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PROCEEDINGS BEFORE REGIONAL COMMISSION FOR EVALUATION OF MEDICAL EVENTS (RCME) IN POLAND AS AN EXTRAJUDICIAL METHOD OF RESOLVING CIVIL DISPUTES INVOLVING PATIENTS

The legal act of fundamental importance from the perspective of protecting patients' rights in Poland is the Act on patient rights and the Commissioner for Patients' Rights. The amendment of 2011 of this Act added a chapter devoted to the alternative method of resolving disputes with the participation of patients, i.e. proceedings before the regional commission for evaluation of medical events. In Poland, these commissions operate in 16 voivodeship. Their functioning is an alternative to traditional court proceedings. The purpose of this study is to present the institution of proceedings before commissions in Poland. The Author will present the purpose and course of the proceedings, and draw attention to the advantages and disadvantages of this solution. The conclusions presented in this study are based on the functioning of one of these commissions, whose Author is the vice-chairperson.

Key words: medical law, patients' claims, extrajudicial proceedings, ADR.

1. Preliminary issues

The development of medical sciences has contributed to the expansion of the catalogue of persons who receive medical assistance or who use health care. Currently, it is not possible to identify the definition of a patient only with a sick

person who is subject to treatment in the strict sense. Dictionary definition of this term, identifying the patient only with a sick person is too narrow, because it does not include in its definition those who, being healthy, go to the doctor for advice for preventive purposes. Dictionary definitions also do not include donors of cells, organs and tissues collected for transplantation purposes during their lifetime who are healthy before the procedure. In connection with the above, in the era of medicine development, attention should also be paid to healthy persons who visit a doctor for cosmetic purposes, associated with performing aesthetic procedures to improve their beauty. It is an increasingly common phenomenon in which a fully healthy person, seeking the advice of a specialist, becomes a patient. However, in this regard it is necessary to clearly distinguish treatments in the field of so-called aesthetic medicine from health services provided by medical professionals. Due to the limited framework of this study, this issue will not be further developed.

The issue of protecting patient rights in the Polish legal order has been gaining importance for many years. The reason for that is the growing number of disputes involving persons using medical services. This is certainly related to the increasing awareness of patients regarding their rights, as well as the mediality of pending court proceedings, the source of which are most often the so-called medical errors made by medical professionals. The Polish legislator creates provisions imposing on the practitioners of medical professions numerous obligations in the field of providing health services, in which the need to act diligently and in accordance with current medical knowledge is emphasized. Patient rights in Poland are rooted not only in basic documents defining human rights or in the provisions of ordinary laws, but also in solutions adopted by the Constitution of the Republic of Poland*. In the perspective of shaping patient rights in the Polish legal system, an important role have been played by legal acts such as the Act on medical chambers**, reactivating the medical self-government, as well as the Code of Medical Ethics, adopted during the Extraordinary Second National Congress of Physicians of 14 December 1991, establishing ethical rules of conduct for doctors and dentists in Poland. In addition, it should be noted that in Poland, from the perspective of patients' rights and their protection, as well as the obligations of medical staff, the most important legal acts are: the Act on patient rights and the Commissioner for Patients' Rights***, as well as the Act on the professions of doctor and dentist****,

* Act of 2 April 1997 – the Constitution of the Republic of Poland (Journal of Laws, No. 78, item 483).

** See: J. Bujny, Prawa pacjenta. Między autonomią a paternalizmem, Warszawa 2006, p. 87.

*** Act of 6 November 2008 on patient rights and the Commissioner for Patients' Rights (Journal of Laws of 2019, item 1127, hereinafter referred to as: APP).

**** Act of 5 December 1996 on the professions of doctor and dentist (Journal of Laws of 2019, item 537).

Act on the professions of nurse and midwife* and the Act on medical activity**. From the perspective of the subject of this study of key importance is a legal act directly devoted to the rights of the patients, because the Act of 28 November 2011*** introduced into it provisions, pursuant to which Regional Commission for Evaluation of Medical Events were established. In the statement of reasons of the Act amending the Act on patient rights, the need to introduce this alternative procedure for pursuing patients' claims was primarily justified by the fact that in the current legal status the basic possible form of claiming compensation in the event of the so-called medical error was a civil lawsuit for compensation or redress. Attention was drawn to the fact that pursuance of these claims in court lasts several years, which can also currently be observed. It seems that the basic premise of introducing into the Act on patient rights provisions regarding proceedings before the regional commission for evaluation of medical events was to enable the patient to pursue claims without going to court. Currently, this form is, apart from mediation in cases involving patients, one of the basic options for alternative pursuance of redress by patients or their relatives.

2. Purpose of proceedings before RCME

The main purpose of introducing an extrajudicial procedure for adjudicating on medical events was primarily to streamline and simplify the pursuit of claims by patients for damages resulting from hospital treatment. This procedure is dedicated to events that result from the provision of health services in a hospital within the meaning of the provisions on medical activity****. The legislator's action was justified by the fact that traditional court proceedings involving patients were inefficient. This was primarily due to the fact that resolving disputes arising from the so-called medical errors in the court consumed too many resources, had a difficult flow of information between interested parties, as well as too formal rules of conduct and, what is important – a much longer time to process and resolve the dispute as well as higher costs of proceedings. In addition, submitting a dispute with the participation of a patient to the court has often had a negative impact on the relationship between the patient and the medical professional, and the emotions that accompany this kind of dispute often bring court proceedings to determination "who is right" and not whether the event being the subject of the dispute was a result of negligence of medical

* Act of 15 July 2011 on the professions of nurse and midwife (Journal of Laws of 2019, item 576).

** Act of 15 April 2011 on medical activity (Journal of Laws of 2018, item 2190).

*** Act of 28 April 2010 amending the Act on patient rights and the Commissioner for Patients' Rights (Journal of Laws of 2011, No. 113, item 660).

**** According to Art. 2 paragraph 1(9) of the Act on medical activity, the hospital is a medical establishment in which the medical entity performs medical activities such as hospital services.

staff towards the patient, thus determining the validity of the claim. *Ratio legis* for the establishment of new quasi-judicial bodies relieved the common courts of cases concerning the so-called medical errors, and the means to achieve this goal was to create a cheaper, faster and more effective alternative to civil proceedings*. For this reason, the functioning of the Commission, in the assumption of the Polish legislator, was to become an alternative to traditional court proceedings, which in this case are generally characterized by excessive length and a high degree of formalization.

The main purpose of introducing the alternative form of resolving disputes with the participation of patients was – as indicated – to shorten the time for injured patients to seek compensation or redress. There are 16 commissions in Poland, which operate at all voivodeship offices in Poland**. The task of the Commissions appointed by the voivodes is to determine whether the event causing material or non-material damage is a medical event. In the Polis legal system the concept of the so-called medical error has not yet been defined. This term is defined as the violation by a medical practitioner of established rules of conduct, principles of practice that contribute to the damage to the health of patients or lead to their death***. In practice, terms such as "medical malpractice", "medical error", "medical mistake" are used interchangeably. It seems that it is not possible to categorically specify the meaning of the terms mentioned above. The justification for this opinion is a different group of entities whose activity can be attributed to an error of an appropriate category, as well as the subject scope of the activity. Lack of definition of the so-called medical error contributed to shaping its scope by both case law and doctrine. This, however, was not conducive to the unification of the rules for classifying specific events in the field of the so-called errors made by medical professionals. While from the perspective of court proceedings this problem is still current, in the proceedings before

* Moskal A., Waszkiewicz K., Zastosowanie alternatywnych metod rozwiązywania sporów w sprawach dotyczących zdarzeń medycznych, ADR 2017, No. 3, p. 45.

** The voivodeship office is a voivodeship organizational unit without legal personality. It is an auxiliary unit of the voivode and organs of the combined government administration. The voivodeship office is the auxiliary apparatus of the voivodes to enable them to perform their statutory tasks. Each office operates based on the provisions of the Act of 23 January 2009 on the voivode and government administration in the voivodeship (i.e. Journal of Laws of 2019, item 1464), as well as on the basis of the statute of a given voivodeship office.

*** Liszewska A. Odpowiedzialność karna lekarza za błąd w sztuce lekarskiej, Cracow 1998, p. 28; S. Raszeja, Zagadnienia prawno-medyczne ze szczególnym uwzględnieniem odpowiedzialności prawnej lekarza, in: S. Raszeja, Wł. Nasiłkowski, J. Markiewicz, Medycyna sądowa. Podręcznik dla studentów, Warsaw 1993, p. 275; S. Rutkowski, Wybrane zagadnienia z zakresu odpowiedzialności karnej lekarza, Prok. i Pr. 1999, No. 9, p. 71; Z. Marek, Błąd medyczny, odpowiedzialność etyczno-deontologiczna i prawna lekarza, Kraków 2007, p. 34; A. Liszewska, Odpowiedzialność karna lekarza za błąd w sztuce medycznej, EP 2009, No. 5, p. 3 et seq.

the Commission the issue of determining the event which may result in the liability of the hospital has been resolved by the legislator.

The Commissions recognize cases related to events resulting from the provision of health services in a hospital in a given voivodeship. The purpose of the proceedings before them is to determine whether the event that resulted in material or non-material damage constituted the so-called medical event (Art. 67i paragraph 1 of APP). The Polish legislator defines in Art. 67a paragraph 1 of APP the notion of a medical event indicating that it is a biological infection of a patient by a disease agent, injury of the body or health disorder or death of the patient resulting from: a) diagnosis, if it caused improper treatment or delayed proper treatment, contributing to the development of the disease; b) treatment, including surgery, resulting in injury; c) the use of a medicinal product or medical device resulting in an infection of the patient with a biological disease agent, injury of the body, health disorder or death.

Considering the above, it should be noted that the analyzed compensation system does not apply to damages related to the doctor's performance: without the patient's "informed" consent, exceeding the scope of consent or against the patient's will, as well as when the doctor operates *lege artis* as to the diagnosis, therapy or use of the medical product or device. Claiming compensation for damages beyond medical events will only be possible through legal proceedings. Consequently, it should be considered that the Commissions do not examine the extent of the damage, nor do they determine the amount of redress or compensation. The task of the Commission is only to declare a medical event or its absence, which presents many practical difficulties in the absence of grounds for substantive judgment, e.g. due to the lack of medical documentation reflecting the patient's diagnostic and therapeutic process. The legislator provides for the possibility of discontinuing the proceedings, however – taking into account the practice of adjudication – the conditions set out by it are not sufficient. The Polish legislator indicates that the Commission may discontinue the proceedings in the case of: a) withdrawal of the application for establishing a medical event by the entity submitting it until the issuance of the decision as a result of the application for re-examination of the case; b) death of the applicant; c) withdrawal of the power of attorney to represent the other heirs. Consequently, if there are technical and organizational obstacles underlying the submission of the application that prevent making any decision resulting in its dismissal – the only possible solution is to issue a decision on the absence of a medical event. At this point, it is worth referring to a specific clinical case, against which the Commission was forced to decide on the absence of a medical event, which was due to the lack of statutory authorization to make a different decision. Namely, in one of the proceedings pending before the Commission in Szczecin, a decision was issued on the absence of a medical event due to – as it turned out during the proceedings – a late application*.

* The case concerned the determination of a medical event, which was consisted in a too late decision to terminate the delivery by caesarean section and failure to

The Commission thoroughly analyzed the course of events relevant for the settlement, which was justified primarily by doubts raised by the medical entity regarding the submission of an application for establishing a medical event within the allowable annual period provided for by the legislator in Art. 67c paragraph 2 of APP. In this case, the Commission came to the conclusion that the evidence gathered in the analyzed case confirmed the submission of an application for establishing a medical event in violation of the provisions of Art. 67c paragraph 2 of APP, which was related to the fact that it was submitted too late. As a result of the proceedings, it was considered that the application to establish the medical event being the subject of proceedings before the Commission was unjustified. This situation confirms that the legislator, by narrowing the catalogue of premises justifying discontinuation of proceedings before the Commission, makes it necessary to issue judgments on the absence of a medical event despite the lack of legitimacy of examining the application in this regard. *De lege ferenda*, it would be reasonable to extend the grounds justifying discontinuance of proceedings by a general rule according to which the Commission would be entitled to discontinue proceedings when, for other reasons, issuing a judgment has become unnecessary or inadmissible.

The procedure before the Commissions from the beginning of their operation caused a lot of controversy due to its hybrid nature*, which on the one hand resembles *quasi*-administrative proceedings, and on the other – is related to the fact that the legislator obliged members of the adjudicating panel to properly apply the provisions of the Code of Civil Procedure**. Each of the 16 Commissions in Poland consists of 16 members, including: a) 8 members with at least a university degree and a master's degree or equivalent in the field of medical sciences, who perform the medical profession for a period of at least 5 years or have a doctoral degree in field of medical sciences; b) 8 members with at least a university degree and a master's degree in legal sciences who have been employed in positions related to the application or creation of law for a period of at least 5 years, or hold a doctoral degree in legal sciences. All these persons must have knowledge of patient rights and enjoy full public rights. 14 members are appointed by the voivode (with 4 members being appointed

perform diagnostic tests of the fetus for Twin Anemia Polycythemia Sequence (TAPS) in the hospital, which was to result in a health disorder of the patient's minor child in the form of cerebral palsy. In the course of proceedings before the Commission, information was obtained that the grounds for submitting the application existed much earlier before the expiry of the one-year period provided for by the legislator, in which it was possible to submit an application for establishing a medical event.

* See: Kowalewski E., Śliwka M., Wałachowska M. Kompensacja szkód wynikłych z błędów medycznych. Ocena projektowanych rozwiązań prawnych, „Prawo i Medycyna", No. 4, Warsaw 2010, p. 23.

** Cf. Klich A. RODO w postępowaniu przed Wojewódzką Komisją ds. Orzekania o Zdarzeniach Medycznych, [in:] K. Flaga-Gieruszyńska, J. Gołaczyński (eds) Ochrona danych osobowych w postępowaniach sądowych i przed organami administracji publicznej, p. 85 et seq.

from among candidates proposed by professional self-governments of doctors, dentists, nurses and midwives as well as laboratory diagnostics based in the voivodeship, while another 4 members are appointed from among candidates proposed by professional self-governments of bar and legal advisors based in the voivodeship, and another 6 – are persons appointed from among candidates proposed by social organizations operating in the voivodeship for the benefit of patient rights); 1 person – by the Minister of Health and 1 person – by the Commissioner for Patients' Rights. The members of the Commission may not be persons who have been finally sentences for an intentional crime or intentional tax offense, as well as fined with sanctions due to disciplinary or professional liability. Pursuant to the provisions of the Act on patient rights, the term of office of the regional commission is 6 years. If a member of the regional commission is dismissed before the end of the term of office, the term of office of the member appointed in their place expires on the date of the expiry of the term of office of the regional commission. The work of the regional commission is managed by the chairperson elected from among its members at the first meeting by a majority of votes in the presence of at least 3/4 of its members in a secret ballot. The Commissions operate on the basis of regulations adopted by them. Many Commissions in Poland also provide for the position of deputy chairperson, who is usually appointed by the chairperson after having given the consent to perform this function. From an organizational perspective, this solution plays a very important role, because in the absence of the chairperson – the deputy is entitled to fulfil the duties. Among the most important duties of the Chairperson of the Commission are:

a) organizational duties (e.g. ensuring the proper organization of the work of the Commission, making decisions on current issues related to its efficient functioning, ensuring the efficiency, correctness and timeliness of the work of the secretariat of the Commission, examining complaints and applications regarding the work of the Regional Commission);

b) duties related to the appointment of adjudicating panels of the Commission (e.g. appointing four-member adjudicating panels and their chairperson, as well as setting the date of the first meeting of the adjudicating panel, or appointing chairpersons and members of adjudicating panels appointed to examine applications for reconsideration of the case, as well as appointed to examine complaints to declare the Commission ruling unlawful);

c) duties related to members of the Commission (e.g. informing the employer of a member of the Commissions about: their appointment, dates of meetings of the Commission and adjudicating panels);

d) duties towards parties to the proceedings before the Commission (e.g. notification of the date of the first meeting of the adjudicating panel of the Regional Commission, the entity submitting the application, the head of the medical entity, the insurer, the employer of the member of the adjudicating panel, as well as performing initial verification of the application for establishing a medical event and submitting it to the chairperson of the

adjudicating panel, as well as reading the letters received by the Commission and issuing relevant orders).

When analyzing the general provisions regarding the proceedings before the Commissions, it is worth noting that the Polish legislator in Art. 67o of APP refers to the appropriate application of the provisions of the Polish Code of Civil Procedure enumerated in it. It should be noted, however, that this reference is not complete, because the legislator selectively takes into account the provisions of the procedural law that should be used in proceedings before the Commission. Consequently, it should be recognized that the provisions of the Polish Code of Administrative Procedure do not apply to these proceedings. At this point, it is worth pointing out that the Polish legislator in proceedings before the Commission orders to apply the provisions regarding: a) exclusion of a judge (in this case – exclusion of a member of the adjudicating panel); b) costs of proceedings; c) serving; d) meetings of the Commission and their course; e) terms; f) suspension and resumption of proceedings; g) hearings; h) evidence and evidentiary proceedings; i) issuing a decision on the substance of the case and j) rectification of decisions. Although we are dealing with a seemingly wide range of civil procedural law provisions, which apply accordingly in proceedings before the Commission, it is necessary to pay attention to their selectivity. The reference in the Act on patient rights to the provisions of the Polish Code of Civil Procedure is not comprehensive and exhaustive. It is noticeable that in some cases, despite the reference used by the legislator, significant legal gaps are visible. It is possible to state that this reference is partly accidental and not well thought out. As a consequence – taking into account the practical aspect of adjudication in proceedings pending before the Commissions – it should be stated that the lack of an explicit reference to the Polish procedural law does not in principle authorize the use of analogies, as the existing gaps are predominantly axiological and only apparent*. For this reason, the way in which the Polish legislator has regulated procedural issues related to the course of proceedings should be approached in a critical manner, which will be the subject of further discussion.

3. The course of proceedings and actions before RCME

The action initiating the proceedings before the commission is the submission of an application for establishing a medical event. The application may be submitted – in the case of infection, injury or health disorder – by the patient or their legal representative, and in the event of the death of the patient – their heir. The legislator – despite referring to the provisions of the Polish Code of Civil Procedure, did not explicitly include the possibility of being represented before the Commission by a professional proxy or by other

* Przybycień A., Szewczyk P. Terra incognita czyli o alternatywnym sposobie kompensacji szkód medycznych, Nowe prawo medyczne – zbiór referatów, EP 2012 (supplement), No. 1, p. XI.

representatives who meet the requirements specified in Art. 87 of the Polish Code of Civil Procedure*. The only exception in this respect is the possibility of initiating proceedings after the death of a patient by one of the heirs, who has the power of attorney to represent the others. The legislator does not refer to the application of Art. 86 of CCP, according to which the parties and their bodies or legal representatives may act before the court in person or through proxies. In practice, for the most part both patients and medical entities are represented by professional representatives who are lawyers or legal advisers. This is justified primarily by the fact that the application forms for establishing a medical event available on the Commission's website contain fields in which the information about the representative as well as their address should be provided. It is also possible to recognize that since the legislator does not provide for only personal action by the patient, their legal representative or the heir of the patient, this is not tantamount to the lack of the possibility of acting by proxy in case of both the applicant and the medicinal entity involved in the proceedings before the Commission.

The application for establishing a medical event should be submitted to the Regional Commission having jurisdiction over the seat of the hospital in a case of occurrence of a medical event after 1 January 2012. The legislator clearly specifies the time limit within which an authorized entity may apply to the commission to determine a medical event. This application must be filed within 1 year from the day on which the entity submitting the application became aware of an infection, injury or health disorder or the patient's death. However, this period may not be longer than 3 years from the day on which the event resulting in infection, injury or health disorder, or the patient's death occurred.

Proceedings before the regional commission for evaluation of medical events: a) are suspended in the case of pending proceedings in connection with the same event regarding the professional liability of a person practicing a medical profession or criminal proceedings in a case of a crime; b) are not initiated, and initiated proceedings are discontinued if, in connection with the same event, a case for compensation is closed with a final decision or civil proceedings are pending. In the event of termination of the proceedings constituting the basis for suspension of the proceedings before the Commission, the decision is taken *ex officio*.

The application for establishing a medical event, which is completed and submitted by the applicants, in the part regarding the subject of the application contains four possibilities for the applicant (their legal representative, heir or proxy) to indicate the type of event: infection, injury, health disorder or death. It is difficult to distinguish individual points because applicants may circle several options, e.g. infection and subsequent health disorder or injury, which results in health disorder or even death. For this reason, every application submitted to the Commission is subject to comprehensive examination. As

* Act of 17 November 1964 – the Code of Civil Procedure (Journal of Laws of 2019, item 1460, hereinafter referred to as: CCP).

indicated, from a practical point of view, there is a tendency for applicants to appear before the Commission with a representation of professional proxies. However, the specifics of the proceedings before the commission do not lead to the full elimination of errors of professional representatives (lawyers, legal advisors) in formulating allegations regarding the conduct of medical personnel. This is expressed in the fact that the allegations they make are not limited to attempting to show that a given event leading to injury, health disorder, infection or death of the patient was an act or omission of medical staff which was not in accordance with current medical knowledge. Often, both professional representatives and applicants independently accuse the opposing party of mistakes and negligence in the implementation of the information obligation, or question the effectiveness of the patient's consent to medical intervention. From the point of view of the subject of the decision made by the Commission, these issues do not *de facto* matter, because – as indicated – the key is to determine whether the behaviour of a medical professional was incompatible with current medical knowledge. This means that the subject of the proceedings before the commission is significantly narrowed, because it does not refer to other elements constituting, in the traditional (procedural) approach, the subject of proceedings and settlements in cases involving patients. Narrowing down the subject of the adjudication to determine whether the behaviour expressed in the act or omission of a medical professional can be found to be incompatible with current medical knowledge cannot be assessed only in a negative way. The discussed method of out-of-court settlement of patients' claims is dedicated to events that meet the conditions for recognizing them as medical events for which a medical professional is responsible when acting in a manner inconsistent with current medical knowledge, which results in injury, health disorder, infection or death.

Submission of an application is subject to a fee of 200 PLN, which is counted towards the costs of proceedings before the Commission. This fee must be paid to the account of the competent voivodeship office. In the case of submitting an incomplete or improperly paid application – it is returned to the entity submitting the application without consideration. In a different situation, i.e. when the application is submitted in a way enabling it to be processed, the Commission pursuant to Art. 67d paragraph 6 of APP immediately forwards it to the head of the medical entity operating the hospital with the activity of which the application is connected, and to the insurer referred to in Art. 67i paragraph 2 point 2 of APP. Both the head of the medical entity and the insurer present their positions within 30 days from the date of receiving the application together with evidence supporting their positions. Failure to present a position is tantamount to acceptance of the application in the scope of the circumstances indicated in it and the proposed amount of compensation and redress. At this point, it should be noted that in practice, for the most part, only heads of medical entities or their proxies show an active attitude in presenting their position. Insurers, in principle, are activated when the Commission decides

that the event described in the application was a medical event. Their activity is reduced to questioning the legitimacy of the substantive decision issued, which is related to their submission of an application for re-examination of the case, which will be the subject of the further part of the study.

The next stage in examining the case is setting a date for the meeting during which evidentiary activities are carried out and a substantive decision is made. In accordance with Art. 67f of APP, the Commissions adjudicate in a four-member panel, i.e. two representatives of legal sciences and two of medical sciences. The work of the adjudication panel is managed by the chairperson, while the date of the first meeting of the adjudication panel and its chairperson is set by the chairperson of the Commission. The legislator has determined that the adjudication panel is appointed by the chairperson of the regional commission in the order of receipt of applications for determining a medical event from the alphabetical list of members of the regional commission. Unfortunately, in practice this is not a good solution, because it often leads to a situation in which the adjudication panel includes representatives of medical professions who, due to another subject of specialization, cannot fully provide substantive assistance to lawyers. The assumption of the Commission was also that the cases examined by a mixed panel, i.e. legal and medical, were settled faster, which is justified by the lack of the need to use specialist opinion due to the knowledge of members of the adjudication panel in the field of medicine. However, the shortcomings in the rules for appointing members of the adjudication panel for a specific case should be noticed. The alphabetical division may lead to a situation in which examination of a case, the subject of which is, e.g. determination whether the infection was a medical event, is done by persons among whom there is no specialist in microbiology who is a member of the Committee, which generates the need for specialist opinion – voivodeship consultant. Such action unnecessarily extends the duration of the proceedings and generates additional costs for the parties. The legislator provides for the possibility of departing from this rule, which is permissible for the reasons specified in Art. 67g paragraph 2 of APP, in which the legislator specified the reasons for excluding a member of the adjudication panel.

Moreover, it is also likely that due to the exclusion of members of the regional commission it might not be possible to designate the adjudication panel. In such situations, the chairperson of the Commission, without any delay, but no later than within 3 days from the date of receipt of the application, informs the Commissioner for Patients' Rights about this fact. Then, the Commissioner, no later than within 7 days from the date of receipt of information about the impossibility to designate the adjudication panel, indicates another Commission competent to examine the application. In this respect, the Commissioner should ensure the most favourable travel conditions for participants in the proceedings. If the case is forwarded by the Commissioner for consideration to another Commission, the Commission which received the application forwards all documentation of the case to the Commission indicated by the Commissioner

immediately, but no later than within 3 days from the date of indication (Art. 67f paragraph 2c of APP).

The Commission issues a decision no later than four months from the date of submission of the application. It is passed by a majority of at least 3/4 votes in the presence of all members of the adjudication panel. In the case of a decision establishing medical event, the hospital insurer is required to submit a proposal for compensation and redress. In this respect, it is the insurer, having an appropriate contract with the hospital, that has the obligation to submit proposals for compensation to patients. The proposal may not, however, be higher than the maximum amount of compensation set out by the legislator in Art. 67k paragraph 7 of APP. Pursuant to this regulation, the maximum amount of benefit (compensation or redress) for one medical event in relation to one patient in case of infection, injury or health disorder – is 100,000 PLN, and in the case of the patient's death – 300,000 PLN. The amount of compensation and redress suggested by the insurer is not binding on the applicant. However, it should be underlined, that if it is accepted by the applicant, the entity submitting the application, together with the submission of the statement on the acceptance of the insurer's proposal, submits a waiver of all claims for compensation and redress for the harm suffered that may result from events recognized by the regional commission as medical events in the scope of damages that became apparent until the date of submission of the application. What is also important, such a declaration made by an heir representing the other heirs is effective against the others. This means that if the case is resolved by the Commission in a positive way, it is for the applicant to decide whether they will accept the insurer's offer or not. In the event of a negative decision, the patient (their legal representative as well as the heir) has the right to take the opportunity to initiate proceedings in a traditional way, i.e. by referring the case to court.

The legislator ensures a kind of two-instance proceedings before the Commission. According to Art. 67j paragraph 7 of APP, within 14 days from the date of delivery of the decision, together with the justification, the applicant, the head of the medical entity operating the hospital, as well as the insurer, have the right to submit to the Commission a motivated application for reconsideration of the case.

It is also important to point out that one of the disadvantages of proceedings before the Commission is the lack of a separate appeal instance. The application for reconsideration of the case in appeal proceedings is *de facto* examined by the same body that issued the decision excluding the member of the adjudication panel who took part in issuing the contested decision. In practice, the contested decision issued, e.g. by the Regional Commission for Evaluation of Medical Events in Szczecin, is recognized by the same Commission, but in a different composition. There is a noticeable lack of an appeal instance common to all 16 commissions.

The medical entity and the applicant, as well as the insurer have the right to submit an application for reconsideration of the case. The implementation of the legitimacy to submit an application for re-examination of the case in practice depends on the decision which was originally issued. If the Commission has determined that the event described in the application is a medical event, most often the right to apply for re-examination of the case is exercised by the medical entity and the insurer. In the opposite situation – in principle the applicant is the patient or their legal representative, heir or proxy. It is important that these applications are submitted within the statutory deadline, which determines the possibility of considering the case. Consequently, it should be considered that the Commission which issued a decision on a medical event or its absence is obliged to re-examine the case. It should be emphasized, however, that the Commission does not consider the application for re-examination of the case as such and does not adjudicate with a separate decision on re-examination of the case. The Commission again decides on the existence or non-existence of a medical event, and therefore considers it substantively, examining the case from the beginning*. Bearing in mind the wording of Art. 67k paragraph 2 point 2 of APP, it should be pointed out – which has been emphasized – that submitted applications for re-examination of the case involve the necessity of the Commission to decide again on the existence or non-existence of a medical event, examining the case from the beginning. On the other hand, the Commission does not dismiss the application or annul (amend) the contested decision, which consequently leads to the recognition that effective submission of the application for re-examination of the case results in the loss of force of the contested decision of the Commission.

4. Course of the meeting and evidentiary proceedings

In the course of the proceedings, the Commission considers evidence submitted by the applicant and the head of the medical entity operating the hospital, with which the application is related, and the insurer with which the medical entity operating the hospital has concluded an insurance contract, as defined in the Act on medical activity. The legislator in Art. 26 paragraph 3 point 9 of APP authorized the Commission to request documentation kept by the medical entity operating the hospital in the scope of conducted proceedings. In connection with the above, a strict interpretation of this provision by the proxies of the medical entity is noticeable. This is expressed in the fact that the medical entity does not spontaneously include the patient's medical records in its position, but requests the Commission to oblige it to submit it within the prescribed period. This action is justified primarily by the fact that, in the light

* I. Kunicki, w: I. Kunicki, J. Sadowska, Postępowanie przed wojewódzką komisją do spraw orzekania o zdarzeniach medycznych. Komentarz do art. 67a–67o ustawy o prawach pacjenta i Rzeczniku Praw Pacjenta, Legalis 2016.

of Polish law, it is the patient who decides who has the access to the medical documentation from the diagnostic and therapeutic process conducted in the hospital and in what way this documentation is to be made available. However, the opposite practice should not be denied in which the head of the medical entity or the proxy representing it, when presenting its position, which is a kind of a response to the application for establishing a medical event, encloses full documentation of the patient's treatment.

According to the general rule of evidence, resulting from Art. 6 of the Civil Code* , the burden of proving the facts – indicated in the application – lies with the applicant, who derives legal effect from these facts. On the other hand, the "procedural" justification for demonstrating the facts (initiatives of the parties) finds its support in the provisions constituting the principle of conducting evidentiary proceedings in civil matters. For this reason, in the scope of evidentiary proceedings, the Commission is guided by the regulations contained in Chapter 13a of the Act on patient rights and the Commissioner for Patients' Rights, as well as the provisions of the Code of Civil Procedure, due to the reference contained in Art. 67o of the Act, in particular in Art. 210, 217, 227-237, 244-257, 258-273 and 299-300 of the CCP.

Bearing in mind the disposition of the abovementioned provisions, it should be noted that the parties in the proceedings before the Commission are obliged to present evidence to establish the facts from which they derive legal effects (Art. 232 of CCP in connection with Art. 67o of APP). Therefore, it is for the applicant to demonstrate that the injury, health disorder, infection or death of the patient resulting from incorrect diagnosis, treatment, including surgery or the use of an incorrect method was a consequence of actions performed not in accordance with current medical knowledge, such as diagnosis, if it caused improper treatment or delayed proper treatment, contributing to the development of the disease; or treatment, including surgery or the use of a medicinal product or medical device. In the course of examining the subject matter, the role of the Commission is to assess whether the applicant has met its obligation in the above-mentioned scope.

According to the well-established position in the literature on the subject, for the Commission to issue a decision on the establishment of a medical event, in addition to the need to classify such an event as an effect of action which was performed not in accordance with current medical knowledge, the following elements must take place: a) an event causing damage for which, according to the law, entities providing health services are responsible; b) material damage to a person and/or non-material damage (harm suffered); c) a causal relationship between this medical event and the damage**. The causes of medical events include, for example, ignorance of the principles of knowledge in the field of medical

* Act of 23 April 1964 – the Civil Code (Journal of Laws of 2019, item 1145, hereinafter referred to as: CC).

** Frąckowiak H. Postępowanie przed Wojewódzką Komisją do spraw orzekania o zdarzeniach medycznych, Warszawa 2016, p. 37.

science, oversight of disease symptoms or identifiable characteristics of the body, improper assignment of a given case to specific rules, careless treatment*, refusal of treatment**, or conduct of medical staff not adequate to the complaints reported by the patient as well as their clinical condition. The role of the patient is to show that the action of medical personnel was "not in accordance with current medical knowledge", which is an absolute premise, the existence of which conditions the recognition of a given event as a medical event. According to the well-established position in the doctrine, the term "current medical knowledge" is not explicit***. There are no permanent and unchanging rules of medical procedure, which is a consequence of the very rapid development of medicine and the emergence of new treatment techniques. Therefore, the patient is entitled to obtain treatment with methods that correspond to the medical knowledge currently available, excluding outdated methods. Considering the above, one should agree with the fact that in order to assess the legitimacy and correctness of the treatment, it is necessary to take under consideration the state of knowledge at the time of taking actions in relation to the patient, and not at the time of pursuing possible redress****. The obligation to be up to date with the current state of medical knowledge is a necessary condition for practicing a medical profession, and this knowledge consists of knowledge about methods and means and the ability to apply them. This issue should always be referred to the individual case and situation of the doctor regarding the methods and means available to him/her during the provision of health services. However, it should be remembered that theoretical knowledge may, in a given situation, be significantly ahead of the real availability of methods and means, because restrictions on access to certain methods and means may be caused by both subjective obstacles (lack of specific practical skills) and objective obstacles (economic, organizational and technical reasons, etc.)*****. This issue is the main subject of evidence in proceedings before the Commission.

The decision of the Commission whether a medical event took place in the analyzed proceedings is based on evidence obtained in the course of the proceedings, including in particular evidence from medical documentation, as well as evidence from testimonies of witnesses or from the opinion of a

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* Karkowska D. Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta. Komentarz, Warsaw 2012, p. 479.

** Serwach M. Odpowiedzialność za zdarzenia medyczne według nowego prawa – pytania i odpowiedzi, Medycyna Praktyczna 2011, No. 9, p. 122.

*** Karkowska D. Ustawa, p. 52; D. Karkowska, in: D. Karkowska, J. Chojnacki, Postępowanie przed wojewódzką komisją do spraw orzekania o zdarzeniach medycznych, Warsaw 2014, p. 117.

**** Karkowska D. Ustawa, s. 106, 108; J. Sadowska, Postępowanie przed wojewódzką komisją do spraw orzekania o zdarzeniach medycznych, Sopot 2015, pp. 36–37.

***** Ogiegło L. Ustawa o zawodach lekarza i lekarza dentysty. Komentarz, Legalis 2015.

voivodeship consultant. At this point it is worth pointing out that pursuant to Art. 67i paragraph 7 of APP, if the statement of circumstances that are significant for the decision requires special information, the Commission seeks the opinion of a doctor in a given field of medicine from a list of national consultants or a voivodeship consultant in a given field of medicine, pharmacy or other field applicable in healthcare. In practice, there are also situations in which applicants attach to the application the opinion of experts or a team of experts prepared for the purposes of previously pending criminal proceedings. At this point, it is reasonable to indicate that in the scope of evidence and the so-called burden of proof in proceedings before the Commission, Art. 232 of CCP is applicable. Pursuant to Art. 67o of APP, in proceedings before the Commission, Art. 231 of CCP is applicable, according to which the court may recognize as established facts that are crucial for to the resolution of the case, if such a conclusion can be derived from other established facts (presumption of fact). At the same time, Art. 232 sentence 2 of CCP is appropriately applied, according to which the court may admit evidence not indicated by a party to the proceedings. On the other hand, pursuant to Art. 233 § 1 of CCP, the court assesses the credibility and strength of evidence according to its own conviction, based on a comprehensive consideration of the collected material. In the light of the cited legal regulations known to Polish civil procedural law, and properly applied in proceedings before the Commission, it should be stated that the Commission examining the case is authorized to accept as established facts significant for determining the existence of a medical event and resulting directly from an expert opinion presented for the needs of the proceedings pending before the Commission.

When considering and in consequence resolving a given case, the Commission – in addition to evidence collected and taken in the course of proceedings – takes into account the position of Polish doctrine and jurisprudence, in which it is assumed that in court disputes involving patients, the establishment with certainty of a causal relationship between the doctor's conduct and the resulting damage is usually impossible. The reason for this is that, in the light of medical knowledge, in most cases it is possible to talk about the probability of a high degree, and rarely about the certainty or exclusivity of the cause*. In the opinion of the Commission, it should be emphasized that if in proceedings involving the patient an attempt is made to demonstrate the cause of damage as certain, it should be borne in mind that if there is a high probability that the circumstance was the cause of the damage, the causal relationship can be considered established. It is assumed that these processes do not require that the cause of the damage is demonstrated with absolute certainty**. In the Commission's opinion, the evidentiary difficulties related to this often mean that the relaxed premises

* Judgment of the Supreme Court of 17 October 2007, II CSK 385/07, Legalis.

** Judgment of the Regional Court in Olsztyn of 11 June 2015, IX Ca 229/15, Legalis No. 1310353.

for establishing a causal relationship should be accepted. If there is a high probability that the circumstance was the cause of the damage, the causal relationship can be considered established*. The Commission, when making the decision, often has the opportunity to determine that the operation of medical personnel was not properly diligent and partly not in accordance with current medical knowledge, which with high degree of probability could have been the reason for the occurrence of a medical event. However, it is important to underline that this conclusion is not based on certainty, but on probability, the application of which is justified. The justification for this position may be, among others, delayed diagnostics, careless conduct of medical staff, which in consequence led to the use of improper treatment, while delaying the correct diagnosis. The task of the Commission is to assess whether the applicant demonstrated a causal relationship between incorrect treatment of the patient and, e.g., health disorder leading to death.

5. Judicial activity of the Commission in Poland – summary remarks

Undoubtedly, the introduction by the legislator to the Polish legal system of a new method of settling disputes with the participation of patients has contributed to some extent to relieving the system of justice. Taking into account the statistics of the functioning of the Regional Commission for Evaluation of Medical Events in Szczecin, from 2012 to the end of the second quarter of 2019, only 356 applications for establishing a medical event have been submitted. In the years 2012 – 2019 (until the end of the second quarter of 2019), the Commission in Szczecin issued 80 decisions on medical events, which are the basis for submission of proposal of compensation and redress by the insurer or the director of a medical entity. In the years 2012 – 2017, the annual average number of claims for compensation filed with the regional and district courts of the first instance reached 905**. There is a noticeable view that proceedings before the commission, as a way of obtaining compensation, have not become a real alternative to court proceedings. However, it seems that explicit criticism of this solution is not justified. Certainly, with the introduction of this alternative dispute resolution method, the awareness of patients who are more and more willing to exercise their rights has increased. For this reason alone, it is necessary to appreciate this form of ADR, which, due to its deformalized nature, often enables the breaking of barriers, the occurrence of which contributes to patients' resignation from pursuing their claims.

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* Justification of the judgment of the Court of Appeal in Katowice of 17 October 2013, I ACA 594/13, Legalis No. 746548.

** Pozasądowe dochodzenie roszczeń przez pacjentów – Informacja o wynikach kontroli, KZD.430.005.2018, Reg. No. 163/2018/P/18/057/KZD, p. 14, https://www.nik.gov.pl/plik/id,18515,vp,21114.pdf (accessed on 28 January 2020).

List of legal acts:

1. Act of 2 April 1997 – the Constitution of the Republic of Poland (Journal of Laws, No. 78, item 483).
2. Act of 23 April 1964 – the Civil Code (Journal of Laws of 2019, item 1145, hereinafter referred to as: CC).
3. Act of 17 November 1964 – the Code of Civil Procedure (Journal of Laws of 2019, item 1460).
4. Act of 5 December 1996 on the professions of doctor and dentist (Journal of Laws of 2019, item 537).
5. Act of 6 November 2008 on patient rights and the Commissioner for Patients' Rights (Journal of Laws of 2019, item 1127).
6. Act of 23 January 2009 on the voivode and government administration in the voivodeship (i.e. Journal of Laws of 2019, item 1464).
7. Act of 28 April 2010 amending the Act on patient rights and the Commissioner for Patients' Rights (Journal of Laws of 2011, No. 113, item 660).
8. Act of 15 April 2011 on medical activity (Journal of Laws of 2018, item 2190).
9. Act of 15 July 2011 on the professions of nurse and midwife (Journal of Laws of 2019, item 576).
10. Judgment of the Supreme Court of 17 October 2007, II CSK 385/07, Legalis.
11. Judgment of the Regional Court in Olsztyn of 11 June 2015, IX Ca 229/15, Legalis No. 1310353.
12. Justification of the judgment of the Court of Appeal in Katowice of 17 October 2013, I ACA 594/13, Legalis No. 746548.

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Кліш А.

Провадження у регіональній комісії з оцінки медичних подій (RCME) у Польщі як позасудовий метод вирішення цивільних спорів із участю пацієнтів

Проаналізовано місце та значення альтернативного розв'язання спорів у сфері охорони здоров'я шляхом залучення Регіональної комісії з оцінки медичних подій за законодавством Польщі.

Досліджено положення Закону Республіки Польща про права пацієнтів та Уповноваженого з прав пацієнтів, присвячені провадженню у таких комісіях за участю пацієнтів. Висвітлено переваги та недоліки цього способу розв'язання конфліктів як для пацієнтів, так і для медичних працівників. Наголошено на неформальній природі провадження у Регіональній комісії з оцінки медичних подій порівняно із судовим розглядом. На основі аналізу статистичних даних, заснованих на функціонуванні однієї з цих комісій, у якій автор є заступником голови, встановлено, що провадження у Регіональній комісії з оцінки медичних подій у Польщі, як позасудовий метод вирішення цивільних спорів із участю пацієнтів, не стало реальною альтернативою захисту ними своїх прав в судовому порядку, однак підвищило кількість звернень пацієнтів за захистом своїх прав.

Ключові слова: медичне право, скарги пацієнтів, позасудове провадження, альтернативне розв'язання спорів.

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