ELECTRONIC HEALTH RECORDS AS A LEGAL BARRIER OF CROSS-BORDER PROVIDING OF HEALTH CARE - PARADOX?

Soňa SOPÚCHOVÁ

Associate Professor, Comenius University in Bratislava, Faculty of Law
E-mail: sona.sopuchova@flaw.uniba.sk

Abstract

The subject of this article is the analysis of the Institute of Electronic Health Documentation, which has been discussed within the European Union for some time, but its current form in the legal systems of member states of the European Union does not correspond to the outlined vision. Electronic health documentation represents one of the pillars of e-Health, whose goal is to provide correct information at the right time, in the right place, and in the right form in all stages and processes of health care. The author deals with Slovak and European legislation related to electronic health documentation, presents the so-called electronic health book existing in the conditions of the Slovak Republic, and draws attention to the proposal for a new European regulation on the European Health Data Space, which aims to harmonize the rules for the creation and use of electronic health data, and thus strengthen the role of electronic health documentation for (including cross-border) provision of health care. The article aims to emphasize the most important challenges of the current and future legal regime of the transfer and exchange of electronic health data and other related ideas.

***Keywords**: e-health, electronic health documentation, electronic health data, electronic health record*

Introduction

The provision of health care is a widely discussed topic within the field. In the case of e-Health, the use of information and communication technologies (hereinafter also referred to as „ICT“) in healthcare-related processes is evident, and it is clear that elements of e-Health can be applied in various areas of health care provision, from the interaction between the patient and the healthcare professional, through data transfer, remote monitoring, to the use of artificial intelligence in robotic surgeries. The term e-Health conceptually encompasses

all aspects of health, not just health care, including individual measures to promote health, for example, in households, health care facilities, or schools. (Středa & Hána, 2016).

The central concept of health care digitization is information and communication technologies. Implementing ICT can increase the efficiency of health care provision and other processes, improve quality of life, and unlock further innovations. Information technology is understood as a term used to describe equipment elements (hardware) and computer programs (software) that allow us to access, acquire, store, organize, manipulate, and present information electronically. Personal computers, scanners, and digital cameras fall into the hardware category. Data storage programs and multimedia programs can be classified as software. Communication technology is perceived as a term used to describe telecommunications equipment through which information can be accessed. This mainly includes telephones, faxes, or television (Unesco, 2003, p. 7). „*The pandemic caused by COVID-19 has accelerate the use of communication technology in the health care, this was the only sustainable "distance measure" in the health crises. And this remained as a post-pandemic solution that became a standard that must be followed.*" (Misheva & Ampovska, 2022, p. 401).

The World Health Organization (WHO) recognizes the importance of electronic health care for public health and health service as a whole. For this reason, it adopted Resolution WHA58.28 eHealth in 2005, defining its strategy for electronic health care. It calls on member countries to plan the use of electronic healthcare services at the national level. In this document, electronic health care is defined as „*an efficient and secure way of using information and communication technologies to support health and health-related activities; it includes the provision of health care, public health monitoring, as well as healthcare literature and education, knowledge base, and scientific research*" (World Health Organization, 2005, p. 121). The eHealth Action Plan for 2012-2020 - Innovative Healthcare for the 21st Century, developed by the European Commission, defines e-Health as „*the use of ICT in healthcare products, services, and processes in combination with organizational changes in healthcare systems and new skills to improve citizens' health, efficiency and productivity of healthcare services, as well as the economic and social value of health. It includes the interaction between patients and healthcare providers, data transfers between different devices, and direct communication between patients and/or healthcare professionals*" (European Commission, 2012, p. 4).

„*Since the start of the development process of e-Health in the EU, the legal and regulatory issues are considered to be among the most challenging aspects of e-Health. This aspect of e-Health includes questions regarding privacy, confidentiality, data protection, and liability, and they all present challenges that need to be addressed to enable sustainable implementation and use of e-Health applications*." (Misheva & Ampovska, 2021, p. 665).

The subject of health service, in general, is the provision of health care. In the conditions of the Slovak Republic, health care has its legal definition in Section 2 (1) of Act No. 576/2004 Coll. on health care, services related to the provision of health care, and the amendment and supplementation of certain acts (hereinafter referred to as the „Act on Health care"), where it is defined as „*a set of work activities performed by healthcare professionals, including the provision of medicines, medical devices, and dietary foods with the aim of prolonging the life of a physical person, improving their quality of life, and promoting the healthy development of future generations; healthcare includes prevention, dispensarization, diagnosis, treatment, biomedical research, nursing care, and obstetric assistance.*" The provision of a special treatment regime to persons in detention under a special regulation, namely Act No. 231/2019 Coll. on the execution of detention and on the amendment and supplementation of certain laws, is not considered health care. The right to health care itself is guaranteed by international treaties to which the Slovak Republic is a signatory, namely the Universal Declaration of Human Rights[1], the International Covenant on Economic Social and Cultural Rights [2], and the Convention on Human Rights and Biomedicine.[3]

An inseparable and undoubtedly very important part of health care provision is health documentation, and like in other areas, its form is undergoing a transformation brought about by the information society and digitalization. The European Union, in its Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (hereinafter referred to as the „Directive on Cross-Border Healthcare"), mentions the establishment of the eHealth network with the aim of facilitating cooperation in the transfer and exchange of health data. What should the transfer and exchange of health data within the European eHealth look like exactly? One possible answer is electronic health documentation, i.e. health documentation in electronic form.

The first chapter of the article is devoted to the analysis of healthcare documentation as an institution within health care. Emphasis is placed on its

[1] Article 25, paragraph 1 of the Universal Declaration of Human Rights: „*Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services; he has the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control*."

[2] Article 12, paragraph 2 of the International Covenant on Economic, Social and Cultural Rights: „*The States Parties to the present Covenant undertake to take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of their available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.*"

[3] Article 3 of the Convention on Human Rights and Biomedicine: „*Contracting parties shall take appropriate measures within their jurisdiction to ensure equitable access to health care, taking into account both the need for health care and available resources*."

electronic form and the related challenges. The second chapter of the article focuses on the presentation of the proposal for a regulation on the European Health Data Space, primarily in the context of electronic healthcare documentation, or the possibilities that the regulation brings in terms of the transfer and exchange of health data.

1. Healthcare documentation as a legal institution

The provision of health care consists of a set of various work activities performed by healthcare professionals and is legally regulated in the legislation of countries. In addition to medical treatment procedures, the provision of health care may also include prescribing medications and medical aids, preventive activities, diagnostics, and others, all with the aim of prolonging lives of individuals or improving their quality of life. Health documentation plays an indispensable role in the provision of health care. As stated and specified by author Policar, health documentation is a record containing personal data of patients necessary for their identification and determination of their medical history, as well as information about the patient's illnesses, course and results of examinations, treatment, and other significant circumstances related to the patient's health condition and the process of providing health care. This record has a written, visual, auditory, electronic, or any other nature that is relevant. It exists in analog or digital form on corresponding media (Policar, 2009). „*Properly and comprehensively maintained health documentation is one of the means of communication between healthcare professionals, promotes continuity of health care, documents the quality and extent of provided health care, is a tool for strengthening the legal protection of healthcare professionals in labor disputes, is a tool for enhancing the safety of care provided and patient safety, and also has forensic significance in potential medical-legal disputes.*“ (Capíková & Nováková, 2020, p. 50).

1.1 Health documentation in the context of the European Union

European strategic and legislative documents do not operate with the term of health documentation or electronic health documentation, but in this context, we draw attention to the term electronic health record (hereinafter also referred to as „EHR“). In 2008, the European Union, in its Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (hereinafter also referred to as „Commission Recommendation on cross-border interoperability of EHR systems“), defines an electronic health record as „*a comprehensive medical record or similar document on the past and present physical and mental health status of an individual in electronic form, which allows immediate access to this data for medical treatment purposes and for other closely related purposes.“* From this

definition, it follows that the legislator emphasizes the immediate availability of data in the form of a medical record, which is the essence of electronic health documentation, as it is composed of multiple electronic health records. In addition, the recommendation also mentions the system of electronic health records for recording and retrieving information in electronic health records and for handling them. The European Commission further emphasizes the interoperability of EHR systems, which is intended to ensure the ability of two or more electronic health record systems to exchange machine-readable data, as well as information and knowledge understandable to humans. The recommendation provides, among other things, a set of guidelines for the development and use of interoperable electronic health record systems enabling cross-border exchange of patient data within the European Union, if necessary for legitimate medical purposes and for the purposes of healthcare. Such EHR systems should enable healthcare providers to provide more efficient and effective health care to patients by having timely and secure access to essential and possibly life-saving health care information, if necessary, and in accordance with the basic rights of patients to privacy and data protection.

Despite the fact that health documentation (regardless of its form) is currently within the jurisdiction of the member states of the European Union (hereinafter also referred to as „member states“), it is clear that unifying its legal regulation, especially in terms of content and the need for digital format, will be inevitably necessary. In line with this, interoperability of electronic records was defined as one of the most important goals in the field of cross-border healthcare provision and e-Health, as outlined in the Commission Recommendation on cross-border interoperability of EHR systems and the Directive on Cross-Border Health care. However, the European Union itself has noted that there are significant differences among member states in the implementation of electronic health records as part of an interoperable infrastructure that allows different healthcare providers to access and update health data to ensure continuity of patient care. While some countries have established detailed requirements for EHR content, others do not specify what this content should be. A similar situation can be observed in the case of the legal regulation of EHRs, as some member states have established specific rules for electronic health records, while others have retained general health records and legislation on personal data protection. Nevertheless, it is possible to agree with the view expressed in the comparative study that the different nature of national legal regulations regarding EHR data content does not pose an obstacle to interoperability between different EHR systems. Interoperability requires an agreement on which EHR extract will be included in the cross-border exchange of health data and how this will be practically ensured (Milieu Ltd., 2014). The question of "how" mainly concerns coding systems and terminology, which have been shown to be very different and therefore represent one of the main obstacles to cross-border health data transfer (Milieu Ltd., 2014).

1.2 Health documentation in the context of the Slovak Republic

Health documentation is legally defined in the conditions of the Slovak Republic. In accordance with Section 2 (6) of the Act on Health care, it refers to „*a set of data on a person's health condition, provided health care, and services related to the provision of health care to this person.*“ This definition is created by naming the content of health documentation. Health documentation is managed as a whole by a general practitioner, and another treating healthcare professional may manage it to the extent of the health care they provide. The management of health documentation itself involves acquiring, collecting, and recording data that constitute its content. In relation to the concept of electronic health record, which is part of the strategic documents and proposed legislation of the European Union, we draw attention to the fact that health records, including electronic ones, are part of health documentation in the conditions of the Slovak Republic, which we will discuss in more detail in the following part of the article.

1.2.1 Content and form of health documentation

The Slovak legislator generally defines firstly the content of health documentation and then according to certain areas which are to be recorded within health documentation. The content of health documentation and the method of recording it are regulated by the professional Guidance of the Ministry of Health of the Slovak Republic on the management of health documentation. The specification materializes during the provision of health care to a specific patient in the form of entries in health documentation. From the perspective of the purpose of creating health documentation, it can be stated that it includes every record containing information usable for the patient in current or potentially future health care. This applies regardless of the medium of this information (paper, data carrier, or expression method - text, sound, audiovisual recording, frequency, etc.) (Humeník & Kováč, 2015).

The content of health documentation is determined by Section 19 (2) of the Act on Health care.

a) personal data of a person receiving health care services, including: first name; last name; date of birth; national identification number; residential address; and further health data necessary for determining medical history. It may also include the person's telephone number and email address if provided.
b) information about instruction and informed consent,
c) information about the person's illness, requests for examinations of common diagnostic and therapeutic components, information about the course and results of examinations, treatment, and other significant circumstances related to the person's health condition and the process of providing health care,

d) information about the extent of provided health care, including prescribed or administered medicinal products, medical devices, and dietary foods, specifying the name of the medication, route of administration, pharmaceutical form, and quantity of the medication in the pharmaceutical form, as well as the name of the dietary food and medical device,
e) information about services related to the provision of health care,
f) information about temporary work incapacity, personal care, treatment regimen and facts important for assessing the person's medical fitness for work,
g) epidemiologically significant facts,
h) identification data of the relevant health insurance company,
i) identification data of the healthcare provider.

Health documentation is maintained as a whole or in fragments. As mentioned above, the general practitioner is responsible for the completeness and continuity of health care provision and should therefore collect all medical records from other healthcare professionals who have provided health care to the patient. In the event that a patient visits a specialized physician or when institutional health care is terminated, the general practitioner should ensure that related records become part of the health documentation and be able to provide subsequent health care. In the case of termination of institutional health care, the treating physician is additionally obliged to prepare a medical discharge report and promptly send it to the respective general practitioner. However, as stated by the author Nováková, the reality is different because treating physicians usually hand over this report directly to the patient instead of sending it to the general practitioner, who often does not even receive it (Freel & Nováková, 2019). In this situation, the use of electronic aspects would be beneficial, namely, the inclusion of a medical discharge report or a record from a specialized physician into the electronic health book in the form of an electronic health record within the meaning of Section 5 (1) (b) points 8 or 9 of Act No. 153/2013 Coll. on the National health information system and on the amendment and supplementation of certain acts (also referred to as the „Act on NHIS“) (Sopúchová, 2021).

The way of managing health documentation is regulated by the Act on Health care and, for various reasons, including e-Health issues, it requires a more comprehensive discussion. In accordance with Section 20 (1) of the Act on Health care, health documentation is kept in an electronic health record in the national healthcare information system with a qualified electronic signature of a healthcare professional, unless Sections 2 and 3 of the Act on Health care provide otherwise. However, the content requirements, structure, scope of recorded data, authorized persons, and provision and accessibility of data from the electronic health record are determined by a separate regulation, which is the Act on NHIS. Furthermore, according to Section 20 (3) of the Act on Health care, health documentation may be kept in paper form by a healthcare provider if, for special reasons, it is not possible to keep the health documentation in an electronic health record. It can be generally summarized that the primary form

of managing health documentation is the electronic form in the electronic health record, except in cases where the law requires[4] or allows[5] paper form.

According to Section 2 (6) of the Act on NHIS, the electronic health record is a set of data from a person's health documentation kept in the National Register of Electronic Health Hecords to the extent determined by the Act on NHIS. It includes the person's identification data, electronic health records, data from the insured person's account, the person's own records, and records of access, provision of data, and every attempt to access or provide data.

One of the key concepts and institutes of managing health documentation in electronic form is the electronic signature, either at the level of a qualified electronic signature or an advanced electronic signature. These are regulated in Article 3 (11) and (12) of Regulation (EU) No. 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (also referred to as the „eIDAS Regulation") and subsequently incorporated into Slovak legislation, specifically into Act No. 272/2016 Coll. on trust services for electronic transactions in the internal market and on the amendment and supplementation of certain acts (also referred to as the „Act on Trust services"). [6][7]

1.2.2 Recording in health documentation and sharing of data

The Act on Health care indirectly defines two types of health documentation, namely paper and electronic. There is a distinction between recording in the electronic health record and recording in paper health documentation. The same division applies to the provision and storage of health documentation, the provision of data from health documentation, and the accessibility of data from health documentation.

The entry into the electronic health record is performed by creating the corresponding electronic health record. In the event of malfunctioning technical devices, the treating physician of the healthcare provider is obliged, in addition to reasons worthy of special attention, to immediately create the corresponding electronic health record in the electronic health book after the technical devices have been restored. However, the Act on Health care does not further regulate what is specifically the subject and content of the electronic record. However, we can deduce this from the provision of Section 4 (5) of the Act on Health

[4] Section 20 (2) of the Act on Health care.
[5] Section 20 (3) of the Act on Health care.
[6] Article 3 (12) of eIDAS Regulation: „*A qualified electronic signature is an advanced electronic signature created using a qualified electronic signature creation device and based on a qualified certificate for electronic signatures."*
[7] Article 3 (11) of eIDAS Regulation: *„An advanced electronic signature is an electronic signature that meets the requirements set out in Article 26 of eIDAS Regulation."*

care, according to which the management of health documentation and the creation of electronic health records in the electronic health book of a person are an integral part of the provision of health care, with reference to Section 5 of the Act on NHIS, which determines the content of the electronic health book. Therefore, within the scope of electronic health care, a healthcare professional is obliged to record many pieces of information related to provided health care (such as preventive examinations, examination results, provision of outpatient healthcare, or prescriptions) in the form of an electronic health record in the electronic health book, which must be signed by an advanced electronic signature of the healthcare professional. It can be a record of a preventive examination, a record of examination results, a record of the provision of outpatient health care, or a prescription record. Furthermore, certain data will be automatically entered into the electronic health book from the information systems of healthcare providers (e.g. outpatient clinics, laboratories, hospitals...) and from the information systems of health insurance companies. In addition, the Act on NHIS introduced in Section 5 (4) the possibility for individuals - patients themselves to enter certain data into the electronic health book, these are called personal records. A person can also set the level of security for their data.

The entry into paper health documentation is regulated in Section 21 (3) of the Act on Healthcare, according to which it contains the following information:

a) date and time of entry,
b) method of instruction, content of instruction, refusal of instruction, informed consent, refusal of informed consent, and revocation of informed consent,
c) date and time of health care provision, if different from the date and time of entry,
d) the scope of provided health care and services related to the provision of health care, including prescribed or administered human medicines, medical aids, and dietary foods to the extent specified in Section 19 (2) (d),
e) the results of other examinations, if they are part of the provided health care, for which a record is made,
f) identification of the treating healthcare professional,
g) identification of the person to whom health care was provided.

Section 21 (4) of the Act on Health care subsequently regulates the identification of the person who makes entries in the healthcare documentation. The treating healthcare professional is identified in paper health documentation by their first and last name, signature, and if the healthcare professional has been assigned a numerical code by the supervisory authority, also by a stamp impression. Furthermore, in the case of electronically kept health documentation, the identification is done by the electronic signature of the treating healthcare professional.

Providing data from health documentation based on the Act on Health care applies to health documentation kept in paper form. The data is provided within an extract from the documentation, which consists of the information specified by law in Section 24 (1) of the Act on Health care. General practitioners, other healthcare professionals, and providers are obliged to provide an extract from the health documentation only to subjects that are taxonomically defined by the Act on Health care. The provision of data from the electronic health record is regulated by the Act on NHIS, which taxonomically defines the individuals to whom the data may be provided, specifying the scope, which varies for each subject. In accordance with Section 5 (6) of the Act on NHIS, this includes, for example, the treating physician, healthcare professional of the emergency medical service, treating nurse, physician of the self-governing region, court-appointed expert, and other individuals. In the case of a request for a larger scope than prescribed by law for a particular subject, the healthcare professional is only authorized to access such data with the consent of the person, the purpose of which the healthcare professional must justifiably demonstrate.

1.2.3 Access of natural persons to the electronic health record

Access to the electronic health record is granted through the National Health Portal, using an official authenticator, which will be discussed below. This applies to access to all records except those specified in Section 5 (1) (b) points three and four of the Act on NHIS, which can be accessed by the treating physician who requested the examination of common examination and treatment components. For the identification and authentication of the entering person's identity, an official authenticator is required for the security and protection of health records. The Act on NHIS refers to the Act No. 305/2013 Coll. on the electronic performance of the powers of public authorities and on the amendment and supplementation of certain acts (also referred to as the „e-Government Act“), which stipulates that only an official authenticator can be used for authentication, which is the identity card (ID card) with an electronic chip and a security personal code according to a special regulation, which is the Act No. 395/2019 Coll. on identity cards and on the amendment and supplementation of certain acts, or a residence permit with an electronic chip and a security personal code according to a special regulation, which is the Act No. 404/2011 Coll. on the residence of foreigners and on the amendment and supplementation of certain acts. Electronic identification is the process of declaring a person's identity when accessing an electronic information system or during electronic communication. After the declaration of identity, electronic authentication takes place, which consists of proving, in other words, verifying the identity of the person concerned. This means that persons who declared their identity demonstrate that they are indeed persons whose identity they declared. Electronic identification and authentication, along with other institutions, are pillars of the digitization of society.

1.2.4 Access of healthcare professionals to the electronic health record

Healthcare professionals are authorized to access the electronic health record for the purpose of obtaining necessary information and creating an electronic health record. The healthcare professional has access to the data in the electronic health record to the extent determined by the Act on NHIS, depending on the type of healthcare professional. In order for a healthcare professional to access a patient's electronic health record, they must necessarily use their electronic identity and undergo processes of identification and authentication of their identity in a virtual environment, similar to what the patient does when entering the electronic health record. In addition, when creating electronic health records, the healthcare professional is required to sign them with an advanced electronic signature. The aforementioned processes of identification and authentication are carried out through the electronic card of a healthcare professional, which is defined in Section 2 (10) of the Act on the NHIS as „*a technical means for the identification, authentication, and authorization of a healthcare professional*." The electronic card of a healthcare professional is issued at the request of the healthcare professional by the National Health Information Center for a period of five years. The basis for its issuance is a contract for the issuance of an electronic card signed by the healthcare professional.

1.3 Health documentation as an electronic healthcare service

The term electronic service is quite general and there are several theoretical explanations for its definition. Author Boyer defines electronic services as „*interactive services provided on the Internet using modern telecommunications, information, and multimedia technologies"* (Boyer, 2002, p. 175).

The development and implementation of digital healthcare services represent a prominent trend in the contemporary world. The availability of public services online ("supply side") was the main focus of policy-making, but in recent years, the priority has also become the utilization of electronic public administration services by citizens ("demand side"). An increasing number of governments, mostly in developed countries, are making greater efforts to increase the utilization of services. They started by realizing that the benefits of electronic public administration services are largely determined by the number and type of users of these services and the frequency of their utilization (Madzova, Sajnoski, Davcev, 2013). Certain prerequisites must be met to enable the development and utilization of digital services. These prerequisites include political will for their introduction, the provision of electronic identification and authentication capabilities for users and service providers, the necessary hardware and software infrastructure, access to the Internet, an online portal encompassing essential information, forms, and service access, and, importantly, information systems from which data is derived to support individual electronic services (Andraško et. al., 2022).

1.4 The context of cyber security

In relation to electronic identification and authentication for the purpose of accessing the electronic health record, the question of cyber security is significant. This issue is regulated in Commission Implementing Regulation (EU) 2015/1502, which establishes minimum technical specifications and procedures for the levels of security of electronic identification means according to Article 8 (3) of eIDAS Regulation, which establishes an electronic identification scheme for determining the identity of a person, which must include a specification of the level of security in accordance with the annex to that implementing regulation: „low", „substantial" or „high", thereby providing assurance that the person claiming a particular identity is indeed the person to whom that identity has been assigned. The level of security depends on the level of trust provided by the electronic identification means. The level of security for a Slovak electronic card of a healthcare professional can be determined based on the assessment of the quality of the registration and authentication phases according to Annex No 4 of the Decree of the Office of the Deputy Prime Minister of the Slovak Republic for Investments and Informatization No 78/2020 Coll. on standards for information technology of public administration (hereinafter referred to as the „Decree on IT Standards"). We believe that if we use the electronic card of a healthcare professional for electronic identification and authentication, we achieve a „high" level of security, as obtaining such a card requires the physical presence of a healthcare professional or the use of a qualified electronic signature. Furthermore, it should be noted that the registration data is known only to the specific healthcare professional and verification requires proof of identity, which are some of the attributes required for achieving a „high" level of security according to Annex No 4 of the Decree on IT Standards.

The electronic health record, which exists in the digital space, represents a risk in terms of vulnerability to the disclosure of highly sensitive data. The digital age brings new ways of compromising privacy, but technologies can be used to improve and protect privacy. An application of an encryption system should contribute to this (Nastič, 2021).

2. The European Health Data Space

The ongoing explosive development of information and communication technologies allows for the use of information and knowledge as a new production factor. This phenomenon has transformed industrial society into an information society. Data has thus become the „property" not only of those to whom it pertains but has become the subject of interest for other entities across the public and private sectors. These changes also affect the field of health care, specifically health data, which are part of the health documentation of every individual.

Slovak legislation allows exceptions for the management of electronic health documentation in the form of paper-based health documentation, resulting in the creation and simultaneous existence of electronic and paper spaces for health data, which are additionally regulated by two legal regulations. This brings about different legal regulations regarding the content, form, and sharing of health data. Given the European Union's vision of cross-border health care provision and an interoperable system of electronic health records, this is not a good starting position.

In this part of the paper, we partially analyze the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (hereinafter also referred to as the „Proposal for the European Health Data Space“), which represents an activity of the European Union following the European Data Strategy of 2020, which set out a plan for the creation of common sectoral European data spaces, and the Proposal for the European Health Data Space is the first proposal for such common sectoral European data spaces.

The Proposal for the European Health Data Space was prepared in 2022, and its main objective is to ensure that individuals in the European Union have greater control over their electronic health data in practice. At the same time, it aims to address issues related to access and sharing of electronic health data contained in electronic health records. This document introduces in Article 2 (2) definitions of several new terms that could improve the inconsistent terminology in this area in the member states. These include personal electronic health data, other than personal electronic health data, data controller, data user, and data recipient. For further context, we particularly emphasize personal electronic health data, which refers to data concerning health and genetic data within the meaning of Regulation (EU) 2016/679 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, repealing Directive 95/46/EC (hereinafter also referred to as the „General Data Protection Regulation“).

One of the most significant things that the Proposal for the European Health Data Space plans to implement in practice is the distinction between primary and secondary use of electronic health data, which we will discuss in more detail in the next part of this paper. The tool for data sharing and its use, whether for primary or secondary use, is intended to be the creation of the common platform Healthdata@EU. Another novelty is the specific requirements that all electronic health records will have to meet, primarily for the purpose of achieving interoperability.

2.1 The primary use of electronic health data

The initial use of electronic health data is regulated in Article 2 (2) (d) of the Proposal for the European Health Data Space, which concerns the processing of personal electronic health data for the purpose of providing healthcare services to assess, maintain, or restore the health status of the individual to whom the data relates, including prescribing, dispensing, and

providing medication and medical devices, as well as for the purposes of relevant social security services, administrative services, or cost reimbursement services. In the context of the primary use of electronic health data, emphasis will be placed on patient rights, as the initial use is directly related to the provision of health care. Patients will have access to their electronic personal health data and will have the opportunity to decide who else will have access to them (which entities other than healthcare professionals). Healthcare professionals will also have access to patients' personal health data, but patients can restrict their access. The Proposal for the European Health Data Space provides a fairly extensive range of patient rights in this area, such as the right to immediate access to their electronic health data, the right to obtain an electronic copy of their data, the right to record their own electronic health data, the right to request data correction, the right to provide access to health data to data recipients, the right to restrict access to data for all healthcare professionals, and the right to information about which healthcare professionals have had access to their personal health data. These rights are regulated in Article 3 of the Proposal for the European Health Data Space.

In connection with the mentioned patient rights, the Proposal for the European Health Data Space establishes in Article 7 (1) an amendment according to which, if data is processed in electronic format, member states shall ensure that healthcare professionals systematically record relevant health data belonging to at least priority categories relating to healthcare services provided to individuals by these professionals, in electronic format in the electronic health record system. From the wording of this provision, it follows that the recording of data in electronic format applies only to data processed in electronic format. Article 3 (5) of the Proposal for the European Health Data Space establishes the obligation for member states to establish one or more access services to electronic health data at a national, regional, or local level, which enables the exercise of rights, and to establish one or more proxy services that allow individuals to authorize other individuals of their choice to access their electronic health data on their behalf. However, if personal health data has not been electronically recorded before the start of the application of the Proposal for the European Health Data Space, member states may require such data to be made available in electronic format. This does not affect the obligation to make personal electronic health data recorded after the start of the application of the regulation available in electronic format. These facts are related to the subject of this paper because they indirectly (through the right of individuals to access their electronic health data) establish the obligation for member states to make health data available electronically. In the case of amending the Slovak legislation relating to the provision of health care aimed at specifying the electronic health record and specifying exceptions leading to its paper form, we believe that the Slovak Republic should provide a suitable basis for the applicability of the obligations arising from the Proposal for the European Health Data Space.

2.2 The secondary use of electronic health data

The Proposal for the European Health Data Space addresses in its fourth chapter a relatively new and previously unregulated area within health care, which is the use of patient health data for secondary purposes. This involves the processing of electronic health data for the purposes set out in Article 34 of the Proposal for the European Health Data Space, such as official statistics, research, education, testing, and product innovation, as well as the provision of personalized health care. The data used may, in accordance with Article 2 (2) (e), include personal electronic health data originally obtained in the context of primary use, as well as electronic health data obtained for the purposes of secondary use.

This activity is accompanied by several principles. First and foremost, it involves the conception of the obligation of the data controller to provide this data, always provided that the legal requirements are met. These are mainly set out in the description of the request for access to health data, which is specified in Article 45 (2) of the Proposal for the European Health Data Space, for example, a detailed explanation of the intended use, a description of the required electronic health data, or a description of the planned guarantees to prevent any other use. If such provision is to be made, the principle of minimization must be observed, which is reflected in the requirement for the data to be provided in an anonymized format and only if the desired purpose cannot be achieved, the pseudonymized format is allowed, subject to the fulfillment of other conditions. Authorities for access to health data provide access to electronic health data only through a secure processing environment with technical and organizational measures and requirements for security and interoperability.

The author's goal is not to comprehensively cover the issue of secondary use of electronic health data, but it is necessary to mention it in the context of the subject of this paper because if a Member State of the European Union, including the Slovak Republic, is to comply with the obligation to provide health data for various activities other than the provision of health care, these will have to be managed in one electronic information system, which will be related to the electronic health record or another platform in which healthcare professionals will collect health data about patients. If we connect this with the primary use of electronic health data, according to which individuals have the right to access their data, the right to record their own data, and to control access by other entities, it is undeniable that these two functionalities of data use should be reflected in one legal institute. This can be precisely the electronic health record, which, according to the current Slovak legislation, specifically according to Section 2 (1) and Section 4 (1) of the Act on NHIS, constitutes the content of the National Register of Electronic Health Records, forming part of the National Health Information System alongside other registers.

Conclusion

One of the most important obligations of a healthcare professional is the proper management of health documentation, which is emphasized in Section 79 (1) (l) of Act No. 578/2004 Coll. on healthcare providers, healthcare professionals, professional organizations in healthcare, and on the amendment and supplementation of certain acts, in conjunction with Section 18 (1) et seq. of the Act on Health care. We consider it problematic that health documentation is regulated in two different acts within Slovak legislation, and some processes that relate to both types of health documentation (electronic health book and paper documentation) are regulated differently. In the following text we summarize some significant differences.

Providing of health care has to be recorded in the health documentation, which is done by creating the relevant electronic health record in the electronic health book. In the case of recording in the health documentation kept in accordance with Section 20 (2) and (3) of the Act on Health care, i.e. in paper form, the Act on Health care emphasizes that this record must be truthful and legible. This raises the question of whether these characteristics of the record should also be observed when recording in the electronic health book, as this requirement is absent in this case. This specific inconsistency between the electronic health book and the health documentation kept in paper form is one of several that the current legal regulation of e-Health elements in the Slovak Republic brings. Other cases can be mentioned, such as the different regulations for providing data from health documentation and electronic health books, as well as the different approaches to making data accessible. The provision of data from health documentation is regulated in the Act on NHIS in the case of the electronic health book, and in the Act on Health care in the case of health documentation kept in paper form. We believe that since both cases involve health documentation, the regulation should be included in one act. Moreover, in the question of making data from health documentation kept in the electronic health book accessible, the Act on Health care refers to the Act on NHIS, so even in this case, the regulation is included in different regulations. The accessibility of data from the electronic health book is conditioned in several places by the consent of the person whose health documentation it is, but if it is health documentation in paper form, the need for consent is not mentioned. We understand that paper documentation is in the hands of the general practitioner and not available to the person concerned, but this should not mean that the person has weaker rights than in the case of the electronic health book. For this reason as well, we consider it important for this issue to be reanalyzed and adjusted in order to reflect the requirements for the proper application of e-Health while also respecting certain exceptions arising from the objective impossibility of implementing elements of digitalization.

In the second part of this paper, we have come to the question of how the Proposal for the European Health Data Space can solve the problem of electronic health documentation in such a way that it becomes a full-fledged

tool for healthcare providers regardless of geographical parameters, that is, regardless of where the patient is located. In our opinion, this issue can represents a barrier to cross-border health care provision because member states may have different legal regulations for the creation and sharing of health records (as there is no full harmonisation), probably not always in electronic format. In practice, this means that a healthcare provider in another country does not have access to all the health data of an individual who needs health care. Within the study of the Proposal for the European Health Data Space, we have raised further questions regarding the primary use of health data in the context of electronic health documentation, namely whether healthcare providers will be obliged to create electronic health records (which will subsequently be accessible to the individuals concerned) even for data that is recorded in paper health documentation in the conditions of the Slovak Republic, and whether they will be required to consult these electronic records in relation to the person they provide health care to.

We believe the Proposal for the European Health Data Space tends to streamline the environment of electronic health records and thus contribute to cross-border health care provision. However, its wording suggests that it probably assumes that each member state of the European Union has a legal regulation for electronic health documentation. However, in the case of the Slovak Republic, there is still health documentation or a part of it, that is kept in paper form. Moreover, the electronic health book is not used as it should be, also due to several exceptions to its use (and despite to the obligation of healthcare providers to make electronic health records) that are present in the Act on Health care.

References

Andraško, J. et al. (2022). *Regulatory challenges of e-Government in the Slovak Republic in the context of European Union law*. Prague: Wolters Kluwer CR.

Boyer, K., Hallowell, R., Roth, A. V. (2002). Services: operating strategy – a case study and a method for analyzing operational benefits. *Journal of Operations Management, no. 2*.

Capíková, S. & Nováková, M. (2020). *Health documentation in relation to the assessment of the employee's health capacity - selected questions. Collection of contributions from the scientific conference Health fitness of employees*. Košice, University of Pavel Jozef Šafárik in Košice.

European Commission. (2008). *Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (notified under document number C(2008) 3282*). Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008H0594

European Commission (2012). *eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century*. Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012DC0736

European Commission. (2015). *Commission Implementing Regulation (EU) 2015/1502 of 8 September 2015 on setting out minimum technical specifications and procedures for assurance levels for electronic identification means pursuant to Article 8(3) of Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market*. Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1502

Council of Europe. (1997). *Convention on Human Rights and Biomedicine*. Retrieved from https://rm.coe.int/168007cf98

European Parliament and the Council. (2011). *Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare*. Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024

European Parliament and the Council. (2014). *Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC*. Retrieved

from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0910

European Parliament and the Council. (2022). *Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space*. Retrieved from https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF

Freel, L. & Nováková, M. (2019). *Health Law*. Bratislava: Wolters Kluwers.

Humeník, I. & Kováč, P. et al. (2015). *Health Care Act. Comment.* Prague: C. H. Beck.

Madzova, V., Sajnoski, K., Davcev, L. (2013). E-Government as an Efficient Tool towards Good Governance**.** *Balkan Socal Science Review, vol. 1*. Retrieved from https://js.ugd.edu.mk/index.php/BSSR/article/view/587/563

Milieu Ltd. (2014). *Overview of national laws on electronic health records in EU member states and their interaction with the provision of cross-border eHealth services, Brussels*. Retrieved from https://health.ec.europa.eu/system/files/201902/laws_report_recommendations_en_0.pdf

Ampovska, M. & Misheva, K. (2021). Legal aspects of eHealth development in North Macedonia. *Vestnik of Saint Petersburg University*. *Law 3*. p. 660–675.

Misheva, K. & Ampovska, M. (2022). The legal aspects of telehealth. *Conference book of proceedings from the international scientific conference „The recovery of the EU and strengthening the ability to respond to new challenges – legal and economic aspects"*. Osijek: University of Osijek.

Nastič, M. (2021). The impact of the informational and communication technology on the realization and protection of human rights. *Balkan Socal Science Review, vol. 17*. Retrieved from https://js.ugd.edu.mk/index.php/BSSR/article/view/4311/3812

National Council of the Slovak Republic. (2019). *Act No. 231/2019 Coll. on the enforcement of detention and on the amendment and supplementation of certain acts*.

National Council of the Slovak Republic. (2004). *Act No. 576/2004 Coll. on health care, services related to the provision of health care and on amendments and supplementation of certain acts*.

National Council of the Slovak Republic. (2013). *Act No. 153/2013 Coll. on the National Health Information System and on amendments and supplementation of certain acts*.

National Council of the Slovak Republic. (2019). *Act No. 395/2019 Coll. on identity cards and on amendments and supplementation of certain acts*.

National Council of the Slovak Republic. (2011). Act No. 404/2011 Coll. on the residence of foreigners and on the amendment and supplementation of certain acts.

Office of the Deputy Prime Minister of the Slovak Republic for Investments and Informatization. (2020). *Decree No. 78/2020 Coll. on standards for information technologies of public administration*.

Policar, R. (2009). *Health documentation in practice*. Prague: Grada Publishing.

Sopúchová, S. (2021). *Electronic healthcare in the Slovak Republic. e-Health and telemedicine*. Bratislava: Wolters Kluwer.

Středa, L. & Hána, K. (2016). *eHealth is telemedicine*. Prague: Grada Publishing.

Unesco. (2003). Developing and Using Indicators of ICT Use in Education. Bangkok: Unesco Asia and Pacific Regional Bureau for Education.

United Nations. (1948). *Universal Declaration of Human Rights*. Retrived from https://www.un.org/sites/un2.un.org/files/2021/03/udhr.pdf

United Nations. (1976). *International Covenant on Economic, Social and Cultural Rights*. Retrieved from https://treaties.un.org/doc/treaties/1976/01/19760103%2009-57%20pm/ch_iv_03.pdf

World Health Organization. (2005). *Resolution WHA58.28 eHealth* retrieved from https://apps.who.int/gb/ebwha/pdf_files/WHA58/WHA58_28-en.pdf