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Proposal for a Regulation on the European Health Data Space (COM(2022) 197 final)

Opinion of the German Social Insurance dated December 7th 2022

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and the national associations for statutory health and long-term care insurance and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have all joined forces to form the "German Social Insurance - European working group" in view of their common European policy interests.

The association represents the interests of its members vis-à-vis the bodies of the European Union (EU) as well as other European institutions and advises the relevant participants in the context of current legislative proposals and initiatives.

As part of Germany's statutory insurance system, health and long-term care insurance, pension insurance and accident insurance provide effective protection against the consequences of major life risks.

I. Preliminary remark

By the proposal for a Regulation on the European Health Data Space, presented on 3 May, the European Commission[1] has presented the first common European data space in a specific area, thus implementing a major cornerstone of its European Union (EU) data strategy.

The umbrella organisations of the German Social Insurance welcome the Commission's goal of establishing a common European Health Data Space (EHDS). It offers the opportunity for added value for patients and social security systems, not only through digital, cross-border access to health data for medical treatment, but also in particular through their meaningful pooling for research and policy-making purposes.

[1] Hereafter only "Commission"

The EHDS is a project of enormous scale. For this to be successfully implemented, the different levels of digitisation in the Member States must be aligned and infrastructure compatible with electronic health data must be created. The technical requirements necessary for this should lead to the least possible adjustments in the Member States, for example with regard to the existing IT systems as well as the applicable national legal framework.

The Member States are responsible for the design of the social security systems. Therefore, the establishment of the EHDS should be carefully done with the aim of integrating existing and proven structures. The focus of the EHDS must be on providing value-added health services to patients. Due to the far-reaching effects on national structures and in order to ensure a practically feasible EHDS, the Member States should also be given a sufficient degree of control and say in the adoption of the necessary specific implementing acts and delegated acts.

The social insurance institutions in Germany generate and process health data to optimise the care of the insured, thus acting as key players. They are not only data owners, users and providers, but also jointly responsible for the development of the national telematics infrastructure in the healthcare sector. Thus, they are particularly affected by the regulatory content of the EHDS. Therefore, the German Social Insurance Institutions should be heard by the relevant political and legislative institutions, so as to be able to contribute their expert knowledge to the formation process. Only if viable and practical solutions are worked out together with the Member States and the institutions responsible for implementation at national level can a functional EHDS emerge.

With the present opinion, the German Social Insurance would like to contribute to the discussion on the proposed Regulation on the EHDS not only with general comments, but also with concrete proposals for amendments.

II. General remarks

1 Harmonisation of existing national infrastructure

Social and health structures differ greatly in the Member States, for example in the level of digitisation, technical governance structures or data protection conventions. In the opinion of the German Social Insurance, good European networking in the EHDS can only succeed if the existing national telematics infrastructure is optimally integrated, the necessary technical and infrastructural supplements are created and the interventions in the national level are reduced to the necessary minimum. Duplicate and multiple structures should be avoided due to any divergent and contradictory specifications, high adaptation efforts and double financing.

Depending on their specific design, uniform European formats and specifications, identification and authentication procedures require extensive adaptations of the current telematics application structures as well as, if necessary, the integration of social insurance institutions that have not been involved so far. In the context of primary data use, the Commission's approach of making available in the electronic health record the entire primary documentation of all service providers as well as the data of the health insurance funds would significantly impede the ongoing implementation of the German electronic health record and the work of the National Contact Point for eHealth. This is because only select information is to find its way into electronic health records in Germany, in contrast to the proposed regulation. Moreover, the patients themselves decide on what they disclose. The implementation of the Commission's completely different approach would mean that the extensive investments made in Germany from insured persons' money would become worthless. Electronic health records should remain aligned with their nationally planned function and not be misappropriated for an unsystematic collection of health and performance data. This could have a negative impact on acceptance among the society.

There are also established structures in the Member States for the secondary use of health data. However, depending on the country, they sometimes have considerable legal, political and organisational differences. Figuratively speaking, the EHDS is intended to create a connecting European infrastructure on top of the existing structures, which will make it possible to retrieve, merge and use data across borders. German Social Insurance sees great potential in the secondary use of health data for the further development of the health situation for people in Europe. In addition to improving medical care, this can potentially reduce work-related risks and health hazards. Therefore, the implementation should be carried

out with the necessary care, a clear system and sufficient time margins. This is of particular importance for the social insurance as a data holder.

2 Drawing up a realistic roadmap and regulatory framework

For a successful implementation of an ambitious large-scale project such as the EHDS, it is absolutely necessary, from the point of view of the German Social Insurance, to realistically draw up the envisaged roadmap and regulatory framework. Particularly in view of the potentials in the area of secondary data use, it seems reasonable to give preference to this area. This is because it can be assumed that harmonisation of the structures for primary data use will be accompanied by lengthy political consensus processes with a high degree of detail, which because of their time requirement should not be at the expense of meaningful secondary data use. In addition, it is suggested to concentrate on the EU for the time being due to the high need for coordination and to postpone the regulations on third-country use (cf. commentary on Article 72).

3 Possibilities of Member States for more influence and control

Member States are responsible for the national implementation of the EHDS, i.e. for meeting European requirements against the background of national circumstances. For this to succeed, the Commission and the Member States must work together to find viable solutions.

The proposed regulation on the EHDS envisages many specifications to be taken in downstream legal acts, for example on data and exchange formats and on the identification and authentication management of electronic health record (EHR) systems. In order to responsibly accompany the design of the implementing acts envisaged in this context, the Member States must be granted a greater degree of control and co-determination right. Therefore, instead of the non-binding advisory procedure in Article 4 of Regulation (EU) 182/2011, the examination procedure in Article 5 should apply. This shall apply to implementing acts of general scope and other implementing acts in the case of high-impact programmes relating to health protection. The EHDS can be subsumed under this, as the envisaged regulations will have a deep impact on the structures and national arrangements for the organisation of health systems and will have a considerable impact on the existing health policy structures (cf. commentary on Article 68).

4 Compliance with data protection standards and uniform interpretation of the GDPR

Data usage must be based on a common understanding and practical data protection under the General Data Protection Regulation (GDPR). Despite the directly applicable GDPR, there are definitely different conventions in the Member States when it comes to its implementation, which have been used to their advantage in the past, especially by multinational digital groups. The guiding principle in dealing with the GDPR must be that the protection of personal data is ensured, but that the necessary and sensible digitisation of structures in the social and healthcare sectors is not prevented. Data protection and digitisation must be in proportion to each other. The legislative process for the EHDS offers the opportunity to balance this relationship responsibly.

From the point of view of the German Social Insurance, the draft regulation raises numerous questions but also risks with regard to data protection. There is a tension between the purposes for which health data is used under the GDPR and as envisaged in the EHDS. Thus, the exemptions of Article 9 para. 2 of the GDPR so far exclusively assume a use of personal health data for reasons of public interest in the area of public health. In contrast, the proposed regulation on the EHDS goes beyond these permissible public purposes and is also intended to allow data use for commercial purposes, among other things. In addition, the draft regulation should be supplemented with statements on special confidentiality obligations, retention periods or the storage period of the health data concerned. Above all, however, it must be possible for patients to continue to have a say in the use of their data at the national level under the GDPR. A distinction should be made between primary and secondary data use.

5 Ensuring high data quality in the EHR

The German Social Insurance warns against including data from wellness applications in the EHR as long as they do not meet adequate quality standards. The voluntary labelling of wellness applications envisaged by the Commission aims exclusively at their interoperability, but without defining quality requirements. Few meaningful data from wellness applications could degrade the overall data quality in the EHR. Therefore, it should be possible to include only data from applications certified as medical devices in the EHR. This is because the data from these applications are valid as they have demonstrated both their medical benefit and the safety of use to an independent authority in accordance with the Medical Devices Regulation (EU) 2017/745 (see commentary on Article 2).

6 Filling the electronic health record in a meaningful way

From the point of view of the German Social Insurance, it is important that health data relevant to the medical treatment of patients flow into the EHR and can be accessed. Filling the EHR with health data from the entire medical treatment documentation of all service providers according to the principle "a lot helps a lot" is not appropriate for healthcare. For this reason, only defined data objects enter the national EHR in Germany. The insured persons decide independently which data are managed and released in their EHR. However, the definition of EHR in Article 2 para. 2 of the Commission's draft Regulation is much broader and includes all primary documentation of all service providers as well as other data from social security institutions. From the point of view of the German Social Insurance, the principles of purpose and the right to informational self-determination of natural persons must be fulfilled (cf. commentary on Article 2).

7 Allowing use of established electronic health records

The Commission's proposed market introduction of EHRs by international providers could have a significant impact on established structures and health systems in Member States. In Germany, for example, the electronic health record offered by the health insurance funds is the central EHR of the insured, into which all relevant health data flows. Thus, this is a central element in the competitively organised health insurance system, in the development of which considerable investments from insured persons' money have already flowed. Therefore, in the requirements for placing EHR systems on the market and putting them into operation, it must be ensured that EHR systems already approved in the Member States may continue to be operated when the Regulation takes effect, also in order to maintain the national acceptance of EHR systems. (cf. commentary on Article 15).

8 No need for regulation of telemedicine

The planned regulations on telemedicine are not part of the ordinance on the EHDS for legislative reasons. Cross-border service provision – including telemedicine – is already regulated in the Directive on the application of patients' rights in cross-border healthcare (Directive 2011/24/EU) (cf. commentary on Article 8).

9 Intensifying the distribution of tasks and competences in the use of primary data

In order to avoid duplication of structures, the tasks of a new digital health authority are to be assumed by the organisations and institutions involved in the establishment and operation of the national telematics infrastructure. The tasks and competences of the proposed national digital health authority described in Articles 10 and 11 are also very comprehensive and include, for example, information and communication rights vis-à-vis patients. It is important to the German Social Insurance that the social insurance institutions remain the primary point of contact for their insured persons in order to be able to continue to inform and advise them in a way that is close to the insured and tailored to their needs. For example, each health insurance fund informs its insured persons about the procedure for applying for the electronic health record and how it works. There is also a risk of mixing tasks and supervisory functions. The operational tasks are to be strictly separated from the supervisory functions (cf. comments on Articles 10 and 11).

10 Aligning data use with the common good

Health data use under the EHDS should always be in the public interest and serve the common good. From the point of view of German Social Insurance, innovations that contribute to health or social security should be favoured. The use of health data in research and policy-making must primarily benefit patients and social and health systems. With regard to the purposes for which the health data may be used, the German Social Insurance suggests that combating misconduct in the health sector be included as an additional reason. This is because the prevention of the illegal use of financial resources, for example through billing fraud, misuse of health insurance cards or inadmissible agreements between service providers, also serves a public interest: The social and healthcare systems are to be protected from expenditures that do not serve the interest of the insured or the patients. It is also suggested that the intended access rights of industry and the use of health data for commercial purposes be critically reviewed. In addition, the data provided by the solidarity community and used by third parties must lead to adequate quid pro quos. The solidarity communities should be remunerated for providing any data to commercial enterprises to develop products and services, the benefit in return through financial compensation. Research results must also be made publicly available (cf. Commentary on Articles 34 and 42).

11 Efficient data provision for data requests

The health data access bodies are to be given the task of granting data authorisations for access to electronic health data. For this purpose, they collect the necessary health data from various data holders, including those of the social insurance institutions. From the point of view of the German Social Insurance, positive synergy effects could be created if within certain areas, such as social insurance, the duties of data holders with regard to data requests could be delegated to other institutions. The Health Research Data Centre as a decidedly trustworthy data intermediary could, for example, fulfil this function for the statutory health insurance in Germany. For the statutory pension insurance, this could be done by the Research Data Centre of the Pension Insurance (cf. Commentary on Article 37).

12 Re-identification via trusted infrastructure

Secondary data use is to be based on pseudonymised data of the insured, where the data subjects can be re-identified without great effort by comparison with other data records. This re-identification is useful if it enables patients to be informed about a critical finding. However, the data access bodies should not be able to re-identify on their own. There is a need for an infrastructure in which trust offices carry out the pseudonymisation and re-pseudonymisation of data and act as a link between data access bodies and data holders (cf. commentary on Articles 38 and 44).

III. Notes on individual regulations

Chapter I - General provisions

Article 1 - Subject matter and scope

Proposed new regulation

The present draft regulates in paragraph 3 the scope of application of the Regulation. Letter a) lists manufacturers and providers of wellness applications.

Proposed amendments

Article	Paragraph	Text proposed by the Commission	Proposed amendments
Art. 1	Para. 3, letter a	This Regulation applies to: (a) manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products;	This Regulation applies to: (a) manufacturers and suppliers of EHR systems and ~~wellness applications~~ ***health applications certified as medical devices*** placed on the market and put into service in the Union and the users of such products;

Justification

Wellness applications run the risk of not generating valid health data. In order to guarantee a high national and European quality standard for health data in medical care, only such data should be included in the scope of application that is considered to have a high level of data protection. In Germany, for example, this is ensured by the fact that, through the establishment of digital health applications in accordance with Section 33a SGB V, only data from applications that have proven both the medical benefit and the safety of the application to an independent authority are taken into account in the EHR. Therefore, the term wellness applications should be deleted from the scope of the Regulation.

Instead, the term "health applications certified as medical devices" should be used. These ensure that their medical utility has been independently confirmed and that they meet the requirements for safety, functional capability and quality, including interoperability, of a medical device in accordance with the Medical Devices Regulation (EU) 2017/745.

Article 2 - Definitions

Proposed new regulation

The present draft regulation regulates the definitions in Article 2.

Proposed amendments

Art. 2	Para. 2, letter m	In addition, for the purposes of this Regulation the following definitions shall apply: […] (m) 'EHR' (electronic health record) means a collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes;	In addition, for the purposes of this Regulation the following definitions shall apply: […] (m) 'EHR' (electronic health record) means a collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes ***and managed by the natural person to whom that data relates;***
Art. 2	Para. 2, letter n	(n) 'EHR system' (electronic health record system) means any appliance or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records;	n) 'EHR system' (electronic health record system) means ~~any appliance or~~ any software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records;
Art. 2	Para. 2, letter o	(o)'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles [...]	o) ~~'wellness application'~~ **'*Health application certified as medical device*** ' means ~~any device or~~ software ***which is classified as a medical device in accordance with the Medical Devices Regulation ((EU) 2017/745); and*** intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles; [...]

Justification

<u>Definition of "electronic health record (EHR)"</u>

The definition of EHR contained in Article 2 para. 2 letter m) refers to a collection of electronic health data relating to a natural person, recorded in the health system and processed for health purposes. According to this very broad definition of the EHR, all primary documentation from all types of service providers is also included. The same applies to the data stored by the social insurance institutions. This comprehensive consideration of primary data documentation in the EHR is neither economical nor appropriate.

Filling the EHR with health data from the entire medical treatment documentation of all service providers according to the principle "a lot helps a lot" is not appropriate for healthcare. For these reasons, a different path has been taken in Germany. Here, the electronic health record rightly does not include primary documentation, i.e. any information from the treatment of a patient. Instead, only defined data objects are stored that the service providers explicitly create for the national EHR. Due to the patients' right to informational self-determination, they can then decide independently which data are managed in their own EHR. From the point of view of the German Social Insurance, it is important that the decision-making sovereignty on the question of which electronic health data are managed in the EHR rests with the patients. This follows, inter alia, from the principle of purpose for the collection and processing of personal data laid down in Article 5 of Regulation (EU) 2016/479 (GDPR) and should also be made clear in the definitions.

Definition of "EHR system"
Article 2, para. 2 letter n) defines an EHR system as any device or software designed by the manufacturer to store, communicate, import, export, convert, edit or display electronic health records. The term "device" suggests that EHR systems could also be hardware record systems. In order to avoid contradictions or misunderstandings, the German Social Insurance suggests deleting the term "device" from the definition of EHR system, as electronic health record systems are exclusively software-based.

Definition of "wellness application"
According to Article 2 para. 2 letter o), any device or software intended by the manufacturer to be used by a natural person for the processing of electronic health data for purposes other than healthcare, such as for the purpose of generating well-being and maintaining a healthy lifestyle, is referred to as a "wellness application". Wellness applications run the risk of not generating valid health data, as neither their medical benefit nor the safety of the application is proven to an independent authority. It must be ensured that the applications meant here have a medical benefit that has been confirmed by an independent body and that meet the requirements for safety, functional capability and quality, including the interoperability of a medical device, in accordance with the Medical Devices Regulation (EU) 2017/745. Therefore, in the definitions, the term wellness application should be replaced by a more precise wording that reflects this claim.

Chapter II - Primary use of electronic health records

Section I - Access to and transmission of personal electronic health data for primary use

Article 3 - Rights of natural persons in relation to the primary use of their personal electronic health data

Proposed new regulation
The proposed Regulation regulates in Article 3 the rights of natural persons regarding the primary use of their personal electronic health data.

Proposed amendments

Art. 3	para. 1	Natural persons shall have the right to access their personal	Natural persons shall have the right to access their personal

		electronic health data processed in the context of primary use of electronic health data, immediately, free of charge and in an easily readable, consolidated and accessible form.	electronic health data processed in the context ~~of primary use of electronic health data~~ ***of the EHR system, without delay***, free of charge and in an easily readable, consolidated and accessible form.
Art. 3	para. 4	Where the personal health data have not been registered electronically prior to the application of this Regulation, Member States may require that such data is made available in electronic format pursuant to this Article. This shall not affect the obligation to make personal electronic health data registered after the application of this Regulation available in electronic format pursuant to this Article.	Deleted
Art. 3	para. 8	Natural persons shall have the right to give access to or request a data holder from the health or social security sector to transmit their electronic health 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 holder. Natural persons shall have the right that, where the data holder and the data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the data holder shall transmit the data in the European electronic health record exchange format referred to in Article 6 and the data recipient shall read and accept it. By way of derogation from Article 9 of Regulation […] [Data Act COM/2022/68 final], the data recipient shall not be required to compensate the data	Natural persons shall have the right to give access to or request a data holder from the health or social security sector to ~~transmit their electronic health 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 holder~~ ***store health data of the categories under Article 5 in their EHR.*** Natural persons shall have the right that, where ~~the data holder and~~ the data recipient is located in ~~different~~ ***another*** Member State~~s and such electronic health data belongs to the categories referred to in Article 5, the data holder shall transmit the data in the European electronic health record exchange format referred to in Article 6 and~~ ,the data recipient shall ~~read and accept it~~ ***retrieve data from the EHR if the natural person grants access.*** ~~By way of derogation from Article 9 of Regulation […] [Data~~

		holder for making electronic heath data available. Natural persons shall have the right that, where priority categories of personal electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers.	~~Act COM/2022/68 final], the data recipient shall not be required to compensate the data holder for making electronic heath data available.~~ Natural persons shall have the right that, where priority categories of personal electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers.
Art. 3	Para. 11, sentence 2	The supervisory authority or authorities responsible for monitoring the application of Regulation (EU) 2016/679 shall also be responsible for monitoring the application of this Article, in accordance with the relevant provisions in Chapters VI, VII and VIII of Regulation (EU) 2016/679. They shall be competent to impose administrative fines up to the amount referred to in Article 83(5) of that Regulation. Those supervisory authorities and the digital health authorities referred to in Article 10 of this Regulation shall, where relevant, cooperate in the enforcement of this Regulation, within the remit of their respective competences.	The supervisory authority or authorities responsible for monitoring the application of Regulation (EU) 2016/679 shall also be responsible for monitoring the application of this Article, in accordance with the relevant provisions in Chapters VI, VII and VIII of Regulation (EU) 2016/679. ~~They shall be competent to impose administrative fines up to the amount referred to in Article 83(5) of that Regulation.~~ Those supervisory authorities and the digital health authorities referred to in Article 10 of this Regulation shall, where relevant, cooperate in the enforcement of this Regulation, within the remit of their respective competences.
Art. 3	para. 12	The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the rights set out in this Article. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the rights set out in this Article. Those implementing acts shall be adopted in accordance with the ~~advisory~~ ***examination*** procedure referred to in Article 68(2).

Justification

The scope of application of an EHR should exclusively refer to defined data objects that are explicitly filled by the service providers for the EHR and stored in it. Thus, the rights of natural persons under Article 3 para. 1 relate to these applications. Within the framework of the right to informational self-determination, patients should be able to

decide independently which data are managed in their own EHR. Therefore, in the sense of a consequential amendment, the primary documentation cannot be used as a basis for structuring the natural persons' entitlement to access. Furthermore, the term "immediately" used in paragraph 1 is to be replaced by without delay" in the sense of "without culpable hesitation", as immediate access hardly seems feasible in practice. In addition, the term immediate is also used in paragraphs 8 and 10. As a consequential amendment to the adaptation of paragraph 1, paragraph 4 shall be deleted.

Paragraph 8 provides that natural persons have the right to give a data holder from the health or social security sector access to their electronic health data or to request the data holder to transfer their data to a data recipient of their choice from the health or social security sector, without delay, free of charge and without hindrance by the data holder or the producers of the systems used by that data holder. Since the national EHR systems are designed in such a way that the exchange of data does not take place from one service provider to another but via the EHR systems, the claim must be limited to the data holder entering the health data of the data subject of the Article 5 categories into the EHR.

The regulatory content of paragraph 11, according to which the supervisory authorities of Regulation (EU) 2016/679 and the digital health authorities referred to in Article 10 shall cooperate in the enforcement of this Regulation, is to be critically questioned. As stated in the opinion on Article 10, the extensive allocation of tasks and competences envisaged there must be limited, as it interferes, among other things, with the national regulatory sovereignty of the social and health systems. This is also expressed in the right to impose fines, which is why the corresponding power should be deleted here.

Paragraph 12 provides that the Commission shall, by means of implementing acts, lay down the requirements for the technical implementation of the rights referred to in this Article. In order to ensure that the Member States have the necessary opportunities to participate, the implementing acts should be adopted in accordance with the examination procedure laid down in Article 5 of Regulation (EU) No. 182/2011 and not in accordance with the rather non-binding advisory procedure laid down in Article 4 of that Regulation.

Article 4 - Access by health professionals to personal electronic health data

Proposed new regulation

Article 4 contains rules on access by health professionals to personal electronic health records.

Proposed amendments

Art. 4	para. 4	Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals shall not be informed of the content of the electronic health data without prior authorisation by the natural person, including where the provider or professional is in-	Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals shall not be informed of the content of the electronic health data without prior authorisation by the natural person, including where the provider or professional is in-

		formed of the existence and nature of the restricted electronic health data. In cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person, the healthcare provider or health professional may get access to the restricted electronic health data. Following such access, the healthcare provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted. Member States' law may add additional safeguards.	formed of the existence and nature of the restricted electronic health data. In cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person, the healthcare provider or health professional may get access ~~to the restricted electronic health data~~ ***to the patient summary according to Article 5 para. 1 letter a)***. ~~Following such access, the healthcare provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted.~~ ***The EHR system must log such access in a form that the natural person can understand and make the log available to him or her.*** Member States' law may add additional safeguards.

Justification

Emergency access under Article 4 para. 4 sentence 2 to all health data is not appropriate. In emergencies, the essential medical data must always be available. Therefore, in Germany, an excerpt of the most important, emergency-relevant data is kept for emergencies in the form of an emergency record. Such a record can be anchored in the patient summary, which can be accessed in an emergency.

The retrospective obligation to inform the data holder in the event of emergency access also appears unnecessarily complex. For corresponding cases, a log is sufficient, which the insured person can retrieve as the data owner. Therefore, paragraph 4 of Article 4 should be amended as set out in the proposed amendment.

Article 5 - Priority categories of personal electronic health data for primary use

Proposed new regulation

Article 5 sets out priority categories of health data and empowers the Commission to extend these categories by means of legislative acts.

Proposed amendments

Art. 5	para. 1	Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data	Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data

		for primary use fully or partially falling under the following categories: (a) patient summaries; (b) electronic prescriptions; (c) electronic dispensations; (d) medical images and image reports; (e) laboratory results; (f) discharge reports. The main characteristics of the categories of electronic health data in the first subparagraph shall be as set out in Annex I. Access to and exchange of electronic health data for primary use may be enabled for other categories of personal electronic health data available in the EHR of natural persons.	for primary use fully ~~or partially~~ falling under the following categories: (a) patient summari~~es~~***y***; (b) electronic prescriptions; (c) electronic dispensations; (d) medical images and image reports; (e) laboratory results; (f) discharge reports. ~~The main characteristics of the categories of electronic health data in the first subparagraph shall be as set out in Annex I.~~ Access to and exchange of electronic health data for primary use may be enabled for other categories of personal electronic health data available in the EHR of natural persons.
Art. 5	para. 2	The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of priority categories of electronic health data in paragraph 1. Such delegated acts may also amend Annex I by adding, modifying or removing the main characteristics of the priority categories of electronic health data and indicating, where relevant, deferred application date. The categories of electronic health data added through such delegated acts shall satisfy the following criteria: (a) the category is relevant for health services provided to natural persons; (b) according to the most recent information, the category	The Commission is empowered to adopt delegated acts in accordance with Article 67 to ***specify and*** amend the list of priority categories of electronic health data in paragraph 1. ~~Such delegated acts may also amend Annex I by adding, modifying or removing the main characteristics of the priority categories of electronic health data and indicating, where relevant, deferred application date.~~ The categories of electronic health data added through such delegated acts shall satisfy the following criteria: (a) the category is relevant for health services provided to natural persons;

		is used in a significant number of EHR systems used in Member States; (c) international standards exist for the category that have been examined for the possibility of their application in the Union.	(b) according to the most recent information, the category is used in a significant number of EHR systems used in Member States; (c) international standards exist for the category that have been examined for the possibility of their application in the Union.
Annex I		*[Contains tabular overview of "Main characteristics of electronic health data categories"]*	Deleted

Justification
In addition to pure formats for the exchange of information about a patient, Article 5 also includes data on the utilisation of services. These are in particular electronic prescriptions. This would have profound consequences for existing healthcare benefit schemes for which Member States are responsible. Since at EU level national specifics in the prescription and dispensing of medicines, therapeutic products and aids as well as other benefits of social insurance cannot be taken into account, there is a high risk that the regulations in Article 5 will have a negative impact on the provision of care at national level. Among other things, when important rules on formal regulation, e.g. for narcotics or T-pharmaceuticals[2], are not included in the EU specifications. Therefore, with regard to the national and EU-wide regulations on the prescription and dispensing of medicinal products, the established procedures according to Article 11 in Directive 2011/24/EU must continue to exist and the national specifics must be taken into account. If this were not done, all the Member States' regulations concerned would have to be adapted.

Furthermore, it should be clarified that the electronic medication plan is also part of the primary categories of electronic health data and that this should be sufficiently taken into account in Article 5. The draft regulation is not sufficiently specific here and leaves room for interpretation as to whether this should be considered part of the electronic health record. A clarification is needed here.

Paragraph 2 grants the Commission powers to add to, amend or delete the list of priority categories of electronic health data in delegated acts. However, from the point of view of the German Social Insurance, more concrete specifications are needed for the description and prioritisation of categories of electronic health data than the draft regulation provides. Annex I merely lists, as a rough framework, the essential characteristics of the categories of data to be exchanged across borders, but does not become sufficiently precise as to which specific characteristics these should include. For this reason, paragraph 2 of Article 5 and Annex I should be deleted.

[2] These are medicines with active ingredients that are teratogenic. These medicines may only be prescribed on special prescriptions, so-called T-prescriptions. In its authorisation decisions, the Commission has required Member States to comply with specific safety measures.

Article 6 - European electronic health record exchange format

Proposed new regulation

Article 6 contains provisions for a European exchange format for patient data.

Proposed amendments

Art. 6	para. 2	Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). Member States shall ensure that where the priority categories of personal electronic health data referred to in Article 5 are provided by a natural person directly or transmitted to a healthcare provider by automatic means in the format referred to in paragraph 1, such data shall be read and accepted by the data recipient.	Those implementing acts shall be adopted in accordance with the ~~advisory~~ ***examination*** procedure referred to in Article 68 para. 2. Member States shall ensure that the ***personal electronic health records from EHR systems are converted into the appropriate format referred to in paragraph 1 for use at EU level (provision to and receipt from a Member State)***. ***Alternatively, the format set out in paragraph 1 may be used directly in EHR systems in the Member States.*** ~~priority categories of personal electronic health data referred to in Article 5 are provided by a natural person directly or transmitted to a healthcare provider by automatic means in the format referred to in paragraph 1, such data shall be read and accepted by the data recipient.~~ Article 6 para. 3 shall be deleted.
Art. 6	para. 3	Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are issued in the format referred to in paragraph 1 and such data shall be read and accepted by the data recipient.	Deleted

Justification

In order for the EHDS to be successful and the exchange of data to be carried out without problems, it must be ensured that there are uniform specifications at European and national level. This can only succeed if the relevant national organisations are also involved. Therefore, the examination procedure should be used instead of the advisory procedure when drafting implementing acts under Article 68 and Member States' national bodies should be involved. The desired harmonisation must avoid the use of different data formats and semantic standards for structuring the data, as this means a technically and semantically complex process. Moreover, it is not guaranteed that semantics can be transformed from one code system to another without loss of

information. For example, transcoding from the reference terminology SNOMED-CT to the International Statistical Classification of Diseases and Related Health Problems (ICD-10-GM) may be erroneous because ICD-10-GM cannot accommodate all the information in a SNOMED-CT coding. The obligation to issue the information according to Article 5 in the corresponding format of the Commission may have the consequence that all specifications on interoperable data formats made in Germany will have to be revised again. The consequence would be a national adaptation of all EHR record systems (including apps for the insured) as well as the corresponding systems of the service providers (primary systems, radiology systems, etc.).

Article 7 - Registration of personal electronic health data

Proposed new regulation

Article 7 regulates the registration, i.e. storage, of personal health data.

Proposed amendments

Art. 7	para. 2	Where electronic health data of a natural person is registered in a Member State that is not the Member State of affiliation of that person, the Member State of treatment shall ensure that the registration is performed under the person identification data of the natural person in the Member State of affiliation.	Where electronic health data of a natural person is registered in a Member State that is not the Member State of affiliation of that person, the Member State of treatment shall ensure that ~~the registration~~ ***access to the patient summary registered in an EHR system in accordance with Article 5 para. 1 letter a*** is granted under the person identification data of the natural person in the Member State of affiliation.
Art. 7	para. 3	The Commission shall, by means of implementing acts, determine the requirements for the registration of electronic health data by healthcare providers and natural persons, as relevant. Those implementing acts shall establish the following: (a) categories of healthcare providers that are to register health data electronically; (b) categories of health data that are to be registered systematically in electronic format by healthcare providers referred to in point (a); (c) data quality requirements pertaining to the electronic registration of health data.	The Commission shall, by means of implementing acts, determine the requirements for the registration of electronic health data by healthcare providers and natural persons, as relevant. ***This also includes measures to ensure the syntactical correctness of the registered data.*** ~~Those implementing acts shall establish the following:~~ ~~(a) categories of healthcare providers that are to register health data electronically;~~ ~~(b) categories of health data that are to be registered systematically in electronic format by healthcare providers referred to in point (a);~~

		Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	~~(c) data quality requirements pertaining to the electronic registration of health data.~~ Those implementing acts shall be adopted in accordance with the ~~advisory~~ ***examination*** procedure referred to in Article 68(2).

Justification

Paragraph 1 stipulates that service providers store priority categories of data in accordance with Article 5. If national legislation decides on further categories of data, the information pursuant to Article 7 para. 1 in conjunction with Article 5 should be understood as a minimum, so that further data categories are to be compulsorily recorded at national level.

Paragraph 2 provides for full access from states that are not the insured person's state of insurance. This requires a far-reaching harmonisation of EHR systems in the EU. However, in addition to the standardisation of health data, it also includes the standardisation of meta data as well as the technical access infrastructure so that insured persons can trace who has accessed which data from which Member State with which rights. However, corresponding adjustments affect essential elements, such as access control mechanisms of the national eHealth infrastructure. Therefore, corresponding adaptations are cost and time intensive and carry the risk of jeopardising the acceptance of existing systems. Such changes require a corresponding conceptual run-up and EU-wide coordination of the relevant bodies responsible for digitisation in the health sector.

Paragraph 3 provides for the establishment by the Commission of the requirements for the registration of health data by healthcare providers and, where applicable, natural persons. The corresponding authorisation allows the Commission to amend categories of healthcare providers, categories of health data and data quality requirements. This would allow the Commission to significantly redesign principles, expand access and adapt the data structure. This is too far-reaching from the point of view of the German Social Insurance.

In principle, it is supported that minimum requirements are to be set for data quality. However, here too, the Commission's scope of competence under paragraph 3 letter c) is too far-reaching: The evaluation of the semantic quality of the data is technically not possible, so that the examination must be limited to the syntactic quality, i.e. to the compliance with formal rules without any content check.

Therefore, the German Social Insurance proposes to delete letters a) to c). Due to the central importance of these issues for a functioning EHDS, it should also be pointed out here that the examination procedure pursuant to Article 5 of Regulation (EU) No. 182/2011 must be applied when adopting the corresponding implementing acts.

Article 8 - Telemedicine in the context of cross-border healthcare

Proposed new regulation

Article 8 provides that Member States that provide for the provision of telemedicine services must also accept services of the same type in the context of cross-border healthcare provided by healthcare providers in other Member States under the same conditions.

Proposed amendments

Art. 8		Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions, accept the provision of the services of the same type by healthcare providers located in other Member States.	Deleted

Justification

The planned regulations on telemedicine are of a health policy nature and relate to questions of benefit law in the healthcare system. For legislative reasons, they do not belong in the regulation on the creation of an EHDS. The applicable European legal basis is the Directive on the application of patients' rights in cross-border healthcare (Directive 2011/24/EU). The entitlement to benefits laid down there in Article 1 para. 2 also includes telemedical services.

Article 9 - Identification management

Proposed new regulation

Article 9 regulates the identification management.

Proposed amendments

Art. 9	para. 2	The Commission shall, by means of implementing acts, determine the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, in accordance with Regulation (EU) No 910/2014 as amended by [COM(2021) 281 final]. The mechanism shall facilitate the transferability of electronic health data in a cross-border context. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	The Commission shall, by means of implementing acts, determine the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, in accordance with Regulation (EU) No. 910/2014 as amended by [COM(2021) 281 final]. The mechanism shall facilitate the transferability of electronic health data in a cross-border context. Those implementing acts shall be adopted in accordance with the ~~advisory~~ ***examination*** procedure referred to in Article 68(2).
Art. 9	para. 4	The digital health authorities and the Commission shall im-	The ~~digital health authorities~~ ***competent organisations referred to in Article 10*** and the

		plement the cross-border identification and authentication mechanism at Union and Member States' level, respectively.	Commission shall implement the cross-border identification and authentication mechanism at Union and Member States' level, respectively.

Justification

Paragraph 1 provides that all electronic identification means recognised in accordance with the eIDAS Regulation (EU) 910/2014 can be used by insured persons when using telemedicine services or accessing health data. Only with digital identities is access by the means mentioned in paragraph 1 envisaged for initial applications, but limited to nationally issued documents (national identity card, eID card, electronic residence permit). The establishment of digital identities is already an extremely complex project in its currently conceived form. Against this background, longer implementation periods and also a phased approach, starting with the electronic patient summary should be envisaged.

In this context, paragraph 2 empowers the Commission to establish requirements for the identification and authentication mechanisms by means of implementing acts. However, these stipulations have an impact on the processes already established and integrated in the German healthcare system, for which a wide variety of special legislative and sub-legislative provisions have been made at national level. In order to be able to take these aspects sufficiently into account, the advisory procedure under Article 68 para. 2 is not sufficient. When adopting the relevant implementing acts, the examination procedure under Article 5 of Regulation (EU) No. 182/2011 should apply, which gives Member States more rights of co-determination. This should also apply to the establishment of services under Article 9 para. 3. Since both the specifications under paragraph 2 and the establishment of the services under paragraph 3 are mandatory prerequisites for the cross-border use of means of identification and authentication under paragraph 1, implementation can only take place at a later date. This must also be reflected in the specifications on the start of validity.

Article 10 - Digital Health Authority

Proposed new regulation

Article 10 regulates the responsibilities and competences of the digital health authority to be designated by the Member State.

Proposed amendments

Art. 10	para. 1	Each Member State shall designate a digital health authority responsible for the implementation and enforcement of this Chapter at national level. The Member State shall communicate the identity of the digital health authority to the Commission by the date of application of this Regulation. Where a designated digital health authority is an entity consisting of multiple	Each Member State shall designate ~~a digital health authority~~ ***the organisations*** responsible for the implementation and enforcement of this Chapter at national level***, as well as the national supervisory authorities who verify that the work is carried out correctly. Tasks b), f), i), j) and k) listed in paragraph 2 must not be carried***

		organisations, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The Commission shall make this information publicly available.	***out by the organisation responsible for a) and/or c).*** The Member States shall communicate the identity of the ~~digital health authority~~ ***organisations*** to the Commission by the date of application of this Regulation. ~~Where a designated digital health authority is an entity consisting of multiple organisations,~~ ***T***he Member State shall communicate to the Commission a description of the tasks between the organisations. The Commission shall make this information publicly available.
Art. 10	para. 2	Each digital health authority shall be entrusted with the following tasks: a) ensure the implementation of the rights and obligations provided for in Chapters II and III by adopting necessary national, regional or local technical solutions and by establishing relevant rules and mechanisms; […] o) draw up, in collaboration where relevant with market surveillance authorities, an annual activity report, which shall contain a comprehensive overview of its activities. The report shall be transmitted to the Commission. The annual activity report shall follow a structure that is agreed at Union level within EHDS Board, to support benchmarking pursuant to Article 59. The report shall contain at least information concerning: […] (ii) percentage of natural persons having access to different data categories of their electronic health records; […] (v) volumes of electronic health data of different categories	Each ~~digital health authority~~ ***organisation*** shall be entrusted with the following tasks: a) ensure the implementation of the rights and obligations provided for in Chapters II and III by adopting necessary national, regional or local technical solutions ~~and by establishing relevant rules and mechanisms;~~ […] o) draw up, in collaboration where relevant with market surveillance authorities, an annual activity report, which shall contain a comprehensive overview of its activities. The report shall be transmitted to the Commission ***which publishes it***. The annual activity report shall follow a structure that is agreed at Union level within EHDS Board, to support benchmarking pursuant to Article 59. The report shall contain at least information concerning: […] ~~(ii) percentage of natural persons having access to different data categories of their electronic health records;~~ […] ~~(v) volumes of electronic health data of different categories shared across borders through MyHealth@EU;~~

		shared across borders through MyHealth@EU; (vi) level of natural person satisfaction with MyHealth@EU services; […]	~~(vi) level of natural person satisfaction with MyHealth@EU services;~~ […]
Art. 10	para. 3	The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation by entrusting the digital health authorities with additional tasks necessary to carry out the missions conferred on them by this Regulation and to modify the content of the annual report	Deleted
Art. 10	para. 4	Each Member State shall ensure that each digital health authority is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and exercise of its powers.	Each Member State shall ensure that each ~~digital health authority~~ ***competent organisation*** is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and exercise of its powers.
Art. 10	para. 5	In the performance of its tasks, the digital health authority shall actively cooperate with stakeholders' representatives, including patients' representatives. Members of the digital health authority shall avoid any conflicts of interest.	In the performance of its tasks, the ~~digital health authority~~ ***organisations*** shall actively cooperate with stakeholders' representatives, including patients' representatives. Members of the ~~digital health authority~~ ***organisations*** shall avoid any conflicts of interest.

Justification

The extensive tasks described in Article 10 are to be ensured by the Member States. It is their task to organise this in such a way that it is adapted to the structures of the respective health systems.

In paragraph 1, the word "digital health authority" is replaced by "organisations". This addresses the responsible institutions already involved in the development of national telematics infrastructure and the introduction of electronic health record systems, such as the statutory health insurance funds or their associations or organisations of service providers. This proposal is made in order to avoid duplication of structures in the Member States. In particular, the information and communication measures in paragraph 2 letter b) should continue to be carried out via the national organisations, as they are in the national context, e.g. in Germany the social insurance for the insured and the National Associations of Statutory Health or Dental Insurance (K(Z)Ven) for the medical and dental professions. The ombudsman offices of the health insurance

funds should continue to be able to fulfil their duties to provide information to insured persons.

The scope of tasks and competences according to paragraph 2 is too broad in the opinion of the German Social Insurance. It includes, in particular, the implementation of the rules in technical specifications and regulations, communication activities towards natural persons (patients), ensuring correct implementation, cooperation at Union level, supervision of the national contact point, market surveillance activities and the obligation to provide telemedicine services. In particular, the tasks of drawing up the technical specifications, approval, supervision and operation must be separated from each other and must not be performed by one organisation, as this organisation would then supervise itself. Therefore, a separation of powers is necessary and national supervisory authorities must be appointed (see proposed amendment to paragraph 1).

With regard to the activity report required in paragraph 2 letter o), it has a disproportionately broad scope of topics which, in the view of the German Social Insurance, goes far beyond the objective of documenting activities. Some suggestions for deletions are made in this regard.

The power of the Commission under paragraph 3 to assign further tasks to the organisations via legal acts is viewed critically. The organisations can only be entrusted with tasks in consultation with the Member States. The mildest legal remedy to ensure this would be the extension of the range of tasks by implementing decisions in the examination procedure.

Article 11 - Right to lodge a complaint with a digital health authority

Proposed new regulation

Article 11 standardises the right to complain to a digital health authority.

Proposed amendments

Art. 11	Headline	Right to lodge a complaint with a digital health authority	Right to lodge a complaint with a ~~digital health authority~~ ***competent organisation under Article 10***
Art. 11	para. 1	Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with the digital health authority. Where the complaint concerns the rights of natural persons pursuant to Article 3 of this Regulation, the digital health authority shall inform the supervisory authorities under Regulation (EU) 2016/679.	Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with ***one of the competent organisations under Article 10*** ~~the digital health authority~~. Where the complaint concerns the rights of natural persons pursuant to Article 3 of this Regulation, the**y** ~~digital health authority~~ shall inform the supervisory authorities of this under Regulation (EU) 2016/679.

Art. 11	para. 2	The digital health authority with which the complaint has been lodged shall inform the complainant of the progress of the proceedings and of the decision taken.	The ***competent organisation under Article 10*** ~~digital health authority~~ with which the complaint has been lodged shall inform the complainant of the progress of the proceedings and of the decision taken.
Art. 11	para. 3	Digital health authorities shall cooperate to handle and resolve complaints, including by exchanging all relevant information by electronic means, without undue delay.	***Competent organisations under Article 10*** ~~digital health authorities~~ shall cooperate to handle and resolve complaints, including by exchanging all relevant information by electronic means, without undue delay.

Justification
Consequential amendment: For the reasons set out in the opinion on Article 10, the term "digital health authority" in paragraphs 2 and 3 should be replaced by "competent organisation under Article 10" as a necessary consequential amendment. In Article 1, if there are several competent organisations, the complaint shall be addressed to one of them.

Article 12 - MyHealth@EU

Proposed new regulation
The proposed Regulation provides that the infrastructure for the cross-border exchange of personal health data, such as the electronic health record or electronic prescriptions, already established in Article 14 of Directive 2011/24/EU, should become mandatory for all Member States.

To this end, the Commission is setting up a central platform for digital health (MyHealth@EU) to enable the exchange of primary digital health data between national contact points for digital health (Article 12 para. 1). Member States shall establish appropriate national contact points for digital health for this purpose (Article 12 para. 2) and communicate them to the Commission and the public. The national contact points shall enable the exchange of personal patient data with all other national contact points using the European electronic exchange format (Article 12 para. 3). The Commission shall lay down, in implementing acts, rules on the security, confidentiality and protection of electronic health data, as well as the conditions for joining and, where appropriate, temporarily exclusion from MyHealth@EU (Article 12 para. 4). The proposal also provides for the Commission to set up two groups to deal with shared responsibility for the cross-border infrastructure MyHealth@EU (primary use) and HealthData@EU (secondary use). These groups shall be composed of representatives of the national contact points for digital health and other authorised participants of these infrastructure (Article 66 para. 1). The groups shall take decisions on the development and operation of cross-border infrastructure and on infrastructure modifications adding additional infrastructure or services or ensuring interoperability with other infrastructure, digital systems or data rooms (Article 66 para. 6).

Proposed amendments

Art. 12	para. 4	The Commission shall, by means of implementing acts, adopt the necessary measures for the technical development of MyHealth@EU, detailed rules concerning the security, confidentiality and protection of electronic health data and the conditions and compliance checks necessary to join and remain connected to MyHealth@EU and conditions for temporary or definitive exclusion from MyHealth@EU. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	The Commission shall, by means of implementing acts, adopt the necessary measures for the technical development of MyHealth@EU, detailed rules concerning the security, confidentiality and protection of electronic health data and the conditions and compliance checks necessary to join and remain connected to MyHealth@EU and conditions for temporary or definitive exclusion from MyHealth@EU. Those implementing acts shall be adopted in accordance with the ~~advisory~~ ***examination*** procedure referred to in Article 68(2).
Art. 12	para. 8	The Commission shall, by means of implementing acts, allocate responsibilities among controllers and as regards the processor referred to in paragraph 7 of this Article, in accordance with Chapter IV of Regulation (EU) 2016/679. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	The Commission shall, by means of implementing acts, allocate responsibilities among controllers and as regards the processor referred to in paragraph 7 of this Article, in accordance with Chapter IV of Regulation (EU) 2016/679. Those implementing acts shall be adopted in accordance with the ~~advisory~~ ***examination*** procedure referred to in Article 68(2).

Justification

The Commission's proposal to establish a central platform for the exchange of personal health data via the national points of contact is to be welcomed. This builds on the preparatory work of the voluntary cooperation of the eHealth network according to Article 14 of Directive 2011/24/EU, thus using the experience gained so far in the electronic exchange of patient summaries and electronic prescriptions.

On this legal basis, the German legislator has already assigned the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), Deutsche Verbindungsstelle Krankenversicherung - Ausland (German Liaison Office for Health Insurance - Abroad) the task of establishing and operating the so-called national eHealth contact point for the cross-border exchange of health data. Set-up and operation must be completed by 1/7/2023 at the latest. Preparations for the implementation work are currently in progress.

Thus, the regulations on the EHDS build on ongoing processes. Therefore, the measures for the technical development of MyHealth@EU to be adopted by means of implementing acts (paragraph 4) must correspond to and meaningfully build on the preparatory work done.

For the adoption of the necessary implementing acts, the examination procedure, which applies to implementing acts of general scope and other implementing acts for programmes with substantial amendments and relating to the protection of health, shall also apply here instead of the advisory procedure (cf. Commentary on Article 68). This ensures the necessary co-determination rights of the Member States and should lead to viable and practical provisions that can be implemented in the Member States.

Chapter III - EHR systems and wellness applications

Section 1 - General provisions for EHR systems

Article 14 - Interplay with legislation governing medical devices and AI systems

Proposed new regulation

The regulatory content of this chapter concerns the interaction between medical devices, AI systems and EHR systems. The provisions in Article 14 essentially serve to establish interoperability between EHR systems on the one hand and medical devices and AI systems on the other.

Proposed amendments

Art. 14	para. 3	Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 that claim interoperability of those medical devices with EHR systems shall prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those medical devices.	Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 that claim interoperability of those medical devices with EHR systems shall prove compliance with the ~~essential~~ requirements on interoperability ***on the basis of the common specifications*** ~~laid down in Section 2 of Annex II of this Regulation.~~ ***according to*** Article 23 of this Chapter ~~shall be applicable to those medical devices~~.
Art. 14	para. 4	Providers of high-risk AI systems as defined in Article 6 of Regulation […] [AI act COM/2021/206 final], which does not fall within the scope of Regulation (EU) 2017/745, that claim interoperability of those AI systems with EHR systems will need to prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those high-risk AI systems.	Providers of high-risk AI systems as defined in Article 6 of Regulation […] [AI act COM/2021/206 final], which does not fall within the scope of Regulation (EU) 2017/745, that claim interoperability of those AI systems with EHR systems will need to prove compliance with the ~~essential~~ requirements on interoperability ***on the basis of the common specifications*** ~~laid down in Section 2 of Annex II of this Regulation.~~ ***according to*** Article 23 of this Chapter ~~shall be applicable to those high-risk AI systems~~.

Justification
The reference in paragraphs 3 and 4 to Annex II Section 2 is not comprehensible in terms of content from the point of view of the German Social Insurance, as Annex II only sets requirements for EHR systems and does not consider medical devices or AI systems. The analogous transfer of the requirements of EHR systems to medical devices and AI systems is also technically not easily possible. The legal norm therefore lacks the necessary clarity. Therefore, the reference should be deleted so that only the common specifications referred to in Article 23 are referred to.

Article 15 - Placing on the market and putting into service

Proposed new regulation
The regulatory content of this chapter concerns the interaction between medical devices, AI systems and EHR systems. Article 15 contains requirements for placing EHR systems on the market and putting them into service.

Proposed amendments

Art. 15	para. 1	EHR systems may be placed on the market or put into service only if they comply with the provisions laid down in this Chapter.	EHR systems may be placed on the market or put into service only if they comply with the provisions laid down in this Chapter. ***For EHR systems which have been approved by a national body in accordance with the provisions laid down in this Chapter, the obligation to draw up the EU declaration of conformity in accordance with Article 26 shall not apply.***
Art. 15	Para. 3 *(new)*		*(Added)* ***The operating environment(s) of the EHR systems must be located on the territory of a Member State of the EU or the EEA.***

Justification
The approach of imposing basic requirements for the commissioning and placing on the market of EHR systems is understandable. However, Article 15 exclusively assumes that the Commission is the only body that can issue such requirements. This neglects the fact that corresponding procedures may already exist at national level which affect the situation regulated in this Article in the same way. It must be ensured that EHR systems in Member States that have received accreditation from their national bodies (in Germany, this is gematik GmbH for the EHR) are allowed to continue operating when the Regulation takes effect, so that the existing nationally certified EHRs used by patients may continue to be used without delay. Otherwise, there is a risk of costly and unnecessary time-consuming re-certification processes. The regulation must therefore be supplemented by a passage that permits the operation and placing on the market of EHR systems even if they are approved at national level by an appropriate body. The proposed addition to the new paragraph 3 ensures that EHR

systems are operated where the GDPR fully applies, thus safeguarding the rights of natural persons. A transfer of personal data to a third country is still possible under Article 45 GDPR.

Article 16 - Claims

Proposed new regulation

The regulatory content of this chapter concerns the interaction between medical devices, AI systems and EHR systems. Article 16 regulates declaration obligations.

Proposed amendment

None.

Justification

The provisions of Article 16 on information about EHR systems are welcomed as they prevent insured persons from receiving untrue information about functions and features of EHR systems, thus being misled.

Section 3 - Conformity of the EHR system

Article 23 - Common specifications

Proposed new regulation

Article 23 empowers the Commission to adopt common specifications for EHR systems by means of implementing acts. These specifications cover a wide range of topics, from semantic specifications, IT security specifications to technical specifications.

Proposed amendments

Art. 23	para. 1	The Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements set out in Annex II, including a time limit for implementing those common specifications. Where relevant, the common specifications shall take into account the specificities of medical devices and high risk AI systems referred to in paragraphs 3 and 4 of Article 14. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	The Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements set out in Annex II, including a time limit for implementing those common specifications. Where relevant, the common specifications shall take into account the specificities of medical devices and high risk AI systems referred to in paragraphs 3 and 4 of Article 14. Those implementing acts shall be adopted in accordance with the ~~advisory~~ ***examination*** procedure referred to in Article 68(2).
Art. 23	para. 3	The common specifications may include elements related to the following: […]	The common specifications may include elements related to the following: […]

		(c) other requirements related to data quality, such as the completeness and accuracy of electronic health data; […] (e) requirements and principles related to security, confidentiality, integrity, patient safety and protection of electronic health data; (f) specifications and requirements related to identification management and the use of electronic identification.	(c) other ***syntactic*** data quality requirements, ~~such as the completeness and accuracy of electronic health data~~; […] (e) requirements and principles relating to security, confidentiality, integrity, patient safety and protection of electronic health data; ***when accessing data from one Member State to data stored in another Member State;*** (f) specifications and requirements related to identification management and the use of electronic identification to ***access data in another Member State***.

Justification

In order to exchange health data across the EU, a common technical basis is needed so that the need for a harmonised specification basis can be understood. However, the Commission's sole right of determination in paragraph 1 is problematic from the point of view of the German Social Insurance. It is true that the Regulation provides in paragraph 5 for consultation of the Medical Devices Coordination Group or the European Artificial Intelligence Board or in paragraph 6 for consultation of the EHDS Board. However, these are only consulted if the concerns of medical devices or AI systems are also affected. In addition, the composition of the working groups and their ability to intervene is unclear. This approach bears the risk that introduced national solutions will not be taken into account. Therefore, at least stronger participation rights of the Member States in the adoption of the corresponding implementing acts are needed. Here, the examination procedure pursuant to Article 5 of Regulation (EU) No. 182/2011 should apply.

In terms of content, the specifications pursuant to paragraph 3 shall include requirements for interoperability as well as specifications for the technology and information technology security of EHR systems. The regulatory competence must be limited to requirements for interoperability and data access between the Member States. All other requirements for EHR systems, such as secure access to data within a Member State, are to be left at national level to ensure the smooth continued operation of national infrastructure.

The corresponding regulations are to be adapted as shown in the proposed amendment to Article 23 para. 3.

Article 24 - Technical documentation

Proposed new regulation

Article 24 contains provisions on the mandatory creation of technical documentation for an EHR system and also regulates who must request this documentation and in which languages it must be available.

Proposed amendments

Art. 24	para. 3	The technical documentation shall be drawn up in one of the official languages of the Union. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the official language of that Member State.	The technical documentation shall be written in one of the official languages of the Union ***in which the EHR system is operated or offered***. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide ~~a translation of~~ the relevant parts of the technical documentation ~~in the official language of that Member State~~***. The manufacturer may request a confidentiality check in advance from the market surveillance authority of a Member State. The translation of the relevant parts of the technical documentation is the responsibility of the requesting Member State. The market surveillance authorities of the relevant Member States shall be informed of the publication and the reference point.***
Art. 24	para. 4	When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, it shall set a deadline of 30 days for receipt of such documentation or translation, unless a shorter deadline is justified because of a serious and immediate risk. If the manufacturer does not comply with the requirements of paragraphs 1, 2 and 3, the market surveillance authority may require it to have a test performed by an independent body at its own expense within a specified period in order to verify the conformity with the essential requirements laid down in Annex II and the	Deleted

		common specifications referred to in Article 23.	

Justification
The regulation on the compulsory preparation of technical documentation is welcomed. As paragraph 2 aims at enabling market surveillance authorities to assess whether the EHR system complies with the essential requirements set out in Annex II, it is proposed to draft and publish the technical documentation in the official language of the Union in which the EHDS system is operated or used. The proposed rules that the technical documentation must be submitted to the market surveillance authority of a Member State in the desired official language of the Union is considered uneconomical and infeasible due to additional translation efforts. In addition, in order to protect possible security-relevant sensitive content, it should be possible to require a confidentiality check from the manufacturer as a matter of principle.

Section 4 - Market surveillance of EHR systems

Article 30 - Handling of non-compliance

Proposed new regulation
Article 28 provides that the scope of the Market Surveillance Regulation (Regulation (EU) 2019/1020) is opened for EHR systems. Member States shall designate the market surveillance authority or authorities responsible for the implementation of this chapter. The authorities designated in accordance with Article 10 may be market surveillance authorities at the same time. Article 30 regulates the handling of non-conformity. It shall determine the cases of non-compliance and the measures which may be taken by the Member State concerned if the request to remedy the non-compliance is unsuccessful.

Proposed amendments

Art. 30	para. 1	Where a market surveillance authority makes one of the following findings, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators to put an end to the non-compliance concerned:	Where a market surveillance authority makes one of the following findings, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators to put an end to the non-compliance concerned ***without delay***:
		(a) the EHR system is not in conformity with essential requirements laid down in Annex II;	(a) the EHR system is not in conformity with essential requirements laid down in Annex II;
		(b) the technical documentation is either not available or not complete;	(b) the technical documentation is either not available or not complete;

		(c) the EU declaration of conformity has not been drawn up or has not been drawn up correctly; (d) the CE marking has been affixed in violation of Article 27 or has not been affixed.	(c) the EU declaration of conformity has not been drawn up or has not been drawn up correctly; (d) the CE marking has been affixed in violation of Article 27 or has not been affixed.

Justification
Where a market surveillance authority finds that non-compliance exists, it shall, in accordance with Article 30 para. 1, require the manufacturer of the EHR system concerned, its authorised representative and any other relevant economic operator to remedy the non-compliance in question. From the point of view of the German Social Insurance, it should be added here that the request must be made "without delay" in the sense of "without culpable delay", so that the manufacturers fulfil their duty of care and prove the conformity of the product.

Chapter IV - Secondary use of electronic health records

Section 1 - General conditions with regard to the secondary use of electronic health data

Article 34 - Purposes for which electronic health data can be processed for secondary use

Proposed new regulation
Article 34 lists the purposes for which a data authorisation may be issued. These purposes include research, innovation, policy-making, education, patient safety, regulatory activities and also personalised medicine. Exemptions for situations of public emergency are also provided for, as is the consideration of trade and business secrets.

Proposed amendments

Art. 34	Para. 1 letter a	activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices;	activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices***, to identify work-related risks and health hazards or the effectiveness of preventive measures;***

Art. 34	Para. 1 letter e	scientific research related to health or care sectors;	scientific research related to health or care sectors; ***as well as healthy work***
Art. 34	Para. 1 letter i *(new, after letter h)*		*(Added)* ***i) Proactive combat misconduct in the health sector***
Art. 34	Para. 5 *(new)*		*(Added)* ***Public bodies as data holders are in principle entitled to process their own data in compliance with the purposes pursuant to paragraph 1.***

Justification

The orientation of the purposes for which health data can be put to secondary use towards public welfare objectives is expressly welcomed. The EHDS is a sensitive project that requires a high level of social acceptance, but is also fundamentally susceptible to data use that deviates from its intended purpose, e.g. in pursuit of purely commercial interests and business models. It is important to have strict guidelines and effective enforcement mechanisms for the claim that the project makes. In the purpose justifications for the secondary use of data in paragraph 1, the German Social Insurance suggests that the proactive combat against misconduct in the healthcare sector be added, as this also serves a public interest. This is because the prevention of the illegal use of financial resources, for example through billing fraud, the misuse of health insurance cards or inadmissible agreements between service providers, also serves the public interest of protecting the social and healthcare systems from expenditures that do not serve the interests of the insured or the patients.

German Social Insurance also suggests that the purposes for which health data are permitted for secondary data use shall be expanded to include combating health hazards in the workplace. In addition to improving medical care, work-related risks and health hazards can potentially be reduced. The proposed adjustment in paragraph 1 clarifies that activities that contribute to the identification of work-related risks and health hazards or the effectiveness of preventive measures also constitute permissible purposes. In addition, scientific research should also include research projects in the field of healthy work, e.g., on occupational diseases, on the reduction of accident risks or on individual preventive measures.

Article 34 provides guidance on the application procedure between non-identical data users and data holders. German Social Insurance assumes that, of course, public bodies can also use their own data for public interest purposes under Article 34. In order to avoid misunderstandings, a clarification on this should be made in paragraph 5.

Article 35 - Prohibited secondary use of electronic health data

Proposed new regulation

Article 35 lists secondary uses of health data that are explicitly not allowed. These include purposes that result in harm to natural persons, discriminatory effects, advertising and marketing activities, disclosure to third parties and the development of illegal products and services.

Proposed amendments

Art: 35		Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 for the following purposes shall be prohibited: […]	Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 for the following purposes ***not laid down in Article 34 (1)*** shall be prohibited: ***This applies in particular to the following purposes***: […]

Justification

Implicitly, it would have to be assumed that such purposes are already excluded on the basis of the requirements for permissible purposes under Article 34. However, the draft regulation establishes the relationship that the data in question already has a data authorisation, which must have been obtained by specifying purposes under Article 34. In this respect, it appears that either the non-compliance with the specified purposes or a downstream use of result data of a data authorisation by the data user is dealt with here. The explicit prohibitions of this Article may create a risk that, contrary to the inclusive positive purposes of Article 34, alternative uses may be accepted because they are not unauthorised.

Article 36 - Health data access bodies

Proposed new regulation

Article 36 establishes the role of the health data access bodies, which are responsible for providing access to electronic health data for secondary use. There can be more than one access body, but only one of them has a coordinating function. In carrying out their tasks, the access bodies shall involve representatives of patients, data holders and data users, but are not bound by any instructions beyond this.

Proposed amendments

Art. 36	Para. 3, sentence 1	In the performance of their tasks, health data access bodies shall actively cooperate with stakeholders' representatives, especially with representatives of patients, data holders and data users. Staff of health data access bodies shall avoid any conflicts of interest. Health data access bodies shall not be bound by any instructions, when making their decisions.	In the performance of their tasks, health data access bodies shall actively cooperate with stakeholders' representatives, especially with representatives of patients, data holders and data users ***as well as the national competent authorities for data protection and data security.*** Staff of health data access bodies shall avoid any conflicts of interest. Health data

			access bodies shall not be bound by any instructions, when making their decisions.
Art. 36	Para. 5 *(new)*		*(Added)* ***Where a Member State designates more than one health data access body, it shall determine which access body a data holder is obliged to transmit to and make this transparent.***

Justification
In order to ensure from the outset that the work of the access bodies complies with national data protection and data security provisions, paragraph 3, as referenced later in Article 37 para. 2, should in principle involve the national competent data protection and data security authorities. If a Member State designates several access bodies for health data, each data holder should only be obliged to transmit to one access body in order to minimise administrative burdens.

Article 37 - Tasks of health data access bodies

Proposed new regulation
Article 37 deals with the tasks of the access bodies in detail.

Proposed amendments

Art. 37	Para. 1, letter gg *(new, after letter g)*		*(Added)* ***(gg) it shall perform data sharing services for public sector data federations with an exonerating effect for data holders and cooperate with providers of such services;***

Justification
From the point of view of the German Social Insurance, it would make sense that for certain areas, obligations of data holders with regard to data requests could be completely delegated to a competent data access body.

The Health Research Data Centre (FDZ Gesundheit), as the responsible trustworthy data intermediary in Germany, could fulfil this function for the statutory health insurance. For the statutory pension insurance, this function could be fulfilled by the Pension Insurance Research Data Centre.

Data requests that cannot be served from the data pool held at the access bodies may be considered as additional content in the subsequent routine delivery cycles to the access point.

Article 38 - Obligations of health data access bodies towards natural persons

Proposed new regulation

Article 38 deals with the tasks of the access bodies to establish transparency about the application and use procedure vis-à-vis natural persons as well as the public and their information rights. In particular, information on critical health findings as a result of data evaluations to data subjects is touched upon.

Proposed amendments

Art. 38	para. 2	Health data access bodies shall not be obliged to provide the specific information under Article 14 of Regulation (EU) 2016/679 to each natural person concerning the use of their data for projects subject to a data permit and shall provide general public information on all the data permits issued pursuant to Article 46.	Health data access bodies shall not be obliged to provide the specific information under Article 14 of Regulation (EU) 2016/679 to each natural person concerning the use of their data for projects subject to a data permit and shall provide general public information on all the data permits issued pursuant to Article 46 ***and make them publicly available by the health data access bodies. The exceptions under Article 14 para. 5 letter b of Regulation (EU) 2016/679 shall apply mutatis mutandis.***
Art. 38	para. 3	Where a health data access body is informed by a data user of a finding that may impact on the health of a natural person, the health data access body may inform the natural person and his or her treating health professional about that finding.	Where a health data access body is informed by a data user of a finding that may impact on the health of a natural person, the health data access body may inform the natural person and his or her treating health professional about that finding ***by way of trusted infrastructure***.

Justification

Article 38 para. 2 limits the data subject rights under Article 14 of Regulation (EU) 2016/679 (GDPR). If a restriction under Article 14 para. 5 letter b) is invoked, it should be clearly identified here.

Informing a data subject about a critical finding from a data analysis requires the possibility of re-identifying the person at the health data access body. In principle, this requires a trustworthy infrastructure in which a trust centre is interposed between the health data access body and the data holder, which carries out the pseudonymisation and re-pseudonymisation of personal data. In Germany, an infrastructure for informing affected patients has already been set up through the interaction of health registers, a trust agency based at the Robert Koch-Institute, the German authority for disease surveillance and prevention, and the statutory health insurance funds. If such infrastructure exists in the Member States, they should also be used as a priority. In this regard, it shall be ensured that the level of false positive notifications under the data users' notification obligations pursuant to Article 46 para. 12 only imposes a reasonable burden

on potentially data subjects. Therefore, Article 44 para. 3 sentence 2 should be amended accordingly.

Article 41 - Duties of data holders

Proposed new regulation

Article 41 lays down the obligations of data holders in exchanges with a responsible access body. This addresses the requirements of submitting accompanying record descriptions and also data quality and utility labels under Article 56 of the proposed regulation and sets a deadline of two months for data feedback to the requesting access body. Furthermore, in the case of enriched data as a result of an existing data authorisation, the data holder shall submit an updated data set to the access body, unless it deems it unsuitable. Data holders of non-personal electronic health data should ensure data access for all users by means of trusted open databases.

Proposed amendments

Art. 41	para. 4	The data holder shall put the electronic health data at the disposal of the health data access body within 2 months from receiving the request from the health data access body. In exceptional cases, that period may be extended by the health data access body for an additional period of 2 months.	The data holder shall put the electronic health data at the disposal of the health data access body within 2 months from receiving the request from the health data access body. In exceptional cases, that period may be extended by the health data access body for an additional period of 2 months. ***If public social security institutions fulfil their obligation to provide data by means of a data sharing service provider, they are exempt from the obligation to provide data on an ad hoc basis within the specified deadline.***
Art. 41	para. 6	Data holders of non-personal electronic health data shall ensure access to data through trusted open databases to ensure unrestricted access for all users and data storage and preservation. Trusted open public databases shall have in place a robust, transparent and sustainable governance and a transparent model of user access.	Deleted

Justification

A feedback period for data deliveries of two months as in paragraph 4 seems too short. Usual cycles in the data procedures - e.g. of the statutory health insurance - set

deadlines of about nine months, especially since in the case of EHDS data requests, competing requests may also have to be processed in parallel. Work to standardise the usual cycles across sectors, to make them binding and to shorten them significantly is in progress. A period of three months after completion of the treatment or "data case" seems feasible in the medium term, at least in the statutory health insurance system.

In the area of statutory health insurance, there should be no obligatory response to ad hoc data requests to the health insurance funds as data holders. In the case of ad hoc enquiries, it makes sense to first address them to the health data access body and check whether they can be satisfied from the existing data pools. Data requests that cannot be serviced from existing data pools at the access point or a data sharing service provider should be provided for with appropriate lead times for future regular data deliveries from data holders to the health data access body. Data requests generally require extensive standardisation processes, so that the tight deadline set in paragraph 4 does not seem very realistic.

The requirement to provide non-personal electronic health data in the form of trustworthy open databases as a matter of principle in accordance with paragraph 6 is a measure in the area of opening up data resources and is not to be regulated in the context of the EHDS.

Article 42 - Fees

Proposed new regulation

Article 42 regulates the charging of fees by health data access bodies and data holders for the provision of health data as well as its enrichment. The fees are based on the costs of the proceedings, should be kept transparent and objective and should not restrict competition.

Proposed amendments

Art. 42	Para. 7 (*new*)		*(Added)* ***Without prejudice to charging for the provision of electronic health data, Member States may provide for mechanisms of compensation for the use of health data for the development of services or products funded or reimbursed by payers.***

Justification

Both the purposes under Article 34 para. 1 letters f), (g) and (h) and the finding of competitive neutrality in paragraph 4 indicate an envisaged use of health data in the EHDS by the health industry for commercial purposes – in addition to those of public interest. Irrespective of the neutrality of competition, mechanisms of compensation for the use of the health data of the social security payers beyond a pure fee schedule would be adequate. This compensation could also include aspects of the evidence

gained of the effectiveness of the products and services promoted by the data, or even the economic benefits that the data user could achieve.

Article 44 - Data minimisation and purpose limitation

Proposed new regulation

Article 44 regulates the principles of data minimisation and definition of purpose in the provision of requested data by the health data access body to the data user. Here, data should always be provided in anonymised form if the purpose can be achieved by doing so. Provision in merely pseudonymised form is only possible if anonymised data is not sufficient to achieve the purpose. It is shown that the health data access body has information for re-identification. Data users are not allowed to re-identify and may be subject to sanctions if they do so.

Proposed amendments

Art. 44	Para. 3, sentence 2	Where the purpose of the data user's processing cannot be achieved with anonymised data, taking into account the information provided by the data user, the health data access bodies shall provide access to electronic health data in pseudonymised format. The information necessary to reverse the pseudonymisation shall be available only to the health data access body. Data users shall not re-identify the electronic health data provided to them in pseudonymised format. The data user's failure to respect the health data access body's measures ensuring pseudonymisation shall be subject to appropriate penalties.	Where the purpose of the data user's processing cannot be achieved with anonymised data, taking into account the information provided by the data user, the health data access bodies shall provide access to electronic health data in pseudonymised format. ***Any reversal of pseudonymisation required is done with the help of trustworthy infrastructure.*** The information necessary to reverse the pseudonymisation shall be available only to the health data access body. Data users shall not re-identify the electronic health data provided to them in pseudonymised format. The data user's failure to respect the health data access body's measures ensuring pseudonymisation shall be subject to appropriate penalties.

Justification

The gradation of anonymisation and pseudonymisation requirements is adequate from the point of view of the German Social Insurance. Scaling and minimisation requirements are essential for sensitive health data. A differentiation between personal data relating to patients on the one hand and to service providers on the other could be regulated. For the latter, there is usually a lower risk of compromise. There may even be a public interest in reporting on healthcare providers by name and identity.

In the view of the German Social Insurance, the health data access bodies should not be able to re-identify personal health data on their own. This also directly affects the

form of data collection. Data transmission should preferably take place in pseudonymised form and in trustworthy infrastructure in which the health data access body, trust point and data holder operate separately from each other.

Article 49 - Access to electronic health data from a single data holder

Proposed new regulation

Article 49 regulates the possibility of direct, bilateral data exchange between an applicant and a single data holder. In this respect, the modalities of the application procedure under Article 45 shall apply as well as for data requests under Article 47. In addition, the assumption of joint responsibility comes into play in this case, as do documentation and information obligations for the central application register.

Proposed amendment

None.

Justification

The possibility of a direct, bilateral data exchange under the conditions of the EHDS is welcomed, insofar as this is an optional regulation that leaves it up to the data holder to comply with the data request. While there are always possibilities for bilateral data exchange at the national level, this regulation could lead to a simplification of procedures in many cases, thus improving data availability for such constellations.

Article 50 - Secure processing environment

Proposed new regulation

Article 50 describes the necessary technical and organisational measures for a secure processing environment that health data access bodies must comply with.

Proposed amendments

Art. 50	para. 1	The health data access bodies shall provide access to electronic health data only through a secure processing environment, with technical and organisational measures and security and interoperability requirements. In particular, they shall take the following security measures: […] f) ensure compliance and monitor the security measures referred to in this Article to mitigate potential security threats.	*(Added)* The health data access bodies shall provide access to electronic health data only through a secure processing environment, with technical and organisational measures and security and interoperability requirements. In particular, they shall take the following security measures: […] f) ensure compliance and monitor the security measures referred to in this Article to mitigate potential security threats. ***The security measures referred to in Article 25 paras. 1 and 2 and Article 32 paras. 1 and 2 of Regulation (EU)***

			2016/679 shall be taken into account.

Justification
The mention of technical and organisational measures as well as security and interoperability requirements is to be welcomed. In order to ensure that the provisions of the EHDS comply with the provisions of the GDPR, reference should be made here to the relevant explanations of Regulation (EU) 2016/679 (Articles 25 and 32).

CHAPTER VI - European governance and coordination

Article 65 - Tasks of the EHDS Board

Proposed new regulation
Article 65 lists the tasks of the EHDS Board in relation to the primary and secondary use of electronic health records.

Proposed amendment
None.

Justification
The envisaged tasks are appropriate from the point of view of the German Social Insurance. However, when adopting the implementing acts, care must be taken not to duplicate the tasks of the European Data Protection Board (EDPB) under Regulation (EU) 2016/679 (GDPR).

CHAPTER VII - Delegation and Committee

Article 67 - Exercise of the delegation

Proposed new regulation
Article 4 of the draft regulation provides that, before adopting a delegated act, the Commission shall consult the experts nominated by each Member State in accordance with the principles received in the Interinstitutional Agreement on Better Law Making (see also recital - 68).

The Institutional Agreement on Better Law Making is accompanied by an understanding on delegated acts. This stipulates in recital 4 that consultations in the preparation and drafting of delegated acts shall take place in existing expert groups or by way of ad hoc meetings with Member States' experts, to which the Commission shall invite through the Permanent Representations of each Member State. It is up to the Member States to decide which experts participate. Recital 4-12 regulates the comprehensive involvement of experts.

Proposed amendment
None.

Justification
The German Social Insurance points out that it is absolutely necessary to involve the German health and social insurance institutions in the preparation and drafting of delegated acts. Only together with the Member States and the institutions responsible for

implementation at national level can a viable and practical implementation of the EHDS be ensured.

For example, statutory health insurance in Germany occupies a special position. On the one hand, as a co-shareholder of gematik GmbH, it is responsible for the national development of the telematics infrastructure for the healthcare system. On the other, the health insurance funds are providers of electronic health records for their insured persons. The National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) supports the health insurance funds in particular by developing and coordinating data definitions and process optimisations for electronic data exchange in statutory health insurance.

The German Social Accident Insurance (DGUV) also occupies a special position in Germany. In the event of an occupational accident or disease, it receives health data from service providers in the German healthcare system and forwards it to the responsible accident insurance institution. The DGUV also supports the accident insurance institutions in the development and coordination of joint data exchange procedures.

For these reasons, and also against the background of possible tasks within the framework of data provision for secondary data use, it is necessary for the social insurance institutions to contribute their expertise with regard to the feasibility and practical implementation possibilities of the EHDS. The downstream specifications in the delegated acts have an impact on the already established processes in the German social and healthcare system, for which a wide variety of legislative and non-legislative provisions have already been made in part at national level. Only if viable and practical solutions are worked out with the Member States and the institutions responsible for implementation at national level can a functioning EHDS be established.

Article 68 – Committee procedure

Proposed new regulation

When adopting delegated acts, the Commission shall be assisted by a committee within the meaning of Regulation (EU) No. 182/2011. The advisory procedure shall apply, whereby the Commission shall adopt implementing acts, taking the utmost account of the outcome of the Committee's deliberations and of the opinion submitted.

Proposed amendments

Art. 68	para. 2	Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	Where reference is made to this paragraph, Article 4 ***5*** of Regulation (EU) No. 182/2011 shall apply.

Justification

The present draft provides for far-reaching competences of the EU for the retention and use of health data. This must be critically reviewed according to the principles of subsidiarity and proportionality. The focus here is in particular on the large number of planned implementing acts. In order to accompany their design responsibly, the Member States must be granted a greater degree of control and co-determination right. Instead of the non-binding advisory procedure in Article 4 of Regulation (EU) No. 182/2011, the examination procedure in Article 5, which applies to implementing acts

of general scope and for the protection of health, should apply in principle. This includes such a far-reaching legal act as the EHDS.

According to Article 3, the Commission shall be assisted in the preparation of an implementing act by a committee composed of representatives of the Member States. The latter shall vote by qualified majority in the examination procedure referred to in Article 5 and, in the event of a negative opinion, the Commission may not adopt the implementing act. It is imperative that the members delegated by Germany to the committee reach an agreement with the competent national organisations so that viable and practical solutions can be worked out.

Chapter XIII - Miscellaneous

Article 69 - Penalties

Proposed new regulation

Article 69 allows Member States to lay down rules on penalties applicable to infringements of this Regulation.

Proposed amendments

Art. 69		Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.	Member States shall ~~lay down the rules~~ ***draft proposals*** on penalties applicable to infringements of this Regulation ~~and shall take all measures necessary to ensure that they are implemented~~. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those ***proposals*** ~~rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them~~***. The Commission draws up a catalogue of penalties based on the proposals of the Member States. The Commission shall, by means of an implementing act, adopt the list of penalties. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 68 (2).***

Justification

Due to the cross-border exchange of health data, it can be assumed that there will also be procedures involving several Member States. There should be a uniform catalogue of sanctions throughout Europe, drawn up by the Commission on the basis of proposals from the Member States. This is to be adopted as an implementing act under the examination procedure.

Chapter IX - Deferred application and final provisions

Article 72 - Entry into force and application

Proposed new regulation

Article 72 regulates the entry into force and the date of application of the Regulation.

Proposed amendments

Art. 72		This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from 12 months after its entry into force. However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31 shall apply as follows: (a) from 1 year after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data.; (b) from 3 years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to process such categories of data; (c) from the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data. Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from 3 years after date of entry into application. This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from 12 months after its entry into force. However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31 shall apply as follows: (a) from ~~1~~ ***2*** year***s*** after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data.; (b) from ~~3~~ ***4*** years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to process such categories of data; (c) from the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data. ***Article 9 para. 1 shall apply five years after the date of application to the categories of personal electronic health data referred to in Article 5 para. 1 and to EHR systems designated by the manufacturer to process such categories of data. For the cross-border use of identification and authentication mechanisms, Article 9***

			para. 1 shall apply at the earliest 18 months after the determinations under Article 9 para. 2, the establishment of the services under Article 9 para. 3 and the implementation under Article 9 para. 4. Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from 3 years after date of entry into application. This Regulation shall be binding in its entirety and directly applicable in all Member States.

Justification
The draft regulation on the EHDS must urgently be checked for compatibility with the respective national legislation and accordingly with the national task definitions. Against this background, as well as because of the very complex technical solution, for which the technical specifications still have to be drawn up, the time frame according to Article 72 - four years after entry into force at the latest - seems extremely ambitious. A gradual implementation is recommended, which should start exclusively with the patient summary (cf. opinion on Article 7).

Also against the background of the requirements for identification and authentication mechanisms, which may be laid down by the Commission by means of implementing acts pursuant to Article 9 para. 2, an adjustment of the date of application is also necessary. However, these determinations have an impact on the already established and integrated processes in the health systems of the Member States. In the German social and healthcare system, for example, a wide variety of special legislative and sub-legislative provisions have already been adopted for this purpose. Since both the specifications under Article 9 para. 2 and the establishment of the services under Article 9 para. 3 are mandatory prerequisites for the cross-border use of means of identification and authentication under paragraph 1, implementation can only take place at a later date (cf. opinion on Article 9).

Annex II - Essential requirements for EHR systems and for products claimed to be interoperable with EHR systems

Proposed new regulation
Annex II contains, among other things, essential requirements for the interoperability and security of EHR systems.

Proposed amendments

Annex II	Point 3, Paragraph 3.10-	[*Essential requirements for EHR systems and products*	*(Added)* ***3.10 The security of an EHR system is proven by means of***

	3.12 *(new)*	*claiming interoperability with EHR systems*]	***an independent security opinion on data protection and information security. These individual assessments are carried out by a qualified independent expert (e.g. ISO/IEC 27001 lead auditor).*** ***3.11 The manufacturer of an EHR system must*** ***(a) demonstrably ensure the detection and analysis of technical hardware or software vulnerabilities,*** ***(b) ensure that technical and organisational procedures are in place to address security deficiencies in the products for the EHR systems it offers during the period of use,*** ***(c) ensure that the system is resilient to the risks identified in the current and the two previous OWASP Top 10 report(s) for the EHR systems it offers,*** ***d) create and apply a test plan for safety tests. The test plan must include all safety tests during the product development phases as well as regular safety tests (penetration tests) by independent security experts,*** ***e) integrate and apply safety activities within the product life cycle (development, operation, decommissioning) of its EHR system, i.e. apply recognised, tested and proven rules.*** ***3.12 An EHR system must comply with the requirements***

			of Regulation (EU) 2016/679, in particular on data protection by design (Article 25) and security of processing (Article 32).

Justification
The definition of interoperability and security requirements for EHR systems, the implementation of which is ensured by the competent national organisations (cf. commentary on Article 10), is welcomed in principle. However, for reasons of transparency, proof of security should be provided by means of an independent security report on data protection and information security. These individual assessments should be carried out by qualified independent experts (e.g. ISO/IEC 27001 lead auditor).

In addition to the system requirements, there are also requirements to be met by the manufacturer of an EHR system, which must at least

- demonstrably ensure the detection and analysis of technical hardware or software vulnerabilities,
- ensure that technical and organisational procedures are in place to address security deficiencies in the products for the EHR systems it offers during the period of use,
- ensure that the system is resilient to the risks identified in the current and the two previous OWASP Top 10 report(s) for the EHR systems it offers,
- create and apply a test plan for safety tests. The test plan must include all safety tests during the product development phases as well as regular safety tests (penetration tests) by independent security experts,
- integrate and apply safety activities within the product life cycle (development, operation, decommissioning) of its EHR system, i.e. apply recognised, tested and proven rules.

In addition, the manufacturer of an EHR system must be obliged to comply with the provisions of Regulation (EU) 2016/679 (GDPR).