REVIEW ARTICLE

Medycyna Ogólna i Nauki o Zdrowiu 2024, Tom 30, Nr 3, 161–167
www.monz.pl

Medical errors – conceptual and medico-legal dilemmas still alive. A voice in the discussion

Błędy medyczne – dylematy pojęciowe i medycznoprawne wciąż żywe. Głos w dyskusji

Katarzyna Kamińska[1,A-F], Kamil Bielak[2,A-F], Marzena Elżbieta Świstak[3,A-F]

[1] *Student – Faculty of Medicine, Medical University, Lublin, Poland*
[2] *Intern, Faculty of Medicine, Medical University, Lublin, Poland*
[3] *Department of IT Law and Legal Professions, Faculty of Law and Administration, Institute of Legal Sciences, Maria Curie-Skłodowska University, Lublin, Poland*
A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of the articl

Kamińska K, Bielak K, Świstak ME. Medical errors – conceptual and medico-legal dilemmas still alive. A voice in the discussion. Med Og Nauk Zdr. 2024; 30(3): 161–167. doi: 10.26444/monz/193123

Abstract

Introduction. The article attempts to indicate the necessity to undertake legislative changes in view of the changing conditions of treatment, increased awareness of citizens – patients. The authors present selected views on the semantic approach to medical error, referring to the developed views of the doctrine for the rest.

Objective. The aim of the review is to demonstrate that, in view of the complex problems associated with the settlement of medical error cases, the pursuit of claims in out-of-court proceedings could be an attractive alternative to the current model of regulation.

Review Methods. An overview of current knowledge is presented about legal problems occurring in the medical environment. The following primary methods were used: analysis of case law and a review of literature, and dogmatic-legal analysis. The historical-legal method was used as an auxiliary, to the extent that it was necessary to show the evolution of the adopted legal-medical solutions.

Brief description of the state of knowledge. The pursuit of claims in out-of-court proceedings could be an attractive alternative to the current model of regulation. Hence, a new solution adopted by the legislator in 2023 was signalled – creation of the Medical Event Compensation Fund Benefits Team.

Summary. Due to the extensive thematic scope of the work, the review is limited to presenting selected views on legal problems occurring in the field of liability of doctors and medical entities, the semantic approach to medical error, categorization of medical errors, and refer the reader to the rich literature in the field of medical law.

Key words

medical error, adverse event, medical malpractice, Medical Events Compensation Fund Benefits Team

✉ Address for correspondence: Katarzyna Kamińska, Student – Faculty of Medicine, Medical University, Lublin, Poland
E-mail: katarzynaakaminska00@gmail.com

Received: 16.06.2024; accepted: 09.09.2024; first published: 20.09.2024

Streszczenie

Wprowadzenie i cel pracy. Artykuł jest próbą wskazania na konieczność podjęcia zmian legislacyjnych wobec zmieniających się warunków leczenia, a także wzrostu świadomości obywateli – pacjentów. Ze względu na obszerny zakres tematyczny pracy ograniczono się do przedstawienia wybranych poglądów na temat ujęcia semantycznego błędu medycznego, w pozostałym zakresie odsyłając czytelnika do wypracowanych poglądów doktryny. Celem badawczym jest wykazanie, że wobec złożonych problemów związanych z rozstrzyganiem spraw o błędy lekarskie dochodzenie roszczeń w postępowaniu pozasądowym mogłoby stanowić atrakcyjną alternatywę dla uregulowanego przepisami i stosowanego obecnie postępowania sądowego.

Metody przeglądu. W artykule przedstawiono przegląd aktualnej wiedzy na temat problemów prawnych występujących w środowisku medycznym.

Opis stanu wiedzy. Celem badawczym autorów jest wykazanie, że wobec złożonych problemów związanych z rozstrzyganiem spraw o błędy lekarskie dochodzenie roszczeń w postępowaniu pozasądowym mogłoby stanowić atrakcyjną alternatywę dla uregulowanego przepisami i stosowanego obecnie postępowania sądowego. Stąd też zasygnalizowano nowe rozwiązanie przyjęte przez ustawodawcę w 2023 r. – utworzenie Zespołu ds. Świadczeń z Funduszu Kompensacyjnego Zdarzeń Medycznych. Jako postulat podano konieczność zdefiniowania zagadnienia błędu medycznego w ustawie szczegółowej, ale wskazano również na cechy postępowania w wybranych trybach pozasądowych. W artykule jako podstawowe zastosowano metody: analizę orzecznictwa i doktryny oraz analizę dogmatycznoprawną.

Podsumowanie. Ze względu na obszerny zakres tematyczny pracy autorzy ograniczą się do przedstawienia wybranych poglądów na temat problemów prawnych występujących w dziedzinie odpowiedzialności lekarzy i podmiotów lekarskich, ujęcia semantycznego błędu medycznego i kategoryzacji błędów lekarskich, w pozostałym zakresie odsyłając czytelnika do bogatej literatury z dziedziny prawa medycznego.

Słowa kluczowe

błąd medyczny, błąd w sztuce lekarskiej, Zespół ds. Świadczeń z Funduszu Kompensacyjnego Zdarzeń Medycznych, zdarzenie niepożądane

INTRODUCTION

Medical progress, the increase in the legal and medical awareness of citizens – patients, as well as the specific nature of the relationship formed between patient and doctor, make it necessary to take a new look at this relationship. It is also necessary to take into account the use of modern methods of conflict resolution, bringing benefits both individually and socially, as well as changes in the law, which could improve the situation of the parties interested in resolving a legal dispute. Hence, the functioning of the new legal and organisational solution adopted by the legislator in 2023 was analysed and evaluated. – the creation of the Medical Events Compensation Fund Benefits Team operating at the Patient Ombudsman.

Due to the extensive thematic scope of the work and the extensive line of doctrine, the review is limited to presenting selected views on the legal problems occurring in the field of medical errors, the semantic approach to medical error and categorisation of medical errors, referring the reader to the views of the doctrine in the remaining scope and, at the same time, treating these issues as the background for the considerations undertaken. The aim of the research is not to present the principles of pursuing claims by patients in civil, criminal or professional proceedings against doctors or medical entities. Instead, the research objective is to demonstrate that, in view of the complex problems associated with the settlement of medical malpractice cases, the pursuit of claims in an effective out-of-court procedure could be an attractive (simpler and faster) alternative to the existing judicial (and even out-of-court – provincial medical incident adjudication commissions) model of regulation. Hence, the current legal and organisational features of the out-of-court patient claims compensation system implemented in 2023 were considered. The following primary methods were used: case law analysis, a literature review and dogmatic-legal analysis. As an auxiliary, the historical-legal method was used to the extent that it was necessary to show the evolution of the adopted legal-medical solutions.

Review of selected semantic and legal medical issues. Definition and scope of the concept of medical error and their types. The meaningful content of a medical error is derived from Article 4 of the Act of 5 December 1996 concerning the medical and dental professions, according to which the doctor is obliged to perform his/her profession in accordance with the indications of current medical knowledge, methods and means available to him/her 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 [1]. However, there is no normative definition that explicitly defines what actually constitutes a medical error. In the literature, terms such as medical malpractice and medical error can be found, which suggest the responsibility of the doctor. However, the concept of medical error seems more appropriate here, as the allegation of malpractice may concern all members of the therapeutic team [2, 3].

In a Supreme Court decision of 1 April 1955 (ref. IV CR 39/54), it was pointed out that medical malpractice is an act (omission) of a physician in the field of diagnosis and therapy that is incompatible with the science of medicine to the extent available to the physician [4]. One of the widespread definitions of medical malpractice was proposed by Prof. B. Popielski, MD, who stated that 'medical malpractice is conduct (action or omission) contrary to the basic, generally recognised principles of contemporary (up-to-date) medical knowledge' [5]. A. Liszewska adds that

> a medical malpractice means a violation by a physician (who is aware that he or she is undertaking a medical act) of the rules of professional conduct applicable to him or her in a particular case, developed on the grounds of science and practice in relation to the legal goods in the form of human life and health, which on the grounds of law constitutes the basis for establishing a violation of the duty of care [6].

Thus, in the most general terms, it can be stated that a medical error is an unintentional act, negligence or omission of a doctor, dentist, nurse, midwife, or a person exercising another medical profession, which causes damage to a patient in the area of particularly protected personal goods – health and life.

The concept of a medical event was introduced by the Act of 28 April 2011 amending the Act on Patients' Rights and Patients' Rights Spokesman and the Act on Compulsory Insurance, the Insurance Guarantee Fund and the Polish Motor Insurers' Bureau. It created a new way of claiming compensation in the event of a medical event. According to its provisions, a 'medical event' is defined as

> infection of a patient with a biological pathogenic agent, bodily injury or disorder of health of a patient or death of a patient resulting from incompatible with current medical knowledge: 1) the diagnosis, if it caused inappropriate treatment or delayed appropriate treatment, contributing to the development of the disease; 2) the treatment, including the performance of a surgical procedure; 3) the use of a medicinal product or medical device.
>
> This provision applies only to medical events following the provision of health services in a hospital, thus excluding health care facilities such as outpatient clinics,
> emergency rooms, etc. It can therefore be concluded that a medical event has the characteristics of an adverse event, as it includes 'an unintended and unexpected event in the diagnostic or therapeutic process causing temporary or permanent harm to the patient [7].

When analysing the different concepts, it can be seen that they are inseparable. This is confirmed by R. Kozela, who explains that a medical error is treated as a premise for an adverse event in the healthcare system [8]. Taking into account that an adverse event is a somewhat broader concept than a medical event, it can be concluded that a medical error determines the occurrence of a medical event [9]. A different approach was presented by R. Cranovsky, who defined that: 'a medical error is called an event that could have been avoided but was not done' [10]. Another difference between these concepts is the indication of who allowed the event to occur. In the case of a medical error, a specific person such as a doctor, nurse or pharmacist must be identified. For this purpose, expert witnesses are appointed to decide whether or not the person in question committed a medical error. If, on the other hand, medical events are involved, the focus is only on the actual occurrence of the event, which must be

investigated by the relevant provincial commission. If the occurrence of the event in question is confirmed, the hospital takes full responsibility for it [11].

The doctrine points to a broad catalogue of events not covered by the concept of a medical event, including mistakes and shortcomings of a technical, administrative or organisational nature that lead to harm to the patient, as well as so-called non-fault medical accidents (medical intervention carried out correctly, by an authorised person, but resulted in negative consequences) and therapeutic risks. In addition, cases related to violation of patient rights, for which the legislator in Article 4 of the Act of 6 November 2008 on Patients' Rights and Patients' Ombudsman (consolidated text Journal of Laws of 2024, item 581) [12], remain out of scope.

As far as the categorisation of medical errors is concerned, the reasons for their occurrence are manifold. In general, medical errors can be divided into the following groups: diagnostic, therapeutic, technical, prognosis error, organisational, and information error. The first of these, i.e. diagnostic error, refers to incorrect diagnosis, omission or incorrect performance of available diagnostic tests, or drawing obviously erroneous conclusions based on them. This error can be positive (disease diagnosed in a healthy person), negative (failure to diagnose disease in a sick person), or mixed (incorrect diagnosis). Within diagnostic errors, there is also a distinction between reasoning error and error by omission [13]. As far as therapeutic error is concerned, irregularities oscillate around the application of an unnecessary or inappropriate method of treatment, or the implementation or conduct of treatment contrary to current medical knowledge.

The most common subgroups of therapeutic errors are: therapeutic error following a diagnostic error, and therapeutic error occurring despite a correctly made diagnosis [13]. A technical error, on the other hand, consists of an incorrect execution of a therapeutic action. As a general rule, this is associated with complex medical services, especially the improper performance of a procedure. An organisational error, on the other hand, results from improper work organisation and concerns not so much a faulty treatment process as poor work organisation. This can form the basis for subsequent technical errors. An example of an organisational error would be when the wrong patient is operated on due to inadequate medical record keeping. An organisational error would be serious damage to the patient's well-being that did not arise as a result of poorly administered treatment, but due to the poorly organised work of the medical staff [14].

The following are most commonly identified as subgroups of technical errors: technical error resulting from violation of general rules of care and technical error resulting from violation of *lege artis rules* [14]. As part of the emerging line of jurisprudence, the Supreme Court initially distinguished two types of medical errors – diagnostic and therapeutic – and, over time, only two additional types – technical and organisational. Thus, it can be hypothesised that the division of medical errors into diagnostic, therapeutic, organisational and technical errors is one of the most widespread divisions. This is evident both from an analysis of a broad spectrum of Supreme Court decisions and a review of the doctrine. 'Therapeutic Error' as a category of error that occurs relatively less frequently. E.M. Guzik-Makaruk, E. Truskolaska and E. Wojewoda conclude that, against the background of the studied facts, there is often a coincidence of organisational error with medical errors of a diagnostic-therapeutic nature [14].

With regard to the consequences for the patient, errors can be divided into: minimal errors – which have no significant impact on the patient, harm-related errors – which cause injury or harm to the patient, and death-related errors – which lead to the death of the patient. With regard to the causes of occurrence, one can speak of human errors, resulting from the actions of medical personnel, such as errors of diagnosis, errors in treatment, errors in procedures, etc., and systemic errors, resulting from problems in the organisation of the healthcare system, such as communication errors [15], lack of standardisation of procedures, inadequate technical support, etc.

With regard to the stages of healthcare, a distinction is made between: prevention errors – related to disease prevention and health promotion; diagnostic errors – related to the assessment of the patient›s condition and the making of a diagnosis; therapeutic errors – related to the treatment and care of the patient; rehabilitation errors – related to the process of rehabilitation of the patient. These classifications do not exhaust the broad analysis of the problem covered in the literature. However, they are often used to analyse medical errors, identify risk factors and develop strategies to prevent errors and improve the quality of healthcare.

Increasingly, patients are claiming liability for medical errors from the healthcare providers who are appointed to organise the treatment process [16]. Holding them liable creates a greater chance of receiving compensation. According to, *inter alia*, the judgment of the Court of Appeal in Lublin of 4 March 2009, 'a hospital is liable under Article 430 of the Civil Code, as entrusting the performance of medical acts to the doctors it employs' [17]. On the one hand, a healthcare entity may bear so-called vicarious liability for the consequences of the actions of medical personnel [18], while on the other hand, it may also be liable for its own negligence of an organisational, administrative nature, e.g. for failing to provide appropriate equipment. Health facilities participate in the treatment process through its coordination, planning and organisation of their activities and to this extent are responsible for the actions attributed to them [19].

On the basis of research conducted by R. Tymiński and M. Serocka, it can be established that lawsuits are most often filed against healthcare entities running hospitals in the area of health services in the following fields: general surgery, orthopaedics, traumatology, gynaecology and obstetrics. The allegations formulated in lawsuits most often relate to the course of treatment. However, medical malpractice lawsuits have a success rate of 50%, and the average amount of damages and compensation awarded is half the expected amount. The majority of cases exhaust the course of instances before the judgment becomes final [11]. Reparation for the damage or harm is by way of compensation, damages or pension. The perpetrator may also incur criminal liability for the medical error and its consequences, as well as disciplinary liability. Liability of a civil law nature, the main function of which, especially compensatory liability, is the compensatory function, the purpose of which is to compensate for the harm suffered by the injured party in legally protected goods? It should be added that only a culpable error may render the doctor liable for the harm caused to the patient.

It is argued in the doctrine that a medical error that will give rise to legal consequences in the form of the need to compensate the patient for the damage and harm suffered, should consist of the following elements:

1) conduct inconsistent with the generally recognised state of medical knowledge, consisting, for example, in failure to perform the necessary examinations or failure to administer the necessary drugs;
2) unintentional fault (recklessness or negligence);
3) the negative effect of the error committed, i.e. damage and harm to the patient;
4) the causal link between the error committed and the negative effect of the treatment procedure in the form of the patient's bodily injury, health disorder, or death.

Of course, a doctor's liability is not limited to civil liability [20]. A doctor's conduct contrary to current medical knowledge and his/her failure to exercise due care may also carry criminal liability. This liability is primarily related to the commission of a medical error (most often fulfilling the elements of offences, such as exposure to direct danger of loss of life or grievous bodily harm; causing grievous bodily harm; violation of organ functions or health disorder, or the offence of manslaughter. In addition to civil and criminal liability, the area of professional (disciplinary) liability is also emerging [21].

Undoubtedly, the doctor's daily work involves discussions with the patient and his or her family regarding the diagnosis made, the course of treatment and the unfavourable prognosis associated with the disease. In order to reduce the level of uncertainty of the doctor, strengthen his/her soft competences and avoid adverse effects in the sphere of the patient's psyche, it is necessary to know the basic principles of interpersonal relations and communication techniques, which may result directly from the predispositions, as well as from the competences acquired and shaped in the process of education. Communication with the patient is a complex process, not only because of the multiplicity of ailments that may arise during the treatment process, but also because of the length of the process and the complexity of human personalities and, consequently, the reactions to such difficult life circumstances. It is undeniable that the possession of skills in the field of communication should occupy the most important place among the spectrum of the doctor's core competences. This would make it possible, for example, to avoid communication errors. This should also be served by a properly (especially effectively) implemented mediation procedure, although this still hardly plays a key role [22], or other methods of out-of-court redress for patients.

Mediation (in-court and out-of-court) is a modern and effective procedure in which the parties seek to reach a mutually acceptable agreement (settlement), while the mediator's role is to assist the parties in actively reaching an agreement by assisting them in communicating with each other, and becoming acquainted with the expectations and needs of the parties. The main principles of mediation are: voluntariness, impartiality, neutrality, confidentiality, deformalisation and acceptability [23]. It is important to note, as is also argued in the literature, that mediation (which appears in civil law, criminal law or even disciplinary proceedings) contributes significantly to the actual implementation of the constitutional principle of the right to court of every citizen, and to the provision of a system of effective dispute resolution. However, in Poland, mediation in medical cases is unfortunately still an under-recognised and relatively rarely used procedure. The Supreme Ombudsman for Professional Liability indicated that between 2010–2020, the Ombudsmen referred 93 cases to mediation proceedings, while the medical courts referred only 28. Although mediation – from the formal legal side – can be used since 2005, it has remained a forgotten institution [24].

Systemic solutions for out-of-court claims by patients for hospital services before provincial commissions for adjudication of medical events. The legislator became convinced of the need to introduce alternative methods of out-of-court adjudication of medical events already in 2012, when a system of adjudication by provincial commissions for adjudication of medical events was introduced [25]. It turned out, however, that the model of out-of-court claims for compensation by patients for damages related to medical treatment, adopted at that time, needed to be thoroughly changed [26]. The purpose of the functioning of the said commissions was to reduce the burden of common courts in the field of compensation proceedings for medical errors. They were thus supposed to be a faster and cheaper alternative to civil litigation [27]. A procedure of this kind entailed certain limitations, primarily of a material nature. The scope of permissible compensation was limited to bodily injury, disorder of health, infection or death resulting from the events enumerated in the Act: diagnosis, therapy or use of a medical device in a manner inconsistent with current medical knowledge. Thus, the consequences of medical accidents, which doctrine includes events of a sudden, unforeseeable nature, occurring regardless of fault, are not covered. Moreover, the limitation also only covers events that occurred in medical institutions (hospitals), not e.g. medical offices, clinics, care facilities. Secondly, this mode was not applicable in cases of violation of patient rights, e.g. the right to obtain consent for treatment, to information about the state of health [28]. It has also been noted in the doctrine that the applied model of gathering evidence on the basis of the provisions of civil procedure, brought the commission mode closer to the court trial mode (with all its consequences, especially shortcomings relating to the duration of the proceedings) [29].

However, analysis of the system of functioning of the provincial commissions for adjudication of medical events in the five-year perspective of their functioning, showed the ineffectiveness of the adopted solutions. The Supreme Audit Office, in its 2018 report, pointed out a number of irregularities and weaknesses in the system established. It found that provincial governors, despite having the power to dismiss commission members, did not properly monitor the performance of both the commission chairman and the other commission members, so as to ensure that they could make an objective assessment in this regard. Serious deficiencies were found in the supervision of provincial office employees carrying out tasks related to the service of the commissions and the failure to enforce their reliable performance of the tasks assigned to them. The provincial officials did not perform (or did so only sporadically) analyses and assessments of the performance of the duties of commission members.

The lack of current assessments of the correctness of the work of the commissions, among others the lack of full

knowledge about the violation of statutory deadlines by the members of the commissions in the process of adjudication, was the reason given for the insufficient reaction to this irregularity by the provincial officials, despite the fact that they possessed the statutory competence to do so. As a result, the length of the proceedings was repeatedly delayed. A number of irregularities were also found in the appointment of the adjudicating panels for the consideration of medical event applications (irregularities affected approximately 50% of the designated panels). This concerned both the possibility of a conflict of interest and the actual way in which the panels were appointed. The protraction in the work of the commission was usually caused by the long waiting time for an expert opinion (some commissions even used 80% of the expert opinion), or by the excessive number (sometimes unnecessary) of commission meetings in a case [30].

The system to-date has also not benefited from a mechanism for awarding damages. The implementing regulations in force specified only maximum rates and, as a consequence, it is difficult for patients pursuing claims to estimate the amount of compensation practically achievable, as treatment entities offered the lowest rates [31].

The Patient Ombudsman negatively assessed the functioning of the provincial commissions for adjudication of medical events between 2012 – 2017, and stated that, contrary to the assumptions made, the functioning system of out-of-court redress for patients did not constitute an alternative to the common courts. The Ombudsman drew attention, *inter alia,* to: a) restriction of the possibility of adjudicating medical incidents only to incidents occurring in hospitals, and b) doubts as to the binding force of decisions issued by commissions towards the courts [32].

It should be added that, *de facto*, there was no reduction in the burden on common courts, as between 2012–2017, the numbers of lawsuits filed with courts were higher than those cited in the impact assessment of the regulations introducing the system of out-of-court redress for patients – almost 10 times higher than estimated.

Hence, in 2023, a statutory amendment to the out-of-court compensation of damages resulting from medical events was proposed. It was considered necessary to create conditions in which the repair of damages suffered by patients could take place under preferential conditions, and on a no-fault basis, i.e. regardless of whether or not the damage was caused by culpable behaviour. An alternative to classic civil liability would be to provide a special form of compensation to patients for adverse medical events that should not have occurred as a result of proper treatment – regardless of the fault of the healthcare provider. This is not an isolated solution, as there are such systems in countries of the European Union where there are special institutions responsible for compensating damages suffered by patients. Such a solution is particularly popular within the ‹Nordic model›, as exemplified by the Danish Patient Compensation Association *(Patienterstatningen),* the Patient Insurance Centre *(Potilasvakuutuskeskus)* in Finland, which is financed from the state budget or contributions from healthcare providers, or the Norwegian Patient Compensation Scheme *(NorskPasientskadeerstatning),* which is outside the group of EU Member States. The basic common assumptions of the model introduced in the Nordic countries are that:

1) access to compensation for injured patients should be easy and universal;
2) the aim of the system should be to foster good relations between medical staff and patients;
3) identification of medical error should serve to promote the safety and quality of healthcare;
4) the emphasis on placing blame on specific individuals does not serve to learn from medical errors and improve patient safety;
5) administrative schemes to provide compensation for injury are more efficient in terms of cost and time.

Other European public institutions dealing with patient compensation include the National Office for Medical Accident Compensation in France (Office national d›indemnisation des accidents médicaux), and the Medical Accident Fund (Le Fonds des Accidents Médicaux) in Belgium [33].

The implementation of a compensation system for damages without an adjudication of guilt is intended to determine whether a medical event has occurred in the case covered by the application, and to indicate the amount of benefit due to the applicant for this. Compensation will be paid more quickly and efficiently than in proceedings before provincial commissions for adjudication of medical events, or in court proceedings. Compensation is to be paid from a separate state purpose fund created – the Medical Events Compensation Fund (modelled on the provisions of the Act of 17 December 2021, amending the Act on Prevention and Control of Infections and Infectious Diseases in Humans and Certain Other Acts (*Journal of Laws* of 2022, item 64, on the basis of which the Protective Vaccination Compensation Fund was created, the disposer of which is also the Patient Ombudsman). In both cases, the purpose of the creation of the special purpose fund is to pay compensation benefits granted by administrative decision issued by the Patient Ombudsman.

Obviously, the proposal for a new compensation system introduced by the amendment to the Act on Patients› Rights and the Ombudsman for Patients› Rights and Certain Other Acts of 16 June 2023 (*Journal of Laws*, item 1675), effective as of 6 September 2023, covered – as was the case previously – only so-called hospital benefits. However, it has not been ruled out that other benefits will also be gradually covered by this system in the longer term of the functioning of the Medical Events Compensation Fund.

The introduction of relevant amendments resulted in the abolition of provincial commissions for adjudicating medical events as of 1 July 2024, while maintaining transitional procedures for proceedings initiated and conducted on the basis of the existing provisions with regard to medical events occurring before the date of entry into force of the amending act. The applicant has the choice of whether to pursue a claim in civil or out-of-court proceedings – filing a case for compensation or damages in court excludes the consideration of the application by the Patient Ombudsman. Within 30 days of the date on which the decision on the award of the compensation benefit has become final, the applicant may submit to the Ombudsman a declaration of acceptance of this benefit, which will be tantamount to a waiver by the applicant of all claims for compensation, pension, and monetary damages that may arise from the medical event to the extent of damages that have manifested themselves up to the date of submission of the application. It will be possible to submit claims for compensation benefits within one year from the date of becoming aware of the medical event, but

no longer than three years from the occurrence of the event.

What is at stake, therefore, is the speed of proceedings, and on the other hand, the amount of compensation. The regulation of the Minister of Health of 10 June 2024 on the manner of determining the amount of compensation for infection with a biological pathogenic agent, bodily injury, health disorder or death of a patient (*Journal of Laws* of 2024, item 883), assumes a maximum amount of compensation of PLN 150,000. Undoubtedly, court proceedings, although lengthy, offer the possibility to claim higher amounts.

CONCLUSIONS

The analysis carried out allows confirmation of the thesis that, in view of the complexity of the occurring medical events, it would undoubtedly be helpful to finally define and introduce a definition of medical error into the legal system. The validity of this conclusion is not only confirmed by the parallel existence of terms such as ‹medical malpractice› or ‹medical error›. As of 6 September 2023, the problem of interpretation seems to be even more serious due to the introduction of a legal definition of a medical event (for the purposes of the implementation of the compensation system in the processing of cases by the Compensation Fund Benefits Panel. Pursuant to Article 3(1) (11) of the Act of 6 November 2008 on Patients› Rights and Patients› Ombudsman (consolidated text in *Journal of Laws* of 2024, item 581), a medical event is an event occurring during the provision of, or as a result of the provision of, or failure to provide, a health care service: a) infection of a patient with a biological pathogenic agent, b) bodily injury or disorder of health of a patient, or c) death of a patient – which with a high probability could have been avoided if the health care service had been provided in accordance with current medical knowledge, or if another available diagnostic or treatment method had been used, unless there were foreseeable normal consequences of the use of a method to which the patient gave informed consent.

There are currently no grounds for an expansive interpretation to assume for the purposes of legal proceedings that a medical event is identical to the concept of a medical error that operates in doctrine and case law. Doubts in this regard should be removed by legislation. A *de lege ferenda* postulate proposes to add a definition of medical error, or to indicate in the definition of a medical event that it covers a specific type of medical error. At the very least, this should be a scope definition (due to the multitude of possible facts that the legislator is not able to list enumeratively). This is all the more justified as the scope of liability for medical errors is broad – covering the area of civil, criminal and disciplinary claims. These are sanctions that are particularly severe for professions of public trust and should therefore have as their basis an event legally defined at the statutory level.

With regard to the proposed solution, i.e. an alternative administrative route in the no-fault compensation system, which has been in operation since 1 July 2024, after the abolition of the provincial commissions for adjudication of medical events, it was emphasised that this could be a helpful tool in resolving disputes in the area of medical law, provided, however, that it is an effective tool and not merely a sham (in terms of coverage and practical spectrum of impact). A fuller assessment of the solution will be possible after about 5 years of operation, in particular as to whether it has avoided replicating the mistakes that occurred when the commission was operating. In addition to organisational issues, concerns are also raised about the disjointed nature of the choice of redress system (whether this will not deter potential claimants) and the civil law specificity of compensation claims, which, if the form of an administrative decision is used, may in practice prove to be an insufficient solution.

REFERENCES

1. Article 4 of the Act of 5 December 1996 on the professions of physician and dentist; consolidated text Journal of Laws of 2024, item 1287.
2. Bonin N. Błąd medyczny – definicja, przykłady i konsekwencje dla placówki i personelu. „Ochrona zdrowia". https://www.wolterskluwer.com/pl-pl/expert-insights/blad-medyczny-definicja-przyklady-konsekwencje-dla-placowki-i-personelu [access: 2024.01.29].
3. Zieliński P. Kilka słów o pojęciu i rodzajach błędu medycznego. MW 2016;8;181–195.
4. Wyrok Sądu Najwyższego z dnia 1 kwietnia 1955, sygnatura akt IV CR 39/54, OSN 1957/1, poz. 7.
5. Popielski B. Pogranicze etyki i prawa. In: Kielanowski T, editor. Etyka i deontologia lekarska. Warszawa; 1985. p. 135.
6. Liszewska A. Odpowiedzialność karna za błąd w sztuce lekarskiej. Zakamycze; 1988, p. 32.
7. Carnovsky RS. O niedoskonałości naszych poczynań czyli o tak zwanych błędach medycznych – wprowadzenie. MP Medycyna Praktyczna. Ginekologia i Położnictwo. 2011;3(73);111–114.
8. Kozela R. Błędy lekarskie a ergonomia. Atest: Ochrona Pracy. 2010;1;14–16.
9. Korytkowska D. Pojęcie błędu medycznego i zdarzenia medycznego. Acta Universitatis Lodzinsis. Folia Oeconomica. 2012;274;61–70.
10. Cranovsky RS. O niedoskonałości naszych poczynań czyli o tak zwanych błędach medycznych – wprowadzenie. MP Medycyna Praktyczna. Ginekologia i Położnictwo 2011;3(73);111–114.
11. Korytkowska D. Pojęcie błędu medycznego i zdarzenia medycznego. Acta Universitatis Lodzinsis. Folia Oeconomica. 2012;274;61–70.
12. Wrześniewska-Wal I. Dochodzenie roszczeń w sprawach o błąd medyczny – uwagi *de lege lata* i *de lege ferenda*. Studia Prawnoustrojowe. 2020;48;247–261.
13. Tymiński R, Serocka M. Kto i ile płaci za błędy medyczne? Analiza linii orzeczniczej wydziałów cywilnych sądów powszechnych w sprawach o błąd medyczny. Ginekologia i Perinatologia Praktyczna. 2018;3(1):32–39.
14. Guzik-Makaruk EM, Truskolaska E, Wojewoda E. Odpowiedzialność za błędy medyczne w Polsce i Republice Federalnej Niemiec – wybrane aspekty. Warszawa; 2021. p. 17–21.
15. Wieczorek E. Odpowiedzialność cywilnoprawna względem pacjenta za błąd w sztuce medycznej. In: Podgórska M, editor. Choroby XXI w. – wyzwania w pracy fizjoterapeuty. Gdańsk; 2017. p. 290–298.
16. Wyrok Sądu Najwyższego z 23.06.2017, sygn. Akt: I CSK 627/16, LEX nr 2333045.
17. Wyrok Sądu Apelacyjnego w Lublinie z 4.3.2009, I ACa 12/09, PiM 2011, Nr 2, p. 128.
18. Art. 1 ustawy z dnia 28 kwietnia 2011 r. o zmianie ustawy o prawach pacjenta i Rzeczniku Praw Pacjenta oraz ustawy o ubezpieczeniach obowiązkowych, Ubezpieczeniowym Funduszu Gwarancyjnym i Polskim Biurze Ubezpieczycieli Komunikacyjnych (Journal of Laws of 2011, No. 113, item 660), który wprowadził rozdział 13a, z mocą od dnia 1 stycznia 2012 r.
19. Wyniki kontroli Najwyższej Izby Kontroli z 2018 r. – „Pozasądowe dochodzenie roszczeń przez pacjentów". https://www.nik.gov.pl/aktualnosci/dochodzenie-roszczen-pacjentow.html, p. 8–14 (access: 2024.03.16).
20. Rozporządzenie Ministra Zdrowia z dnia 27 czerwca 2013 r. w sprawie szczegółowego zakresu oraz warunków ustalania wysokości świadczeń w przypadku zdarzenia medycznego (DzU z 2013 r. poz. 750).
21. Stanowisko Rzecznika Praw Pacjenta – informacja uzyskana przez Najwyższą Izbę Kontroli na podstawie art. 29 ust. 1 pkt 2 lit. f ustawy o Najwyższej Izbie Kontroli.
22. Safjan M. Prawo i medycyna. Ochrona praw jednostki a dylematy współczesnej medycyny. Warszawa; 1998. p. 76–77.

23. Uzasadnienie do projektu ustawy o zmianie ustawy o prawach pacjenta i Rzeczniku Praw Pacjenta oraz niektórych innych ustaw (projekt nr IX.3259).
24. Gmurzyńska E, Morek R. O problemach dotyczących rozstrzygania sporów o błędy lekarskie i o roli mediatora. Kwartalnik ADR. 2011;3(15);67.
25. Przylepa-Lewak A. Współczesne wyzwania mediacji medycznej. Krytyka Prawa 2023;3;238–254.
26. Bargiel K, Sułkowski M. Błąd medyczny – termin, rodzaje i podstawa prawna. Sztuka Leczenia. 2023;38(2):24–122.
27. Chludziński B. System opanowywania sporów wynikających z naruszenia praw pacjenta lub zdarzeń medycznych. In: Bączyk-Rozwadowska K, Chludziński B, editor. Alternatywne metody rozwiązywania sporów w sprawach medycznych. Toruń; 2021. p. 11–31.
28. Bączyk-Rozwadowska K. Pozasądowe procedury kompensacji szkód doznanych w związku z leczeniem. In: Bączyk-Rozwadowska K, Chludziński B, editor. Alternatywne metody rozwiązywania sporów w sprawach medycznych. Toruń; 2021. p. 33.
29. Bączyk-Rozwadowska K. Pozasądowe procedury kompensacji szkód doznanych w związku z leczeniem. In: Bączyk-Rozwadowska K, Chludziński B, editor. Alternatywne metody rozwiązywania sporów w sprawach medycznych. Toruń; 2021. p. 40–41.
30. Bączyk-Rozwadowska K. Odpowiedzialność cywilna za szkody wyrządzone przy leczeniu. Toruń; 2013. p. 335–371.
31. Szpitale płacą coraz więcej za błędy lekarskie, Dziennik Gazeta Prawna, https://prawo.gazetaprawna.pl/artykuly/435585,szpitale-placa-coraz-wiecej-za-bledy-lekarskie.html (access: 2024.01.29).
32. Trnka J, et al. Podstawy błędu medycznego z uwzględnieniem pracy lekarza rodzinnego. Family Medicine & Primary Care Review. 2007;9(3):880–883.
33. Art. 53-art. 112 ustawy z dnia 2 grudnia 2009 r. o izbach lekarskich; Kondraciuk K, Rytel M. Odpowiedzialność prawna za błąd medyczny. Gazeta Prawna 10.10.2021. https://serwisy.gazetaprawna.pl/orzeczenia/artykuly/8266806,odpowiedzialnosc-prawna-za-blad-medyczny.html (access: 2024.01.19).
34. Rojek-Socha P, Zemke-Górecka A. Nie działa pozasądowy system w sprawach błędów medycznych. https://www.prawo.pl/zdrowie/dlaczego-mediacja-nie-dziala-przy-bledach-medycznych-dr-zemke,518480.html (access: 2024.01.20).