Exploring the Implications of the New EHDS Regulation for Telemedicine and the EEHRxF

Telemedicine has emerged as a promising tool in modern healthcare delivery, offering opportunities for improved patient outcomes, increased efficiency, and cost savings. Within the European Union (EU), where the movement of citizens across borders is facilitated, the potential for cross-border telemedicine services holds particular significance.

The newly adopted European Health Data Space (EHDS) regulation aims to advance interoperability and data exchange, thereby addressing some of the existing limitations in cross-border and intranational telemedicine. It is important to acknowledge the developments that come with this regulation. This post explores some possible implications of the EHDS for European telemedicine.

The EHDS regulation was first proposed in 2022, and was finally adopted in April 2024. It establishes a comprehensive framework for the secure and interoperable exchange of health data across the EU. The text agreed on is foreknown to anticipate further legislative elaborations in the form of implementing acts. They will detail the concrete specifications relating to many of the Articles of the EHDS Regulation.

The EHDS Regulation uses the European Electronic Health Record Exchange Format (EEHRxF) as the means for ensuring the secure and interoperable exchange of electronic health data across the EU. The EEHRxF comprises a set of requirements and technical specifications supporting both structured and unstructured data types. The format's scope is based on six priority categories of personal electronic health data in the EHDS: patient

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summaries; electronic prescriptions; electronic dispensations; medical imaging studies and related imaging reports; medical test results, including laboratory and other diagnostic results and related reports; discharge reports. These domains encompass many use cases and will be able to support numerous digital health applications. Still, some digital health applications may currently fall out of the format's scope, some of which are potentially part of the telemedicine umbrella (for example: auto-generated data from telemonitoring devices). Hence the need for understanding the position of telemedicine inside the EHDS Regulation as it stands.

Telemedicine in the New EHDS Regulation

One thing is for sure, the adopted EHDS regulation recognises telemedicine's potential to enhance healthcare, for it highlights the latter in several provisions: Recitals 21 and 22, and Article 13. Below we provide a short study of the implications that can be expected for each of these.

Recital 21

Recital 21: "Telemedicine is becoming an increasingly important tool that can provide patients with access to care and tackle inequities and has the potential to reduce health inequalities and reinforce the free movement of Union citizens across borders. Digital and other technological tools can facilitate the provision of care in remote regions. When digital services accompany the physical provision of a healthcare service, the digital service should be included in the overall care provision. Under Article 168 of the Treaty on the Functioning of the European Union (TFEU), Member States are responsible for their health policy, in particular for the organisation and delivery of health services and medical care, including regulation of activities such as online pharmacies, telemedicine and other services that they provide and reimburse, in line with their national legislation. Different healthcare policies should not, however, constitute barriers to the free movement of electronic health data in the context of cross-border healthcare, including telemedicine, such as online pharmacy services."

Whilst Member States remain responsible for their domestic health policy, they are advised to work together in order to not create barriers to the free movement of electronic health data in the context of cross-border healthcare, including telemedicine. Concretely, this recital mentions the of online pharmacy services. Here, the reference is made to electronic prescriptions (eP) and electronic dispensations (eD). This recital reinforces the presumption that the EEHRxF will soon become applicable to data movements related to telemedicine services, with a first focus on cross-border cases. Furthermore, Recital 21 also recognises the role of telemedicine for providing care in remote regions, indicating that the use of the format for telemedicine can also be foreseen for intra-national use cases with benefits.

On online pharmacies, it is useful to note that, in Article 12 (6), the Regulation explicitly considers online pharmacies the same way as physical pharmacies. In fact, the paragraph directs Member States to treat the two equally with regards to their duty to ensure they dispense ePrescriptions from other Member States, and report dispensations back to the issuing Member State.

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Recital 22

Recital 22: “Regulation (EU) No 910/2014 lays down the conditions under which Members States perform identification of natural persons in cross-border situations using identification means issued by another Member State, establishing rules for the mutual recognition of such electronic identification means. The EHDS requires a secure access to electronic health data, including in cross-border scenarios. Electronic health data access services and telemedicine services should implement the rights of natural persons regardless of their Member State of affiliation, and should therefore support the identification of natural persons using any electronic identification means recognised pursuant to Article 6 of Regulation (EU) No 910/2014. Considering the possibility of identity matching challenges in cross-border situations, supplementary access tokens or codes may need to be issued by Member States to natural persons who arrive from other Member States and receive healthcare. The Commission should be empowered to adopt implementing acts for the interoperable, cross-border identification and authentication of natural persons and health professionals, including any supplementary mechanisms that are necessary for ensuring the possibility for natural persons to exercise their rights to personal electronic health data in cross-border situations.”

Recital 22 talks to the secure access to electronic health data and advises telemedicine services to support electronic identification means in the scope of cross-border services. It calls for mutual recognition of electronic identification means across Member States and the issuance of supplementary access tokens or codes to facilitate identity matching in cross-border healthcare. For this, the aim is to exploit the already operational eIDAS setting which passed as regulation first in 2014, and was amended by Regulation 2024/1183 in 2024, the so-called “eIDAS 2”. It establishes the European Digital Identity Framework, governing electronic identification and trust services for electronic transactions.

Not explicitly mentioned in this Recital, yet highly relevant is the challenge of authenticating healthcare professionals. Healthcare professionals are as much users of telemedicine services as are patients. Hence, both need to be considered as such and for instance, be securely identified. This area is currently under scrutiny within another EU project, Joint Action Xt-EHR.

Article 13

Article 13: 1. “Member States may provide through MyHealth@EU supplementary services that facilitate telemedicine, mobile health, access by natural persons to their translated health data, exchange or verification of health-related certificates, including vaccination card services supporting public health and public health monitoring or digital health systems, services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare. The Commission shall, by means of implementing acts, set out the technical aspects of such services. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).”

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Telemedicine is cited as the first of the so-called supplementary cross-border digital health services that Member States may provide through MyHealth@EU. This represents a first step towards a planned expansion of the scope of the EHDS, which will be crystallised by related implementing acts. Therefore, telemedicine can thus expect to be one of the first suitors for the coming expansion waves of the EHDS. Similarly, since the exchange of personal electronic health data across the EU through the EHDS' interoperability platform MyHealth@EU must be based on the EEHRxF according to Article 12 (3.), it can be expected that telemedicine will become an area falling under the scope of the EEHRxF.

Use cases of EHDS-empowered telemedicine

The integration of telemedicine within the EHDS' scope offers numerous potential use cases that could significantly enhance healthcare delivery across the EU. These use cases span various domains, primarily teleconsultation/second opinions or specialised expertise, and telemonitoring.

With teleconsultation, patients can access healthcare providers remotely for consultations, reducing the need for travel, especially for those in remote or underserved areas. For example, a patient in a rural area can have a video consultation with a specialist in a city, discussing symptoms, receiving diagnoses, and getting prescriptions without leaving their home. This directly supports the EU's Digital Decade eHealth target of 100% EU citizens having access to electronic health records by 2030.

Teleconsultation can also facilitate communication between healthcare providers. A general practitioner can consult with a specialist to discuss a patient's case, seek a second opinion, or gain specialised insights, ensuring the patient receives the most informed and comprehensive care. This can be particularly beneficial for complex or rare conditions where specialised expertise is needed.

Telemonitoring, in turn, can be used for wellness checks and preventive health monitoring. Individuals can use wearable devices to track vital signs such as heart rate, physical activity, sleep patterns, and more. This data can be monitored by healthcare providers to identify early signs of potential health issues, encouraging timely interventions and promoting overall wellness.

Furthermore, patients with chronic conditions such as diabetes, hypertension, or Chronic obstructive pulmonary disease can benefit from continuous telemonitoring. Devices can track blood sugar levels, blood pressure, and lung function, respectively. Healthcare providers can monitor this data in real-time, adjusting treatment plans as needed and providing timely advice to prevent complications and hospitalizations. For patients recovering from acute conditions or surgeries, telemonitoring can provide a safety net. Vital signs and recovery progress can be tracked, allowing healthcare providers to detect any signs of deterioration early and intervene promptly, ensuring a smoother and safer recovery process.

Similarly, continuous telemonitoring can be critical in emergency situations. Patients at risk of sudden medical events (e.g., cardiac arrest) can be monitored continuously, with alerts sent to healthcare providers at the first sign of trouble. This enables rapid response and potentially life-saving interventions. In intensive care units, telemonitoring can enhance patient care by

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providing additional layers of oversight. Remote specialists can monitor patients alongside on-site staff, ensuring that any changes in patient status are noticed and acted upon immediately, improving outcomes in critical care settings.

Evidently, the newly adopted EHDS regulation marks a significant milestone in the evolution of telemedicine within the European Union. Looking ahead, the provisions within the EHDS start providing a clearer roadmap for the integration and expansion of telemedicine services. Yet it is the future implementation acts anticipated by the EHDS regulation which will be the key crucial catalyser for telemedicine for they will be detailing the technical specifications and concrete operational guidelines necessary for framing further advancements. These acts will likely focus on ensuring seamless identity verification, data security, and patient privacy, which are essential for building trust and ensuring the efficacy of telemedicine services.

Moreover, the integration of telemedicine into platforms such as MyHealth@EU suggests a broader vision where telemonitoring and other advanced telehealth services become commonplace. This will not only improve continuity of care but also enable real-time health monitoring and timely interventions, thus enhancing overall healthcare quality and efficiency. As Member States implement these regulations, the potential for telemedicine to transform healthcare delivery and improve patient outcomes through a more integrated, efficient, and accessible health system across Europe will be increasingly realised.

In conclusion, it appears evident that XpanDH and similar EU projects such as Xt-EHR that are focused on advancing digital health stand to play a pivotal role in the forthcoming developments of telemedicine in Europe, and thus should futureproof by preparing and nurturing for related developments both in policy and in practice.

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