

BRE-JBZ

From: Kaai, Geran
Sent: vrijdag 3 april 2015 15:58
To: Verweij, Ellen
Subject: FW: Letter to JHA and Health Attachés - Data protection regulation - Focus on HEALTH DATA
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From: BRE-JUS
Sent: dinsdag 10 december 2013 09:45
To: Kaai, Geran; Bos, Nicoline
Subject: FW: Letter to JHA and Health Attachés - Data protection regulation - Focus on HEALTH DATA

From: BRE-VWS
Sent: maandag 9 december 2013 14:08
To: BRE-JUS
Subject: FW: Letter to JHA and Health Attachés - Data protection regulation - Focus on HEALTH DATA

Ook voor jullie dames?

Gr.
 Ilse

From: [redacted] [mailto:[redacted]]
Sent: maandag 9 december 2013 14:02
To: [redacted]
Subject: Letter to JHA and Health Attachés - Data protection regulation - Focus on HEALTH DATA

Dear Justice and Home Affairs Attachés,
 Dear Health Attachés,

Please find enclosed a letter from [redacted], CPME President, and Ms [redacted], CPME Secretary General, on the General Data Protection Regulation.
 The letter highlights the concerns of medical doctors with regard to the impact of the Regulation on health data.

With kind regards,

[redacted]

[redacted]
 EU Policy advisor

CPME

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before printing, please check that it is necessary... let us protect the environment!



09 December 2013

General Data Protection Regulation - COM(2012) 11 final

Dear Justice and Home Affairs Attachés,
Dear Health Attachés,

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

The legislative proposal of the Commission on Data Protection being cross-sectoral, the collection, storage and transfer of health data will be profoundly impacted by its implementation.


After the Parliament's vote on 21st October 2013, we urge the Council to support the following considerations:

- Data protection law should in no way trump medical law and its ethical approach to **consent**. We urge you to refuse the unethical approach of the Parliament which introduces in Article 81.1.b(new) that *"the consent may be given for one or more specific and similar researches"*.
- An exemption to the **right to be forgotten** should be foreseen for direct treatment purposes. This is currently not the case since article 17.3.b, only foresees an exemption for public health purposes. Article 17.3.b should read *"for health purposes in accordance with Article 81"*.
- The introduction of a **Data Protection Officer (DPO) and Impact Assessments** should not create unsustainable burden for physicians. Parliament's proposal to set to 5000 data subjects a year the limit by when a DPO should be hired and an impact assessment conducted would be unsustainable for small medical practices in Europe.

We call on the European Union and its Member States to ensure patients the best data protection possible and to protect medical practice in Europe. We sincerely believe this is crucial to the provision of high quality care and we hope you will engage to reach these objectives.

Sincerely,


CPME President


CPME Secretary General



➤ **Consent requirements - Articles 4, 6, 7 and 81**

The act of seeking and agreeing to treatment should automatically be considered as consent of the subject for his data to be processed for the purpose of his or her medical treatment.

In the context of processing data for research purposes (such as data used in biobanks or similar repositories), the informed consent of the research subject should be sought. This particularly applies to identifiable data. Identifiable data should not be collected, stored or transferred before the informed consent has been provided by the research subject. There are cases when this obligation to obtain the informed consent might be impracticable or even impossible, but the use of the concerned data has then to be explicitly approved by an independent research ethics committee. Articles 26 and 32 of the widely accepted and used World Medical Association Declaration of Helsinki are unambiguous in this regard¹.

We therefore have extremely grave concerns about the adoption by the Parliament of a new paragraph 1.b. in Article 81 stating that: *"Where the data subject's consent is required for the processing of medical data exclusively for public health purposes of scientific research, the consent may be given for one or more specific and similar researches. However, the data subject may withdraw the consent at any time."* This paragraph is extremely dangerous since it paves the way for researchers not to fully inform the research subjects of the characteristics of a study, and even to use their identifiable data without formally informing them. While this paragraph could be applied to anonymised data, it is absolutely unethical for the use of identifiable data. This will inevitably lead in practice to legal uncertainties at the detriment of the research subjects' rights to control their personal data. Data protection law is not to replace medical law and its approach to consent which is based on the ethical concept of autonomy.

➤ **Right to be forgotten – Article 17**

The right to be forgotten is essential to the protection of data subjects' rights. However some exemptions are needed for certain specific and well-defined cases. Practicing physicians need to retain patients' data for confidentiality and liability obligations, e.g. cases where a physician is challenged in Court, complaint procedures, obligation for the physician to document the treatment provided, etc. This has been well recognised in the proposed regulation.

However, the proposal of the Commission does not recognise the need for a physician to retain patients' data for purposes of preventive and occupational medicine, medical diagnosis, provision of care and treatment or for the management of healthcare services. Article 17.3.b. in fact only recognises the necessity to retain health data *"for reasons of public interest in the area of public health"*, and not for direct treatment provision. We are concerned that this could weaken the capacity for physicians to store medical records, whether they are paper based or electronic health records, hence putting the patients at a risk. Despite our requests to the Parliament to clarify this

¹ <http://www.wma.net/en/30publications/10policies/b3/index.html>



point, no substantive change has been introduced, we do hope the Council will take this into account.

➤ **Data Protection officer and data protection impact assessment – Articles 33 and 35**

A significant number of European physicians practice in small and medium sized medical practices. We are worried that the creation of **impact assessments** (Article 33) and **data protection officers** (Article 35) constitute in the future heavy financial and administrative burden for physicians. While the Commission's proposal provided that small and medium sized enterprises would benefit from special consideration through delegated acts, the text of the Parliament leaves it unclear whether medical practices will be concerned by these provisions. Whereas specific provisions for health care have been introduced in Art. 32a Para. 2 d) and Art. 35 Para. 1 d) it is unclear whether medical practices fall under the scope of such provisions with the consequence of being exempted from the obligation to conduct an impact assessment and to designate a data protection officer.

Indeed, Article 32(a)(new) categorises "*specific risks*" arising from processing operations that would require the conduct of impact assessments. It is unclear if these specific risks would at all apply to medical practices, and if yes, which one exactly would apply. Similarly, Article 35 as modified by the Parliament, does not seem to exclude medical practices from having to designate a data protection officer. Article 35 (1)(d) concerns controllers which have as their "*core activity*" the processing of special category of data listed in Article 9(1). The core activity of medical practices is not to process health data, but to treat patients. Therefore this provision appears not to apply. The question is of whether Article 35(1)(b) will remain applicable to medical practices, since most physicians process more than 5000 "data subjects" a year.

We warn against any kind of bureaucratic complexity that would be unsustainable for medical practices and impede physicians to deliver good quality care to their patients.