



Notification Number: 2017/343/F

Decree on the hosting of personal health data and amending the French Public Health Code

Date received : 20/07/2017

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Issue of comments by : Italy

Message

Message 002

Communication from the Commission - TRIS/(2017) 01922

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2017/0343/F

No abre el plazo - Nezaahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késések - Ma' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201701922.EN)

1. Structured Information Line

MSG 002 IND 2017 0343 F EN 20-07-2017 F NOTIF

2. Member State

F

3. Department Responsible

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Délégation à la stratégie des systèmes d'information de santé

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4. Notification Number

2017/0343/F - SERV

5. Title

Decree on the hosting of personal health data and amending the French Public Health Code

6. Products Concerned

Services for hosting personal health data collected during prevention, diagnosis, treatment, or social or socio-medical monitoring

7. Notification Under Another Act

- Directive 2006/123/EC on services in the internal market
- Directive 98/48/EC Information Society services only
- Requirements reserving access to particular suppliers
- The new Article R1111-8-8 of the French Public Health Code created by the draft Decree defines the activity of hosting personal health data and restates that providers of health data hosting services must be certified.

Article 3 of the draft Decree defines the conditions for obtaining prior authorisation to host personal health data in digital format (sub-section 2 'Hosting of personal health data in digital format subject to certification').

8. Main Content

This draft Decree is issued pursuant to Article L1111-8 of the French Public Health Code, as amended by Order No 2017-27 of 12 January 2017 on the hosting of health data. It clarifies in particular that the hosting of personal health data collected during prevention, diagnosis, treatment, or social or socio-medical monitoring must be performed by a certified or approved hosting provider.

More specifically:

- Article 1 II defines the scope of hosting activities subject to certification;
- Article 3 defines:
 - the scope of certification for hosting personal health data in digital format;
 - hosting provider obligations, particularly those that must be listed in the hosting contract agreed with the customer;
 - the conditions for certifying providers of hosting services for personal health data: only hosting providers certified by a certification organisation accredited by the French Accreditation Body [comité français d'accréditation] or the national accreditation body of another Member State of the European Union that is a member of the European co-operation for accreditation and has signed multilateral mutual recognition agreements covering the certification in question, may offer services for hosting personal health data in digital format.

Hosting providers are certified based on a certification standard drawn up by the public interest group mentioned in Article L1111-24 of the French Public Health Code (Shared Healthcare Information Systems Agency) approved by order of the Minister for Health after consultation with the French Data Protection Authority [Commission nationale de l'informatique et des libertés].



9. Brief Statement of Grounds

Given the particular sensitivity of health data, the certification procedure aims to ensure that the hosting provider has sufficient safeguards to ensure the security and confidentiality of health data. It is fully in line with 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, which recommends setting up certification mechanisms.

This new certification procedure is also well-known in the industrial world. It is transparent and predictable (based on a set of standards that is public and hence can be audited) and more flexible (it is scalable through the implementation of a life cycle for the set of standards), under reduced timeframes for hosting providers. This new procedure also takes into account the potentially international nature of hosting (hosting providers under international law, hosting activities exercised outside the national territory).

Certification is justified in order to protect fundamental rights as recognised by the Court of Justice as an overriding requirement in the general interest as regards the right to privacy and the right to the protection of personal data. Its mechanism is implemented to safeguard the security and confidentiality obligations incumbent on providers of hosting services for personal data, particularly pursuant to the provisions of Law 78-17 of 6 January 1978 as amended on information technology, data files and civil liberties, and more broadly under the above-mentioned European Regulation No 2016/679 on personal data protection. This certification is established to provide natural persons with a guarantee that their privacy and medical confidentiality will be respected. It should reduce the risk that personal data will be breached by strengthening the conditions for hosting such data.

In conclusion, this certification is appropriate, necessary and proportionate to the objective pursued, insofar as it applies only to providers of hosting services for personal health data collected during prevention, diagnosis, treatment, or social or socio-medical monitoring, which is particularly sensitive data and inherent to the private lives of individuals.

10. Reference Documents - Basic Texts

Reference(s) to basic text(s): Order No 2017-27 of 12 January 2017 on the hosting of personal health data

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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13. Confidentiality

No

14. Fiscal measures

No

15. Impact assessment

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16. TBT and SPS aspects

TBT aspect

No - the draft has no significant impact on international trade.

SPS aspect

No - the draft is neither a sanitary nor phytosanitary measure.

European Commission

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