Berufsverband Deutscher Psychologinnen und Psychologen e. V.

Proposals of the Association of German Professional Psychologists (BDP) to amend and supplement the Regulation of the European Parliament and of the Council on the European Health Data Space (EHDS)

(Proposed amendments are shown in red, proposed deletions in strikethrough font)

EHDS 2022	Proposal of the BDP	Reasons and comments
Recital 5 More and more people in Europe are crossing national borders to work, study, visit relatives or travel. To facilitate the exchange of health data and empower citizens, they should be able to access their health data in an electronic format that can be recognised and accepted throughout the Union. Such personal electronic health data could include personal data relating to the physical or mental health of a natural person, including the provision of health services, revealing information about his or her state of health, personal data relating	Recital 5 More and more people in Europe are crossing national borders to work, study, visit relatives or travel. To facilitate the exchange of health data and empower citizens, they should be able to access their health data in an electronic format that can be recognised and accepted throughout the Union. Such personal electronic health data could include personal data relating to the physical or mental health of a natural person, including the provision of health services, revealing information about his or her state of health, personal data relating	The insertion reflects relevant aspects of the realities in the public and political discussion and also in responses of many citizens in opinion polls regarding autonomy and data sovereignty.

to the inherited or acquired genetic characteristics of a natural person which provide unique information about the physical condition or health of that natural person and which are specifically the result of an analysis of a sample of biological material from that natural person, and data determinants of health such as behaviour, environment, physical influences, medical care, social factors or educational/training-related factors. Electronic health data also includes data originally collected for research, statistical, policy-making or regulatory purposes, which may be made available under the rules in Chapter IV. Electronic health data concern all categories of such data, whether provided by the data subject or other natural or legal persons, such as health professionals, or processed in relation to the health or well-being of a natural person, and should also include inferred and derived data, such as on diagnoses, tests and medical examinations, as well as automatically collected and recorded data.	to the inherited or acquired genetic characteristics of a natural person which provide unique information about the physical condition or health of that natural person and which are specifically the result of an analysis of a sample of biological material from that natural person, and data determinants of health such as behaviour, environment, physical influences, medical care, social factors or educational/training-related factors. Electronic health data also includes data originally collected for research, statistical, policy-making or regulatory purposes, which may be made available under the rules in Chapter IV. Electronic health data concern all categories of such data, whether provided by the data subject or other natural or legal persons such as health professionals, or processed in relation to the health or well-being of a natural person, and should also include inferred and derived data, such as on diagnoses, tests and medical examinations, as well as automatically collected and recorded data. The wide range of data types requires regulation with differentiated	

	access rights to protect third party data without their consent. In particular, this also fundamentally concerns social data and mental health data in general.	
Art 1 para 2 a) This Regulation (a) strengthens the rights of natural persons in relation to the availability of and control over their electronic health data;	Art 1 para 2 a) This Regulation (a) strengthens the rights of natural persons in relation to the availability of, and control over, their electronic health data in ~~relation to the~~ primary and secondary use of their electronic health data;	The absence of this complement makes one suspicious: Primary and secondary use are the main subject of this regulation - but the rights of natural persons are exhausted in the mention of availability and control. In particular, what control consists of is not obvious in the rest of the text of the regulation. The mention here makes it clear that it is about the self-determination of natural persons.
Art 2 para 1 m) "Electronic health record (EHR)" means a collection of electronic health data relating to a natural person, recorded in the health system, processed for health purposes.	Art 2 para 1 m) "Electronic health record (EHR)" means a collection of electronic health data relating to a natural person, recorded in the health system, processed for health purposes. The EHR contains a locker that can only be accessed by the natural person, so that primary and secondary use of the health data stored in the locker is only possible if	If the storage of particularly sensitive data cannot be specifically excluded by an opt-in, we recommend a "personal locker" as an alternative. Here, strikingly called "locker", this addition to the EHR secures what sometimes seems doubtful in the EHDS: that the data subject himself is the linchpin of the processing of his own personal health data.

	the natural person has consented to it;	If, in the draft, the EHEA - especially with regard to secondary use - does not have the guarantee that priority will be given to those concerned to decide on use, this will be safeguarded by the locker.
Art 3(4), first sentence: 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.~~	Art 3 para. 4 sentence 1 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 in so far as it is regulated there that the natural person must have consented to it.	This addition is advisable, because otherwise the first possible place where the rights of the data subjects are observed would remain unmentioned.
Art 3 para. 8 sentence 1: 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.	Art 3 para. 8 sentence 1 and sentence 2 (inserted): 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. They may revoke their decision within	This is duplicate data. It is not justifiable to remove them - once they have been set - from the patient's disposition, even though they change their mind, if the data may still be available at the original location (or they had already been deleted there for data protection reasons, in which case it is legally compliant not to perpetuate them in the EHR purely out of a desire to collect them).

	the meaning of sentence 1 at any time; the data transmitted shall be deleted from the recipient without delay.	
Art 3 par.9 Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of health professionals to all or part of their electronic health data. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.	Art 3 par.9 Notwithstanding Article 6(1)(d) of Regulation (EU) 2016/679, natural persons shall have the right to restrict access ~~of health professionals~~ to their electronic health data or parts thereof, so that when using the EHR neither the data nor its existence and its restriction are identifiable; in particular, the natural person may decide that health data are stored only in the locker or are moved from the EHR to the locker. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.	The explicit designation of health professionals leads to the question of who, by implication, can access the data without the natural person being able to restrict it. Since the possibility to restrict is an expression of a fundamental and human right, the restriction to health professionals should be deleted. Patient autonomy must be taken into account: If the right of restriction is used, it must also be effective. Only a blocking that reveals the existence of the data forces the person entitled to it to explain or justify himself on demand.
Art 4 par.1 a) Where they process data in an electronic format, health professionals shall: (a) have access to the electronic health data of natural persons under their treatment, irrespective of the	Art 4 par.1 a) Where they process data in an electronic format, health professionals shall: (a) have access to the electronic health data of natural persons under their treatment, irrespective of the	dito

Member State of affiliation and the Member State of treatment;	Member State of affiliation and the Member State of treatment; to the extent and for as long as they have consented and have not withdrawn their consent;	
Art 4 para. 3 sentence 1 Member States shall ensure that access to at least the priority categories of electronic health data referred to in Article 5 is made available to health professionals through health professional access services.	Art 4 para. 3 sentence 1 Member States shall ensure that access to at least the priority categories of electronic health data referred to in Article 5 is made available to health professionals through health professional access services to the extent and for as long as those natural persons have consented thereto and have not withdrawn their consent.	dito
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 informed of the existence and nature of the restricted electronic health data. In cases where processing is necessary in order to	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 with~~out~~ the prior authorisation by the natural person, including where the provider or professional is informed of the existence and nature of the restricted electronic health data. In cases where processing is necessary in order to	The restriction loses considerable value if it is always recognisable as such. The wording with the "content" means that the existence of the data remains visible in the file. In general, it is appropriate to primarily take into account that also in such cases the persons concerned are at least involved in the decision or their decision should be followed and

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.	protect the vital interests of the data subject or of another natural person and there is no capacity to consent, 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.	taken into account as far as possible. It is therefore proposed to allow a decision over the head of the natural person concerned only if he or she is not capable of giving consent.
Art 33 par.5 Where the consent of the natural person is required by national law, health data access bodies shall rely on the obligations laid down in this Chapter to provide access to electronic health data.	Art. 33 par. 5 Insofar as the data referred to in paragraph 1, including any additions pursuant to paragraph 7, are personal health data, secondary use shall only be possible insofar as the natural persons have consented and have not revoked their consent.	This proposed amendment is intentionally a fundamental change to the proposed regulation. In the view expressed here, it is indispensable that EU citizens, as patients, have full sovereignty over their health data, even in secondary use. Secondary use is only possible with the informed consent of the data subjects. If patients have the right to make decisions at the time of primary use, they must have the right to make

		decisions at the time of secondary use. The fact that data protection measures are certainly recognisable further down in the text of the regulation when authorising data is not enough. At the beginning of the regulation, the fundamental decision-making power of the persons concerned is required at a central point, and this must also take effect before personal health data reaches an access point. Not to make this fundamental change would mean going over the heads of EU citizens and processing their most sensitive data, thus making them the object of economic and research interests.
ANNEX II 1. General requirements 1.1. An electronic health record system (EHR system) shall achieve the performance intended by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose and	ANNEX II 1. General requirements 1.1. An electronic health record system (EHR system) shall achieve the performance intended by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose and	Here, the mandatory part of the locker is specified in Annex II as new 1.5. Here, it can also be added that the data on mental illnesses are automatically entered into the locker - unless the patient consents otherwise.

its use does not put at risk patient safety. 1.2. An EHR system shall be designed and developed in such a way that it can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its intended use. 1.3. An EHR system shall be designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II of this Regulation. 1.4. An EHR system that is intended to be operated together with other products, including medical devices, shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between the device and the EHR system.	its use does not put at risk patient safety. 1.2. An EHR system shall be designed and developed in such a way that it can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its intended use. 1.3. An EHR system shall be designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II of this Regulation. 1.4. An EHR system that is intended to be operated together with other products, including medical devices, shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between the device and the EHR system.	The last sentence is important, as it makes clear that it is not about circumventing the goal of interoperability via the locker. It is about the data sovereignty of the patients.

	1.5 An EHR system must provide a locker in the EHR. The locker must ensure that the data contained therein can only be processed for the primary and secondary use described in this regulation if the natural person has consented. The locker must ensure that in the primary and secondary use - not even for the health data access bodies - it is not recognizable which data is stored there. The EHR system must ensure that data about mental illnesses and their treatment documentation are automatically stored in the locker unless the natural person has consented to storage on the EHR outside of the locker. The locker should meet the interoperability requirements.	

Download full text of the proposal: https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A52022PC0197&qid=1680020413172