

e-Transformation in the Polish Healthcare System. Data in Healthcare Entities*

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ABSTRACT This publication aims to familiarise the reader with the digital transformation that has taken place in the Polish health care system; To draw attention to the category of data processed as part of the “e-Health” phenomenon, as well as their role in the system. To describe to the reader the basic legal and organisational solutions for the processing of medical data in the health care system.

1. Introduction, or some remarks on the digital transformation in the Polish health care system

Health care is an important task of every modern state, being part of the so-called prestative administration. For this reason, the provision of health care services either directly by the state or, as part of gradual privatisation, by private entities equipped with public funds, is widely accepted. There is also no doubt that the implementation of public tasks in the field of health care and their supply should be carried out according to certain values, among which the compliance with the principles of: quality and safety, equal access to the system and continuity of health services are crucial.

Health services - as a result of the transformation of society into an information society - are increasingly taking the form of services provided electronically,¹ i.e. with the use of information and communication technologies (ICT). According to the Polish Act of 18 July 2002 on provision of services by electronic means,² implementing Directive 2000/31/EC of the European Parliament and

of the Council of 8 June 2000 - a service provided by electronic means is a service which: 1) is provided at a distance, 2) via electronic processing equipment, 3) at the request of the recipient of the service and 4) for remuneration.³ The phenomenon of electronically delivered medical services is referred to as: telemedicine, teleconsultation, sometimes a general term appears in their context, i.e. “e-Health”, although these are not synonymous terms. Without entering into detailed discussions in this regard, it is only necessary to point out that the term “telemedicine” refers to activities directly aimed at achieving a therapeutic objective, including in its scope: prophylaxis, diagnosis, treatment and control of patient’s state of health, carried out with the use of means of distance communication. The Polish legislator does not introduce a legal definition of the notion of ‘telemedicine’, however, it allows for the possibility of providing medical services by means of teleinformation systems or communication systems.⁴ In such an

³ Although the Polish legislator does not introduce the premise of remuneration, it is present in the provisions of EU law, in particular in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, as amended by Directive 98/48/EC. According to the case law of the CJEU - the premise of remuneration does not imply a requirement for the person who uses the service to pay for it, the economic dimension of the service in question is important.

⁴ Article 3(1) of the Act of 15 April 2011 on therapeutic activity, (single uniform text in Journal of Laws 2022.633 of 2022.03.18).

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¹ The literature points out that due to the Community nature of the concept of ‘information society service’, it is not uniformly transposed by national legislators, e.g. the Polish legislator uses the concept of ‘electronically provided service’. On this subject: I. Wrobel, *Pojęcie usługi społeczeństwa informacyjnego w prawie wspólnotowym*, in *Cbke e-biuletyn*, no. 4, 2007, https://www.bibliotekacyfrowa.pl/Content/22509/PDF/Pojecie_uslugi_spoleczenstwa_informacyjnego.pdf.

² Single uniform text in Journal of Laws 2020 of 3 March 2020.

approach, the notion of ‘telemedicine’ is similar to the notion of ‘teleconsultation’, which, regulated and named in the Polish national law, means precisely health services provided at a distance with the use of tele-information systems or communication systems.⁵ Thus, telemedicine or teleconsultation services should be referred to services which have the nature of health services. On the other hand, the notion of ‘e-Health’ is broader than the notion of ‘telemedicine’ and ‘teleconsultation’ and, apart from actions aimed directly at achieving a therapeutic goal, also includes accompanying services consisting in: processing of data about the patient’s state of health, maintaining electronic medical records, issuing e-prescriptions, e-referrals and e-medical leave, the broadcasting of medical procedures for students or e-learning services in general. However, according to some doctrinal positions, not all e-Health services can be qualified as information society services, e.g. a simple teleconsultation consisting of an exchange of information and experience between medical specialists will not have such a character.⁶ On the basis of the analysis of the normative material and the jurisprudence of the CJEU - a certain line of demarcation in this regard may be the assessment whether the “e-Health” services are inextricably linked to the relevant telemedicine or teleconsultation service, and if the answer is in the affirmative, it is possible to qualify the e-health service as an information society service.⁷

Providing health services by electronic means in the Polish health care system - being an innovative form of providing medical care - is increasing, also under the influence of experiences related to the SARS-CoV-2 virus

⁵ The concept of teleconsultation is regulated in the Regulation of the Minister of Health of 12 August 2020 on the organisational standard for teleconsultation in primary healthcare (uniform text in Journal of Laws 2022.1194 of 2022.06.06).

⁶ D. Gęsicka, *Pojęcia „usługi telemedycyny”, „telemedycyna”, „e-zdrowie”* in I. Lipowicz, G. Szpor and M. Świerczyński (eds.), *Telemedycyna i e-Zdrowie. Prawo i informatyka*, Warsaw, 2019.

⁷ In this context, attention may be drawn to motive 18 of Directive 2000/31/EC, according to which the notion of information society services encompasses a wide range of activities carried out on line and includes both services providing the opportunity to conclude contracts on line and services offering information and commercial services; ECJ judgment of 4.05.2017, C-339/15, Criminal proceedings against Luc Vanderborght, ZOTSiS 2017, no. 5, item I-335.

pandemic. Some of these services - taking into account previous findings - will have the hallmark of information society services, while others, which will not be inseparable from the provision of health services, will be part of the broadly understood e-Health phenomenon, (e.g. a medical examination or a procedure performed in the doctor’s office with the physical presence of the patient with the use of electronic equipment). The purvey of health services via electronic means results in a win-win situation for the patient, which of course is not without some associated risks. Among the advantages of telemedicine is that it facilitates access to specialists, not only for groups subject to social exclusion (e.g. inhabitants of rural areas and small towns), as is generally assumed, but also in situations where, due to the high level of complexity of a specific case, it becomes necessary to conduct a meeting with a wider group of specialists (e - procedure, e - surgery). The literature emphasises that the benefits of well-integrated ICT tools, such as lower costs and health safety for patients, include preventing or postponing the placement of patients in inpatient care, which is costly and sometimes even ineffective from the perspective of the patient’s recovery.⁸

Information and communication technologies (ICT) can be used directly for patient health care, in particular when they mediate a visit (so-called e-visit), or when a patient, e.g. after hospitalisation or with a chronic illness, requires continuous monitoring of his or her health condition (e.g. with the help of an e - ECG, e - ultrasound or e - stethoscope) together with the assessment of parameters by a medical specialist at any time. It is also necessary to take into account such solutions that indirectly contribute to the protection of individual health, the axis of which will be preventive and educational activities, i.e. those consisting in e - instruction, e - rehabilitation and e - prophylaxis. Going one step further, it is worth pointing to solutions in the field of video monitoring applied to persons with intellectual disabilities or senile dementia, which are intended to protect the above-mentioned categories of persons from the

⁸ See I. Lipowicz, *Administracja świadcząca na odległość – Nowe wyzwania administracyjnoprawne*, in I. Lipowicz, G. Szpor and M. Świerczyński (eds.), *Telemedycyna i e-Zdrowie. Prawo i informatyka*, Warsaw, 2019.

dangers of damaging their health or even loss of life. It should also be kept in mind that, despite the increase in areas where telemedicine can be used effectively, it cannot be treated as an alternative to traditional forms of treatment. Therefore, in some cases, it will not find justifiable use (e.g. when - for reasons of the patient's state of health, treatment and prognosis - services performed in the direct presence of the patient are necessary). This distinction is illustrated in the figure below.

Application of information and communication technologies in medicine:		
Directly used to protect the health and life of the patient (e-visit, e-ultrasound, e-medical documentation);	Indirectly used to protect the health and life of the patient (e-instruction, e-prophylaxis);	There are areas where the use of ICT will be incompatible with patient safety;

Figure 1: Application of information and communication technology in medicine

Thus, to summarise the previous considerations - health services provided via ICT means, i.e. telemedical services, can be effectively provided in the Polish health care system. It should be borne in mind that telemedicine benefits should correspond to the same level of professional requirements - which are appropriate for traditional health insurance benefits, of course taking into account the specificity of telemedicine services. The provision of telemedicine services - as previously agreed - is possible if: this is in accordance with the requirements of current medical knowledge and with the principles of professional ethics, the supply of these services does not conflict with legal regulations and - as will be discussed later - all requirements for the security of data processing are met.⁹

The use of information and communication technologies in health care requires the development and implementation of a system capable of sharing information, i.e. an interoperable system. Such a system should take into account the needs of patients. It should be directed towards secure access, exchange and use of electronic health information, through patient websites, using mobile applications and artificial intelligence.

⁹ *Jak skutecznie wykorzystać potencjał telemedycyny w polskim systemie ochrony zdrowia?*, Warsaw, 2018, 36, report prepared for the Telemedicine Working Group Foundation, available on the website: http://telemedycyna.raport.pl/api/file/events/rtgr/DZP_raportTGR%20raport-www.pdf.

Such systems should also meet requirements to ensure the integrity of the content and data contained therein, permanent access for authorised persons and access control. In the Polish healthcare system, as part of ensuring interoperability of the healthcare system, a solution has been implemented that consists of the use of electronic document templates in a standard allowing for the inclusion of strictly defined data and the exchange of this data between individual systems used in the medical environment. The templates discussed here are part of a globally used standard - HL7 (Health Level Seven). The use of ICT tools or other medical devices also requires the creation of a range of organisational arrangements that make the solutions discussed here accessible to users. Moreover, due to the fact that the consequence of e-Health involves the removal of natural barriers protecting privacy, and the subject is the circulation of data, especially personal data, including sensitive data concerning the patient's state of health, it is necessary to design legal and organisational resolutions, and then to implement them correctly, in a manner which will guarantee the security of data and will express concern for the well-being, privacy and safety of the patient, i.e. - the beneficiary of the health care system.

The change that has taken place in the Polish health care system as a result of the use of ICT is significant. The analysis of the basic solutions in this area makes it possible to distinguish certain areas in which ICT solutions are used. First of all, we can distinguish the area of telemedicine in general, which - referring to the previous findings - consists in providing health services at a distance. Within this area, attention should be paid to e-medical leave, e-prescriptions and e-referrals embedded in the system, as well as solutions in the field of diagnostics, treatment and prevention of certain diseases (e.g. cardiovascular and respiratory diseases). Another area in which ICT solutions are used is medical documentation. The Polish regulation in this area establishes as a rule the keeping of medical records - in electronic form.¹⁰ Another significant area using ICT is the flow of medical data and archiving (Internet Patient Account). In this context, it

¹⁰ Regulation of the Minister of Health of 6 April 2020 on types, scope and models of medical records and the manner of their processing (single uniform text in Journal of Laws 2022.1304 of 2022.06.22).

should be noted that the diagnostic and therapeutic process depends to a large extent on the exchange of information between units of the system. The flow of medical data via IT systems undoubtedly improves the diagnostic and treatment process. Finally, one can mention the area of promoting research and development activities and entrepreneurship in the field of e-Health. The Polish legislator has also recognised the need to implement IT tools in the area of collecting data on adverse events and the occurrence of potential non-compliance in the practice of a healthcare entity.

Some telemedicine or e-Health solutions take the shape of pilot programmes, the aim of which is to identify the basic barriers to implementation and to gather knowledge on the functioning of a given solution, its evaluation and possible correction. Currently, in Poland, the project evaluates, among other things: the usefulness of using ECG patches to remotely monitor a patient's health condition, and the usefulness of using e - spirometers and e - stethoscopes for post-covid prophylaxis. An e - registration scheme is also being implemented, assessing the effectiveness of patient queue management using an algorithm.

2. Data in healthcare entities

An element of the purvey of healthcare services as information society services, among others, is the processing and storage of data.¹¹ Thus, the widespread use of efficient ICT systems implies the creation and functioning of various databases and medical registers.¹² In the health care system, data are processed that are necessary for the public health policy, for improving the quality and availability of services and for health care tasks to be cost-effective. Accordingly, data in the health system is data that is collected not only by healthcare entities as part of their actual activities, but also as a result of collection from various measuring and diagnostic devices, brought in by patients and cooperation with various other entities of the system.¹³

¹¹ M. Podleś, in J. Gołaczyńskiego (ed.), *Umowy elektroniczne w obrocie gospodarczym*, Warsaw, Difin, 2005, 251.

¹² By way of example only, the following medical registers can be mentioned: Register of Medicinal Products; Register of Medical Assistants; Register of Pharmacies; Register of Healthcare Providers.

¹³ K. Wojsyk, 2. *Jakość danych związanych z lokalizacją w przestrzeni*, in I. Lipowicz, G. Szpor and M. Swierczyński (eds.), *Teledygnia i e-Zdrowie. Prawo*

Thus, the data collected in the health system can be diverse and serve different purposes. We can speak of statistical, financial, structural or qualitative data. Therefore, it can be hypothesised that data lies at the heart of an organised health system. In other words, the more the health system wants to meet the demands placed on it and respond to the needs of its stakeholders, the more attention it must pay to the collection and gathering of adequate, high-quality data¹⁴ and its proper analysis. The variety of data in the health system is presented in the figure below.

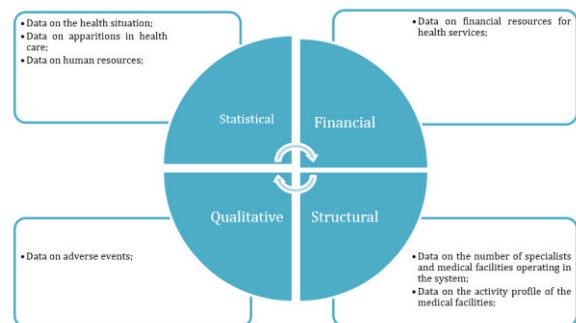


Figure 2: Types of data collected in the health system

Data processing in the health system has a variety of undertows, and is carried out under different legal titles. Among the many categories of data commonly collected in the health care system, those containing information about individuals occupy a special category.

3. Medical data as a special category of data

The processing of personal data in healthcare entities includes a variety of activities related to patient data, which may consist of: the collection of information during patient registration - both conducted in traditional form and using ICT tools; consultation with a specialist, including through telemedicine or teleconsultation; the completion of medical records in an ICT system; the exchange of information about a patient's health status; sometimes the transfer of data to other country, as well as the storage of medical records and their deletion. The source of these data can be either - a human being, i.e. a healthcare professional, or the entire organised infrastructure for the provision of a specific healthcare service. With reference to the previous adjudications, it should be recalled that

i informatyka, Warsaw, Wolters Kluwer, 2019.

¹⁴ High-quality data is data from a reliable source, verifiable, unambiguous, identifiable.

the consequence of the supply of health services through information and communication means is the processing of data in an electronic environment, which leads to an intrusion into the privacy of the patient. The data processing is necessary for the fulfilment of the database administrator's legal obligation, while it is beneficial for the patient. For this reason, health is combined with an interference with another issue - privacy. Because the activities for the protection of health of an individual cannot override his/her right to privacy - it became necessary to develop legal means and to determine the conditions under which the personal data of a patient will be processed.

Patient's data is a special category of data, the so-called sensitive data, which determines their special protection (as their processing may cause risk for the data subjects) and certain obligations of medical entities providing health services in this respect. These obligations - as rightly noted by the representatives of the doctrine - should aim at securing personal data and consist in the implementation of adequate technical and organisational solutions which are to enable safe and lawful processing of personal data of individuals, including persons using the services offered by the healthcare entities.¹⁵ The detailed manner of handling the data in question here and the relevant obligations of healthcare entities are normalized in particular - common to all Member States - by the EU Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (GDPR),¹⁶ which regulates the most important issues in this regard, and by the national regulations adopted in the Member States, which are sometimes complementary.¹⁷ The aforementioned regulations formulate as their objective - the protection of data subjects from the negative consequences

of the processing operations, which is why the above-mentioned regulations indicate, in particular, the rights of data subjects and define the specific obligations of database administrators and other processing entities (so-called processors), which process the data of natural persons in an automated manner.

A patient's personal health data is information that concerns the physical and mental health of an identified or identifiable natural person. It is worth emphasising that the mere possibility of identifying a person, through the association of information, makes the information personal data. The identification of a patient can be made on the basis of: first name, surname, PESEL number, international classification of diseases (ICD-11), internet identifier and many other characteristics. It is also worth emphasising that certain health data - due to anonymisation - will not be subject to the GDPR regulations (e.g. statistical data).

Among the sensitive data protected, the GDPR includes - "all data about the health status of the data subject revealing information about the past, present or future physical or mental health of the person". The GDPR specifies that this will include, but is not limited to: information collected during registration and during the provision of healthcare services; information from laboratory tests or medical examinations; information about the disease, disability, disease risk, medical history, clinical treatment and physiological or biological state of the data subject.¹⁸ Nevertheless, it should be kept in mind that the information listed in the GDPR, which constitutes a category of personal data of the patient, is only of illustrative, interpretative value, as the scope of the data is in fact broader.

The Data Protection Regulation in Article 9(1) formulates a general prohibition on the processing of sensitive data, including data relating to health, however, healthcare providers may process patient data on the basis of Article 9(2)(h) - for the purposes of preventive health or occupational medicine, for the assessment of a worker's fitness for work, medical diagnosis, the provision of healthcare or social security, treatment or the management of healthcare or social security systems and services on the basis of EU law, Member State

¹⁵ P. Fajgielski, *Prawo ochrony danych osobowych. Zarys wykładu*, Warsaw, 2019, 20.

¹⁶ Journal of Laws UE.L.2016.119.1 of 2016.05.04, GDPR.

¹⁷ These will be legal regulations of various types and ranks, ranging from constitutional provisions, international and EU law, national laws and implementing acts; The national regulation that serves the application of the GDPR - is the Act of 10 May 2018 on the protection of personal data (uniform text in Journal of Laws 2019.1781 of 2019.09.19).

¹⁸ The legal definition of health data can be found in Article 4 para. 15 of the GDPR, it is complemented by motive 35 of the GDPR preamble.

law or in accordance with a contract with a healthcare professional subject to the conditions and safeguards referred to in Article 9(3) GDPR. In addition, under Article 9(2)(i), it is possible to process data when this is necessary for reasons of public interest in the field of public health, such as protection against serious cross-border health threats or ensuring high standards of quality and safety of healthcare and medicinal products or medical devices, on the basis of EU or Member State law, which provides for appropriate specific measures to protect the rights and freedoms of data subjects, in particular professional secrecy.

Healthcare institutions processing sensitive data (database administrators) have been obliged to secure such data by implementing adequate technical and organisational solutions to enable the safe and lawful processing of personal medical data. At the same time, the GDPR does not explicitly formulate specific technical and organisational conditions, it only indicates in Article 32 - system features and functionality, which is probably dictated by the fact that the processing of personal data takes place in the face of constant technological progress.¹⁹

Medical entities not only process, but also transfer - on the basis of contracts, by law, or on specific request - the patient's medical data to other entities, organisations and institutions operating in the health care system (e.g. other medical specialists) and public authorities (National Health Fund (payer), control and supervisory bodies). In case the healthcare entity (administrator) transfers the data to other entities, institutions and organisations on the basis of the personal data processing entrustment agreement (processor) - it is obliged to choose the processing entity which provides the guarantee of implementation of appropriate technical and organisational measures which are to ensure lawful and secure processing for the data subjects. When entering into a processor entrustment agreement, the administrator must ensure that it complies with the requirements set out in Article 28 GDPR. In practice - the administrator (healthcare provider), before entering into an entrustment agreement, should verify that the processor, inter alia: already processes health

data or other sensitive data; has appointed a Data Protection Officer; has implemented technical and organisational measures that will protect the rights of data subjects; has carried out a data protection impact assessment; has implemented procedures for security incident management; undergoes regular data security audits; ensures that persons authorised to process data are bound by confidentiality agreement; and has joined a code of conduct or certification mechanism.²⁰

4. *Protection of patient medical data under the GDPR*

Patient information as sensitive data is subject to special legal protection. This applies to medical data as well as other data, such as identification or contact data. Ensuring the appropriate level of this data - as mentioned above - is particularly important when providing telemedicine services. For this reason, administrators - or other processors - are obliged to secure these data by implementing adequate technical and organisational solutions to enable safe and lawful processing of the patient's personal data. The administrator is furthermore obliged to implement the rights of data subjects, among which - according to the GDPR - are: The right of access to personal data; the right to rectification of personal data; the right to be forgotten; the right to restrict the processing of personal data; the right to data portability; and the right to object. The exercise of some of these rights may be limited due to national law (e.g. the right to erasure of data contained in medical records cannot be exercised before the expiry of the statutory retention period). The protection of patients against the negative consequences of unlawful data processing takes into account the application of measures of a preventive nature (consisting precisely in determining the principles of data processing and the obligations of administrators and processors) and repressive measures (e.g. administrative fines).

5. *Conclusion*

The use of information and communication tools in health care brings a number of benefits to all participants of the health care sys-

¹⁹ On this topic, among others: B. Marcinkowski, 3.3. *RODO*, in I. Lipowicz, G. Szpor and M. Świerczyński (eds.), *Telemedycyna i e-Zdrowie. Prawo i informatyka*, Warsaw, Wolters Kluwer, 2019.

²⁰ *Jak skutecznie wykorzystać potencjał telemedycyny w polskim systemie ochrony zdrowia?*, Warsaw, 2018, 89, report prepared for the Telemedicine Working Group Foundation, available on the website: http://telemedycynaraport.pl/api/file/events/rtgr/DZ_P_raportTGR%20raport-www.pdf.

tem. Telemedicine - as a complementary form - in relation to the classic form of providing services allows to respond to some of the needs of an ageing society. Thanks to the use of telemedicine solutions, the effectiveness of telemedically delivered health services is steadily increasing. The widespread use of telemedicine solutions is supported at European Union level, which, in the context of a mobile society, is to be welcomed.

