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TELEMEDICINE IN THE PAST AND NOW – POLISH REGULATORY FRAMEWORK AND THE SCOPE OF CIVIL AND CRIMINAL LIABILITY OF THE MEDICAL STAFF

Dr. habil. Justyna Król-Całkowska, University Professor

Faculty of Law and Administration, Lazarski University in Warsaw, Poland e-mail: kancelaria.prawomed@gmail.com; https://orcid.org/0000-0002-8370-0154

Daniel Walczak, M.A.

Faculty of Law and Administration, Lazarski University in Warsaw, Poland e-mail: daniwalczak@gmail.com; https://orcid.org/0000-0001-8981-506X

Dr. Waldemar Szymański

University of Social Sciences in Łódź, Poland e-mail: walditm@interia.pl; https://orcid.org/0000-0001-5979-4691

Abstract. The development of telemedicine prompts us to focus on legal aspects related to the provision of ICT services by physician, as well as criminal liability for causing exposure to immediate risk of loss of life or health, as well as civil liability in the event of damage, excluding issues related to the provision of services by persons performing other medical professions (e.g. nurses, midwives, laboratory diagnosticians, pharmacists). Although telemedicine has become a permanent part of the scenario of providing services, the provisions of law refer to the discussed issue in a fragmentary manner. At the same time, the specificity of services implies a wide risk of the guarantor's criminal liability for exposing the patient to the immediate risk of loss of life or health. The above is directly related to the omission of personal doctor-patient contact, which increases the probability of making a diagnostic or therapeutic error. Before the entry into force on 12 December 2015 of the Act of 9 October 2015 amending the Act on the information system in health care [...], only individual legal regulations related to the use of ICT to provide health services, as well as documents on the principles of medical ethics and deontology. Currently, there are no doubts that the provision of health services with the use of ICT is permissible and in accordance with the applicable law. The pandemic period contributed to the introduction of provisions regulating the principles of providing health services with the use of ICT in strictly defined areas, including, inter alia, primary health care.

Keywords: telemedicine, ICT in medicine, new technologies in treatment, legal aspects of telemedicine, medical law





INTRODUCTION

New technologies currently support most areas of life, including undoubtedly the provision of health services. The above is clearly visible in the implementation of medical activities with the use of information and communications technology.¹ Telemedicine on many levels replaces the classic diagnostic and therapeutic process that implies personal contact between the doctor and the medical staff.

In the literature it is argued that, depending on individual preferences, telemedicine can be seen as an alternative to the standard procedure for providing health care services in the same geographical location, including physical contact, for a form of information exchange between a doctor and a patient, or as a collective category of new medical procedures, that use computer science and telecommunications in medicine [Glanowski 2015, 978–82]. It should be emphasized that telemedicine is an inherent component of the concept of e-health, which is associated with the use of technologies for medicine in the health sector [Sarnacka 2016, 268].

The discussed topic is extremely extensive, hence the authors of the study focused on the legal aspects related to the provision of ICT services by physician, as well as criminal liability for causing exposure to immediate risk of loss of life or health, as well as civil liability in the event of damage, excluding issues related to the provision of services by persons performing other medical professions (e.g. nurses, midwives, laboratory diagnosticians, pharmacists).

The aim of the study is to show that although telemedicine has become a permanent part of the scenario of providing services, the provisions of law refer to the discussed issue in a fragmentary manner. At the same time, the specificity of services implies a wide risk of the guarantor's criminal liability for exposing the patient to the immediate risk of loss of life or health. The above is directly related to the omission of personal doctor-patient contact, which increases the probability of making a diagnostic or therapeutic error.

1. ADMISSIBILITY OF PROVIDING HEALTH SERVICES WITH THE USE OF ICT MEDIA

Before the entry into force on December 12, 2015 of the Act of 9 October 2015, amending the Act on the information system in health care [...],² to use ICT to grant healthcare services, only individual legal regulations related. An example is, *inter alia*, Article 3(d) of the "cross-border" directive,³ which

¹ Hereinafter: ICT.

² Journal of Laws item 1991 as amended.

³ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on

refers to the implementation of telemedicine services, stating that "[...] In the case of telemedicine, healthcare is considered to be provided in the Member State in which the healthcare provider is established."

Direct possibility of the use of ICT tools in the treatment process was also provided for in the Code of Medical Ethics,⁴ whose Article 9 states that a physician may undertake treatment only after prior examination of the patient. The exceptions are situations where medical advice can only be provided remotely.

Although the CME is not a normative act, it is emphasized in the literature that "ethical norms may be incorporated into the legal system by means of legal acts. The act on medical chambers made such an incorporation of the standards of the Code of Medical Ethics. The norms of this Code specified the content of the legal norms contained in the Act on medical chambers [...]" [Safjan 2011, 28]. It follows that the application of the provisions of CME in the context of providing health services without personal contact with the patient is justified in exceptional situations, the assessment of which depends each time on the individual assessment of the doctor.

Although the subject of telemedicine was the subject of insufficient legal regulations, these issues were already analyzed in the literature of the previous decade, including in the context of teleconsultation of acute poisoning [Zajdel, Krakowiak, and Zajdel 2010].

According to the amended Article 42(1) of the Act of 5 December 1996 on the professions of doctor and dentist,⁵ "A doctor adjudicates about the health of a specific person after prior, personal examination or examination via teleinformatic systems or communication systems." The use of the word "adjudicates" in the content of the quoted provision raised many doubts as to the scope of the regulation in question. Bearing in mind the purposeful and functional interpretation, this word should be identified with the assessment of health condition and the possibility of making a diagnosis – i.e. understanding the verb "adjudicates" in the material sense [Glanowski 2015, 978–82].

Scientists rightly note that the interpretation of the verb in question on the basis of Article 42(1) PDD in a way leading to the conclusion that the hypothesis of the norm constructed by this provision, which includes the provision of health services, other than the determination of a person's health condition, goes beyond its possible linguistic meaning [Kaczan 2017, 93–105].

Before the amendment to the provisions of the Act on the professions of doctor and dentist, the judicature contained statements that the use of telemedicine tools should not be identified with healthcare services. In the judgment

the application of patients' rights in cross-border healthcare, Official Journal of the European Union L 88/45.

⁴ Hereinafter: CME.

⁵ Journal of Laws of 2020, item 514 as amended [hereinafter: PDD].

of 23 June 2015,⁶ the Provincial Administrative Court in Krakow emphasized that: "Telemedicine services provided via the Internet are in fact providing advice, lectures and provide guidelines on how to perform exercises, their assessment and monitoring, consultations in the field of health education. These activities cannot be considered medical care [...]." Bearing in mind the current wording of Article 42(1) PDD it should be assumed that the use of teleinformatic means of communication during the provision of health services, as well as non-therapeutic activities undertaken by a doctor, undoubtedly constitute the performance of medical care.

In the opinion of the authors, the conceptual difference between the terms "personal contact" and "direct contact" should be emphasized. Using the ICT to establish contact between the doctor and the patient does not avoid direct contact, but only personal contact understood as a meeting of natural persons at the same place and time. Proper understanding of the concept of "direct contact" has significant consequences under the Act of 25 June 1999 on cash benefits from social insurance in the event of sickness and maternity.⁷ Pursuant to Article 55(4)(1) of the aforementioned Act, "adjudication on temporary incapacity to work due to illness, hospital stay [...] or the need to personally care for a sick family member takes place after direct examination of the health state of the insured or sick family member."

Direct examination cannot be identified with a personal examination carried out as a result of physical contact between the doctor and the patient, but only with the need to assess the state of health immediately before making the decision to issue a certificate of incapacity for work. The exception allowing the use of ICT media in the process of deciding on the patient's health condition is Article 11(1) of the Act of 19 August 1994 on mental health protection,⁸ according to which "a decision about the health condition of a person with mental disorders, an opinion or a referral to another doctor or psychologist or medical entity may be issued by a doctor only on the basis of a prior personal examination of that person."

From the literal wording of Article 11(1) MHP there is a need for a personal examination to assess the patient's health or to issue a referral for further treatment. The possibility of using ICT media is also provided for in Article 3(1) of the Act of 15 April 2011 on medical activity,⁹ according to which "medical activity consists in providing health services. These services may be provided through ICT systems." There is no doubt that "remote" health services have grown in popularity with the outbreak of the COVID-19 pandemic. In the context of services provided in this period, the concept of telemedicine

⁶ Ref. no. I SA/Kr 721/15, Lex no. 1813436.

⁷ Journal of Laws of 2020, item 870 as amended.

⁸ Journal of Laws of 2020, item 685 as amended [hereinafter: MHP].

⁹ Journal of Laws of 2020, item 295 as amended [hereinafter: MA].

visit and telemedicine advice should be clearly distinguished. In the authors' opinion, the telemedicine visit should be identified with any medical service provided remotely in connection with an illness, health problem, disease other than related to SARS-CoV-2. On the other hand, telemedicine advice should be equated with a service provided through ICT systems or other communication systems in connection with suspected SARS-CoV-2 infection or falling ill with COVID-19.

Pursuant to Article 7(4) of the Act of 2 March 2020 on special solutions related to the prevention, counteracting and combating COVID-19, other infectious diseases and emerging crisis situations:¹⁰ "A physician and a dentist [...] may provide health care services in connection with counteracting COVID-19 through the ICT system made available by the unit subordinate to the minister competent for health matters competent in the field of healthcare information systems, hereinafter referred to as «telemedicine advice» [...]." The duty of the doctor providing telemedicine advice is to keep medical records in the form of a telemedicine advice card, which must be kept for 30 days from the date of cancellation of an epidemic threat or state of an epidemic (Article 7(7) and (9) of u.COVID). It should also be noted that the possibility of giving witness telemedicine advice excludes taking medical actions aimed at issuing an opinion, decision or certificate.

The physician performing the telemedicine visit is obliged to keep medical documentation in accordance with the rules set out in the Regulation of the Minister of Health of 6 April 2020 on the types, scope and templates of medical documentation and the method of its processing¹¹ to archive it for the period specified in Article 29(1)(1–4) of the Act of 6 November 2008 on the rights of patients and the Patient Rights Ombudsman.¹² Thus, the recording of audio and video during video consultations does not replace medical documentation, the scope and principles of which are specified in the above-mentioned regulation.

It should be noted that all regulations relating to the provision of health services with the use of ICT refer to services financed from public funds. The above does not preclude the appropriate application of these provisions to commercial services.

Currently, the very use of ICT has been envisaged in both primary and specialized healthcare. Tele-services in primary health care are provided on the basis of the regulation of the Minister of Health of 24 September 2013 on guaranteed benefits in the field of primary health care and ordinance No. 177/2019/DSOZ of the President of the National Health Fund of 30 December

¹⁰ Journal of Laws of 2020, item 1842 as amended [hereinafter: u.COVID].

¹¹ Journal of Laws item 666 as amended.

¹² Journal of Laws of 2020, item 849 as amended [hereinafter: PR].

2019 on the conditions conclusion and implementation of contracts for the provision of healthcare services in the field of primary health care.

In turn, services in the area of specialist healthcare are provided on the basis of the Regulation of the Minister of Health of 6 November 2013 on guaranteed benefits in the field of outpatient specialist care and ordinance No. 182/2019/DSOZ of the President of the National Health Fund of 31 December 2019 conditions for concluding and implementing contracts for the provision of healthcare services such as outpatient specialist care. As a rule, the services covered by the contract with the National Health Fund must be provided personally by persons with appropriate qualifications.

The exception from the rule are services related to the performance of computed tomography and magnetic resonance imaging (para. 9(2)), which may be provided with the use of ICT tools. Based on para. 4(3)(e, g) and (4) (d, e) of the Regulation of the Minister of Health of 6 November 2013 on guaranteed services in the field of therapeutic rehabilitation,¹³ public funds finance, *inter alia*, the services of hybrid cardiac telemedicine rehabilitation and cardiological hybrid telemedicine rehabilitation after myocardial infarction, implemented in a center or day ward or in stationary conditions.

Pursuant to the Regulation of the Minister of Health of 6 April 2020, amending the regulation on guaranteed services in the field of outpatient specialist care,¹⁴ on 3 April 2020, added the possibility of a physician from a dialysis center to provide healthcare services with the use of ICT systems or communication systems. This applies to the following areas: peritoneal dialysis, hemodialysis with a 24-hour emergency and hemodiafiltration. On 17 March 2020, the Regulation of the Minister of Health of 16 March 2020, amending the regulation on guaranteed benefits in the field of psychiatric care and addiction treatment,¹⁵ entered into force. The newly added para. 3a made it possible to provide psychiatric care inpatient, outpatient and daily services with the use of ICT systems, provided that the availability of the personnel required for their implementation at the place of provision of services is ensured.

Pursuant to the ordinance No. 78/2020/DSOZ of the President of the National Health Fund of June 2, 2020 amending the ordinance on the terms of concluding and execution contracts for the provision of healthcare services such as psychiatric care and addiction treatment, points 33 and 34 were added in para. 18(1) to the ordinance No. 7/2020/DSOZ of the President of the National Health Fund of 16/01/2020 on the terms of concluding and execution contracts for the provision of healthcare services and addiction treatment.

¹³ Journal of Laws of 2021, item 265.

¹⁴ Journal of Laws item 612.

¹⁵ Journal of Laws item 456.

Evidence of the provision of services with the use of ICT systems is the recording of the communication tool used in the individual internal medical documentation of the services recipient, and additionally, during the medical session, recording the hours and minutes of its start and end. At the same time the para. 4 was amended in para. 18 of the ordinance No. 7/2020/DSOZ, indicating that in the case of the provision of services: individual psychotherapy session, family psychotherapy session, group psychotherapy session and psychosocial support session, the service provider is obliged to record in the individual internal documentation of the services recipient the hour and the minute of starting and end the session.

The specificity of telemedical visit, their number and importance have led to the creation of standards or procedures as part of their implementation. The basis for introducing the standards is Article 22(5) MA, according to which "the minister competent for health may define, by way of a regulation, organizational standards of health care in selected fields of medicine or in specific entities performing therapeutic activities, guided by the need to ensure adequate quality of health services."

An entity performing medical activities is required to apply organizational standards of healthcare when providing health services, if they have been defined pursuant to Article 22(5) MA for the field of medicine covered by the scope of health services provided by this entity performing medical activities or for the type of medical activity performed by such entity.

The standards of conduct in the field of providing "telemedicine" services are set out in the Regulation of the Minister of Health of 11 April 2019 on organizational standards of healthcare in the field of radiology and imaging diagnostics performed via ICT systems. On 29 August 2020, the organizational standards of the telemedicine advice at primary health care¹⁶ entered into force. It should be noted that the use of the word "telemedicine advice" in the regulation should be considered incorrect, because the specificity of services provided in primary health care is associated with a wide range of activities, including those not related to SARS-CoV-2 and COVID-19 infection. In addition, the use of ICT media in the treatment process has a direct impact on taking into account the criteria of financial and organizational effectiveness, and thus reducing health care costs [Noel, Vogel, Erdos, et al. 2005].

¹⁶ Journal of Laws item 1395.

2. A DOCTOR'S CRIMINAL LIABILITY WHEN PROVIDING MEDICAL SERVICES AT A DISTANCE

Human life and health are of such a significant value that the Act of 6 June 1997, the Criminal Code,¹⁷ apart from liability for infringement of these goods, also establishes liability for their exposure to danger. Therefore, criminal law protection appears already at the stage preceding the occurrence of a specific effect, which is directly related to the passive subject of the crime whose law order has been violated [Zoll 2017, 525–27].

Pursuant to the wording of Article 160(1) CC, whoever kills a human on his demand and under the influence of compassion for him, is subject to the penalty of deprivation of liberty for between 3 months and 5 years. Article 160(2) CC specifies the qualified type, according to which, if the perpetrator has a duty to take care of the person exposed to danger, he is subject to the penalty of deprivation of liberty for between 3 months and 5 years. Article 160(3) CC defines criminal liability for committed without intent para. 1 or 2. In the event of without intent the perpetrator is liable to a fine, the restriction of liberty or imprisonment for up to one year.

It should be emphasized that while the perpetrator of a common crime specified in Article 160(1) CC [Zoll 2017] can be anyone, so the perpetrator of the qualified type under Article 160(2) CC, can only be a guarantor who was obliged to take care of a person exposed to danger, and this is undoubtedly such as are medical professionals.

Pursuant to Article 4 PDD, a doctor is obliged to exercise their profession in accordance with the indications of current medical knowledge and with due diligence. For the physician – the guarantor, the above is an obligation to take measures to prevent the emergence of a specific threat to life or health, as well as the obligation to take all actions aimed at reducing the degree of danger that already existed at the time of the implementation of health services [Zoll 2017].

The jurisprudence emphasizes that the effect referred to in Article 160(1-3) CC is not only to cause a threat in a situation in which before the perpetrator's behavior no danger threatened the aggrieved party, but this effect will also take place when the perpetrator with his behavior increases the threat to the already occurring danger. In particular, this will apply to situations where the perpetrator is obliged to prevent the danger, fails to fulfill his obligation, which was confirmed in the judgment of the Supreme Court in the judgment of 10 August 2000.¹⁸

¹⁷ Journal of Laws of 2020, item 1444 as amended [hereinafter: CC].

¹⁸ Ref. no. WA 23/00, Lex no. 532395.

In the context of liability related to the provision of health services with the use of ITC, the position of the judicature plays a significant role, e.g. the judgment of the Court of Appeal in Łódź of 10 September 2015¹⁹ according to which the crime stipulated in Article 160(1) CC, is a criminal offense and consists in causing a state of immediate danger to a person of losing their life or causing serious damage to their health. A similar position was taken by the Supreme Court in its judgment of 5 April 2013,²⁰ stressing that as a result of the offense under Article 160(2) and (3) CC, it is not only to cause a situation in which the patient is, without being previously in a position that poses a direct threat to his life or health, but also maintaining (not reversing or reducing) the already existing level of this dangers at the time when the duty of the doctor-guarantor was fulfilled. Moreover, the offense is committed from the moment of exposure to danger, even if the exposed person has not suffered any harm.

The above is confirmed in the literature where it is emphasized that as a result of the crime under Article 160 CC is to cause a threat not only in a situation where no danger threatened the aggrieved before the perpetrator's behavior, but also when the perpetrator's behavior increases the threat to the immediate danger that already exists [Bielski 2005, 119].

In the case of criminal liability for omission, it is irrelevant whether, as a result of failure to provide a health service, the guarantor-doctor caused the patient to be in a situation that posed a direct threat to life or health, even though he was not in such a state previously, or the guarantor, as a result of the omission to provide a health service, intensifies the course and development of disease processes in the patient by his inaction in such a way that they began to directly threaten his life or health.²¹

Although the most common cause of negative effects on life and health are diagnostic and therapeutic errors, the specificity of providing health services "at a distance" implies the possibility of their occurrence due to organizational errors [Kunert 2019, 164]. In the authors' opinion, organizational errors may be related, *inter alia*, to improper preparation of facilities to provide services with the use of ICT, including the lack of appropriate IT equipment, as well as providing services in the mode of remote work at home and on the basis of private IT equipment belonging to a physician. The responsibility specified in Article 160(1–3) CC, applies in particular to primary care physicians who are undoubtedly guarantors of patient safety [Wąsik 2018, 43], and are the only specialists obliged to apply organizational standards issued by executive regulation.

¹⁹ Ref. no. II AKa 162/15, Lex no. 1808686.

²⁰ Ref. no. IV KK 43/13, Lex no. 1318212.

²¹ This is also the way in which the judgment of the Supreme Court of 5 November 2002, ref. no. IV KKN 347/99, Lex no. 74394.

Thus, the element of exposure may occur not only in connection with the failure to properly assess the patient's health condition, but also with the waiver of a personal visit, cancellation of a telemedicine visit in violation of the standard rules, as well as the provision of services to patients who have been excluded from the group entitled to receive ICT care services.

In the context of criminal liability, the content of Article 24 of the Act of 28 October 2020 deserves attention, on amending certain acts in connection with counteracting crisis situations related to the occurrence of COVID-19,²² according to which it does not commit an offense referred to, inter alia, in Article 160(3) CC, whoever, during the period of announcing the state of epidemic threat or state of epidemic, providing health services on the basis of PDD as part of the prevention, diagnosis or treatment of COVID-19 and acting in special circumstances, committed a prohibited act, unless the result was the result of gross failure to exercise caution required in the given circumstances.

The consequence of the medical incident may be the occurrence of damage to the health of the patient or even his death. Then the prosecutor conducting the investigation should apply the cumulative qualification of Article 160(2) CC or Article 160(3) CC with one of classifying provisions of law: involuntary manslaughter Article 155 CC), grievous bodily harm (Article 156(1)(1) and (2) CC), other bodily harm (Article 157(1) CC).

The legislator defined Involuntary manslaughter in Article 155 CC, pursuant to whoever kills a human on his demand and under the influence of compassion for him, is subject to the penalty of deprivation of liberty for between 3 months and 5 years. Grievous bodily harm in Article 156 CC it may consist of depriving a person of their sight, hearing, speech or the ability to procreate. The second form of causing serious inflicts on another person a crippling injury, an incurable or prolonged illness, a potentially fatal illness, a permanent mental illness, a permanent total or significant incapacity to perform a profession, or a permanent serious bodily disfigurement or deformation. The perpetrator of this act is subject to the penalty of deprivation of liberty for a period not shorter than 3 years. Other bodily harm in Article 157(1) CC consists in causing a violation of the activities of an organ of the body or an impairment of health, other than those specified in Article 156(1) CC, but lasting more than 7 days and the perpetrator is liable to imprisonment for between three months and five years.

3. CIVIL LIABILITY FOR THE RESULTING DAMAGE

While criminal liability has been excluded in some situations of providing health services in connection with COVID-19, the provisions on civil liability

²² Journal of Laws item 2112.

will apply in any situation of damage occurring during the provision of health services, including that provided remotely.

The scope of responsibility will, however, be implied by the contribution of the aggrieved party, the consequences of the perpetrator's behavior, as well as the diligence of the guarantor. Provision of health services with the use of ICT involves additional risk related to the quality and efficiency of the equipment and the quality of the internet connection.

This does not exempt the entity performing medical activities from providing such devices that will be capable of safe use, required in a given situation and circumstances, which can be expected from the guarantor of the protection of human health and life.²³

The fact of concluding a treatment contract, which is concluded between the patient and the entity providing medical services with the use of ICT, is also important.

The treatment agreement, as a consensus agreement, is intended to fulfill the obligation of providing a health service, towards an activity that will be used to prevent, preserve, save, restore or improve health, and other medical activities resulting from the treatment process. Assigning responsibility for damage caused in the treatment process also depends on the way in which medical activities are performed. The general rule is that it is the medical entity that will be borne by the entity that concluded the treatment contract with the patient.

In the case of an oral treatment agreement, its content should be read with the PDD and PR. The main responsibilities and powers of the parties should be defined. Despite the fact that the patient concludes a treatment contract most often with a healthcare clinic or hospital, they mainly come into contact with a doctor. The doctor's duties are defined, inter alia, in Article 4 PDD, according to which a doctor is obliged to practice in accordance with the indications of current medical knowledge available to him about methods and means of preventing, diagnosing and treating diseases, with the principles of professional ethics and with due diligence; in Article 30 PDD, imposing the obligation on the doctor to provide medical assistance in any case when delay in providing it could result in a risk of loss of life, serious injury or serious health impairment, and in other urgent cases; in Article 31 PDD in the scope of providing the patient or his statutory representative with accessible information about his health condition, diagnosis, proposed and possible diagnostic and treatment methods, foreseeable consequences of their application or omission, treatment results and prognosis; in Article 36 PDD as an obligation to respect the intimacy and personal dignity of the patient; in Article 40 PDD,

²³ E.g. judgment of the Supreme Court of 22 August 1980, ref. no. IV CR 299/80, unpublished; see also judgment of the Supreme Court of 11 May 1983, ref. no. IV CR 118/83, OSNCP 1983, No. 12, item 201.

imposing an obligation to keep confidential information related to the patient, obtained in relation with the exercise of the profession; and in Article 41 PDD Law, pursuant to which the doctor was obliged to keep individual medical records of the patient.

The counterparts of the above obligations are the patient's rights resulting from the PR, in particular a very broad right to health services (Article 6 and 7 PR), the right to health services provided with due diligence (Article 8 PR), the right to information (Article 9–12 PR), the right to report adverse effects of medicinal products (Article 12a PR), the patient's right to confidentiality of information related to him (Article 13 PR), the patient's right to consent to the provision of health services and to refuse such consent (Article 15–17 PR), the right to respect their intimacy and dignity, the treatment of pain and the presence of a relative (Article 20 and 21 PR), the right to access medical records (Article 23 PR), the patient's right to object to a doctor's opinion or decision (Article 31 PR), the patient's right to respect for private and family life, including the right to contact other persons and to additional care (Article 33 and 34 PR), the right to pastoral care (Article 39 PR).

With regard to tort and contractual liability, the provisions on due diligence apply to the latter, referred to in Article 355 of the Act of 23 April 1964 the Civil Code²⁴ which is tightly correlated with the patient's rights, as defined in Article 8 PR. In the case of a treatment agreement concluded in a written or documentary form (most often concluded between the patient and private entities conducting medical activities), apart from the provisions of PR, the scope of liability will result from the content of the agreement. Within the scope of the treatment agreement, the liability of the entity performing medical activities will be based on qualified due diligence (Article 355(2) CiC), and in the event of a personal injury, this liability will result from contractual provisions.

Such an entity performs its obligation with use of services performed by medical personnel, on the basis of a pre-existing legal relationship between them, such as an employment contract or the so-called contract, i.e. a civil law contract.

The above will be significant in relation to the regulation concerning the indemnity as a substitute, i.e. for the act of another.

Compensation for the damage in the situation described above is the result of a legal relationship between the person causing the damage and the person entrusting the activity. In Article 429 and 430 CiC, the Polish legislator regulated the above circumstance.

²⁴ Journal of Laws of 2022, item 1740 [hereinafter: CiC].

In the case of telemedicine advice, it is the entity performing the medical activity that is obliged to act diligently in the given relationships, and this is certainly the provision of means of communication and equipment that guarantees the possibility of adjudicating on the patient's health condition.

However, the provisions of the Telecommunications Law relating to the fulfillment of obligations by the operator of the public telecommunications network are irrelevant for this relationship.

Failure to execute or improper execution of the contract between him and the entity performing medical activities may be the basis for the entity performing medical activities to submit a recourse claim in the event of liability for damages. A recourse claim against tort is based on the provisions of Article 441(2) and (3) CiC.

In order to confirm the above, it should be noted that despite the previous legal status, on which the two above-mentioned judgments of the Supreme Court also in the current legal status in jurisprudence²⁵ in cases where defective, malfunctioning, undesirable operation or outdated diagnostic equipment became the basis for further actions of medical personnel in relation to the patient, as a result of which the damage occurred, also the organizational fault of the entity performing the medical activity is accepted as the basis for liability. This was also confirmed by the CJEU in a judgment of the 21 December 2011²⁶ in a case where a medical facility was responsible for burns to a patient due to a malfunction of the heat regulation system in a heated mattress. The responsible entity, Besancon Teaching Hospital argued that liability for the damage should be borne by the manufacturer of the product in accordance with Directive 85/374/EEC.²⁷ The CJEU confirmed that the responsibility of the hospital, as a provider of medical services, does not arise from the aforementioned directive. Liability for damages may be assigned to such an entity under the domestic law of a Member State, even if no fault can be attributed to it, which is not contrary to the provisions of the Directive, provided that the aggrieved party or the aforementioned service provider remain able to hold the producer liable on the basis of this directive, if the conditions set out in it are met. This judgment correlates very well with Polish jurisprudence, aiming at the guarantee and protection of the weaker entity in a dispute for compensation, i.e. the injured patient.

Although the legal relationship between the doctor and the entity performing medical activities is important for assigning the basis of liability, it is not

²⁵ E.g. judgment of the Court of Appeal of Gdańsk of 23 October 2013, ref. no. I ACa 866/11, unpublished.

²⁶ Ref. no. C-495/10, ZOTSiS 2011, No. 12C, sec. I-14155.

²⁷ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 7.8.1985, p. 29.

of great importance when assessing the extent of the victim's contribution or when examining the scope and degree of careful action.

From the point of view of pursuing the claim by the injured party, it is important to assign the fault to a specific perpetrator of the damage. In the case of entities performing medical activities, when such a person who has inflicted damage cannot be clearly identified, the structure of organizational fault may apply. However, these concepts will apply to the use of ICT, insofar as it is possible to prove an organizational error of the entity performing the medical activity, manifested in its negligence in terms of organization, safety, hygiene and care of the patient.

With regard to the ICT, such an organizational error could consist in the insufficient quality of the Internet connection used for video advice. It should be noted that the nature of the liability of the telecommunications operator will be decided by the increased assessment of the nature of conducting this activity in accordance with Article 355(2) CiC. In addition to professionalism, the control model is probably also the quality of the telecommunications service provided, which includes data transmission speed, uninterrupted connection, no transmission disruptions, etc. The detailed scope of duties is usually specified in the contract of the provision of a telecommunications service and in the regulations that define the conditions and quality of the service offered. Additionally, on the part of the entity to whom the telecommunications service is to be provided, there is usually an obligation to obtain appropriate technical equipment necessary to receive the service in the declared quality by the telecommunications service provider. All these variables will be taken into account to assess whether the telecommunications service provider has performed the service properly. It will be relevant, in particular, when there is a loss to the patient in connection with the service provided. Failure to meet the hardware requirements of the entity performing medical activities may be considered as contributing to the damage.

CONSCLUSIONS

On December 12, 2015, the Act of 9 October 2015 amending the Act on the information system in the health care and some other acts,²⁸ entered into force, the content of which amended, inter alia, the then wording of Article 2 of PPD by adding section 4 in the following wording: "A doctor, dentist may perform the activities referred to in sec. 1 and 2, also via ICT systems or communication systems." For the activities specified in Article 2(1) and (2) include health services consisting, in particular, in examining the state of health, diagnosing and preventing diseases, treating and rehabilitating patients, providing medical advice, as well as issuing medical opinions and certificates, in the case of

²⁸ Journal of Laws item 1991 [hereinafter: the Act of 9 October 2015].

dentists, on the implementation of the above-mentioned services in the field of dental diseases, the oral cavity, the facial part of the skull and adjacent areas. Pursuant to the Act of 9 October 2015, the content of Article 42(1) PPD has amended wording: "A doctor decides on the health condition of a specific person after prior, personal examination or examination via ICT systems or communication systems."

Before the entry into force on 12 December 2015 of the Act of 9 October 2015 amending the Act on the information system in health care [...], only individual legal regulations related to the use of ICT to provide health services, as well as documents on the principles of medical ethics and deontology. Currently, there are no doubts that the provision of health services with the use of ICT is permissible and in accordance with the applicable law. The pandemic period contributed to the introduction of provisions regulating the principles of providing health services with the use of ICT in strictly defined areas, including, inter alia, primary health care.

Before the COVID-19 pandemic, binding standards of conduct in the provision of "telemedicine" services were defined, for example, in the Ordinance of 11 April 2019 of the Minister of Health on organizational standards in the field of radiology and imaging diagnostics performed via ICT systems.²⁹ The necessity to limit personal contact at the doctor-patient level, forced by the development of the pandemic, resulted in the introduction of the organizational standard of teleportation in primary health care,³⁰ which came into force on 29 August 2020.

Omitting personal contact for the purpose of providing health services is now permissible and often replaces the classic contact of the patient with a person performing a medical profession. Despite this, no provisions have been created that would directly refer to the civil and criminal liability of people who use ICT tools to provide health services. Thus, the basis of civil liability and criminal responsibility for the consequences of actions and omissions of persons providing health services with the use of ICT tools are the general rules resulting from the provisions of the Civil Code and the Criminal Code. The lack of regulations that would limit or, in strictly defined situations, exclude liability for damages resulting from the provision of remote services, implies an increased risk of liability for the so-called "Malpractice" or failure to exercise the due care. The above is important considering the fact that medical services provided remotely carry a natural risk that increases the possibility of committing an error, which results from the lack of personal contact with the patient. Thus, it seems necessary to introduce regulations that would clarify the scope of responsibility of persons providing health services with the use of ICT media.

²⁹ Journal of Laws item 834.

³⁰ Journal of Laws item 1395 as amended.

REFERENCES

- Bielski, Marek. 2005. "Prawnokarne przypisanie skutku w postaci konkretnego narażenia na niebezpieczeństwo – uwagi na marginesie postanowienia Sądu Najwyższego z dnia 3 czerwca 2004 r., V KK 37/04." Przegląd Sądowy 4:119–33.
- Glanowski, Grzegorz. 2015. "Telemedycyna w świetle ustawy o zawodach lekarza i lekarza dentysty." *Monitor Prawniczy* 18:978–82.
- Kaczan, Damian. 2017. "Telemedycyna w prawie polskim i kilka uwag na tle prawa unijnego." Zeszyty Prawnicze 1:93–105.
- Kunert, Ireneusz. 2019. "Błąd organizacyjny w działaniach służby zdrowia jako przedmiot spraw o tzw. błędy medyczne z perspektywy praktyki prokuratorskiej." *Prokuratura i Pra*wo 7–8:164–80.
- Noel, Helen, Donna Vogel, Joseph Erdos, et al. 2005. "Home Telehealth Reduces Healthcare Costs." *Telemedicine Journal and e-Health* 10, no. 2:170–83. https://doi.org/10.1089/ tmj.2004.10.170
- Sarnacka, Emilia. 2016. "Telemedycyna i e-Recepta nowe wyzwania legislacyjne." In Nowe procedury medyczne a prawo, edited by Jacek Sobczak, and Magdalena Reshef, 127–32. Toruń: Adam Marszałek.
- Safjan, Marek. 2011. Prawo wobec medycyny i biotechnologii. Zbiór orzeczeń z komentarzami. Warszawa: Wolters Kluwer.
- Wąsik, Damian. 2018. "Błędy w sztuce lekarskiej w praktyce lekarza medycyny rodzinnej aspekty prawnokarne i prawnomedyczne." Prokuratura i Prawo 5:43–61.
- Zajdel, Radosław, Anna Krakowiak, and Justyna Zajdel. 2010. "Analiza podstaw legalności telekonsultacji i telediagnostyki w codziennej praktyce klinicznej. Czy wolno konsultować przez telefon?" *Medycyna Pracy* 61, no. 4:155–63.
- Zoll, Andrzej. 2017. In *Kodeks karny. Część szczególna*. Vol. 2. Part 1: *Komentarz do art. 117–211a*, edited by Włodzimierz Wróbel, 525–27. Kraków: Wolters Kluwer.