

System of e-Health Tools. The Example of Poland*

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ABSTRACT E-Health is the electronic transfer of information between entities of the healthcare system. The provisions of the law define the comprehensive e-Health system. This system encompasses the e-appointment, which is a remote medical consultation, and the Electronic Medical Records, which includes electronic prescriptions and electronic re-referrals. A particular means of electronic communication is the Patient Online Account, which is a module of the public ICT system used by the patient to obtain and transfer information. Technical tools, which are related to e-Health, have a positive impact on the situation of healthcare institutions and patients.

1. Introduction

E-Health is an element of technical progress. Electronic communications enable easier access to the healthcare system. This article is about medical law and the new possibilities and obligations under Polish law (as a result of digitization, e-Health in the Polish healthcare system).

New technology allows patients to obtain medical consultations remotely and to obtain a prescription or doctor's referral electronically. There was no legal basis for going to an appointment with a doctor without personal, direct contact between doctor and patient in the past. Digitization of this field makes the functioning of healthcare entities easier and increases health security for the patient (through quick consultations). Of course, digitization of the healthcare system also provides greater comfort for patients in obtaining healthcare services.

2. E-Health

New technology and digitization of the healthcare system are related to the functioning of healthcare entities, but the rights and obligations of the healthcare provider and the patient are also affected. Changes have been introduced into patient registration, security of medical records and the method of contact with patients and other entities within the healthcare system (hospitals etc.) and with state healthcare-system institutions (e.g. National Health Fund)¹.

E-Health is primarily about remote healthcare services² (e.g. medical consultations), and the ability to obtain a prescription or doctor's referral remotely. Additionally, the respective impact on the patient's actual and legal situation should be emphasized – effective access to medical assistance and remote access to medical records and test results. Technical progress in healthcare is improving the standard of medical services, and is giving patients greater access to the healthcare system while offering greater opportunities of professional training for medical staff³.

There are currently numerous notions related to the rapid development of digitization of the healthcare system and these should be properly recognized, while some should not be interpreted as being synonymous with the concept. The notion of 'TEC' should first be presented with regard to the notion of 'E-Health'. This is an acronym of 'Technology-Enabled Care'. TEC is the broadest notion in the digitization of the healthcare system. It refers to every use of new technologies in caring for the patient. The notion of 'E-Health' is related to telemedicine

gust 2004 on health services financed from public funds (consolidated text Journal of Laws 2021, item 1285 with amendments), hereinafter HSFPP.

² Serviced by health care entities – regulations based on the Act of 15 April 2011 on Medical Activity (consolidated text Journal of Laws 2022, item 2770), hereinafter AMA.

³ M. Floreczak and S. Sebastian, *Telemedycyna w polskim prawie administracyjnym*, in I. Lipowicz, G. Szpor and M. Świerczyński (eds.), *Telemedycyna i e-Zdrowie. Prawo i informatyka*, Warsaw, Wolters Kluwer, 2019.

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¹ National Health Fund established by the Act of 27 Au-

and telehealth (which is narrower). Telehealth includes telemedicine, management procedures, monitoring procedures and the popularization of knowledge about healthcare (the meaning of telemedicine and telehealth is flexible; these terms are interconnected). The narrowest concept is telemedicine, which encompasses: 1) remote health services, 2) crossing geographical barriers – users can be in various locations during the call, 3) the use of different, new types of ICT technology (Information and Communication Technology), 4) increasing the standard of healthcare services and popularization of new treatment methods⁴.

The legal basis of telemedicine in Polish law is Article 3, para. 1 of the Act on Medical Activity of 15 April 2011. Medical activity is primarily based on healthcare services. These services can be provided to the patient through ICT systems or a communication system⁵. The healthcare service is an activity for maintaining and recovering health or improving the level of health, as well as other medical activities related to medical treatment or based on other regulations⁶.

It should be emphasized that the legality of telemedicine is also conditional on the regulations related to the medical professions, which are regulated, in particular, in the Act on the Medical Profession and the Act on the Profession of Nurse and Midwife. The profession of a doctor is based on the provision of healthcare services by an appropriately-qualified person (with documented qualifications). In addition to direct, personal contact, healthcare services (and other activities related to the profession of doctor, e.g. scientific research or teaching the medical profession) can be provided via ICT systems⁷. Activities related to the professions of nurse and midwife can also be performed remotely, through ICT systems⁸.

E-Health, as classified in public law, is a part of the provision of public administration, which, according to the Polish doctrine of administrative law, is related to the performance by the government

administration of public tasks directly and indirectly providing tangible and intangible services to the citizens⁹. Furthermore, e-Health is also a part of e-government, because of the use of electronic tools, ICT systems, for providing public services – enabling patients to effectively exercise their constitutional right to healthcare.

E-Health can be also defined as a set of ICT infrastructure and technical tools intended to provide medical care. The ICT infrastructure in Poland especially includes the Medical Information System and the Patient Online Account. This infrastructure enables patients to obtain medical information via e-consultations, as well as e-prescriptions and e-referrals.

3. E-Appointment

The notion of ‘e-appointment’ is not a normative term. It refers to the provision of medical consultations remotely, namely with the use of various types of communication tools. The legal basis of the e-appointment is Article 42, para. 1 of the Act on the Medical Profession: the doctor determines the patient’s health situation after a personal examination, or after an examination through the ICT systems, as well as after analysing the patient’s available medical records.

The Polish legal system has no legal definition of ‘doctor’s determination’. The legal doctrine refers to two senses of this notion – formal and physical. In the formal sense, it is the issuance of a certificate by a doctor, which then enables the patient to exercise some of his or her rights, based on the law (the patient’s rights). In the physical sense, the doctor makes a substantive assessment, namely a statement on the patient’s health and, in particular, the recommendations for further medical treatment¹⁰.

The examination of a patient through ICT systems needs a very broad interpretation. The doctor can therefore handle the treatment remotely in any way that is effective. In particular, this can be via a phone call with the patient, consultation through an appropriate

⁴ *Ibidem*.

⁵ Art. 3 item 1 AMA.

⁶ Art. 2 item 1 point 10 AMA.

⁷ Art. 2 on the Act of 5 December 1996 on Medical Profession (consolidated text Journal of Laws 2022, item 2770).

⁸ Art. 11 item 1 on the Act of 15 July 2011 on the profession of nurse and midwife (consolidated text Journal of Laws 2023, item 185).

⁹ J. Jagielski, in J. Jagielski and M. Wierzebowski (eds.), *Prawo administracyjne*, Warsaw, Wolters Kluwer, 2022, 38.

¹⁰ M. Malczewska, *Commentary on the article 42, in Ustawa o zawodach lekarza i lekarza dentystry. Komentarz*. Wydanie III, E. Zielińska (ed.), Warsaw, Wolters Kluwer, 2022.

application enabling video and audio contact, or also obtaining information (automatically created medical results) from a device that is analysing the patient's health (e.g. patient's ECG – electrocardiogram)¹¹. The e-appointment also includes issuing an electronic prescription or an electronic referral¹².

In connection with the notion of 'e-appointment', it is worth clarifying a term coined by the Polish legal system during the period of the Covid-19 epidemic, namely 'teleadvice' [Polish: *teleporada*]. In order to combat the epidemic, the Polish legislator decided to enable doctors to provide healthcare services in connection with the battle against the Covid-19 epidemic through an ICT system provided by an entity subordinated to the Minister of Health responsible for healthcare information systems. This legal regulation expired because it was only established for a definite term (365 days)¹³. Teleadvice was therefore a type of e-appointment through which the healthcare service was only provided in order to battle against Covid-19. The epidemic is a dynamic threat – it resulted in some patient rights, as well as regulations on medical records not being applicable or being applicable to a narrower extent, according to the standard of the remote healthcare service.

The Polish legislator established two types of technical conditions for ICT systems used to holding e-appointments. This division is based on the status of the ICT system. The public IST system, which is only used for e-appointments (it is only used by public entities providing healthcare services), should satisfy the minimum conditions specified by law. Polish law does not lay down any special technical conditions for a private ICT system, in the sense of infrastructure used by private entities (which provide healthcare services). Therefore, if the healthcare service is being provided by an entity which does not perform public tasks, the doctor, dentist, nurse or midwife can practice their professions by providing healthcare services, including healthcare services with the use of any ICT

systems, provided that they comply with the fundamental rules on this (confidentiality and safety of the information sent).

4. The national healthcare information system.

The National Healthcare Information System is used to process data, which are necessary, among other things, to provide health services¹⁴. The National Healthcare Information System is a collection of databases operating within the Medical Information System¹⁵. The health service provider enters electronic prescriptions and electronic referrals, as well as data from the electronic medical record, into the National Healthcare Information System¹⁶. The provider is also required to enter data on medical events into the Medical Information System¹⁷. The Medical Information System is operated by the Electronic Platform for Gathering, Analysing and Distributing Digital Resources on Medical Events, which is the public ICT (Information and Communication Technology) system¹⁸. This platform enables providers to access data on health services that have been provided and planned¹⁹, as well as to exchange electronic medical records with other providers²⁰.

5. The patient online account

The Patient Online Account is a means of electronic communication used by the patient to obtain and provide information. This account is a module of the public ICT system – the Electronic Platform for Gathering, Analysing and Distributing Digital Resources on Medical Events²¹. The patient has online access to this account directly or through a

¹¹ *Ibidem*.

¹² Art. 95b on the Act of 6 September 2001 on Pharmaceutical law (consolidated text Journal of Laws 2022, item 2301), hereinafter PL; Art. 59aa HSFPF.

¹³ Amended art. 7 item 4 on the Act of 2 March 2020 "Anti-COVID19" (consolidated text Journal of Laws 2023, item 412).

¹⁴ Art. 1 item 1 the Act of 28 April 2011 on the National Healthcare Information System (consolidated text Journal of Laws 2022, item 1555 with amendments), hereinafter NHIS. K. Świtała emphasizes that the Medical Information System is one of the types of basic state infrastructure. K. Świtała, *System informacji w ochronie zdrowia a problematyka planowania i ewaluacji polityk zdrowotnych w Polsce*, in *Roczniki Kolegium Analiz Ekonomicznych*, Vol 52, 2018, 105.

¹⁵ Art. 5 item 1 point 2 NHIS.

¹⁶ Art. 11 item 5 point 1-2 NHIS.

¹⁷ Art. 56 item 2a NHIS.

¹⁸ Art. 5 item 2 point 2 in connection with art. 7 item 1 point 1 NHIS.

¹⁹ Art. 7 item 1 point 1 NHIS.

²⁰ Art. 7 item 1 point 3 NHIS. B. Michalak, *Dokumentacja medyczna 3D*, in *Studia Ekonomiczne Uniwersytetu Ekonomicznego w Katowicach*, Vol 199, 2014, 192.

²¹ Art. 2 point 19 in connection with art. 7 item 1 NHIS.

public mobile application²².

The Patient Online Account offers two types of functions: 1. access to general information²³ or information about the legal situation of the patient (the recipient of the health service)²⁴; 2. the ability to submit applications²⁵ and declarations²⁶.

Patients or statutory representatives of minor patients have access to this online account²⁷.

The Patient Online Account has basic standards for authorized access. These standards apply to technical and organizational requirements.

The technical standard of access to the Patient Online Account applies to the authentication of the patient or other authorized person. Two types of authentication are admissible, depending on the type of access to the account. The first, which is used for direct access to this account, is the use of electronic identification related to the National Electronic Identification Node²⁸. The second is the use of a public mobile application. This type of authentication involves the use of an electronic certificate²⁹.

²² According to art. 7b item 1a NHIS, access to the Patient Online Account can be ensured over public mobile application.

²³ Access to general information refers to inter alia data on the amount of reimbursement for medicinal products (art. 7a item 1 point 8 NHIS.); data on health prevention and healthy lifestyle, which are based on individual medical data of the service recipient (art. 7a item 1 point 15 NHIS.).

²⁴ Access to information about legal situation of patient related to inter alia: data on the right to health services (art. 7a item 1 point 2 NHIS.); data on issued medical certificates (art. 7a item 1 point 6 NHIS.); data on the amount of health care contribution, which is paid by the service recipient (art. 7a item 1 point 7 NHIS.); data on the service provider and the health services provided by him (art. 7a item 1 point 11 NHIS.).

²⁵ Applications submitted over the Patient Online Account include inter alia: an application for a European Health Insurance Card (art. 7a item 1 point 12 NHIS.); an application or a complaint to the Patient's Rights Ombudsman, the Minister of Health and the National Health Fund (art. 7a item 1 point 14 NHIS.).

²⁶ The Patient Online Account may be also used to: authorize a third party to access medical records (art. 7a item 1 point 3 NHIS.); sending consent to provide health services (art. 7a item 1 point 5 NHIS.); sending a declaration of choosing a health service provider (art. 7a item 1 point 10 NHIS.).

²⁷ Art. 7b item 2-3 NHIS.

²⁸ Art. 7b item 1 NHIS. in connection with art. 20a item 1 point 1 Act of 17 February 2005 on the computerization of the activities of entities performing public tasks (consolidated text Journal of Laws 2023, item 57), hereinafter CAEPPT.

²⁹ Art. 7b item 1a NHIS. in connection with art. 19e

The organizational standard of access to the Patient Online Account includes blocking access for the statutory representative of the health service recipient (the patient) if his authorization for access expires³⁰.

6. Electronic Health Records

Electronic Medical Records also constitute an element of e-Health. These records are generated in connection with the provision of health services³¹. The electronic medical records include electronic prescriptions and electronic referrals.

These records are available free of charge in the public ICT system, and comply with the technical standard for ensuring data integrity and the authorization of the entity that prepared these records³².

An electronic prescription is a document issued electronically³³. The rule is currently to issue electronic prescriptions. The provisions of the law specify exceptions under which paper prescriptions may be issued³⁴.

An electronic referral is also a document issued electronically³⁵. An electronic referral is issued for health services, which are specified in the list of the Minister of Health³⁶. The provisions of the law also lay down the exceptions, by which a referral may be issued only in paper form, in the case of health

item 1 CAEPPT.

³⁰ Art. 7b item 5 NHIS.

³¹ Judgment of the Supreme Administrative Court of 6 October 2020, II GSK 557/18, CBOSA. According to the judgment, electronic medical records, which include a document generated in connection with the provision of health services, is subject to authorization with electronic authorization means. See also Z. Maj, *Elektroniczna dokumentacja medyczna – wybrane aspekty prawne*, w *Przegląd Prawa Medycznego*, Vol 1, 2022, 116.

³² According to art. 2 point 6 NHIS., the Electronic Medical Records includes electronic documents issued with a qualified electronic signature, a trusted signature, a personal signature or using the means of confirming the origin and integrity of data available in the public ICT system, which is provided free of charge by the Social Insurance Institution.

³³ Art. 95b item 1 PL.

³⁴ Art. 95b item 2 PL.

³⁵ Art. 59aa item 1 the Act of 27 August 2004 on health services financed from public funds (consolidated text Journal of Laws 2021, item 1285 with amendments), hereinafter HSFPF. The provisions of law equals an electronic referral with a referral issued in paper form (art. 59aa item 1 HSFPF).

³⁶ Art. 59aa item 2 HSFPF in connection with the Ordinance of the Minister of Health of 15 April 2019 on referrals issued in electronic form in the Medical Information System (consolidated text Journal of Laws 2022, item 1417).

services for which, as a rule, an electronic referral is issued³⁷.

The provisions of the law define a uniform model for transferring information on electronic prescriptions and electronic referrals, as well as the security standards regarding these documents.

There are two levels of data transfer related to electronic medical records. These are the provision of access to electronic medical records and the distribution of information about these records.

The first level, which involves the provision of access to electronic documentation, is passive in nature. This level includes enabling authorized personnel to view these records, which are stored in a public ICT system. Electronic prescriptions and electronic referrals are simultaneously recorded in the Medical Information System³⁸ and are then made available through this system³⁹. The objective of providing access to this documentation is to provide a technical tool to the authorized person enabling the use of this system.

The second level, which involves the provision of information on electronic medical records, is active in nature. This information is received by authorized personnel. Information related to these electronic medical records includes data which are necessary for authorizing the use of the documents. This information also includes the data of the persons issuing these documents and the data of the addressees of these documents⁴⁰. Information on electronic prescriptions also includes data on the medication and its use⁴¹, as well as information on whether the patient is entitled to receive the medication free of charge⁴². This information may be sent to the addressee by e-mail or by text messages, as

well as in the form of a printout⁴³. The provision of information on electronic medical records is a technical activity of a declaratory nature. The objective of providing information on this documentation is to transfer it to an authorized person.

The provisions of law lay down the security standards for electronic prescriptions and electronic referrals⁴⁴. These standards apply to the authorization to issue these documents and maintain their integrity. The standard for authorizing the issuance of these documents is the requirement that they are signed with a qualified electronic signature, a trusted signature, a personal signature, or another public means of electronic authorization⁴⁵. The standard for maintaining the integrity of electronic prescriptions and electronic referrals includes a special procedure for changing their content. An effect of this change is the cancellation of the original version of the electronic prescription or electronic referral and the issuance of a new prescription or new referral⁴⁶. The objective of this procedure is to ensure that the doctor or other person issuing these documents has control over their content.

The provisions of the law also lay down the regulation on setting the technical requirements for Electronic Medical Records. The Minister of Health defines the formats of Electronic Medical Records⁴⁷, as well as the standards for exchanging these medical

³⁷ Art. 59aa item 3 HSFPF.

³⁸ Art. 96a item 9a PL, and art. 59aa item 5 in connection with art. 59aa item 2 HSFPF.

³⁹ Art. 11 item 2 NHIS. A. Klich, *Wybrane zagadnienia prawne elektronicznej dokumentacji medycznej*, w *Ekonomiczne Problemy Usług*, Vol 1, Issue 2, 2017, 355. According to art. 59b item 2b HSFPF, the Internet Patient Account ensure access to the electronic referral.

⁴⁰ Art. 96b item 1 PL and art. 59b item 1 HSFPF.

⁴¹ Art. 96b item 1 point 10-14 PL.

⁴² (art. 44a item 3 in connection with art. 44a item 1 and art. 44b item 2 in connection with art. 44b item 1 the Act of 12 May 2011 on the reimbursement of medicines, foodstuffs intended for particular nutritional uses and medical devices (consolidated text Journal of Laws 2022 item 463 with amendments).

⁴³ Art. 96b item 2 PL in connection with art. 7 item 1 NHIS., and art. 59b item 2 HSFPF in connection with art. 7 item 1 NHIS.

⁴⁴ A. Klich emphasizes that the Electronic Medical Record ensures greater data security compared to the documentation issued in paper form. A. Klich, *Wybrane zagadnienia prawne elektronicznej dokumentacji medycznej*, in *Ekonomiczne Problemy Usług*, Vol 1, Issue 2, 2017, 352. The similar stance was expressed by J. Pacian, A. Pacian, T. B. Kulik, A. Stefanowicz, H. Skórzyńska, D. Żolnierczuk-Kieliszek, M. Janiszewska, *Ochrona danych medycznych zawartych w dokumentacji medycznej a wykorzystanie bezpiecznego podpisu elektronicznego*, in *Zdrowie Publiczne i Zarządzanie*, Vol 10 (B), 2012, 194.

⁴⁵ Art. 96a item 1 point 3 PL and art. 2 point 6 letter c NHIS. in connection with art. 59aa item 2 HSFPF. Judgment of the Supreme Administrative Court of 6 October 2020, II GSK 557/18, CBOSA. According to this judgment, the requirement to use a means of electronic identification (electronic signature) is the result of the digitization of the Electronic Medical Records. See also E. Kawiak-Jawor, M. Kaczoruk, P. Kaczor-Szkodny and E. Dudzińska, *Bezpieczeństwo danych medycznych w kontekście wdrożenia elektronicznej dokumentacji medycznej*, in *Medyczna Wokanda*, Vol 9, 2017, 130.

⁴⁶ Art. 96a item 9b PL and 59aa item 6 HSFPF.

⁴⁷ Art. 11 item 1a NHIS.

records⁴⁸. These requirements are published in the Public Information Bulletin⁴⁹.

7. Conclusions

The healthcare system in Poland has been partially digitized. Information on health services may be transferred electronically. The provisions of the law distinguish the level of interference in the manner of this communication. A significant amount of interference applies to the gathering and transfer of the Electronic Medical Records. These activities can take place through the Medical Information System. A slight amount of interference applies to the requirements for remotely providing medical consultations. The entities providing healthcare services can freely choose the ICT system or communication system over which these services are provided. However, an e-appointment will not replace comprehensive medical assistance provided after a personal examination of the patient. Therefore, the scope of health services provided remotely should be limited proportionally to the patient's needs. The digitization of the healthcare system is an important value for society. Nevertheless, the priority should be safety of life and health in connection with the provision of the health service.

⁴⁸ Art. 11 item 1b NHIS.

⁴⁹ Art. 11 item 1a-1b NHIS.