

FRENCH REPUBLIC

Ministry of Health, Families,
Autonomy and Persons with
Disabilities

Decree No. _____ of [DATE] amending certain provisions of the Public Health Code relating to the hosting of personal health data
NOR: SFHL2514369D

Target audience: patients, natural or legal persons responsible for processing personal health data, providers contributing to the delivery of a hosting service for personal health data, certification bodies.

Purpose: the decree modifies certain provisions of the public health code relating to the hosting of personal health data. It specifies the obligations of the hosting provider regarding the storage of personal health data in the territory of a Member State of the European Union or party to the agreement on the European Economic Area, as well as regarding the information of its current or potential customers concerning the measures taken to address the risks of transfer of this data or unauthorised access to it by third countries outside the European Union.

Entry into force: the text enters into force the day after its publication, except for organisations holding a valid health data hosting provider (Hébergeur de Données de Santé - HDS) certificate on the date of entry into force of this decree. For the latter, Article 3 recalls the conditions for renewing the certificate.

Application: This decree is issued pursuant to Article 32 of Law No. 2024-449, of 21 May 2024, aimed at securing and regulating the digital space.

The Prime Minister,

On the report of the Minister of Health, Families, Autonomy and Persons with Disabilities,

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Having regard to Regulation (EU) No 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 (General Data Protection Regulation);

Having regard to Directive 2015/1535 of the European Parliament and of the Council, of 9 September 2015, laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;

Having regard to the Public Health Code, in particular Article L. 1111-8 thereof;

Having regard to Law No. 78-17 of 6 January 1978, as amended, on data processing, data files and individual liberties;

Having regard to Law No. 2024-449 of 21 May 2024, as amended, on securing and regulating the digital space, in particular Article 32 thereof;

Having regard to Decree No. 2018-137 of 26 February 2018, concerning the hosting of personal health data, in particular Article 3 thereof;

Having regard to the Opinion of the National Council of the Order of Nurses dated [DATE];

Having regard to the Opinion of the National Council of the Order of Pedicurists-Podiatrists dated [DATE];

Having regard to the Opinion of the National Council of the Order of Midwives dated [DATE];

Having regard to the Opinion of the National Council of the Order of Dental Surgeons dated [DATE];

Having regard to the Opinion of the National Council of the Order of Physicians dated [DATE];

Having regard to the Opinion of the National Council of the Order of Massagists dated [DATE];

Having regard to the Opinion of the National Council of the Order of Pharmacists dated [DATE];

Having regard to the Opinion of the National Commission for Information Technology and Civil Liberties dated [DATE];

Having regard to Notification No. XX sent on [DATE] to the European Commission;

Having heard the Council of State (Social Affairs Section),

Hereby decrees:

Article 1

Subsection 2 of Chapter I of Title I of Book I of Part One (regulatory) of the Public Health Code is amended as follows:

1. In paragraph 6 of Article R. 1111-9, after the words: “safeguarding health data”, the following words are added: “, in particular electronic archiving”;

2. After Article R. 1111-9, an Article R. 1111-9-1 is inserted as follows:

“*Art. R. 1111-9-1. - I. -* When the activity of hosting personal health data on digital media as defined in Article R. 1111-8-8 involves the storage of this data, it is implemented exclusively in the territory of a Member State of the European Union or party to the agreement on the European Economic Area, without prejudice to the cases of remote access mentioned in section II.

“*II. -* In the event that the service offered by the hosting provider or one of its subcontractors involves remote access to the data mentioned above in section I from a country that is not a member of the European Union or a party to the Agreement on the European Economic Area, this access is based on an adequacy decision of the European Commission taken pursuant to Article 45 of the 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 or, failing that, on one of the appropriate guarantees provided for in Article 46 of the same regulation. If this access is based on one of the appropriate safeguards, the hosting contract provided for in section I of Article L. 1111-8 mentions the absence of an adequacy decision, details and documents the appropriate safeguards put in place to govern this remote access, as well as, where applicable, any other measure to ensure a level of data protection equivalent to that guaranteed by European Union law. ’;

3. In Article R. 1111-11:

a) In paragraph 4 of section I, the words: “data portability” are replaced by the words: “access, rectification, erasure and portability of data, as well as restriction of processing and objection to processing, where applicable, under the conditions provided for in Articles 15 to 21 of Regulation (EU) No 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”;

b) In paragraph 8 of section I, after the word: “hosted”, the following words are added: “as well as, where applicable, information relating to possible remote access from a country

outside the European Union or the European Economic Area mentioned in section II of Article R. 1111-9-1”;

c) After point 14 of section I, the following point 15 is added:

“15. If the hosting provider or one of its subcontractors is subject to the legislation of a third country that does not ensure an adequate level of protection, within the meaning of Article 45 of the aforementioned regulation (EU), of 27 April 2016, the following information:

- the list of non-European regulations under which the hosting provider or one of its subcontractors involved in providing the hosting service is required to allow a transfer of data or unauthorised access to personal health data, within the meaning of Article 48 of the same regulation;
- the measures implemented by the hosting provider to mitigate the risks of data transfer or unauthorised access to personal health data caused by these non-European regulations;
- a description of the residual risks of transfer of personal data or unauthorised access to such data that would remain despite these measures;

If the hosting provider is not subject to any legislation of a third country requiring it to transfer data or to grant unauthorised access to personal health data within the meaning of Article 48 of the aforementioned regulation (EU), it shall indicate this in the contract and provide proof”;

d) The article is supplemented by a section III worded as follows:

“III. - The hosting provider shall make public and update the mapping of transfers of personal health data to the territory of a State not belonging to the agreement on the European Economic Area, of possible remote access to this data and of the risks of access not authorised by Regulation (EU), of 27 April 2016, mentioned in section I, according to the terms specified in the certification reference mentioned in section I of Article R. 1111-10. ”.

Article 2

This decree shall enter into force on the day following its publication, with the exception of paragraphs 2 and 3 of Article 1, which shall enter into force within six months of the date of publication.

Article 3

The Minister of the Economy, Finance and Industrial, Energy and Digital Sovereignty, the Minister of Health, Families, Autonomy and Persons with Disabilities, and the Minister of Culture are each responsible, within their respective areas of competence, for the implementation of this decree, which will be published in the *Official Journal* of the French Republic.

Signed on [Date]

By the Prime Minister:

The Minister of Health, Families, Autonomy and Persons with Disabilities,

Stéphanie RIST

The Minister of the Economy, Finance and Industrial, Energy and Digital Sovereignty,

Roland LESCURE

The Minister of Culture,

Rachida DATI