deemed to be issued by the responsible body;

Whereas Article 49 of the Proposal for a Regulation also provides for a single data holder to process data access applications directly for data they hold, without the intervention of the health data access body;

Whereas, finally, Article 48 of the Proposal for a Regulation provides for public sector bodies and Union institutions, bodies, offices and agencies to access data without a data permit;

Considers that a data access application should only be granted on the express authorisation of the body responsible for this access;

Requests, therefore, that the provisions for the tacit granting of a data access application that has not been examined within the time limit be deleted;

Considers also that no data access application should be allowed to be filed directly with the single data holder and that Article 49 should therefore be deleted;

Requests that public sector bodies and Union institutions, bodies, offices and agencies should also file a data access application which should be assessed by a health data access body, except in the event of a public health emergency as defined in Regulation (EU) 2022/2371;

- *On data security*

Whereas health data processing for secondary use should be conducted in a secure processing environment;

Whereas MyHealth@EU and HealthData@EU are not databases grouping together the health data of European patients, rather, the former is a data exchange tool, and the latter a dataset catalogue;

Whereas there are many risks affecting health data security;

Whereas disclosure of their health data can have a great impact on patients;

Whereas the Proposal for a Regulation stipulates that EHR systems will be subject to self-certification carried out by manufacturers, distributors or importers;

Whereas non-European legislation may have extraterritorial scope;

Supports the use of secure processing environments for secondary use processing of health data;

Welcomes the fact that the Commission does not intend to compile the health data of all European patients in the same database;

Requests that EHR systems be certified by a third party, namely a notified body registered at European Union level;

Requests that the hosting of electronic health data, and associated services, be carried out within the European Union by a European company in which cumulated direct or indirect foreign holdings do not constitute a majority;

Recalls that under the terms of the GDPR, personal data can only be transferred to a third country if the level of data protection is at least equivalent to that offered in the European Union;

Considers that the transfer of electronic health data to a third country should be subject to the consent of the person concerned which may consist in the absence of opposition to the processing of their data for secondary use;

**Implementing shared governance**

- *Excessive use of implementing acts and delegated acts*

Whereas the Proposal for a Regulation states that the Commission may adopt various implementing acts in the framework of an advisory procedure, in accordance with Article 4 of Regulation (EU) No 182/2011;

Whereas, under Article 290 of the TFEU, the Commission may be delegated the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act;

Whereas Articles 12, 50 and 52 of the Proposal for a Regulation allow the Commission to adopt, in the context of an advisory procedure, implementing acts determining the technical specifications of MyHealth@EU, secure processing environments and HealhData@EU respectively;

Whereas Article 42 of the Proposal for a Regulation authorises the Commission to adopt by means of an implementing act, in the context of an advisory procedure, principles and rules for fee policies and fee structures;

Whereas the purpose of Article 55 is to empower the Commission to adopt, by means of implementing acts, in the context of an advisory procedure, the minimum information elements that data holders must provide pertaining to the datasets that they hold;

Whereas Articles 5, 33, 41 and 45 are intended to empower the Commission to adopt delegated acts to amend, respectively, priority categories of personal health data for primary use processing, categories of personal electronic health data for secondary use processing, the duties of data holders, and the information to provide for a data access application for secondary use;

Considers that the implementing acts provided for in Articles 12, 42, 50, 52 and 55 should be adopted in the framework of the

examination procedure set out in Article 5 of Regulation (EU) No 182/2011;

Requests that the Commission should not amend by means of delegated acts the elements mentioned in Articles 5, 33, 41 and 45 of the Proposal for a Regulation;

- *For shared and consistent governance*

Whereas Article 64 of the Proposal for a Regulation sets out the establishment of a European Health Data Space Board and two groups with joint responsibility for data processing pertaining to MyHealth@EU and HealthData@EU respectively;

Whereas acts relating to the establishment, management and functioning of the European Health Data Space Board will be adopted by the Commission by means of an implementing act in the framework of an advisory procedure, in accordance with Article 4 of Regulation (EU) No 182/2011;

Whereas the Proposal for a Regulation states that each Member State should designate a digital health authority responsible for implementing the rights and obligations of patients in the context of processing their health data for primary use;

Whereas the Proposal for a Regulation states that each Member State should designate one or more bodies responsible for access to data in the context of processing for secondary use;

Whereas health professionals, data holders, patients and Member States play an essential role in the implementation of a European Health Data Space;

Whereas Article 51 of the GDPR establishes an independent supervisory authority responsible for ensuring compliance with the provisions of this Regulation;

Considers that the implementing acts provided for in Article 64 of the Proposal for a Regulation should be adopted by means of an examination procedure, in accordance with Article 5 of Regulation (EU) No 182/2011;

Asks that patients' associations, healthcare professionals' associations and data holders be represented, at national level, in digital health authorities and health data access bodies;

Asks also that these associations and data holders be represented on the European Health Data Space Board;

Calls for conditions guaranteeing effective cooperation between the entities that will be designated in accordance with the Regulation, once it is enforced, and the supervisory authorities provided for in Article 51 of the GDPR.