European Committee of the Regions

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DRAFT OPINION

European Health Data Space

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Deadline for tabling amendments:

3 p.m. (Brussels time) on **24 January 2023**. Amendments must be submitted using the online tool for tabling amendments (available through the Members' Portal at https://memportal.cor.europa.eu/).

Number of signatures required: 6

Reference document

Proposal for a regulation of the European Parliament and of the Council on the European Health Data Space

COM(2022) 197 final

2022/0140 (COD)

Draft opinion of the European Committee of the Regions –
European Health Data Space

I. RECOMMENDATIONS FOR AMENDMENTS

Amendment 1
Article 1(2) new letter (a[1])

Text proposed by the Commission	*CoR amendment*
This Regulation: (...)	This Regulation: (..) ***(a[1]) strengthens the rights of data users in relation to access to health data for the purposes set out in Chapter IV of the Regulation.***

Reason
It is also important to mention data users' right to process health data.

Amendment 2
Article 2.2(y)

Text proposed by the Commission	*CoR amendment*
‘data holder’ means any natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law, or in the case of non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;	"data holder" means any natural or legal person, ***at national or regional level, depending the health organization of the Member State,*** which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law, or in the case of non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;

Reason
Self-explanatory.

Amendment 3
Article 2.2(ad)

Text proposed by the Commission	*CoR amendment*
'data quality' means the degree to which characteristics of ***electronic*** health data ***are***	"data quality" means the degree to which characteristics of health data ***meet the***

suitable for ***secondary*** use;	***requirements*** for use;

Reason
The definition of the quality of information generated in the healthcare sector cannot be based solely on secondary use. The concept of quality should also take into account the aim of providing care. Furthermore, different uses may have different data requirements; the same data can be deemed as having different quality depending on how they are used.

Amendment 4
Article 3(6)

Text proposed by the Commission	***CoR amendment***
Natural persons may insert their electronic health data in their own EHR or in that of natural persons whose health information they can access, through electronic health data access services or applications linked to these services. That information shall be marked as inserted by the natural person or by his or her representative.	Natural persons may***, in accordance with the rules of their healthcare provider,*** insert their electronic health data in their own EHR or in that of natural persons whose health information they can access, through electronic health data access services or applications linked to these services. That information shall be marked as inserted by the natural person or by his or her representative.

Reason
To highlight the importance of healthcare providers being able to control which information can be added to the medical record. Otherwise, there is a risk of collecting large volumes of sensitive personal data that is of poor quality.

Amendment 5
Article 3(9)

Text proposed by the Commission	***CoR amendment***
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.	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. ***These rules and protective measures must not hinder the ability of healthcare services to provide good, safe and equitable care. Natural persons should be informed of the patient safety risks associated with limiting access to health data.***

Reason
The aim of providing care must take precedence over any possibility of restrictions. It should not be possible to block access to certain information, such as warning notices; nor should legal guardians have the right to block children's data at their own discretion.

Amendment 6
Article 4(3)

Text proposed by the Commission	*CoR amendment*
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. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access services, free of charge.	Member States ***and, where appropriate, local or regional authorities*** 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***, including for cross-border care,*** through health professional access services. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access services, free of charge.

Reason
To take account of regional competences in the field of health in various Member States.

Amendment 7
Article 4(4)

Text proposed by the Commission	*CoR amendment*
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 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.	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 health data without prior authorisation by the natural person***. However,*** the provider or professional ***must be able to see that such*** restricted health data ***exists***. 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.

Reason
Healthcare professionals should be informed that certain information is blocked, even if the content of this information is not available. Providing good care presupposes knowing whether or not all the

information is available.

Amendment 8
Article 5(2)

Text proposed by the Commission	*CoR amendment*
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. (...) (c) international standards exist for the category that have been examined for the possibility of their application in the Union**.**	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. (...) (c) international standards exist for the category that have been examined for the possibility of their application in the Union***; (d) the need to share information in the priority categories shall be determined by the Member States.***

Reason
The priorities of new categories must be guided by real needs in the Member States. In many countries, the regional and local level is responsible for healthcare and must be involved in the prioritisation process.

Amendment 9
Article 10(1)

Text proposed by the Commission	*CoR amendment*
Digital health authority (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 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.	Digital health authority 1. Each Member State shall designate a digital health authority responsible for the implementation and enforcement of this Chapter at national level. ***The Member States may also complement this with regional e-health authorities responsible for implementation and enforcement at regional 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 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.

Reason
To introduce the possibility of designating regional e-health authorities.

Amendment 10
Article 10 (2) (h)

Text proposed by the Commission	*CoR amendment*
Each digital health authority shall be entrusted with the following tasks: (...) (h) contribute, at Union level, to the development of the European electronic health record exchange format and to the elaboration of common specifications addressing interoperability, security, safety or fundamental right concerns in accordance with Article 23 and of the specifications of the EU database for EHR systems and wellness applications referred to in Article 32;	Each digital health authority shall be entrusted with the following tasks: (...) (h) contribute, at Union level***, and in cooperation with the local and regional level within the Member States,*** to the development of the European electronic health record exchange format and to the elaboration of common specifications addressing interoperability, security, safety or fundamental right concerns in accordance with Article 23 and of the specifications of the EU database for EHR systems and wellness applications referred to in Article 32;

Reason
Where the regional and local level is responsible for healthcare within a Member State, it is not sufficient for a State authority to contribute to developing the format.

Amendment 11
Article 10 (2) (k)

Text proposed by the Commission	*CoR amendment*
Each digital health authority shall be entrusted with the following tasks: […] (k) ***offer***, in compliance with national legislation, telemedicine services and ensure that such services are easy to use, accessible to different groups of natural persons and health professionals, including natural persons with disabilities, do not discriminate and offer the possibility of choosing between in person and digital services;	Each digital health authority shall be entrusted with the following tasks: […] (k) ***where a Member State allows the provision of telemedicine services,*** in compliance with national legislation, ***facilitate the provision of*** telemedicine services and ensure that such services are easy to use, accessible to different groups of natural persons and health professionals, including natural persons with disabilities, do not discriminate and offer the possibility of choosing between in person and digital services;

Reason
Digital health authorities should not provide telemedicine services; Member States which do offer such services should facilitate the provision thereof.

Amendment 12
Article 10(2)(m)

Text proposed by the Commission	*CoR amendment*
(m) cooperate with other relevant entities and bodies at national or Union level, to ensure interoperability, data portability and security of electronic health data, as well as with stakeholders representatives, including patients' representatives, healthcare providers, health professionals, industry associations;	(m) cooperate with other relevant entities and bodies at ***local, regional,*** national or Union level, to ensure interoperability, data portability and security of electronic health data, as well as with stakeholders representatives, including patients' representatives, healthcare providers, health professionals, industry associations;

Reason
To take account of regional competences in the field of health in various Member States.

Amendment 13
Article 23(1)

Text proposed by the Commission	*CoR amendment*
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.	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. ***When developing common specifications, the starting point shall be the use of electronic health record systems to support good healthcare.***

Reason
The main purpose of patient records is to support good healthcare. This must be the starting point when developing common specifications with a view to tapping good practices and the experience of Member States which have already developed a system of electronic health records.

Amendment 14
Article 29(4)

Text proposed by the Commission	*CoR amendment*
Manufacturers of EHR systems placed on the market shall report any serious incident involving an EHR system to the market surveillance authorities of the Member States where such serious incident occurred and the corrective	Manufacturers of EHR systems placed on the market shall report any serious incident involving an EHR system to the market surveillance authorities of the Member States where such serious incident occurred and the corrective

actions taken or envisaged by the manufacturer. Such notification shall be made, without prejudice to incident notification requirements under Directive (EU) 2016/1148, immediately after the manufacturer has established a causal link between the EHR system and the serious incident or the reasonable likelihood of such a link, and, in any event, not later than ***15*** days after the manufacturer becomes aware of the serious incident involving the EHR system.	actions taken or envisaged by the manufacturer. Such notification shall be made, without prejudice to incident notification requirements under Directive (EU) 2016/1148, immediately after the manufacturer has established a causal link between the EHR system and the serious incident or the reasonable likelihood of such a link, and, in any event, not later than ***7*** days after the manufacturer becomes aware of the serious incident involving the EHR system.

Reason
The time limit should not exceed one week. The deadline of 15 days for notification of a serious incident considerably increases the risk of it causing serious harm.

Amendment 15
Article 33

Text proposed by the Commission	***CoR amendment***
CHAPTER IV Secondary use of electronic health data Section 1 General conditions with regard to the secondary use of electronic health data Article 33	CHAPTER IV Secondary use of electronic health data Section 1 General conditions with regard to the secondary use of electronic health data Article 33 ***Rights of natural persons in relation to the secondary use of their personal electronic health data*** ***For the secondary use of their data, natural persons shall have the right to express their decision to opt-out the system of health data-sharing in order not to make available their health-related data to third persons, in accordance to article 21 of Regulation (EU) 2016/679.***

Reason
The natural persons should have the right to control the use made of their own data.

Amendment 16
Article 33(1)

Text proposed by the Commission	***CoR amendment***
Data holders shall ***make the following*** categories of electronic data available for secondary use in accordance with the provisions	***The Member States*** shall***, in consultation with the Commission, determine which*** categories of electronic data ***data holders shall make***

of this Chapter***: (a) (...) (o)***	available for secondary use in accordance with the provisions of this Chapter***. This can be regulated by means of implementing acts adopted in accordance with the advisory procedure referred to in Article 68(2).***

Reason
The Regulation should not specify all categories. More work and analysis is needed to determine the types of data to be shared. It would therefore be more appropriate to do this with implementing acts. The list significantly interferes with existing national legislation.

Amendment 17
Article 33.5

Text proposed by the Commission	***CoR amendment***
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.	Where the consent of the natural person is required by national law ***or when the natural person has decided to opt out from the data sharing system for the secondary use of data***, health data access bodies shall rely on the obligations laid down in this Chapter to provide access to electronic health data.

Reason

Amendment 18
Article 35(e)

Text proposed by the Commission	***CoR amendment***
(e) developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages***,*** tobacco products***, or goods or services which are designed or modified in such a way that they contravene public order or morality.***	(e) developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages ***or*** tobacco products***.*** ***(f) developing products or services that may create discriminations (in terms, of race, gender, age or sexual orientation).***

Reason
What constitutes public order and morality is a question of values. It is therefore inappropriate for the EU to introduce rules concerning morality in the EHDS. Where specific goods and services are concerned, they should instead be explicitly specified, possibly by means of an implementing act. The reasons for subparagraph (f) are self-explanatory.

Amendment 19

Article 36(3)

Text proposed by the Commission	*CoR amendment*
(3) 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.	(3) 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. ***A conflict of interest shall be understood to mean the existence of a direct or indirect formal link with one or more entities that are data holders or beneficiaries.*** Health data access bodies shall not be bound by any instructions ***from another external entity***, when making their decisions.

Reason
The term "conflict of interest" requires a clearer definition. The wording "shall not be bound by any instructions" needs to be clarified. Internal rules/regulations should not be included in this category.

Amendment 20
Article 38(3)

Text proposed by the Commission	*CoR amendment*
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 ***shall*** inform the natural person and his or her treating health professional about that finding***, unless the natural person has objected, by means of a registered declaration of intent to the data holder, to receiving such information.***

Reason
The reporting of such findings to the person concerned and to his or her treating health professional should be made mandatory, provided the natural person does not object to receiving such information.

Amendment 21
Article 43.1

Text proposed by the Commission	*CoR amendment*
1. Health data access bodies shall monitor and supervise compliance by data users and data holders with the requirements laid down in this Chapter.	1. Health data access bodies shall monitor and supervise compliance by data users and data holders with the requirements laid down in this Chapter ***and the Regulation (EU) 2016/679***.

Reason
The GDPR Regulation should be taken into account.

Amendment 22
Article 43(4)

Text proposed by the Commission	*CoR amendment*
Health data access bodies shall have the power to revoke the data permit issued pursuant to Article 46 and stop the affected electronic health data processing operation carried out by the data user in order to ensure the cessation of the non-compliance referred to in paragraph 3, immediately or within a reasonable time limit, and shall take appropriate and proportionate measures aimed at ensuring compliant processing by the data users. In this regard, the health data access bodies shall be able, where appropriate, to revoke the data permit and to exclude the data user from any access to electronic health data for a period of up to 5 years.	Health data access bodies shall have the power to revoke the data permit issued pursuant to Article 46 and stop the affected electronic health data processing operation carried out by the data user in order to ensure the cessation of the non-compliance referred to in paragraph 3, immediately or within a reasonable time limit, and shall take appropriate and proportionate measures aimed at ensuring compliant processing by the data users. In this regard, the health data access bodies shall be able, where appropriate, ***to fine (up to 10% of the data user's annual turnover for the previous financial year) or*** to revoke the data permit and to exclude the data user from any access to electronic health data for a period of up to 5 years.

Reason
The sanctions must be reinforced in case of misuse of the Regulation.

Amendment 23
Article 46.3

Text proposed by the Commission	*CoR amendment*
3. A health data access body shall issue or refuse a data permit within ***2*** months of receiving the data access application. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period for responding to a data access application by 2 additional months where necessary, taking into account the complexity of the request. In such cases, the health data access body shall notify the applicant as soon as possible that more time is needed for examining the application, together with the reasons for the delay. Where a health data access body fails to provide a decision within the time limit, the data permit shall be issued.	3. A health data access body shall issue or refuse a data permit within ***3*** months of receiving the data access application. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period for responding to a data access application by 2 additional months where necessary, taking into account the complexity of the request. In such cases, the health data access body shall notify the applicant as soon as possible that more time is needed for examining the application, together with the reasons for the delay. Where a health data access body fails to provide a decision within the time limit, the data permit shall be issued.

Reason
The health data access body might need some time to assess the applications.

Amendment 24
Article 47(3)

Text proposed by the Commission	*CoR amendment*
Where an applicant has requested a result in an anonymised form, including statistical format, based on a data request, the health data access body shall assess, within 2 months and, where possible, provide the result to the data user within 2 months.	Where an applicant has requested a result in an anonymised form, including statistical format, based on a data request, the health data access body shall assess, within 2 months and, where possible, provide the result to the data user within 2 months. ***Where it is not possible to provide the data, the health data access body shall provide the applicant with a reasoned explanation for the refusal.***

Reason
The article states that the data is to be provided "where possible". Where it is not possible to provide the data, the applicant should receive a reasoned explanation of why this is not possible.

Amendment 25
Article 49.1

Text proposed by the Commission	*CoR amendment*
1. Where an applicant requests access to electronic health data only from a single data holder in a single Member State, by way of derogation from Article 45(1), that applicant may file a data access application or a data request directly to the data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47. Multi-country requests and requests requiring a combination of datasets from several data holders shall be addressed to health data access bodies.	1. Where an applicant requests access to electronic health data only from a single data holder in a single Member State, by way of derogation from Article 45(1), that applicant may file a data access application or a data request directly to the data holder. The ***single data holder shall refuse the data authorisation in the circumstance of which individual cases may be attributed to a specific person despite pseudonymisation. The*** data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47. Multi-country requests and requests requiring a combination of datasets from several data holders shall be addressed to health data access bodies.

Reason
Anonymity is key concerning health data.

Amendment 26
Article 50 (1, f)

Text proposed by the Commission	*CoR amendment*
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 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 ***minimise*** potential security threats.

Reason
The aim of security measures should be to minimise potential security threats and not merely mitigate them.

Amendment 27
Article 65(1)

Text proposed by the Commission	*CoR amendment*
Tasks of the EHDS Board (1) The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III: (...) (b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards: (...)	Tasks of the EHDS Board (1) The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III: (...) (b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, ***taking into account the regional and local level,*** in particular as regards: (...)

Reason
To highlight the importance of including the local and regional level.

II. POLICY RECOMMENDATIONS

THE EUROPEAN COMMITTEE OF THE REGIONS

Regarding data security and protection:

1. welcomes the Commission's proposal for a European Health Data Space (EHDS) and stresses the need for healthcare services to be able to benefit from such infrastructure, while ensuring the security of patients' privacy and data rights[1];

2. welcomes the ambition in the proposal to create new and expanded opportunities for primary and secondary use of health data for the benefit of patients, healthcare, research and society as a whole. Improving access to health data is a prerequisite for developing modern healthcare;

3. believes that giving patients access to their own health data and enabling them to share it with healthcare services facilitates joined-up care, improves patient safety and gives patients more opportunities to be active co-creators of their own care. Controlled and privacy-proof use of health data for research, policy-making and product development is also an important prerequisite for new medical progress, greater patient safety and better monitoring of health care outcomes;

4. points out that the overarching purpose of health data, and of sharing it, is to provide patients with the best possible healthcare and to ensure the quality of the healthcare provided;

5. considers that EHDS objectives and rules have a positive impact on the free movement of goods and services as well as on patients' access to good healthcare in their home country;

6. highlights the fact that medical records are one of the most important tools for healthcare providers and professionals in organising and providing good healthcare that is safe for patients; it must therefore be possible to develop medical documentation with due regard for both the common standards established by the EHDS and the additional national and regional standards established by each Member State in line with specific local needs;

7. draws attention to the need to clarify whether or not social services are covered by the new Regulation, as some Member States record both social and health data together, while others make a distinction;

8. believes that the Regulation will require major development work at European, national, regional and local level, which will take up substantial financial, time and human resources. The cost estimates included in the proposal do not identify local and regional costs clearly enough. While these costs can undoubtedly be partly funded under various EU programmes, it is unclear to what extent Member States' transition costs will be covered and how the costs incurred by the various stakeholders will be handled;

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1 CoR opinion on A pharmaceutical strategy for Europe and legislative proposal for changing the mandate of the European Medicines Agency (EMA).

9. stresses that, as the digitalisation of health data increases cybersecurity risks, all parties involved must comply with the highest standards of data protection and security. Europeans must be assured that their personal health data will be processed with the utmost care, based on a robust framework and robust data protection and security systems with appropriate safeguards;

10. stresses that, in seeking to empower individuals to have increased access to and control over their electronic health data, the Regulation needs to ensure that vulnerable groups, and in particular older people with limited digital skills or limited access to digital resources, are not neglected[2];

11. regrets that the right of self determination of natural persons is completely disregarded in the Regulation and protests against the fact that the Regulation does not comply with the obligations under the Regulation (EU) 2016/679 (GDPR);

12. highlights that the creation of the EHDS is made more difficult by a lack of experts and technical know-how and by a limited number of providers with the necessary expertise to build and maintain health data systems and infrastructure that meet high security and data protection requirements;

13. calls on the Commission to discuss and present suggestions on how the Union can support the development of additional physical infrastructure for data storage in the Member States, including at local and regional level;

Regarding interoperability:

14. is concerned that, in the absence of clear guidelines, the implementation of the EHDS could lead to a fragmented approach, similar to the GDPR experience, resulting from uneven implementation and different interpretations at national and even regional level across the EU;

15. considers that common specific rules, operating models and solutions are therefore needed if the Regulation is to be implemented uniformly across all Member States and to ensure that the cross-border use of health data respects Europeans' right to privacy; in this regard, is pleased that the current proposal makes it mandatory to use the electronic health record exchange format;

Regarding data quality:

16. points out that the data used for research or policy-making, as well as for the provision of healthcare, must be reliable, consistent, fit for purpose, representative and measurable; welcomes the requirements set out in the proposal – specifying the types and main characteristics of the health data – but considers that the quality requirements warrant greater attention;

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2 Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies.

17. notes, however, that several Member States are already working at national and decentralised level to find digital solutions for the exchange of data across sectors, and for many of the other elements contained in the Regulation. Therefore, the experience acquired through this type of initiative should be harnessed and tapped in future through the EHDS;

18. further points out that the development of the framework for exchanging data between Member States must be based on international standards such as FHIR profiling and SNOMED CT standards. This will make European work relevant to any non-EU countries that are already looking towards and collaborating with a number of Member States on the fluid exchange of data across systems, etc.;

19. considers that giving individuals the right and option to modify and enter data in their personal electronic health records might lead to problems with the quality of those records, and suggests that more detailed consideration be given to how these issues could be addressed;

Regarding governance:

20. stresses that the success of the EHDS requires a multi-level governance approach and solutions not only at EU and national level, but also at regional and local level;

21. believes that one of the challenges involved in rolling out the EHDS will be providing sufficient resources and infrastructure, including physical infrastructure at national, regional and local level, to cover the storage of, access to and exchange of health data for healthcare provision, research, policy-making and regulatory activities;

22. stresses the need to further clarify the role and powers of the EHDS Board. While the board is to be composed of representatives of the digital health authorities and health data access bodies from all of the Member States, the role of the observers, experts, stakeholders and other third parties, and the arrangements for their participation in the work of the board, are unclear;

23. notes that the proposal requires the standardisation of data across Member States in order for data to be exchanged. This could have significant administrative and financial implications for local and regional authorities, as any new data standards would need to be integrated into authorities' existing IT systems and staff would need to be given training to work with these new standards;

24. calls for the CoR, as the representative of local and regional authorities, to be represented on the EHDS Board;

25. believes that, as the current proposal provides leeway for implementing many of its practical aspects through implementing acts, this risks increasing fragmentation and delays and moving away from the needs of patients and innovators, especially as these needs go beyond the technical aspects and also encompass the tasks of the digital health authorities and health data access bodies, the minimum categories of data for secondary use, detailed rules and specifications, etc.;

26. regrets that the Regulation does not propose any notable security or sanctions, particularly financial sanctions, such as fines, in order to make sure that data-users, under chapter 4, will use the health-data of natural persons in a way that comply with the present Regulation, the Regulation (EU) 2016/679 (GDPR) and The Charter of Fundamental Rights of the European Union;

Regarding subsidiarity:

27. in its current form, the proposal for a regulation does not appear to pose any problems as regards its compliance with the principle of subsidiarity in terms of the proposed objectives of portability and interoperability of data, as these cannot be properly regulated by Member States/regions and/or local authorities acting alone. Furthermore, the EHDS has a number of benefits which contribute to closing the gap between EU regions and to providing reliable information used to devise health policies geared to local needs. Another aspect which must not be overlooked is the scientific benefits regarding the positive or negative (adverse) effects of the various medical technologies used, the findings of which can be rapidly put to use in the most far flung or disadvantaged regions. However, care must be taken to ensure that the proposed Regulation does not exceed the EU's competences and that it does uphold the rights of Member States and/or regional or local authorities with regard to the organisation of healthcare, given that a number of countries have chosen to devolve various responsibilities for healthcare to regional or local authorities, allowing decisions to be taken as closely as possible to citizens.

Brussels, ...

III. PROCEDURE

Title	European Health Data Space
Reference(s)	COM(2022) 197 final
Legal basis	Art. 307(1)
Procedural basis	Rule 41a)
Date of Council/EP referral/Date of Commission letter	30 June 2022
Date of Bureau/President's decision	
Commission responsible	Commission for Natural Resources
Rapporteur	**Daniela Cîmpean (EPP/RO)**, President of Sibiu County Council
Analysis	13 July 2022
Discussed in commission	22 November 2022
Date adopted by commission	22 November 2022
Result of the vote in commission (majority, unanimity)	majority
Date adopted in plenary	Scheduled for 8-9 February 2023
Previous Committee opinions	
Date of subsidiarity monitoring consultation	