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# Legal Aspects of Telemedicine in Poland and Challenges in Times of Pandemic

**Abstract:** The article presents the legal regulations on telemedicine applicable in Poland. Despite the adoption of legislation enabling the provision of health services at a distance via teleinformation or communication systems (ICT), telemedicine services were not widely used. In the opinion of doctors themselves, one of the basic barriers to the development of telemedicine in Poland was the lack of clarity of legal regulations. There was a need for legislative changes defining not only organisational and technical standards for providing medical advice at a distance, but also concerning the principles of civil, criminal and professional liability of doctors and guaranteeing the safety of patients and the protection of personal health data. The outbreak of the pandemic contributed significantly to the development of telemedicine services in Poland, in particular teleadvice, televisit and teleconsultation, as well as the wider use of technical devices monitoring the patient's condition at a distance. It was driven by demands regarding the protection of patients' health, the need to reduce the risk of the spread of COVID-19 and to maintain the capacity of the health system in relation to the growing needs of the population. Nevertheless, due to the necessity of quick response to emerging challenges, the legal solutions adopted during the prevailing epidemic were not without flaws.

**Keywords:** telemedicine, remote healthcare, ICT systems, COVID-19, pandemic, legal regulations, Poland

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**Aspekty prawne telemedycyny w Polsce i wyzwania w czasach pandemii**

**Abstrakt:** Artykuł przedstawia rozwiązania prawne w zakresie telemedycyny obowiązujące w Polsce. Mimo wprowadzenia przepisów umożliwiających udzielanie świadczeń zdrowotnych na odległość za pośrednictwem systemów teleinformatycznych lub systemów łączności, usługi telemedyczne nie były rozpowszechnione. W opinii samych lekarzy jedną z podstawowych barier rozwoju telemedycyny w Polsce był brak jasności regulacji prawnych. Konieczne były zmiany legislacyjne określające nie tylko standardy organizacyjne i techniczne w zakresie udzielania porad medycznych na odległość, ale także dotyczące zasad odpowiedzialności cywilnej, karnej i zawodowej lekarzy oraz gwarantujące bezpieczeństwo pacjentów i ochronę danych osobowych dotyczących zdrowia. Wybuch pandemii w znacznym stopniu przyczynił się do rozwoju usług telemedycznych w Polsce, w szczególności teleporad, telewizyt i telekonsultacji, a także szerszego wykorzystania urządzeń technicznych monitorujących stan zdrowia pacjenta na odległość. Było to podyktowane postulatami ochrony zdrowia pacjentów, koniecznością ograniczenia ryzyka rozprzestrzenia się COVID-19 i utrzymania wydolności systemu opieki zdrowotnej w stosunku do rosnących potrzeb zdrowotnych ludności. Niemniej jednak, ze względu na konieczność szybkiego reagowania na pojawiające się wyzwania, rozwiązania prawne przyjęte w czasie panującej epidemii nie były pozbawione wad.

**Słowa kluczowe:** telemedycyna, zdalna opieka zdrowotna, systemy teleinformatyczne, COVID-19, pandemia, regulacje prawne, Polska

## 1. Lack of proper definition of telemedicine and e-health in Polish legal acts

The legal acts applicable in Poland do not contain a legal definition of telemedicine and eHealth. In this context, in order to define the area of interest, reference should be made to definitions developed by international organisations and institutions, as well as legal doctrine. The concept of "e-Health" proposed by the WHO is substantially wide in scope and includes the use of information and communication technologies (ICTs) for healthcare and the provision of medical services.[2] "Telemedicine," on the other hand, has been defined by identifying the key characteristics of technology-enabled healthcare delivery: it provides clinical support, aims to overcome geographical barriers by connecting users who are not in the same physical location, involves the use of various types of ICT and aims to improve health outcomes.[3] European Commission

[2] World Health Organisation, *eHealth – Report by the Secretariat*, 58th World Health Assembly, 7th April 2005, A58/21.

[3] World Health Organisation, *Telemedicine. Opportunities and Developments in Member States. Report on the Second Global Survey on eHealth Global Observatory for eHealth Series*, 2010.

defines "telemedicine" as the provision of healthcare services, through use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients.[4] It should be noted, however, that the definition referred to is provided for in a communication, i.e. a sui generis legal act with no binding force in the EU legal order. In legal acts of binding nature there are references to telemedicine[5] and e-health,[6] but lacking a definition of the indicated terms.

There is also no clear definition of e-health and telemedicine in the doctrine, as concepts at the interface of law, medicine and information technology. One study found 104 peer-reviewed definitions of telemedicine, a diversity that makes comparisons between different studies difficult. The authors pointed out that definitions are unique, legitimate, and explanatory in their respective contexts and inferences. This large number of definitions reaffirms that telemedicine is neither homogeneous nor generic.[7] Taking into account the definitions formulated in the doctrine, it should be assumed that the notion of "e-Health" surpasses the concept of "telemedicine," including all information and telecommunication technology solutions applicable in the area of health care in the provision of health services.[8] In contrast, "telemedicine" or "medicine at a distance," involves the provision of medical services aimed at improving health, by means of remote communication, without the simultaneous physical presence of the patient and the doctor.

It should be noted that the term "telemedicine" was used only once by the Polish legislator in the Act of 28 April 2011 on the information system in health care[9] in Article 36(1)(4) concerning the educational and information portal, the purpose of

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4 European Commission, *Communication on Telemedicine for the Benefit of Patients, Healthcare Systems and Society*, 4th November 2008, COM/2008/0689 final.

5 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, OJ L 88, 4.4.2011, p. 45; Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 Establishing a Programme for the Union's Action in the Field of Health ('EU4Health Programme') for the Period 2021-2027, and Repealing Regulation (EU) No. 282/2014, OJ L 107, 26.3.2021, p. 1.

6 Commission Implementing Decision 2019/1765 of 22 October 2019 Providing the Rules for the Establishment, the Management and the Functioning of the Network of Nauthorities Responsible for eHealth, and Repealing Implementing Decision 2011/890/EU, OJ L 270, 24.10.2019, p. 83.

7 S. Sood et al., *What Is Telemedicine? A Collection of 104 Peer-Reviewed Perspectives and Theoretical Underpinnings*, "Telemedicine and e-Health" 2007, vol. 13, no. 5, p. 574.

8 D. Gęsicka, *Usługi medyczne jako usługi społeczeństwa informacyjnego* [in:] *Telemedycyna i e-zdrowie. Prawo i informatyka*, I. Lipowicz, G. Szpor, M. Świerczyński (eds.), Warszawa 2019, p. 75.

9 "Journal of Laws 2011", no. 113, item 657, as amended.

which was, inter alia, to "disseminate knowledge on the functioning of IT systems in health care and telemedicine." The indicated provision was repealed in 2018.

## 2. Legal regulations and conditions for providing a medical services at a distance in Poland

Before the outbreak of the pandemic, there was limited understanding among patients and doctors of telemedicine and remote health services. A report on Pole's knowledge and opinions on the situation of e-health and telemedicine in Poland was published in 2018.[10] As much as 55 percent of the surveyed patients associated the term telemedicine with distance medicine, while 29 percent of patients had no associations with the term telemedicine. In contrast, 21 percent of the doctors surveyed understood the term telemedicine as a form of contact between the doctor and the patient via the Internet or telephone in the form of providing advice and diagnosis. However, the percentage of doctors who could not answer the question of what is telemedicine amounted to 25 percent.

In the opinion of the doctors themselves, one of the basic barriers to the development of telemedicine in Poland was the lack of clarity in the legal regulations. There was a need for changes in the existing regulations, not only enabling the provision of medical advice at a distance, but also clearly resolving the problem of liability for telemedicine and guaranteeing the protection of personal data.[11] The legal basis for the provision of health services through ICT in the Polish legal system derives from Article 3 (1-2a) of the Act of 15 April 2011 on therapeutic activity.[12] Prior to the introduction of general provisions on the principles of providing healthcare services via teleinformation or communication systems, Polish regulations provided for remote forms of communication only in emergency cases, i.e. during the action of carrying out medical rescue activities and the provision of medical advice by radio at sea by the Maritime Telemedical Assistance Service.[13]

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10 LekSeek Polska, *Report E-health in the Eyes of the Polish People - Knowledge and Opinions of the Polish People about the Situation of E-Health and Telemedicine in Poland*, 2018.

11 W. Zgliczyński et al., *Telemedycyna w Polsce – bariery rozwoju w opinii lekarzy*, "Medycyna Ogólna i Nauki o Zdrowiu" 2013, vol. 19, no. 4, p. 496.

12 "Journal of Laws" 2011, no. 112, item 654, as amended.

13 Article 41(3) of the Act of 8 September 2006 on State Medical Rescue Services, "Journal of Laws" 2020, item 882; Article 125 of the Act of 9 November 2000 on Maritime Safety, "Journal of Laws" 2020, item 680.

In accordance with the provision referred to

Article 3. 1. The therapeutic activity shall consist in the provision of health services. These services may be provided through teleinformation systems or communication systems.
2. The therapeutic activity may also consist in:
1) health promotion

or

2) the performance of teaching and research tasks in connection with the provision of health services and health promotion, including the implementation of new medical technologies and treatment methods.

2a. The activities referred to in paragraph 2 may be performed by means of teleinformation systems or communication systems.

The referred provision was introduced by the Act of 9 October 2015 amending the Act on the health care information system and certain other acts, which entered into force on 12 December 2015.[14] As indicated in the proposed draft, the purpose of the amendment was, inter alia, to clarify "the interpretative doubts regarding the legal basis for telemedicine, creating barriers to its development." In addition, "the definition of therapeutic activity was made more precise by supplementing the provision with the possibility of providing health services also via teleinformation or communication systems (telemedicine)."[15] It can be concluded that the Polish legislator indirectly defines telemedicine as the provision of health services via teleinformation or communication systems. In practice, this allows for a healthcare professional to remotely communicate with a patient by way of: telephone, Internet or other means of distance communication, in particular audio or video sharing.

The aforementioned Act of 9 October 2015 also introduced a corresponding amendment to Article 2(4) of the Act of 5 December 1996 on professions of doctors and dentists,[16] indicating that a physician and dentist may provide health services, in particular consisting in the examination of the state of health, diagnosis and prevention of diseases, treatment and rehabilitation of patients, providing medical advice, as well as issuing medical opinions and judgments "also through teleinformation systems or communication systems." This also corresponds to the content of Article 42(1) of the cited Act according to which "a physician shall decide on the state of health of

14 "Journal of Laws" 2015, item 1991.
15 Parliamentary form 3763, 7th term of the Sejm.
16 "Journal of Laws" 1997, no. 28, item 152, as amended.

a particular person after prior personal examination of that person or examination of that person through teleinformation systems or communication systems, as well as after analysis of the available medical records of that person."[17] Comparable amendments were introduced with regard to the provision of health services by nurses and midwives[18] and the provision of pharmaceutical services by pharmacists.[19]

However, it should be pointed out that in certain situations, the law still stipulates the obligation to first examine the patient in person before issuing a ruling on his or her state of health. For example, a ruling on the state of health of a person with a mental disorder, an opinion or a referral to another doctor or psychologist or a therapeutic facility may be issued by a doctor only on the basis of a prior personal examination of that person.[20] Similar obligations arise with regard to the assessment of the capacity of a participant in the proceedings to appear at a summons of the court[21] or the ability of the person deprived of his or her liberty to appear at the summons of a court or authority conducting criminal proceedings.[22] Also the case of the determination of the death of a person can only take place on the basis of a personally conducted examination and findings.[23] In addition, the issuance by a doctor of a certificate of temporary inability to work due to illness or due to the need for personal care of a sick member of the family may take place only after a direct examination of the state of health of the person in relation to whom the certificate is to be issued.[24]

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17 The current wording of the provision established by the Act of 20 July 2018 amending the Act on the Information System in Health Care, "Journal of Laws" 2018, item 1515.

18 Article 11(1) of the Act of 15 July 2011 on Nursing and Midwifery Professions, "Journal of Laws" 2020, item 562, as amended.

19 Article 2a(2a) of the Act of 19 April 1991 on Pharmacy Chambers, "Journal of Laws" 2019, item 1419, as amended.

20 Article 11(1) of the Act of 19 August 1994 on Mental Health Protection, "Journal of Laws" 2020, item 685, as amended. At present Article 4 (6) of the Act of 10 December 2020 on the Profession of Pharmacist, "Official Journal" 2021, item 97, as amended.

21 Article 11 of the Act of 15 June 2007 on the Medical Examiner, "Journal of Laws" 2007, no. 123, item 849, as amended.

22 § 2 Regulation of the Minister of Justice of 16 January 2008 on the Procedure for Issuing a Certificate Confirming the Ability or Inability of a Person Deprived of Liberty to Attend a Summons or a Notification of a Court or a Body Conducting Criminal Proceedings, "Journal of Laws" 2008, no. 14, item 87, as amended.

23 Article 43 of the Act of 5 December 1996 on Doctors and Dentists Professions, "Journal of Laws" 1997, no. 28, item 152, as amended.

24 § 6 and § 13 of the Regulation of the Minister for Labour and Social Policy of 10 November 2015 on the Procedure and Manner of Assessing Temporary Inability to Work, Issuing a Medical Certificate and the Procedure and Manner of Correcting an Error in a Medical Crtificate, "Journal of Laws" 2015, item 2013.

In the framework of telemedicine services in Poland, with regard to the participating parties, we can distinguish between teleconsilium (where professionals provide an exchange of medical expertise) and teleadvice or televisit (where medical professionals provide medical care to patients). Thus, it should be assumed that teleconsultation refers to the consultation of specialists for general practitioners by means of teleinformation or communication systems, particularly important for patients living in suburban areas who have difficult access to specialists. On the other hand, teleadvice refers to medical advice given in an outpatient setting at a distance using teleinformation or communication systems, while televisit refers to a nursing visit given in an outpatient setting at a distance using teleinformation or communication systems.

Among the first publicly funded telemedicine services already from 1 October 2015 were the geriatric teleconsilium and the cardiology teleconsilium. It included an interview, interpretation of diagnostic tests and consultation of the patient's treatment plan, without the patient's physical presence. In this respect teleconsilium was reported and billed by a healthcare provider employing a specialist in geriatrics or cardiology who participated in a medical consultation using telemedicine equipment. The introduction of new ranges of services was aimed at people in rural areas receiving care from a geriatrician or cardiologist, providing the possibility of remote consultation of patients without the need for the patient to visit the distant specialist centre personally. According to the order of the President of the National Health Fund, the team of specialists was to provide consultations for family doctors practising in rural areas in situations where medical support in the management of the patient would be required.[25]

Despite the introduction of changes enabling the provision of health services at a distance in 2015, "televisit" and "teleadvice" were legally addressed not until a regulation of the Minister of Health, which entered into force on 5 November 2019.[26] However, it should be pointed out that the legislator has not given a definition of these services, indicating only their characteristics in a descriptive manner. It was indicated that medical advice may be given and a visit carried out "in an ambulatory setting in direct contact with the patient or at a distance using teleinformation or communication systems." The legal definition of teleadvice appeared only after the outbreak of the pandemic. Detailed rules on the standards for the organisation of teleadvice, in

[25] Order no. 63/2015/DSOZ of the President of the National Health Fund of 30 September 2015 Amending the Ordinance on Defining the Conditions for the Conclusion and Execution of Contracts in the Type of Health Services Contracted Separately.

[26] Regulation of the Minister of Health of 31 October 2019 Amending the Regulation on Guaranteed Primary Healthcare Services, "Journal of Laws" 2019, item 2120, as amended.

particular with regard to the way it is carried out and the information obligations for patients, are set out in the Regulation of the Minister of Health of 12 August 2020, which defines teleadvice as "a health service provided at a distance using teleinformation or communication systems."[27]

For the provision of telemedicine services in Poland, it is important to consider the medical documents that are issued in electronic form via ICT systems and relevant legal regulations. Previously, these documents were issued in paper form and their electronic version, in conjunction with the establishment of an electronic medical system on the P1 platform, has considerably enhanced the remote provision of medical services in Poland. In this respect, the following electronic documents can be specified:

- electronic medical certificate of a temporary incapacity for work ("e-leave")[28] mandatory from 1 December 2018;
- electronic order to dispense or prepare a medicinal product in a pharmacy ("e-prescription")[29] mandatory from 8 January 2020;
- electronic disposition ordering a consultation with a specialist, commissioning a diagnostic test or referring the patient for treatment ("e-referral")[30] mandatory from 8 January 2021;
- electronic order for medical devices ("e-order")[31] from 1 April 2020.

In the context of the above documents, it is important to clarify the concepts of medical records kept in electronic form as opposed to electronic medical records ("EDM"). From 1 January 2019, healthcare entities shall keep medical records in electronic form in their ICT system.[32] Classic (paper) documentation is allowed only when organisational and technical conditions make it impossible to keep documentation in an electronic form. The documentation is signed with a qualified electronic signature, while internal documentation can also be signed using the internal mechanisms of the ICT system. Paper documentation can be digitised by drawing up a digital repro-

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27 Regulation of the Minister of Health on the Organisational Standard of Teleadvice in Primary Health Care of 12 August 2020, "Journal of Laws" 2020, item 1395, as amended.

28 Article 55 of the Act of 25 June 1999 on Cash Benefits from Social Insurance in the Event of Sickness and Maternity, "Journal of Laws" 2020, item 870, as amended.

29 Article 95b of the Act of 6 September 2001 Pharmaceutical Law, "Journal of Laws" 2020, item 944, as amended.

30 Article 59aa of the Act of 27 August 2004 on Health Care Services Financed from Public Fund, "Journal of Laws" 2020, item 1398, as amended.

31 Article 38c(1) of the Act of 12 May 2011 on Reimbursement of Medicines, Foodstuffs for Particular Nutritional Uses and Medical Devices, "Journal of Laws" 2020, item 357, as amended.

32 § 1 of the Regulation of the Minister of Health of 6 April 2020 on Types, Scope and Forms of Medical Records and the Manner of Their Processing ("Journal of Laws" 2020, item 666, as amended).

duction of it and affixing it with a qualified electronic signature, a trusted signature or a personal signature by a person authorised to authenticate the conformity of the digital reproduction with the document in paper form. On the other hand electronic medical records ("EDM") refers to documents created in electronic form and bearing qualified electronic signature, trusted signature, personal signature, or with the use of a confirmation method made available free of charge by the Social Insurance Institution.[33] Electronic medical records include among others: e-prescription, e-referral, e-order and vaccination cards. From 1 July 2021, all medical entities are required to exchange electronic medical records and report on medical events to the electronic platform P1. The aim is to collect information within the electronic medical records of all patients and the register of medical events.

The development of telemedicine services in Poland has been greatly facilitated by the establishment of an electronic platform for public health services in the field of health care in accordance with the Act of 28 April 2011 on the information system in health care.[34] The main project for the digitalisation of health care in Poland is the „Electronic Platform for Collection, Analysis and Sharing of Digital Medical Records (P1)."The main objective of P1 is the establishment of an electronic platform of public services, which contributes to the improvement of patient care by ensuring better quality and accessibility of information on the health status of patients (medical data) and the improvement of patient care (electronic services related to the provision of health services), which has an impact on increasing the number of telemedicine services provided in Poland.[35] The system covers all medical entities, regardless of the source of financing of the services provided in them, which were obliged to connect to the system no later than 31 December 2019. It consists of digital medical services (e-prescription, e-referral, Electronic Medical Record, Medical Events), medical applications (Internet Patient Account, mojeIKP, gabinet.gov.pl) and solutions to streamline the processes of planning and implementing healthcare services. The digitalization of healthcare in Poland is most associated with the implementation of the P1 platform. But it is the "Platform for providing online access to digital health record services and resources for entrepreneurs" (P2) built between 2007 and 2012, is

[33] Article 2(6) Act of 28 April 2011 on the Information System in Health Care ("Journal of Laws" 2011, no. 113, item 657, as amended) and Regulation of the Minister of Health of 8 May 2018 on Types of Electronic Medical Records.

[34] "Official Journal" 2011, no. 113, item 657, as amended.

[35] M. Brożyna, S. Stach, Z. Wróbel, *Rozwój telemedycyny w Polsce po wdrożeniu „Elektronicznej Platformy Gromadzenia, Analizy i Udostępniania zasobów cyfrowych o Zdarzeniach Medycznych (P1)"*, [in:] *Telemedycyna i e-zdrowie. Prawo i informatyka*, I. Lipowicz, G. Szpor, M. Świerczyński (eds.), Warszawa 2019, p. 92.

the foundation that allows P1 to become functional. It provides reference data from medical registers, which contain data on medical professionals, healthcare providers, pharmacies, pharmaceutical wholesalers and authorised medicinal products.[36] Building Platforms P1 and P2 was a major step forward, as previously medical informatics and communication technology systems were set up separately by individual health units, with limited compatibility and coordination.[37]

## 3. Considerations of medical ethics and doctors' liability in providing medical services at a distance

Legislative changes introduced in 2015 allowing doctors to provide health care services at a "distance" correspond with the provisions of the Code of Medical Ethics.[38] Prior to the amendment, significant doubts were raised about the lack of convergence of the legislation with Article 9 of the Code of Medical Ethics, according to which "a doctor may undertake health treatment only after a prior examination of the patient. Exceptions are made when medical advice can only be given at a distance."[39] It was pointed out that, despite this formulation of ethical norms, the law did not provide for the possibility of the doctor to diagnose the patient without "personal" contact, which undoubtedly affected the status of telemedicine services in Poland.[40] It was believed that the Code of Medical Ethics expressed a conservative stance towards the use of information and communication technologies in medical treatment, ruling out their admissibility. Treating this regulation as an interpretative guideline, it was stated that the assumptions of telemedicine contradicted the drafting of ethical norms and legal

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36 Article 6 Act of 28 April 2011 on the Information System in Health Care ("Journal of Laws" 2011, no. 113, item 657, as amended).

37 A. Sagan et al., *Poland: Health System Review*, "Health systems in transition" 2011, vol. 13, no. 8, p. 104.

38 Resolution of the Extraordinary 2nd National Congress of Physicians of 14 December 1991 on the Code of Medical Ethics, as amended. Avaliable at: https://nil.org.pl/dokumenty/kodeks-etyki-lekarskiej (12.04.2023).

39 The present wording of the provision was established by the resolution of the Extraordinary 7th National Congress of Physicians of 20 September 2003 amending the resolution on the Code of Medical Ethics.

40 M. Chojecka, A. Nowak, *Telemedycyna na tle polskich regulacji prawnych – szansa czy zagrożenie?*, "Internetowy Kwartalnik Antymonopolowy i Regulacyjny" 2016, no. 8, p. 78.

norms, interpreted substantively, i.e. identifying medical assessment ("orzekanie") with treatment ("leczenie").[41]

One of the commentators holding the position of Minister of Health pointed to the narrow scope of Article 9 of the Code of Medical Ethics, stating that "giving advice to unseen patients over the phone or Internet and prescribing drugs for months to patients who do not attend follow-up appointments are given as examples of behaviour to be avoided."[42] Before the outbreak of the Covid-19 pandemic, the established view was that the provision of advice only at a distance was permissible by way of exception, but the decision as to the type of situations in which this regulation may be applied was left to the doctor. This required an assessment by the doctor in each case, especially in the context of the criterion of due diligence, and taking into account whether this form of provision would be sufficient in the particular case and would not result in worse consequences for the patient than a refusal to provide health care.[43]

Cases concerning the professional responsibility of doctors fall within the competence of the medical courts, i.e. the district medical courts and the Supreme Medical Court. The research that was conducted and the results published in the literature indicate that between 1994 and 2017, a total of 38 judgements were issued regarding professional misconduct under Article 9 of the Code of Medical Ethics. The most frequently applied penalties: reprimand (42.8%) and caution (33.3%). There was also a fine applied four times and in one case a suspension of the right to practise the profession.[44]

The cases concerned, in particular, the use by doctors of means of remote communication (telephone, e-mail, Skype), with inadequate - in the opinion of the disciplinary court - assessment of the patient's condition and lack of proper analysis of medical records. The most well-known case heard by the Supreme Court[45] was that of a psychiatrist who issued a certificate on the mental health of a patient against whom his son wished to carry out an incapacitation procedure in court proceedings. The basis for issuing such a certificate was an interview with the patient conducted through

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41 G. Glanowski, *Telemedycyna w świetle ustawy o zawodach lekarza i lekarza dentysty*, "Monitor Prawniczy" 2015, no. 18, p. 978.

42 K. Radziwiłł, *Kodeks Etyki Lekarskiej: Odcinek 16: Czy można badać i leczyć na odległość?*, "Medycyna Praktyczna" 2014, no. 6, pp. 124-125.

43 K. M. Zoń, *Kodeks etyki lekarskiej wobec leczenia na odległość – rozważania na tle art. 9*, "Medyczna Wokanda" 2016, no. 8, p. 88.

44 K. M. Zoń, *Stosowanie art. 9 kodeksu etyki lekarskiej w świetle orzecznictwa sądów lekarskich,* [in:] *Telemedycyna i e-zdrowie. Prawo i informatyka*, I. Lipowicz, G. Szpor, M. Świerczyński (eds.), Warszawa 2019, pp. 144-147.

45 Order of the Supreme Court of 27 October 2016, ref. SDI 49/16.

the door. In the cassation complaint, the doctor's defence counsel alleged that both medical courts failed to address the fact that the doctor directly heard the voice of the person being examined through the door. In addition, the legislation does not contain a definition of the term 'personal examination.' The Supreme Court upheld the medical court's reprimand, indicating that conducting a psychiatric examination without personal contact with the patient and issuing a certificate of illness on this basis for judicial purposes constitutes a breach of medical ethics.

Polish law has not provided for separate provisions on a doctor's civil, criminal and professional liability related to the provision of healthcare services via teleinformation or communication systems. The principles of practising the profession are unalterable regardless of the form in which health services are provided. A doctor is obliged to practice his profession in accordance with the indications of current medical knowledge, methods and means available to him for the prevention, diagnosis and treatment of diseases, in accordance with the principles of professional ethics and with due diligence, as well as in accordance with the applicable legal norms.[46] Thus, the principles and conditions of a doctor's liability for medical error in the case of the provision of services in direct contact with the patient and those provided at a distance are the same. However, it may be argued that in a situation where medical services are provided via electronic systems, the doctor should exercise greater care, as he lacks direct contact with the patient.

According to the case law of the Supreme Court, a medical error is an act (omission) of a doctor in the field of diagnosis and therapy that is incompatible with the medical science to the extent available to the doctor.[47] The doctrine and case law distinguish several types of medical error: diagnostic, therapeutic, technical and organisational. A diagnostic error is a type of medical malpractice meaning an incorrect diagnosis of the patient's condition.[48] A therapeutic (treatment) error occurs after a previous diagnosis and may be a consequence of a diagnostic error or may occur on its own when an incorrect treatment method is applied after a correct diagnosis. A technical error consists of the incorrect execution of a medical activity and is most frequently committed during complex surgical interventions or procedures requiring the use of assistive technical devices. In turn, an organisational error refers to an inadequate organisation of the work of the medical entity, and is the result of a failure in the

[46] Article 4 of the Act of 5 December 1996 on Doctors and Dentists Professions, "Journal of Laws" 1997, no. 28, item 152, as amended.

[47] Judgment of the Supreme Court of 1 April 1955 ref. no. IV CR 39/54.

[48] P. Zieliński, *Kilka słów o pojęciu oraz rodzajach błędu medycznego*, "Medyczna Wokanda" 2016, no. 8, p. 188.

conduct of medical activities and the provision of health services.[49] Due to the lack of direct contact with the patient, the most common errors in telemedicine services are likely to be diagnostic or therapeutic errors, while medical entities will be liable for organisational errors related to the way in which remote medical services are provided.

## 4. The impact of the COVID-19 pandemic on the legal framework for telemedicine in Poland

The first COVID-19 case was reported on 8th December 2019 (the first date of symptom onset based on the patients' recall during the investigation) in Wuhan City, the provincial capital of Hubei Province in Central China.[50] On 11th March 2020, the World Health Organisation declared that the COVID-19 outbreak had become a global pandemic. At that time, legislative solutions aimed at facilitating the provision of telemedicine services in Poland were limited. From the letter of the Minister of Health to the Speaker of the Sejm in response to a parliamentary interpellation on the need to make telemedicine consultations widely available,[51] we learn that, just before the outbreak of the pandemic reimbursed telemedicine services in Poland were restricted to geriatric teleconsultation, cardiac teleconsultation and hybrid rehabilitation. The letter clarified that the Ministry of Health, with regard to telemedicine in public health sector facilities, used the data of the National Health Fund obtained on the basis of information collected in connection with the settlement of health services. The data showed that the use of telemedicine procedures increases every year, nevertheless, their further popularisation requires continuous active measures on the part of all stakeholders of the health sector, including the Ministry of Health. Shortly before the outbreak of the pandemic, the Supreme Medical Council – the organ of the Polish Chamber of Physicians and Dentists – in its statement[52], pointed out that the statutes, which enable the provision of health services with the use of teleinformatic or communication systems seem to be insufficient in view of the observed development of telemedicine in Poland. It was argued that it is necessary to define in detail the standards and guidelines for

[49] *Ibidem*, pp. 189-191.

[50] B. Yu, X. Chen, S. Rich et al., *Dynamics of the Coronavirus Disease 2019 (COVID-19) Epidemic in Wuhan City, Hubei Province and China: A Second Derivative Analysis of the Cumulative Daily Diagnosed Cases During the First 85 Days*, "Global Health Journal" 2021, vol. 5, p. 4.

[51] Letter from Undersecretary of State at the Ministry of Health Janusz Cieszynski to Speaker of the Sejm Elżbieta Witek dated 18 October 2019, number EZK.9094.7.2019.AR.

[52] The Statement no. 100/19/P-VIII of the Supreme Medical Council of 25 October 2019 on Certain Aspects of the Development of Telemedicine in Poland.

the provision of telemedicine services, which will guarantee the safety and protection of patients, doctors and dentists. Moreover the telemedicine consultation should be of an adequate quality, carried out in accordance with the applicable principles of medical ethics, in particular respecting medical confidentiality and compliance with the doctor's conscience, with the patient being thoroughly informed of the possible limitations of a specific telemedicine method and the possibility for the patient to choose direct contact with the doctor, at any stage of such telemedicine service.

The COVID-19 outbreak has changed the approach to the provision of health services at a distance, which the legislator has also recognised by successively introducing implementing regulations on the standards and requirements to be observed in the case of teleadvice.[53] Of fundamental importance is the Act of 2 March 2020 on special measures related to preventing, counteracting and combating COVID-19 and other infectious diseases and emergencies induced by them.[54] Detailed rules on the standards for the organisation of teleadvice, particularly with regard to the way it is conducted and the information obligations for patients, are set out in the Regulation of the Minister of Health of 12 August 2020 on the organisational standard for teleadvice in primary care,[55] which defines teleadvice as "a health service provided at a distance using teleinformation or communication systems." Due to Covid-19, the possibility of teleadvice has been extended also for outpatient specialised care, for the benefit of patients continuing their care in a particular specialised clinic, according to the established plan of care and the patient's clinical condition.[56] According to the provisions, the conduct of the teleadvice should take place under conditions that guarantee confidentiality, including ensuring that no unauthorised persons have access to the information transmitted via ICT systems in connection with the provision of remote health care services. Alongside a regulation of the Minister of Health, the Guidelines of the National Consultant in Family Medicine for teleadvice in primary care provided during an epidemic caused by the SARS-CoV-2 were published.[57] It

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53 M. Serwach, *Nowe standardy teleporady w podstawowej opiece zdrowotnej*, "Medycyna Praktyczna" 2021, no. 4, pp. 146-150.

54 "Journal of Laws" 2020, item 374, as amended.

55 Regulation of the Minister of Health on the Organisational Standard of Teleadvice in Primary Health Care of 12 August 2020, "Journal of Laws" 2020, item 1395, as amended.

56 Order no. 182/2019/DSOZ of the President of the National Health Fund of 31 December 2019 on Defining the Terms and Conditions for the Conclusion and Realisation of Agreements on the Provision of Healthcare Services in the Type of Outpatient Specialist Care.

57 Ministry of Health, *Guidelines of the National Consultant in Family Medicine for Teleadvice in Primary Care Provided During an Epidemic Caused by the SARS-CoV-2*, 14 August 2020, https://www.gov.pl/web/rpp/teleporada-w-podstawowej-opiece-zdrowotnej (12.04.2023).

was acknowledged that teleadvice is a tool that, through the delivery of healthcare at a distance, enhances safety of patients and medical professionals by limiting direct contact to clinically justified situations. In March 2021 after the start of the vaccination of the population and one year after the first case of coronavirus was diagnosed in Poland, the Minister of Health restricted the provision of teleadvice to simpler clinical situations.[58] This solution was designed to eliminate the possibility of teleadvice in relation to the most vulnerable groups of patients, presenting intensified and diverse health needs, primarily children under 6 years of age, people with chronic diseases and oncology patients.

The legal provisions do not determine which particular information or communication systems may be used to provide remote health services. It is up to the medical professional or healthcare provider to decide between the telephone or computer programmes and applications enabling video and audio transmission. It should also be noted that there are some distinctions in the organisation of telehealth services due to the way in which remote health services are provided. Entities providing exclusively outpatient health services via ICT systems are not required to meet the technical requirements for premises and equipment required for entities providing services in the form of personal contact between patient and doctor.[59] Also, the place of providing remote health services shall be the place of residence of the medical professionals providing these services.[60] In terms of services financed by the National Health Fund, the patient's identity can be verified on the basis of data transmitted via the system by which the telemedicine service is provided, including by telephone.[61]

Due to the necessity to address the vital practical issues of remote medical assistance during a pandemic, the Supreme Medical Council adopted guidelines for the medical staff concerning practical aspects of telemedicine services.[62] The guidelines in question were developed by the Supreme Medical Council's Telemedicine Team in conjunction with the Telemedicine Working Group and intended to be used for the provision of telemedicine services by doctors in the exercise of their profession. The

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58 Regulation of the Minister of Health of 5 March 2021 Amending the Regulation on the Organisational Standard of Tele-treatment Within Primary Healthcare, "Journal of Laws" 2021, item 427.

59 Article 22 (3a) (3b) of the Act of 15 April 2011 on Therapeutic Activity.

60 Article 24 (2a) of the Act of 15 April 2011 on Therapeutic Activity.

61 § 11 (1) Regulation of the Council of Ministers of 19 April 2020 on the Establishment of Certain Restrictions, Orders and Prohibitions in Connection with the Occurrence of an Epidemic Outbreak ("Official Journal" 2020, item 697).

62 Resolution no. 89/20/P-VIII of the Supreme Medical Council of 24 July 2021 on the Adoption of Guidelines for the Provision of Telemedicine Services.

guidelines explained the legal requirements for the processing of personal data within the framework of telemedicine (i.e. the principles of legal liability of the doctor providing teleadvice, the catalogue of the doctor's duties and the patient's rights), practical issues (i.e. the principles for ensuring the confidentiality of the telehealth visit, verification of the patient's identity, access to medical records), as well as technical and organisational requirements. The guidelines addressed important ethical problems applicable to the provision of health services "at a distance" and described the "10 steps of a telemedicine visit" explaining the essential stages in the provision of telehealth services. The adoption of such provisions by the organ of the Polish Chamber of Physicians and Dentists was important for practitioners who previously had little experience with telemedicine, which has become a major form of healthcare delivery during the pandemic.

The suddenly emerging pandemic has accelerated the legal regulation of telemedicine in Poland. Nevertheless, due to the necessity for a rapid response to emerging challenges, the legal solutions adopted during the reigning epidemic were not flawless. In order to protect public health, the Polish authorities adopted a number of legal acts that significantly affected the activities of healthcare facilities and the medical personnel. A significant number of laws were adopted in a fast-track legislative procedure, often without proper public consultation. Adequate vacatio legis was not provided for in laws and regulations, entering into force either on the day of publication in the Journal of Laws (what frequently occurred in the evening) or on the day following the day of publication. The requirement of an appropriate period of adaptation is a necessary element of the principle of proper legislation, allowing the addressee to become familiar with the new provisions and adapt to the new legal regulation. It may be assumed that such a rapid course of the legislative process and the lack of an adequate vacatio legis may have been justified on the grounds of other constitutional values, primarily with a view to protecting human life and health. Nevertheless, this affected to a large extent the manner in which legal aid was provided and the need for constant monitoring of legal regulations, which were not always accurate from the point of view of the principles of sound legislative technique.

Another characteristic feature of the legal solutions adopted during the pandemic was the "multi-level" nature of the regulations. Legal measures concerning a given issue were introduced at the level of a statute, then specified in regulations of the Minister of Health, and finally made more detailed in individual contracts concluded with the National Health Fund. In addition, many recommendations to healthcare entities and medical staff were introduced in the form of communications from the Minister of Health, i.e. internal ministerial acts that do not have a binding legal character. As an example, there was a communication to health care workers providing health care

services to patients suspected of being infected with coronavirus or diagnosed with COVID-19 to refrain from working with other patients, in other health care entities or units of the health care system.[63] In a communication published on the Internet, the Minister of Health asked medical staff for absolute compliance with these rules with immediate effect, while announcing that work is underway to introduce them into the legal system. This was questionable because, on the basis of a recommendation published online, it significantly restricted the right to work in entities where the individuals concerned were bound by employment contracts. Ultimately, this issue, which raised many questions of interpretation, was covered by a regulation of the Minister of Health.

## 5. Concluding remarks

In the wake of the COVID-19 pandemic, Poland experienced a significant development of telemedicine solutions, particularly in the provision of healthcare services in outpatient settings at a distance using teleinformation or communication systems. Before the outbreak of the pandemic, there was the benefit of teleconsultations, where specialists provided an exchange of medical knowledge particularly important for patients living in suburban areas who have difficult access to specialists. The spread of infectious disease forced the development of further telehealth solutions in the form of and teleadvice or televisit, where medical professionals provide medical care to patients mostly by telephone, video transmission or applications on mobile devices.

The provision of health services at a distance has significant benefits, which were already identified in 2008 in a communication from the European Commission on telemedicine for the benefit of patients, healthcare systems and society.[64] In the context of the prevailing pandemic in Poland, the primary benefit was to reduce the risk of COVID-19 spreading between patients seeking medical care. There were also fewer technical requirements for the premises and equipment required for providers providing services in the form of personal contact between patient and doctor. Among the benefits was the removal of geographical barriers facilitating access to specialised medical care for residents of small towns and rural areas, as well as the time and cost

63 Minister of Health, *Communication to Health Care Professionals*, 26 March 2020, https://www.gov.pl/web/zdrowie/komunikat-do-pracownikow-ochrony-zdrowiahttps://www.gov.pl/web/zdrowie/komunikat-do-pracownikow-ochrony-zdrowia (13.04.2023).

64 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Telemedicine for the Benefit of Patients, Healthcare Systems and Society, COM/2008/0689 final.

savings associated with travelling to an in-patient appointment. In addition, telemedicine has facilitated rapid diagnosis and emergency medical care, as well as reduced waiting times for doctors' appointments.

Despite the accelerated development of telemedicine services due to the epidemic situation, there are still some shortcomings and problems concerning the functioning of healthcare in Poland. In the strategic document "National Transformation Plan for 2022-2026"[65] the Minister of Health, identified the main problems faced by the Polish health care system in providing services at a distance, and these are the lack of adequate legal regulations, financial solutions and appropriate infrastructure. Another limitation in this regard is the insufficient knowledge and skills of medical personnel in providing healthcare services using modern ICT or other communication systems. Other barriers to accessing telemedicine services are low public awareness of the benefits for patients and a lack of trust in new technologies as a medium of communication with the medical professionals regarding health-related issues. Furthermore, the phenomenon of digital exclusion is significant, as according to a Eurostat study conducted in 2021, only 43% of people aged 65-74 use the internet in Poland, compared to an EU average of 61%.[66] Based on research conducted by a leading Polish internet provider after the third wave of the pandemic, almost 20% of families still do not have internet access at home.[67] Technical barriers are also associated with cyber threats to ICT systems. The COVID-19 pandemic has brought the health sector to the forefront and further illustrated the importance of protecting health services and medical data. Healthcare providers and outlets for essential medical products are vulnerable to cyber-attacks as critical infrastructure.[68]

A survey conducted in January 2022 shows that as much as 80% of people in Poland used telemedicine services in 2021.[69] During the pandemic more than 44% of respondents used remote medical services because they did not have the opportunity for an in-person visit. It also appears that the age of the patients was not a barrier, as those aged over 60 used telemedicine services with similar frequency to younger

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65 Announcements of the Minister of Health of 15 October 2021 on the National Transformation Plan, "Official Journal of the Ministry of Health" 2021, item 80.

66 Eurostat, *How Popular Is Internet Use among Older People?*, 21 may 2021, https://ec.europa.eu/eurostat/web/products-eurostat-news/-/edn-20210517-1?redirect=%2Feurostat%2F.

67 Fundacja Stocznia, *Wykluczenie społeczno-cyfrowe w Polsce. Stan zjawiska, trendy, rekomendacje*, 2021, https://admin.fundacja.orange.pl/app/uploads/2021/11/RAPORT_WYKLUCZENIE-SPOLECZNO-CYFROWE-W-POLSCE_2021.pdf.

68 M. Muthuppalaniappan et al., *Healthcare Cyber-attacks and the COVID-19 Pandemic: An Urgent Threat to Global Health*, "International Journal for Quality in Health Care" 2021, vol. 33, no. 1, p. 1.

69 Biostat, *Zdrowie Polaków – telemedycyna w 2021*, https://www.biostat.com.pl/az-80-polakow-skorzystalo-w-2021-roku-z-uslug-telemedycznych.php (13.04.2023).

patients. In this respect, the pandemic can be considered to have contributed to the faster development of telemedicine services in Poland. This was driven by the demands of protecting the health of patients and maintaining the capacity of the health system in relation to the increasing health needs of the population.

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