KBV

KASSENÄRZTLICHE
BUNDESVEREINIGUNG

EUROPEAN HEALTH DATA SPACE

OPINION OF THE KBV

(GERMAN NATIONAL ASSOCIATION OF STATUTORY HEALTH INSURANCE PHYSICIANS)

ON THE PROPOSAL OF THE EUROPEAN COMMISSION FOR A REGULATION ON THE EUROPEAN HEALTH DATA SPACE COM(2022)197 DATED 03 MAY 2022

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FOR COMMENTS

Comments on the contents of the individual provisions have been provided below. If there are no comments, then the regulation has been welcomed by the Kassenärztliche Bundesvereinigung (KBV) or it does not affect the interests of the outpatient physicians or outpatient psychotherapists or KBV is neutral towards the proposal for the regulation.

For readability reasons, only one form of personal pronouns was used for the most part. It also includes all other forms.

GENERAL INFORMATION

On 03 May 2022, the European Commission published a proposal for a regulation on the formation of a European Health Data Space (hereinafter, briefly: EHDS). In principle, the KBV welcomes the goals of the EHDS to give patients better access to their health data and to also make electronic access to relevant patient information easier for physicians and other health professionals.

Trust and medical confidentiality

From the perspective of the KBV, a European Health Data Space can be successful only if it builds upon the trust of the patients and health services. The protected space to which only physicians and patients have access must also be guaranteed within the framework of the EHDS. A primary prerequisite is therefore the guarantee of medical confidentiality, which must not be compromised by the formation and technical implementation of EHDS. Physicians and psychotherapists are first and foremost committed to the wellbeing of their patients and, in this respect, also to the trustees of their health data. A third party's usage proposition of this data, whatsoever the intention, must not put this basis of trust into question.

Effort and cost

It is necessary to ensure that the impact of the EHDS regulation on the primary use of electronic health data does not result in the impairment of the healthcare processes; this is especially in view of the fact that physicians are to be required to systematically register treatment data in an electronic format in an electronic patient file (EHR – Electronic Health Record). This is associated with additional cost and administrative effort for physicians and psychotherapists. This effort must be kept as low as possible. Secure automated processes must be guaranteed in the same way as financial regulations which balance the cost incurred. Neither of the prerequisites is currently met. Governments are therefore required to budget the massive financial investments required for the digitisation of the healthcare system.

Definitions

It is also noteworthy that the proposal for the regulation lacks important definitions that are essential for its understanding. Furthermore, the content of some provisions needs to be explained. This applies in particular to the term EHR within the meaning of Article 2 Para. 2 lit m. From the overall view, an unbiased interpretation of the text of lit c and lit i reveals an almost boundless breadth of the term, which in the future would be gathered by access (or scheduling) services, even communication services, and finally would cover the entire previous subject matter of the regulation on telematics infrastructure in addition to electronic patient files. If this understanding is taken as a basis, any use of health data (starting with appointment portals) would be normatively transferred into the new system with its requirements.

Legislative powers of the EU Commission

In almost a third of the proposed provisions in the draft regulation, the EU Commission grants itself extensive powers to enforce delegated legislative acts and implementing acts. The number of delegated legislative acts and implementing acts make it difficult to predict the full impact of the proposal. A better assessment of the legal, social, technical, and financial consequences for physicians, other health professionals, patients, and the healthcare system is necessary as a whole, especially to evaluate whether the implementation costs will be proportionate to the benefits. This applies particularly to the Member States which have already invested considerable personnel and financial resources in digital health systems, including electronic patient records.

Introduction of the EHDS in Germany

In Germany, for outpatient doctors and psychotherapists to accept the EHDS, it would be crucial for the proposed rules to be compatible with the existing national or planned technical stages of the electronic patient records and the telematics infrastructure. A cost-intensive conversion would entail considerable additional efforts and additional costs. Financial support for physicians and other healthcare providers, all of whom are obligated to connect to the national electronic healthcare system and to the EHDS, would therefore be crucial. Modules for medical practice management systems in particular will need to be adapted and financed.

The EHDS regulation and the services associated with it do not reveal any direct added values for healthcare – particularly with regard to the national work involved in the development of electronic infrastructure and the applications supported by it. The provisions of the EHDS regulation do not appear to be synchronised with the national efforts. However, this synchronisation is absolutely essential.

The individual, selected provisions relevant for the KBV are discussed below.

COMMENTS IN DETAIL

LEGAL BASIS

The EU Commission bases its proposal for the EHDS regulation on Article 16 of the Treaty on the Functioning of the European Union (TFEU) (data protection) as well as Article 114 of the TFEU (establishment of the internal market). There is no reference to health protection pursuant to Article 168 of the TFEU. In particular, the provisions on primary use have implications on medical treatment, healthcare, and the health systems of the individual Member States. The regulation should therefore be urgently considered in terms of health protection. In particular, the provisions must be checked to ascertain whether there is any friction with the responsibility of the Member States for their healthcare systems in accordance with Article 168 Para. 7 of the TFEU.

ARTICLE 2 DEFINITIONS

The definitions applicable for the purpose of the regulation are set out in Article 2 Para. 1.

The definitions contained are incomplete. Definitions which are essential for understanding the proposal for the regulation are missing, such as definitions for the terms “anonymisation” and “pseudonymisation” which are central to secondary use, or that for the terms “health data” and “data holder”. To achieve uniform standards with the General Data Protection Regulation and to maintain legal certainty during implementation, a uniform understanding is indispensable.

ARTICLE 3 RIGHTS OF NATURAL PERSONS IN RELATION TO THE PRIMARY USE OF THEIR HEALTH DATA

Paragraph 1 Right of access to electronic health data

According to Article 3 Para. 1 of the proposal, natural persons have the right to access their personal electronic health data, which is processed in the context of primary use of electronic health data, immediately, free of charge and in an easily readable, consolidated and accessible format.

If the primary documentation of the outpatient physicians is to be accessed, it is necessary to ensure that there is no risk of loss of data in the physician’s medical practice. The technical infrastructure of the physician’s medical practice must not be compromised by this, and access by unauthorised persons to the patient’s health data stored in the medical records must be prevented in a technically secure manner.

Furthermore, the provision of information from the physician’s treatment documents must be possible with little effort. Therefore, only such data which is structured and in an interoperable format should be processed in an EHR. To ensure this, rules must be established to ensure that a gradual, low-effort export of treatment-relevant information is possible in line with the progress made in creating data interoperability. For implementation on a national level, the KBV offers to provide support in identifying treatment-relevant fields of application and processes so that they can be supported by interoperable medical information objects.

Paragraph 3 Restriction of the right of access

According to Article 3 Para. 3, access to the data may be restricted if this is necessary in light of patient safety and ethical principles for the protection of natural persons. In this case, access will be delayed for a limited period of time until a health professional can appropriately communicate and explain to the natural person information which could have a significant consequences with regard to their health.

This provision does not go far enough. Significant therapeutic reasons or other significant rights of third parties could preclude an inspection of and therefore also access to the patient records, as currently governed in § 630g Para. 1 of the BGB (German Civil Code). In European law, the rights and freedoms of third parties are also protected in Article 15 Para. 4 of the GDPR (General Data Protection Regulation). Particularly in the context of psychotherapeutic treatment, but also in pediatric and adolescent medicine and, generally in the context of medical treatment, unrestricted access to patient data could entail significant therapeutic consequences and result in risk to the health and safety of the patients. The restrictions from § 630g Para. 1 of the German Civil Code must therefore also be reflected in European law.

Paragraph 4 Retroactive provision of health data ("legacy databases")

Article 3 Para. 4 provides that the Member States can require that the existing personal health data from a period prior to the application of the regulation be provided at a later time.

A retroactive obligation to register electronic health data entails significant efforts for the physicians and is therefore rejected.

Paragraph 7 Right to rectification of electronic health data

In Article 3 Para. 7, the obligation of the Member States provides that natural persons could readily apply online for a rectification when exercising their right to rectification.

This rectification process must be technically secure and must not breach the limits of Article 16 of the GDPR so that – as before – a right to rectification does not apply to medical records and findings of the physician.

Paragraph 8 Right to transmit electronic health data and obligation to read

Sentence 1

According to Article 3 Para. 8 Sentence 1, natural persons have the right to give access to or request a data holder from the health or social security sector to transmit their data to a data recipient of their choice from the health or social security sector, immediately, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that data holder.

It is necessary to ensure that the burden on the physician's medical practice is kept as low as possible.

Sentence 4

According to Article 3 Para. 8 Sentence 4, natural persons have the right that other healthcare providers read and accept the data if it is transmitted or made available.

This specification can result in significant delays in a patient's treatment, especially if the data is particularly extensive. This is particularly true if data is transmitted which is not relevant to the concrete upcoming treatment of the patient. As before, physicians and patients should decide together which data is important for the treatment. An obligation to read all data is rejected.

ARTICLE 4 ACCESS TO HEALTH DATA BY HEALTH PROFESSIONALS

Article 4 deals with access by health professionals to personal electronic health data.

The provisions must not interfere in the existing documentation obligations of the treating physicians provided for at various levels under national law.

ARTICLE 5 ELECTRONIC HEALTH DATA FOR PRIMARY USE

According to Article 5 Para. 2, the EU Commission is empowered to adopt delegated acts to add to, modify or remove the list of priority categories of electronic health data and also the main characteristics of the priority categories according to Annex I.

It is necessary to ensure that the proposed possibility of amending the categories is designed appropriately and is compatible with the national planning for the development and expansion of the infrastructure. Modification of priority categories is one of the most essential decisions and should therefore be done in close consultation with the Member States. The KBV therefore refuses to be able to implement this in the form of a delegated act by the EU Commission.

ARTICLE 7 COMPULSORY REGISTRATION OF HEALTH DATA IN EHR SYSTEMS

According to Article 7, Member States must ensure that health professionals register the categories mentioned in Article 5 for personal electronic health data in an EHR system.

During implementation, it is important to have a process that is as automated as possible, with which the burden on the outpatient physicians is kept as low as possible.

ARTICLE 8 CROSS-BORDER TELEMEDICINE

Article 8 describes telemedicine in the context of cross-border healthcare.

This provision must not lead to the development of commercial health service providers which are under the influence of non-specialist financial investors. The protection of the independence of medical decisions and the maintenance of a trusting doctor-patient relationship must continue to be guaranteed. Under no circumstances must a pan-European company displace self-employed physicians through provider dominance. Finally, even in case of telemedicine services, any follow-up treatment by physicians on site must also be considered. This provision should therefore be removed.

ARTICLE 14 ET SEQQ. HERE: SELF-CERTIFICATION OF EHR SYSTEMS

The proposal for the regulation states that providers of EHR systems should themselves establish compliance with the interoperability and security requirements laid down in the regulation.

However, mandatory self-certification systems cannot meet the security requirements of the General Data Protection Regulation. The KBV therefore rejects the possibility of self-certification and supports the recommendation of the EDPB-EDPS (European Data Protection Board and European Data Protection Supervisor) to subject the EHR systems to a conformity assessment procedure by third parties. This ensures that the process of exporting documented treatment data and importing it to an IT system in the physician’s medical practice is made possible without compromising the processes of the medical practice and patient treatment.

ARTICLE 31/32 DATA FROM WELLNESS APPLICATIONS

Articles 31 and 32 provide information on data from wellness applications in the EHDS, both in terms of its voluntary labeling and registration.

In the KBV's view, the processing of data from wellness applications should be removed from the proposal for the regulation. Health data which is generated by wellness applications and other digital health applications is not subject to the same requirements of data quality as the data generated by medical devices. Furthermore, these applications generate a large volume of data and can be highly invasive since they relate to each step which an individual takes in daily life and do not provide any approach of systematically separating data and valuable medical information relevant for the treating physician. Even if health data could actually be separated from other data, conclusions can be easily drawn on dietary habits and other habits, as a result of which particularly sensitive information could be disclosed.

ARTICLE 33 SECONDARY USE OF HEALTH DATA

Paragraph 1 Minimum categories of health data and conditions of secondary use

According to Article 33 Para. 1 lit a, data holders are required to provide the EHR for secondary use and must accordingly cooperate with the competent authorities according to Article 41, otherwise fines may be imposed according to Article 43. Data holder is defined in very broad terms according to Article 2 Para. 1 lit y. It can therefore be assumed that, for example, the databases of the health insurance funds are also affected. Any restrictions on the use of data in the ePA or in the electronic patient summaries could be avoided by means of this direct access.

Physicians as data holders should be exempted from the obligation to provide health data for secondary use, since direct contributions for the care do not preclude the need for massive structural adjustments in the medical practices. Furthermore, the principle of one-time transmission should be applied, i.e. natural or legal persons must transmit data only once to public bodies or providers of electronic patient records within the scope of the regulation for primary use. Public bodies in turn should take the necessary steps to use this data for secondary purposes – including across borders, in which the data protection rules and other restrictions must be noted. This is necessary to avoid duplications and unnecessary efforts for physicians, especially in individual private practices, of providing data again. It is necessary to rule out that patient-related health data is transmitted by the physician's medical practices to the access bodies, as the proposal for the regulation still provides. A provision must be urgently found here as to how pseudonymisation can be implemented in medical practices before transmission to the access body.

Paragraph 2 Exceptions for micro enterprises

So far, only micro enterprises with up to 10 employees and whose annual turnover does not exceed 2 million euros are to be exempted from the obligation to provide data for secondary use.

If, despite the disproportionately high efforts required, an obligation is to be introduced for medical practices, the KBV supports an exception for small enterprises with up to 50 employees and whose annual turnover does not exceed 10 million euros. Thus duplications and unnecessary efforts of physicians can be avoided with regard to providing data again. In these cases, too, it is necessary to ensure that any expenses that are incurred by the affected parties are compensated in full by tax-financed funds.

Paragraph 5 Patient autonomy in the context of secondary use of health data

It is unclear how this provision must be interpreted.

In the context of secondary use, the proposal for the regulation does not stipulate that the affected patients must be informed before any intended transfer of their data, nor does it stipulate a right of objection.

It is not clear from the provision stipulated in Article 33 Para. 5 whether the secondary use must take place only with the patient's consent. This provision could create the possibility of granting direct access to the personal data stored in the ePA, even if access were to be restricted nationally.

The KBV warns that the need for compliance with medical confidentiality, professional secrecy, and requirement to obtain consent must not be superseded by the processing activity for secondary purposes. Patients may hesitate to make information available or even to consult their treating physician if they fear that this information will not remain confidential.

Paragraph 7 Modification of data categories for secondary use

According to Article 33 Para. 7, the EU Commission is empowered to modify the categories of electronic data to be made available for secondary use in the form of delegated acts.

From KBV's perspective, this is an important decision which is reserved to the legislator. Paragraph 7 must therefore be removed (see above in Article 5 relating to primary use).

ARTICLE 38 OBLIGATIONS OF THE DATA ACCESS BODIES TOWARDS NATURAL PERSONS

According to Paragraph 3, the access body for health data should be able to inform natural persons or the health professionals responsible for them of their findings.

However, the fundamental right to not be informed – equally important as the right to information – is called into question if this data also contains information about a disease or a risk of disease. National regulations are therefore required to clarify whether, how and to what extent health data is provided on express request.

ARTICLE 46 PERMIT PROCEDURE AND FICTITIOUS PERMIT IN THE EVENT OF A NON-DECISION

It is worth noting that Article 46 stipulates hardly any specifications for the procedure to be followed. The Member States should therefore be granted the necessary flexibility.

The fictitious permit contained in Paragraph 3 is unacceptable. According to this, a data permit is deemed to be issued after two months with the possibility of extending it by another two months if there is no decision from the access body until then. This fictitious permit for electronic data after expiry of the specified period is extremely susceptible to abuse and should be removed without substitution.

ARTICLE 49 DIRECT ACCESS TO INDIVIDUAL DATA HOLDER

Article 49 provides for the possibility of directing access applications to individual data holders, too. This provision, too, would be susceptible to abuse, since the allocation of health data to individual persons and groups of persons can be easier based on the geographical reference and a small number of data records.

The access body for health data should therefore also be responsible for data requests to individual data holders and should then be able to refuse data permits if it was possible to allocate health data to a specific person despite pseudonymisation.

ARTICLE 72 DATE OF APPLICATION

Article 72 lays down the date of application and transition periods.

The KBV considers the timeline stipulated in the proposal for the regulation to be too ambitious. Experience in extensive projects such as the ordinance on medical devices has shown how difficult EU-wide implementation is. Particularly in view of the fact that digitisation has progressed at different rates in the individual Member States, the application date for large sections of the regulation should be reconsidered one year after the adoption.

SUMMARY

From KBV's perspective, the guarantee of medical confidentiality, the protection of privacy and personal data, and the consent of the individual are crucial to the processing of electronic health data in the EHDS. Furthermore, it is necessary to ensure that the additional tasks that physicians will need to carry out do not result in disproportionately high administrative efforts and costs.

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The Kassenärztliche Bundesvereinigung (KBV) represents the political interests of approx 183,000 physicians and psychotherapists involved in providing care under a health insurance scheme at a federal level. It is an umbrella association of 17 Kassenärztliche Vereinigungen (KVen) (Association of Statutory Health Insurance Physicians) which ensure that 73 million individuals covered by statutory health insurance in Germany receive outpatient medical care. The KBV concludes agreements with the statutory health insurance schemes and other social insurance carriers relating to, for example, the remuneration of general practitioners and psychotherapists and to the range of services provided by statutory health insurance schemes. The KVs and the KBV are public bodies as institutions of medical self-administration.