The European Health Data Space

Examining A New Era in Data Protection

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Chapter 2

The EHDS and Electronic Health Records

GDPR+ or Transforming Patients' Rights?

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2.1 Introduction

Record keeping is an essential aspect of healthcare, which can serve multiple aims. It can support the provision of safe and efficient healthcare through facilitating communication between healthcare workers. For patients, records can enable them to understand and monitor their health. Effective use of health records avoids unnecessary duplication of examinations and tests, thereby saving resources and supporting patient well-being. As healthcare systems have become increasingly digitised, in some member states, electronic health records (EHRs) are now the norm. Under perfect conditions, healthcare records are no longer locked in cabinets and can be easily and safely accessed by healthcare workers and patients alike using secure digital platforms.

Chapter III of the General Data Protection Regulation (GDPR) provides for a catalogue of rights of relevance to EHR but assessments have shown that patients struggle to exercise these rights in the healthcare context,[1] as also described in the 2023 Court of Justice judgement, *FT v DW*.[2] Differences in how the GDPR has been implemented across the Union in healthcare have resulted in legal fragmentation in this sphere with implications for patients' rights over their data.[3] Progress is unevenly distributed among member states (MSs).[4] While in some MSs, patients can easily access their electronic health data (EHD), in others, healthcare data is not stored electronically nor is there an available platform that allows the citizen to safely access their information. National law often provides limited patient access to healthcare data, and exercising control over such data can be burdensome.[5] Furthermore, even where electronic infrastructure is in place, this is often not interoperable, even within member states. This means that EHD does not straightforwardly flow between providers inside and outside the state, inhibiting patient choice and slowing treatment.

In light of these barriers, the European Health Data Space (EHDS) aims to revolutionise individuals' access to and control over their EHD. The Regulation supports the European Commission's ambitious vision to grant all European Union (EU) residents access to their EHR by 2030.[6] It concretises the rights provided for under the GDPR and transforms the voluntary provisions in Article 14 of the Patients' Rights Directive[7] into binding obligations across the Union.

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The aim of this chapter is to analyse the extent to which the EHDS transforms patients' rights, specifically their control over electronic health records. It focuses on Chapter II of the EHDS which provides for new rights and obligations related to access to and transmission of personal EHD for primary use. The chapter also draws on examples from Danish legislation to illustrate how the rights proposed in the EHDS may function in practice. The member state position is important as the relevant provisions of the EHDS will need to be implemented at the domestic level and, due to the differences among member states, will have varied implications. Denmark is used as a case study as a 2023 report prepared for the Commission on e-health indicators identified the country as a best practice example.[8] As will be highlighted, in Denmark, there is also an ongoing political backlash against documentation, which is used to nuance some of the praise surrounding its digitisation of health records. It is submitted that it will be helpful for member states to assess the relevance of such considerations for their implementation of EHR. Reference to other member states' legislation is included, though this analysis primarily relies on a report published in 2014 prepared for the Consumers, Health and Food Executive Agency (Chafea) under the mandate of the European Commission.[9] The report is, where possible, cross-referenced with the 2023 study.[10] Thus, the scope of this chapter is not to lay out member state law in detail but to provide reflections on key challenges for implementation based on selected past experiences.

The next section introduces electronic healthcare records, including the central challenges facing the Union and member states and the proposed exchange format. Following this, the duty to record health data electronically under the EHDS is explained. The subsequent section compares the rights included in the EHDS with the rights already provided for under the GDPR. Finally, the chapter concludes by assessing the transformative potential of the EHDS.

2.2 Electronic Health Records in EU: From Voluntary Measures to Binding Obligations

Prior to the EHDS, the legal position was that Directive 2011/24/EU on the application of patients' rights in cross-border healthcare placed an obligation on the Union to support and facilitate cooperation and exchange of information among member states within a voluntary network connecting authorities responsible for ehealth.[11] Subsequent to this provision, several member states took part in the eHealth Digital Services Infrastructure, which allows for cross-border exchange of eprescriptions.[12] The eHealth network has issued several guidelines on interoperability of certain categories of health data, such as the patient summary.[13]

Successive reports conclude that this voluntary approach has proven unsuccessful.[14] Currently, only nine member states use MyHealth@EU for cross-border healthcare, specifically for eprescriptions and patient summaries.[15] In a 2019 recommendation on a European Electronic Health Record exchange format, the Commission highlighted that EHR information systems used across the Union are incompatible.[16]

The EHDS marks a shift in the EU's strategy in the field of electronic health records from merely encouraging harmonisation to mandating it. The Commission is now under an obligation to establish MyHealth@EU as an interoperability platform for digital health.[17] The platform will provide services to support and facilitate the exchange of personal health data between national contact points for digital health. A national contact point will be designated by each member state, and these shall enable the exchange of EHD based on the now-mandatory European exchange format. Supplementary cross-border digital health services and infrastructures may be provided for by member states.[18]

Key to these obligations is how electronic health records are defined, as this has important ramifications for what data healthcare workers must record and to what information patients have a right of access. The EHDS describes EHR as 'a collection of electronic health data related to a natural person and collected in the health system, processed for the purpose of the provision of healthcare' (Article 2(2)(j)). Meanwhile, recital 7 further describes EHRs as 'typically contain[ing] a natural person's medical history, diagnoses and treatment, medications, allergies, and vaccinations, as well as radiology images and laboratory results, spread between different actors in the health system, such as general practitioners, hospitals, pharmacies or care services'. Note that there is somewhat of a disconnect between these two descriptors, with the former focused on the health system and provision of healthcare, while the latter is wider, stretching to entities like pharmacies and care services, which are not necessarily traditionally considered as part of the health system.

While the above descriptors mention a wide range of data, the EHDS does not currently create *obligations* on providers to record and grant access to *all* of these data types. Instead, certain categories of heath data should be prioritised. Mirroring the 2019 Commission Recommendation, the priority categories listed in Article 14(1) are patient summary, electronic prescription and dispensations, medical imaging studies and related imagining reports, medical test results, including laboratory and other diagnostic results and related reports, and hospital discharge reports. The characteristics of these categories are described in Annex I of the EHDS, which the Commission is empowered to amend subject to criteria specified in Article 14(2). Member states may provide for access and exchange of further categories of EHD under national law. The EHDS thereby seeks to establish a middle ground, designed to fit both the least and most digitised member states. This position however carries a risk of fragmentation.

Based on the e-health indicators study, some states do not provide access to even the priority categories at present. The study found that eprescription and edispensation data are the most widely accessible and frequently updated health data categories to which patients have access (75% of member states provide access). Meanwhile, most member states provided online access to personal information, dates of procedures and operations, and current and past medicines. The least accessible category was electronic results and reports.[19] Medical images were only available online in a quarter of member states.[20] This suggests that for many member states, the provisions, described in the coming

sections of this chapter, will mark a significant transformation in terms of access to electronic healthcare data.

Central to the EHDS is that priority categories of EHD must be issued in the European electronic health record exchange format, the technical specifications of which the Commission must lay down (Article 15(1)). The format should be: 'commonly used, machine-readable and allow transmission … between different software applications, devices and providers'. Chapter III sets out the requirements for EHR systems, such as the declaration of conformity, CE marking and documentation requirements. In summary, the EHDS seeks to ensure that member states and the Commission put conditions in place that allow for patient information to cross boundaries seamlessly. Interoperability is crucial for guaranteeing that the data subject can make effective use of their rights of access, portability, etc. As the voluntary approach has been unsuccessful, the Regulation will, in the future, place binding obligations on manufacturers and providers.

It is imperative in light of the EU and member states' human rights obligations that the proposed benefits of EHR are enjoyed equally. On the one hand, digitisation has the potential to support citizens in attaining the right to the highest attainable standard of health. Recital 9 EHDS recognises, for example, that paper records can inhibit access to timely care. Digital health records give patients the opportunity to check that they have correctly understood a conversation with a doctor and monitor their health, through for example reviewing how their blood pressure or blood tests change over time. For example, for people who are hearing or memory impaired, easy access to medical records can facilitate inclusion.

On the other hand, there are also risks that digital transformation leaves some groups behind. Electronic health systems must therefore be developed in an inclusive manner to ensure that they benefit all citizens. This is confirmed in Directive (EU) 2016/2102 (Web Accessibility Directive). The final text includes greater references to accessibility and persons with disabilities than the Proposal, which is welcomed. A concrete step is the inclusion of a provision requiring member states to promote and support digital literacy.[21] However, key concerns remain such as digital access.

2.3 The Duty to Register Health Data in an EHR and Patients' Rights

Article 13 of the EHDS imposes an obligation on member states to ensure that health professionals register at least priority categories of health data in electronic format in an EHR system. The obligation to record only relates to the provision of healthcare, not social care, for example. There is thereby a risk that parallel systems of health records will be in place, which could create extra burdens for healthcare workers, confusion and maintain data siloes.

It remains to be seen how member states will construct this obligation in national law. In some jurisdictions, medical records are understood as forming part of the healthcare worker's professional duties. For example, Danish legislation

places authorised healthcare workers, such as doctors and nurses, under an obligation to keep patient records.[22] Information on investigations and treatments carried out on a patient must be recorded.[23] This includes notes on the patient's condition and planned or carried out treatments.[24] The stated aim of record keeping is to record information that is necessary for good quality and safe treatment.[25] EHR is further explained as a 'work tool' for healthcare workers that should be constructed in a manner that enables the healthcare worker to grasp the patient's condition and planned treatments.[26] This physician-oriented standard differs from member states that require that specific categories of information must be included.[27] This approach is found in inter alia Latvian law,[28] which is more akin to the approach chosen for the EHDS.

Where the healthcare record is part of the healthcare worker's professional obligations, it is the latter, not the patient, who determines the information that must be recorded. Under Danish law, the healthcare worker decides which information must be regarded as 'necessary' based on the concrete situation.[29] As will be discussed below, understanding patient records as a professional responsibility can place limitations on patients' rights to control the information contained therein. Furthermore, when patients gain automatic access to their records, healthcare professionals may adapt the type of information that they record.[30]

2.3.1 Opting Out of EHR Under the EHDS

During the negotiation of the EHDS, a question has been how the Regulation should construct the tension between self-determination and patient safety/professional interests. The position taken in the Proposal was that citizens could restrict access to their EHR but not refuse to take part in the infrastructure. In Denmark, healthcare information is generally not stored in the patient record based on patient consent but based on GDPR articles 6(1)(e) and 9(2)(h).[31] In this manner, the GDPR can be considered to place limitations on the citizen's right to private life which can be justified as necessary to ensure that adequate healthcare can be provided. A healthcare worker may consider that it is unsafe to treat a patient whose medical history they are not aware of. This position can be criticised for forcing patients to take part in digitisation, and thereby the processing of sensitive personal data when they can adequately recall such information. This can be of particular concern for citizens in countries like Denmark that allow for secondary use of healthcare data, including data in patient records, without the individual's consent or the ability to opt-out.[32] This scenario is contrary to the promises of control forged in the EHDS.

The final EHDS allows member states to adopt rules establishing a right for individuals to object to access to EHD by anyone except the original data controller. If the member state makes use of this legal basis and the patient in turn opts out, the patient will not be able to use the health data services and MyHealth@EU established under the EHDS. However, the patient's treatment will continue to be documented, and the provider will have access. This

provision thereby represents an opt-out, not an opt-in. As of 2014, both models were found in EU member states, meaning that this will prompt changes in states like Germany.[33]

It is also for the member states to determine whether the right to object to registration of data should be absolute or subject to an emergency override. The question of how patients should be informed prior to the creation of an EHR also seems to have been left up to states to determine (following information requirements of the GDPR, they should be informed of the processing of their sensitive personal data in any event). Member states must also establish adequate safeguards should they provide for the right to object.

Recital 10 also mentions that member states can put restrictions in place on the initial registration of EHD, such as requiring consent to register genetic data. It can be questioned whether consent is the correct legal basis in this case (if this is what the recital is inferring) given that the citizen will suffer a detriment (i.e., not being able to use the EHR infrastructure) should they refuse consent. These provisions appear to have been necessary to reach an agreement but create a risk of fragmentation across the Union. Wellness applications are another area where patients can exercise control over their health record as such data can only be transmitted to the patient's EHR with their consent (Article 48(2)).

2.3.2 Risks to Patient Rights

It is furthermore important to reflect on not only the positive transformations that mandatory EHRs offer but also the negative implications for patient safety. For example, in Denmark, patients have been given the wrong medicine doses due to problems with the software, resulting in injuries and deaths.[34] The Danish Data Protection Authority has also seriously criticised a healthcare region for data breaches in its EHR system.[35] Thus, with even the most digitised member state in the Union struggling to bring an EHR system in line with the GDPR, concerns may be raised regarding the prospect of the EHDS to guarantee that patient data is stored safely.

Scholars have also noted that by making EHR mandatory, vital public functions become dependent on Big Tech and its infrastructure.[36] These systems can eat up substantial healthcare resources and may not be fit for purpose. In the Danish case, the leading US software for EHR, Epic, was installed in several healthcare regions. The system has been seriously criticised, including because it was developed with the US healthcare system in mind, based on billing and not a tax-financed public system.[37]

Generally, in Denmark, there has been significant backlash against documentation among healthcare workers and politicians. The arguments include that there is a lack of time to document, the systems are difficult to use, and that documentation takes time away from patient care and is arduous, especially for healthcare workers working in their non-native language.[38] Criticisms have led to populist initiatives by the government to 'reduce bureaucracy'

and 'release' professionals from documentation requirements.[39] Furthermore, implementing new EHR systems can be time-consuming and challenging.[40] EHR can cause frustration among doctors.[41] It is vital that healthcare workers are provided with adequate training and assistance in digital transitions. For example, an audit ordered by the Danish state auditor found that the introduction of the new e-health platform in several healthcare regions was carried out without adequate training and testing.[42]

Reflecting on and developing mitigation strategies for these risks may be instructive for other less-digitised states when undertaking the transformation required by the EHDS. In this regard, it is positive that the final text includes obligations in relation to upskilling for health professionals that were not present in the Proposal. Following Article 83, states are under an obligation to develop and implement or provide access to training programmes for health professionals on their obligations to register health data.

Finally, the thorny question of language must be mentioned, namely in what language patient information across borders should be recorded. According to the Ehealth Network patient summary guidelines, the summary should be recorded in the local language and then translated to the language of the receiving country.[43] If healthcare providers are obligated to accept data from other member states, how can they guarantee that they adequately grasp the context and instructions? This raises questions regarding the importance of obtaining faithful translations to avoid risks to patient safety and whether AI is equipped to meet this need.

2.4 Rights Under the EHDS

Moving to the rights provided for in the EHDS, these build on and concretise rights contained in the GDPR. The EHDS rights are described in this section and, where relevant, compared to the protection already afforded to data subjects under the GDPR.

2.4.1 Rights of Access to Health Records

The EHDS includes a right of access to health records, which is not new to European law but instead supports Article 8 ECHR,[44] Article 15 GDPR and Article 9 of the Council of Europe Convention 108+ on Data Protection. The coming sections focus on Article 15 GDPR as it offers the most specificity.

2.4.1.1 Scope of Access Under EHDS and GDPR

The EHDS asserts a right of access to EHD without charge and in easily readable, 'consolidated and accessible format'.[45] Access should be provided immediately after registration, though the final text specifies 'respecting, technological practicability'. It remains to be seen whether some member states will interpret this room for manoeuvre in a manner that waters down the immediacy of the

right. The right encompasses 'at least' priority categories of data. This open-ended phrasing means that the scope of the right may vary subject to member state law. Patients will furthermore have a right to download a free electronic copy of at least the priority categories of health data. This addition will hopefully improve information accessibility compared to the Proposal.

Meanwhile, Article 15 GDPR is wider in scope than the EHDS, comprising of three parts: confirmation of processing of personal data, access to personal data and access to information about the processing, including the presence of automated decision-making and profiling.[46] The controller is under an obligation to provide a copy of the personal data being processed, while any further copies may be subject to 'a reasonable fee based on administrative costs'. Meanwhile, it is not clear from the wording of the EHDS whether 'an electronic copy' should be understood as one copy or encompasses further copies. Following the GDPR, where the request is transmitted electronically, the information must be provided 'in a commonly used electronic form' (Article 15(3)). Access must be provided within one month of receipt of the request, though the period may be extended by two months where necessary (Article 12(3)). The EHDS thereby provides for faster access, and seemingly no charge may be levied for further copies. As outlined in recital 9 of the EHDS, Article 15 GDPR does not mandate electronic access unlike the EHDS. However, where a provider uses analogue records, the EHDS does not create obligations, meaning that patients would have to submit separate requests to gain access to all data relevant to their health, should paper records still be used alongside EHR.

Until the 2023 CJEU judgement *FT v DW*, the scope of Article 15 GDPR in the context of healthcare records was unclear.[47] The case relates to an individual who had requested access to their medical records related to dental care where they believed that errors had been made and wished to establish liability. The provider refused, arguing that the individual must cover the costs as provided for by the German Civil Code. The individual then initiated domestic proceedings against the provider. The patient's right of free access was upheld at first instance and on appeal. In the course of a further appeal, the German Federal Court of Justice referred several questions to the CJEU for a preliminary ruling on, inter alia, the charging system put in place by the member state prior to the entry into force of the GDPR and the scope of access to the patient's personal data.

The CJEU upheld that the first copy of the individual's personal data must be provided free of charge. A reasonable fee, attributable to administrative costs, may however be levied for further copies.[48] The Court recalled that the data subject does not have to give reasons for the data request. While the right to a first copy of one's records is not absolute and may be restricted following Article 15(4) and Article 23(1)(i),[49] the data provider cannot put in place a blanket fee requirement for the first copy merely to protect their economic interests.[50]

For our purposes, it is pertinent to note that the CJEU held that Article 15 includes access for patients to 'data concerning their health, for example the data in their medical records containing information such as diagnoses, examination results, assessments by treating physicians and any treatment or interventions provided'.[51] According to the CJEU, individuals should be 'given access to the data contained in their medical records as fully and precisely as possible, but also in a form which is intelligible'.[52] The Court continued that

> the provision of a simple summary or a compilation of those data by the medical practitioner, in order to present them in an aggregated form, could create the risk of some relevant data being omitted or incorrectly reproduced, or, in any event, of it being made harder for the patient to verify how accurate and exhaustive those data are and to understand those data.[53]

Thus, access to medical records following Article 15 must be 'a faithful and intelligible reproduction' of the data.

Based on the Court's judgement, depending on how access is framed in national law, the EHDS may not provide patients with access to more detailed health records than what is already provided for under this now-authoritative interpretation of the right to access under the GDPR. Where the EHDS is most significant therefore is by mandating that member states put in place infrastructure that enables patients to exercise their rights. This includes health data access services following Article 4 and a Digital Health Authority responsible for ensuring implementation of the rights and technical solutions following Article 19(2).

2.4.1.2 Proxy Services

Furthermore, the EHDS not only concerns access for the patient but also requires that member states put in place interoperable proxy services free of charge to enable guardians and other representatives to access the healthcare record of those they represent.[54] This will enable patients to provide a friend or relative with access to their record to support them in understanding their healthcare. For those without legal capacity, it could allow smoother access for those already supporting their healthcare in practice. The services must be easily accessible for persons with disabilities, vulnerable groups and persons with low digital literacy.

It is again up to member states to establish the contours of proxy services. This is sensible given the variations among the domestic laws of member states in relation to legal capacity and the age of consent. Access for representatives raises important questions regarding the balance between protection of patients with limited capacity from harm and patient privacy. Children have a right to private life under Article 8 of the European Convention on Human Rights and a right to privacy under Article 16 of the Convention on the Rights of the Child. It should be possible to restrict guardians' access to information

if the patient's interest in protecting the confidentiality of such information outweighs the guardian's interest in accessing it, such as may be the case with information on abortion, sexual health or mental health. Likewise, adults with limited capacity or who require support in certain areas may wish to restrict access to certain types of information, and this must be possible. The author can also foresee situations where abusive partners/relatives may demand access as a form of coercive control, and it is therefore vital that access can be limited in a manner that does not alert the representative to the presence of confidential information.

2.4.1.3 Restrictions on the Right of Access

The right of access envisaged under the EHDS is subject to limitations. While the Proposal allowed for certain limitations, it did not refer to Article 23 GDPR, which is now mentioned in the final text. Following Article 23(1)(e), GDPR rights may be restricted by national law provided such restriction respects 'the essence of the fundamental rights and freedoms' and is a necessary and proportionate measure in a democratic society to safeguard, inter alia, other important objectives of general public interest, including public health, and the protection of the data subject or the rights and freedoms of others.

Following the EHDS, member states may restrict the scope of access to EHR 'in particular' when necessary for the protection of the natural person based on patient safety and ethics by delaying access for a limited time until a health professional can properly communicate and explain information that 'can have a significant impact' on the individual's health. Recital 10 EHDS describes how it could be unethical to inform a patient of an incurable diagnosis electronically and that it should therefore be possible to delay access to such data. As compared to the Proposal, the scope for restrictions of access is significantly widened through the addition of 'in particular' and reference to Article 23. Following Article 12(5) GDPR, requests may be refused where they are 'manifestly unfounded or excessive', which could fall under 'objectives of general public interest'. Yet again, the potential for fragmentation arises as the precise framing of possible restrictions is left to member states. Still, it seems wise that the scope of restrictions on rights of access now corresponds to the GDPR. Furthermore, what is judged as ethically acceptable likely differs among member states, and it may thereby be sensible to allow for differences to safeguard national medical norms.

The question therefore remains what the scope of such restrictions should be. The explanatory report to the Council of Europe Convention 108+ specifies that access to health data should be through a health professional 'when it is in the interest of the data subject, notably to help him/her understand the data or ensure that the data subject's psychological state is appropriately considered when imparting information – in line, of course, with deontological principles'.[55] The 1997 recommendation to the 1981 CoE Convention[56] recognised that access could be refused, limited or delayed if provided by law and

subject to other specified criteria, including that the information is 'likely to cause serious harm to the data subject's health'.[57] It seems that several member states allow for access to health data to be restricted if the medical professional judges that access may cause harm.[58] For example, Latvian law allows for healthcare workers to not transmit information if they determine that it may threaten the life or health of the patient or other persons.[59] It is submitted that the scope of any permitted delays should be designed with patients' interests in mind, such as allowing the patient to determine whether they wish to access the information prior to seeing their healthcare professional. From a patients' rights perspective, it is positive that a paternalistic position on refusal of access has not been mandated.

In summary, while the right of access under the EHDS mirrors that which is provided for under the GDPR, it makes important advances in relation to cost (no provision is made for levying charges) and the immediacy of access. This is logical given that the EHDS will put in place the necessary infrastructure to facilitate immediate digital access. The scope of restrictions among member states is likely to vary based on traditions of domestic medical law, which may lead to fragmentation and hamper cross-border access. This again is to be expected due to the EU's limited competences within the field of healthcare.

2.4.2 Right to Rectification

Access and rectification are viewed as symbiotic in the EHDS, i.e., as per recital 13 access to electronic health records enables patients to identify incorrect data and request its correction. The EHDS requires that EHR services provide individuals with the ability to easily request rectification of their personal data online.

The Regulation now clearly specifies the duty bearers in response to a key criticism of the EDPB and EDPS that the EHDS proposal had failed to make clear who was under a duty to rectify patient data.[60] The final text also added that the service provider can check the validity of the rectification requested with a health professional. As the operative text does not specify an immediate obligation, it appears that the time limits provided for under the GDPR apply, i.e., without undue delay and within one month. However, recital 13 suggests that the obligation should be immediate and free of charge, as with the right of access. This, however, does not appear in the operative text, suggesting that it is aspirational.

As already described in the access section, all rights under the GDPR can be restricted following Article 23. In the case of health records, patient safety could be relied upon to justify restricting the right to rectification. For example, imagine a patient considered a description of their condition inaccurate while the treating healthcare worker found it to be valid. In such instances, it could be necessary and proportionate to refuse a request to rectify that involved deletion or supplementation of the information in order to safeguard the protection of the data subject.

A right of erasure, following Article 17(1) of the GPDR, is not envisaged in the EHDS. As of 2014, this was only a possibility in two member states, France and Austria.[61] Under Danish law, a healthcare worker can correct or add to the patient record but the original text must be retained.[62] Had the EHDS included a right to erasure, this would have been a significant step towards more control for patients over their records. At the same time, such a departure could also be questioned on grounds of patient safety. Permanently deleting healthcare information could limit patients' abilities to complain about sub-par care or receive compensation. Furthermore, it may be important to retain this information so that healthcare workers can get a full picture of the patient's treatment history.

Still, a middle ground could have been reached, whereby erasure would be provided for subject to restrictions. There may be scenarios where information in the EHR is no longer necessary nor proportionate as the patient's interest in having information deleted outweighs competing concerns. One could imagine cases of misdiagnoses that are not relevant to the patient's current and future health. This may be possible in some member states, depending how they interpret the right to rectification, i.e., whether it allows for editing in a way that deletes erroneous information. A further middle ground could be to archive some health information. This could be previous diagnoses or procedures that are no longer relevant but remain part of the patient's history, such as previous abortions or diagnoses of sexually transmitted diseases. This is envisaged by the right to restriction, explored further below.

2.4.3 Right to Insert

The EHDS provides for a further and significant possibility for advancing patients' rights in the context of EHR, namely the right of individuals to insert information. This right is considered in detail in Chapter 3. In the Proposal, Council and Parliament texts, the decision of whether patients may add data to their record was left to the member states. The compromise text instead marked a significant transformation for European patients as the right to insert is now established. The 2014 study found that few member states allowed patients to directly alter their medical record (only Germany and Portugal).[63] No member state allowed the patient to directly alter information inputted by a healthcare professional, which position is maintained by the EHDS. The regulation provides that information provided by the patient or their representative must be clearly distinguishable and that patients must not be able to directly alter the information entered by healthcare professionals. Recital 12 notes that the reason for rendering information entered by patients distinguishable is that it does not have the same clinical nor legal value as information added by health professionals. The EHDS thereby cements a hierarchy among professionals and patients. A lingering question is whether the health professional can alter information added by the patient or refuse to accept the insertion of observations that they find misleading or incorrect. It is left to member states to construct

duties for the healthcare professional, such as a requirement to review and consider the information recorded by the patient.

The rights to rectification and insertion are also important as EHR data will be reprocessed for secondary-use pursuant to Chapter IV of the EHDS. Scholars have expressed concerns regarding the reliability of the data found in medical records.[64] Studies have identified racial and ethnic bias in records inputted by healthcare workers.[65] For example, one study in the US found that black patients had 2.54 times higher odds of being given a negative descriptor in their EHR than a white patient.[66] There is a risk that biased EHR data are then fed into algorithms which will in turn result in biased decisions on prioritisation or treatment. By enabling the patient to correct and contribute to their record, the patient may be able to facilitate more accurate data for secondary uses or counter such bias. However, this will not remedy all the risks of bias associated with EHR, such as access to healthcare.[67]

2.4.4 Right to Restriction

Article 11 EHDS provides healthcare workers with an entitlement to access 'relevant and necessary' personal EHD of persons under their treatment across the Union. However, such access is not absolute as Article 8 of the final text provides patients with a right to restrict access. This provision is an important means by which patients can control access to their data and thereby protect their right to private life.

As with the other rights provided for in the EHDS, the right to restriction is not necessarily absolute. Per recital 17, the scope of possible limitations is left up to member states. Article 3(9) of the Proposal specified that Article 6(1) (d) GDPR could be relied upon in emergency situations as it provides a legal basis for processing that is necessary in order to protect the vital interests of the data subject or of another natural person. The Council text added the example of restriction for purposes of public health in the case of highly contagious and hazardous disease (recital 13). These limitations have been removed, and it is now up to member states to decide whether and how to permit limitations on the right to restriction in line with the GDPR.

Examples where a patient's restriction of access may be legitimately overridden could be where a patient is unconscious and immediate healthcare decisions with implications for their survival need to be made. Imagine a patient who has previously restricted access to information on, for example, their use of prescription medications, who is brought to an emergency room in a confused state. In such a scenario, the healthcare workers' obligations to provide safe and effective treatment may conflict with the patient's right to private life. An autonomy-focused view could hold that the patient's autonomy should triumph, and they – as a rational individual – should be free to run this risk. A more paternalistic or protective standpoint suggests that the individual right can be restricted for the patient's 'own good'. The question of when the 'rights of others' could override the patient's wishes is more complex. Relevant

considerations could be diagnoses of communicable diseases or the presence of genetic variants that may inform a close contact or relative's care or risk profile. Here, a balance must be found between the patient's right to privacy and the third party's right to life and healthcare.

Returning to Danish practice, a right of restriction is already operationalised through 'private marking', whereby patients can mark health information in their electronic health record as private. For example, a patient could conceal that specific medicine has been prescribed to them from all healthcare workers, though not the one who prescribed the medicine. Patients can also restrict access to information about stays in hospital or appointments in specific treatment facilities or periods of time.[68] This promotes patients' control over their personal health information, though, as with the EHDS, the right is not absolute and can be overridden.

The right to restrict access to one's health information is important in increasingly digitised healthcare systems. The question of the scope of any possible limitations on such rights requires careful consideration. Should patients have an absolute right to restrict access even though it can impair the standard of care they receive or lead to worse health outcomes? It is left to the member states to determine the relative weight that should be afforded to patient autonomy versus protection/ paternalism, which seems in line with existing norms. The final text specifies that patients must be made aware that such restrictions may impact the quality of healthcare afforded to them, which is an important safeguard.

2.4.5 Information

A further right provided for following Article 9 is the right of the patient to obtain information on the healthcare providers and professionals that have accessed their EHD for healthcare purposes. Such a right should be 'without delay' (though no longer immediate as in the Proposal) and free of charge through EHD access services. This right is an important means by which patients can monitor and protect their privacy rights.

In Denmark, patients can see who has accessed their patient record and complain where they believe that their data has been accessed unlawfully. There have been numerous complaints to the Danish Healthcare Worker's disciplinary authority where acquaintances or former partners have unlawfully accessed a patient's record.[69] The right provides an important means by which patients can preserve their integrity and privacy.

At the same time, it is important that healthcare workers who are acting lawfully are protected and not subject to harassment or misuse of their personal data. Thus, it is welcomed that the EHDS allows member states to restrict this right in exceptional circumstances. While these circumstances are not defined, it could include instances where a healthcare worker is at risk of being targeted, such as where the patient has previously harassed or misused the personal data of a treating healthcare professional.

2.4.6 Right to Data Portability

Another significant innovation of the EHDS for patients' rights to control their health data is the right to data portability provided for under Article 7. This provision offers individuals a right to give access to or request a healthcare provider to transmit all or part of their EHD to another healthcare provider of their choice. This right should be immediate, free of charge and without hindrance. Furthermore, in the case of priority categories of data, other healthcare providers will be obligated to accept the transported data.

The right to data portability in the EHDS goes beyond the more limited right provided for in Article 20 GDPR. Notably, the EHDS includes inferred data (not just data provided by the data subject) and is not limited to data processed subject to specific legal bases.[70] However, as compared to the Proposal, the final text is more limited in relation to which providers are covered. The individual can only request that a *healthcare provider* transmit EHD to a *social security or reimbursement services sector provider*, not the other way round. Article 3(8) of the Proposal had applied to data holders from the health or social security sector, though the provision quickly seemed doomed given that the Council and Parliament texts sought to limit it to healthcare providers. It remains to be seen how a healthcare provider will be understood under domestic law. For example, does the right apply to healthcare provided to a resident of a social care institution by that institution, such as delivery of prescription medications or basic wound care? The 2023 e-health indicators report noted that geriatric nursing homes are the institutions least connected to domestic EHR infrastructures, which poses a barrier to these citizens enjoying their EHDS rights. Another example is treatment for alcoholism or addiction by a social care provider. It is recalled that the definition of primary health data in Article 2 of the EHDS includes social care. The right to access applies to data processed for the provision of healthcare, which appears to include the scenario mentioned above, while the use of the term 'provider' may be narrower. It seems counterintuitive and contrary to patients' rights that social care data may be shared for secondary use but not primary use.

The EDPB-EDPS joint opinion highlighted that the right does not establish a corresponding obligation to transmit the data.[71] For example, in member states where Article 9(2)(h) GDPR is relied upon as a processing ground, Article 9(3) specifies a professional secrecy obligation. The transmission of data gathered under this legal basis based on portability may violate such obligations. This may also require domestic legislation to be amended, and the question has not been resolved in the final text.

For the provision of cross-border care, portability is particularly crucial as it provides for a right to transmit data to a recipient in another member state and an obligation on the latter to read and accept this data. Per recital 33, this is particularly vital for those living in border regions given that the nearest provider may be across a border, not in the member state of residence.

It remains to be seen how providers will respond to these new obligations, which may require a cultural shift among providers who typically order new tests for new patients.

2.4.7 Right to Complain

Finally, rights can be toothless where rights holders are not provided with complaints' mechanisms. A question is therefore to whom patients can complain should their rights under Chapter II EHDS not be respected. The Proposal established the Digital Health Authority (DHA) as the complaints body in such cases. Meanwhile, the Council's proposal would have required the DHA to transmit the complaint to the supervisory authorities and consult and cooperate with them in dealing with the complaint, whereas the Commission's proposal merely required the DHA to inform the data protection authorities. The final text has resolved that complaints related to access, insertion, rectification, data portability, restriction and objection must be transmitted by the DHA to the relevant data protection authority. This appears to be an appropriate solution given that there is a risk that adding further complaints bodies would be of detriment to patients' rights instead of supporting them in enjoying their rights. At domestic level, member states are likely to already have established complaints mechanisms, and it is vital that the EHDS does not add to regulatory complexity. At the same time, data protection authorities are notoriously overburdened and under resourced. Thus, it is important that extra resources and training are provided for to enable them to fulfil these new obligations.

2.5 Conclusion

This chapter concludes by emphasising the transformative potential of the European Health Data Space in relation to patients' rights to control their EHR, particularly in the EU's least digitised member states. The relevant provisions necessitate profound changes, mandating legal frameworks that compel healthcare professionals to digitally document patient care. The chapter aligns with the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) in recognising that the rights conferred by the EHDS to individuals concerning their personal data are essentially 'add-ons' to those established by the General Data Protection Regulation (GDPR).[72] However, these enhancements are anticipated to significantly boost patients' rights, granting them increased access to and control over their EHR, thereby reshaping patients' control of their data throughout the EU. Thus, Chapter II of EHDS can be considered to amount to both GDPR+ and a transformation for patients' rights.

The EHDS sets a foundation for improving patients' informational self-determination by facilitating access to health data without charge and promptly. In light of *FT v DW*, the EHDS does not significantly expand EU law in respect

to the scope of access. However, the specificity of the EHDS may help to streamline and accelerate access to health data for patients. Access will be enabled through mandating member states to put in place the necessary infrastructure. Furthermore, through easier access, patients will be able to enjoy other rights, such as rectification. It remains to be seen to what extent rectification will encompass erasure, as this right is omitted from the EHDS. The EHDS also expands the rights to data portability and restriction, potentially enhancing patient choice and control. Additionally, it introduces the right to insert, enabling patients to actively contribute to their healthcare records. Through the right to object, patients have enhanced possibilities to opt-out of taking part in the EHDS, though in some member states, this position represents less control than the status quo.

The chapter questions, however, the exclusion of social care services from provisions of the text on primary use. The significance of healthcare data to patients is based on its relevance to their health rather than its location. The original ambition of the EHDS to include social security providers was scaled back in the final text, limiting its scope to primarily healthcare-related data. However, as is seen in other chapters of this volume, the EHDS is more ambitious when it comes to secondary use of care data.

The potential for transformation also comes with the caveat of likely fragmentation among member states, given the latitude provided in determining the extent of their rights. The Regulation's mix of prescriptive 'shall' and permissive 'may' renders continued fragmentation in EHR practices across the EU all but unavoidable. The lack of clarity on how these differences will be reconciled poses a potential obstacle to the full realisation of patients' rights. This challenge reflects the inherent complexity of harmonising aspects closely related to healthcare provision, considering the EU's limited healthcare competencies and variations among member states' healthcare systems.

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