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Deutsche Sozialversicherung
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Feedback from German Social Insurance European Representation on the European Health Data Space (EHDS)

German Social Insurance European Representation (DSV) welcomes the aim of creating a common health data space (EHDS). It offers the opportunity for added value for patients and healthcare systems, both through digital, cross-border access to health data for medical treatment and its meaningful pooling for research purposes.

The following aspects are of particular importance to DSV:

Compatibility with the national infrastructures
The best possible European interconnection must go hand-in-hand with the least possible encroachment into national telematics infrastructures (TI) and institutions. A step-by-step approach, starting with the exchanging of electronic patient summaries, might also make sense against this background. However, the measures envisioned in the draft regulation would severely affect the ongoing national implementation of the electronic health record (EHR), the National Contact Point for eHealth, and other TI applications. Uniform European formats and specifications, identification and authentication procedures as well as the networking of health data for research purposes, which is currently being established, would lead to extensive adjustments having to be made to the current specifications for the TI application structures, but this would depend on their specific designs. When it comes to the specifications still to be prepared, member states' opportunities for co-determination must be strengthened in order to maintain the principle of proportionality and the intended timeframe must also be reviewed.

The special role of social insurance institutions
Social insurance institutions generate and process data for optimising national care structures and are therefore key actors for secondary use. They are not only data owners, but also data users and data providers. This needs to be made clearer in the regulation. The EHR offered by health insurers must continue to be the central electronic health record for their insured. A market launch of EHR by organisations outside of health insurance providers would have a significant impact on established care structures and the health insurance system.

Ensuring the overall benefit to society
The provision of health data for research purposes should, in principle, also be based on public welfare criteria. Research should be oriented towards the needs of the care and health systems. Research results should become publicly available. Social insurance institutions already provide data for research purposes. The existing discretion as to what data is released should be maintained. If data from the European solidarity community is used by commercial enterprises to develop products and services that are financed by social insurance, then this must be taken into account in a price-reducing way.

Respecting the quality and data (protection) standards
Data usage must be based on a common understanding and practical data protection under the GDPR. It is inevitable that health data should only be held where it will be processed. The designated data access point must not hold its own health data. The minimum categories of electronic health data for secondary use, their usage purposes and the people entitled to apply for it must be critically reviewed. The inclusion of wellness applications should be rejected as long as they do not have adequate quality standards. On the other hand, valid data from medical devices certified under EU Regulation 2017/745 should be

included in the EHR. The proposed regulations covering telemedicine are of a benefit law nature and they do not belong in the regulation for regulatory reasons. The option of patients having a say in the use of their data must continue to be regulated at national level and should also be differentiated between primary and secondary use.