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Review

Organization and functioning of Regional Commission for Evaluation of Medical Events after a year of operation

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ARTICLE INFO

Article history:
Received 8 February 2013
Accepted 8 July 2013
Available online 9 July 2013

Keywords:
Compensation
Patient
Regional Commissions for Evaluation of Medical Events
Alternative to court mode of obtaining damage claims
Medical events

ABSTRACT

Introduction: The Act of 28 April 2011 amending the Act on Patient's Rights and Ombudsman of Patient's Rights introduced section 13a, entitled "Rules and procedures for determining compensatory damages in case of medical events." Amended act introduces an alternative to court mode of obtaining redress from hospitals for the damages caused. Since the Act entered into force, one can assert a claim for medical damages either in civil cases in courts (according to the principles in force) or in the proceedings carried out by Regional Commissions for Evaluation of Medical Events (Commissions). The choice of procedure belongs only to the victim (or their legal representatives or heirs). The purpose of the proceedings of Commission is to determine whether the event, as a consequence of which material or non-material damage has occurred, was a medical event.

Amended act describes in detail organization of Commissions and their functioning. It also includes the specific procedure used by Commissions in determination of medical events as an alternative to, by definition, long-term and complex proceedings of civil courts.

Aim: The aim of this work was to present circumstances which gave rise to the appointment of Commission. The authors' intention was also to clarify the rules for their functioning and organization. The authors also provide statistical data on the work of Commission on 30 November 2012.

Material and methods: Legal-dogmatic interpretation of the law in force in Poland was provided with particular reference to justification of draft amendment to the Act on Patient's Rights and Ombudsman of Patient's Rights, and analysis of the opinions expressed by the environment and associations of patients and their families was presented.

Discussion: The authors describe organization and functioning of Commissions appointed under the amended Act on Patient's Rights and Ombudsman of Patient's Rights, which identify issues relating to medical events. The Commission consists of 16 members, including 8 members who have at least university degree and master's degree or the

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1230-8013/$ - see front matter
http://dx.doi.org/10.1016/j.poamed.2013.07.005

equivalent in the field of medical sciences. The remaining 8 members have at least university degree and master's degree in the field of science of law or Ph.D. in the science of law. All members of the Commission also have the knowledge on patient's rights and enjoy full civil rights. The purpose of the proceedings of Commission is to determine whether the event, as a consequence of which material or non-material damage has occurred, was a medical event. In case of positive decision of the Commission, the applicant may request claim from damages incurred (material) and pain and suffering compensation (non-material). The maximum value of the benefit (compensation and redress) due to one medical event for one patient is (a) in case of infection, bodily harm or health disorder of the patient – 100,000 zloty, and (b) in case of death of a patient – 300,000 zloty.

The authors draw attention to the manner of proceeding of Commissions, including the position of the insurer in the analyzed proceedings, entities permitted to submit a claim and methods and deadlines for appeals against decisions of the Commission.

Conclusions:

1. The Polish legislator has finally noticed the need to ensure patients injured in the treatment process with a rapid and possibly easy way to claim damages.
2. Appointment of the Commission did not increase the number of damage claims against hospitals.
3. Commissions were appointed as a quasi-judicial body, mediation and conciliation, although their status is not entirely clear.
4. The proceedings before Commission is not as simple as the legislator had assumed; in many ways it is unreadable and complicated for the potential applicants.
5. Amendments to the Act on Patient's Rights and Ombudsman of Patient's Rights on the appointment of the Commission should be assessed positively; however, further work on the proposed changes is still required.

1. Introduction

The increasing level of education of Polish society implies a growing awareness of citizens to assert their rights as patients. Hence, there was also a need to work on legislation that enables each patient to investigate claims of malpractice, without taking the legal action, which is frequently long and expensive.

It should be noted that with the increasing awareness of the patients themselves, there is also a growing awareness of courts in respect to medical errors, since the amount of damages awarded in proceedings conducted before courts also increases. It is estimated that these are several times higher than over a decade ago: in 1996–1998 the amount of compensation for hepatitis B infection oscillated within 5000–8000 zloty (which is equivalent to approximately $1500–$2500, while the average monthly wage in the national economy in the fourth quarter of 2012 in Poland was $1166.12). Currently, in case of extremely serious condition following a faulty conduct of labor recoverable amounts of compensation are not less than 500,000 zloty. A few years ago, compensation paid to a child for such malpractice did not exceed 150,000 zloty. In judicial practice there are also no further payment claims of 20,000–50,000 zloty in case of hepatitis C infection.[14]

As stated in the explanatory memorandum to draft amendment to the Act of 28 April 2011 on Patient's rights and Ombudsman of Patient's Rights and the Act on Compulsory Insurance, Insurance Guarantee Fund and Polish Motor Insurers Bureau, introducing possibility of asserting claims for medical errors, without taking legal action, may increase the number of claims requested.[14]

Association of Patients “Primum Non Nocere” reports that in Poland every year at least 20,000 malpractices take place. Seeing no chance of winning the case, only about 10% of victims bring lawsuits, notify Prosecutor's Office or assert complaint to the Medical Chamber.

In accordance with data of the above mentioned association, patients claims related to medical errors usually include

- labor (37%),
- hospital infections (24%),
- undiagnosed myocardial infarction (9%),
- injury during thyroid surgery (8%),
- leaving a foreign body after a surgery (5%), and
- damage of temporomandibular joints during dental prosthetics (4%).[8]

Global patient organizations have already recognized the problem faced by patients injured in the treatment process and prepared a document called the European Chart of Patient's Rights.[3] This is an informal non-governmental document prepared by Active Citizenship Network organization in cooperation with 12 organizations from different countries of the European Union, including 14 patient's rights[2] that would guarantee a high level of human health protection (guaranteed also by Art. 35 of

the Chart of Fundamental Rights of the European Union[6]) and ensure high quality of services provided by various health systems in Europe. These rights also include the right to compensation, according to which every person has the right to receive adequate compensation within a reasonable time, if they suffered physical, moral or psychological harm caused by malpractice.

Several years ago a system based solely on liability insurance was considered a good form of protection of patients injured in the treatment process. However, as shown by the experience of countries such as Germany, United Kingdom, France or Nordic countries, this system is not sufficient to ensure adequate standard of protection of patient's rights.[4] It was thus necessary to find other systems that would guarantee complete protection of injured patients.

The specificity of the therapeutic process and the associated risks of adverse effects of the treatment, which are not normal, foreseeable negative consequences associated for example with a risk of surgery,[7] and pressure of environments of both patients and physicians themselves have led to the long postulated amendments to the Act of 6 November 2008 on Patient's Rights and Ombudsman of Patient's Rights (hereinafter referred to as the Act).[13]

Following the example of other countries (particularly Nordic)[12] it was considered necessary to introduce a system of liability of healthcare facilities, giving patients the right to obtain financial compensation for health damage incurred during treatment, out of court, without the need to prove the guilt of healthcare professionals.[1]

From 1 January 2012, section 13a introduced to the Act, entitled "Rules and procedures for determining compensatory damages in case of medical events" came into force. The amended Act introduces in this section an alternative to court mode of obtaining redress from hospitals for the damages caused, either in civil cases in courts (according to the principles in force) or in the proceedings carried out by the Regional Commissions for Evaluation of Medical Events (Commission). The choice of procedure belongs only to the victim (or their legal representatives or heirs).[10] The purpose of the proceedings of Commission is to determine whether the event, as a consequence of which material or non-material damage occurred, was a medical event.[9] Medical event, in accordance with Art. 67a paragraph 1 of the Act is "patient infection with biological pathogen, bodily injury or detriment of health of a patient or his death, resulting from non-compliant with the current medical knowledge:

- diagnosis, if it led to inappropriate treatment or delayed initiation of the appropriate treatment, contributing to the development of the disease,
- treatment, including surgical procedure,
- use of medicinal product or medical device."[14]

It should be also remembered that damage claims can be sought only from hospitals, since as it is stated in the provision of Art. 67a paragraph 2 of the Act, provisions on the rules and procedures of determining damage and redress for medical events apply only to medical events resulting from providing healthcare services in hospital, within the meaning of regulations on medical activity.

2. Aim

The aim of this work was to present circumstances which gave rise to the appointment of Commission. The authors' intention was also to clarify the rules for the functioning and organization of Commission appointed by the amendment of the Act.

3. Materials and methods

Legal-dogmatic interpretation of the law in force in Poland was provided with particular reference to justification of draft amendment to the Act, and analysis of the opinions expressed by the environment and associations of patients and their families was presented.

4. Discussion

4.1. *Organization of Commissions*

Section 13a, introduced to the Act to determine the occurrence of medical event, appoints Commissions which are responsible for identifying medical events, as defined by the Act.

Although Commissions tasks do not constitute exercise of public authority, their seats are located in the competent voivodeship offices.

The Commission consists of 16 members, including 8 members who have at least university degree and master's degree or the equivalent in the field of medical sciences and have been practicing medicine for at least 5 years or hold a Ph.D. in medical sciences. The remaining 8 members must have at least university degree and master's degree in the field of science of law and for at least 5 years be employed in the position associated with the use or creation of law, or hold a Ph.D. in the science of law. All members of the Commission also have the knowledge on patient's rights and enjoy full civil rights.

In total, 14 of the members of the Commission are appointed by the Governor, including

- 4 persons from candidates nominated by professional self-governing bodies of physicians, dentists, nurses and midwives and laboratory diagnosticians established in certain region,
- 4 persons from candidates nominated by chamber of lawyers or legal advisors established in certain region, and
- 6 persons from candidates nominated by civil society organizations working in the region for the benefit of patient's rights.

The remaining two members are appointed by the Minister of Health (one member) and Ombudsmen of Patient's Rights (one member).

As was fairly stated by Karkowska, the Act does not indicate who will evaluate and control the work of members of Commissions. It might have a particular importance in case of the need to revoke a member before the end of term (by the organ that appointed them) due to improper

performance of duties of a Commission member (Art. 67e paragraph 9 item 6 of the Act).[5]

Commissions term of office lasts for 6 years and its works are coordinated by the chairman elected in secret ballot from among its members at the first meeting by a majority of votes of at least 3/4 of its members.

The Commission operates under its by-laws, which by their nature cannot be in conflict with the Act or other rules of law.

Commissions adjudicate in the composition of four of its members. The adjudicating panel is appointed by the chairman of Commission of the alphabetical list of members of Commission, who are assigned to each case according to the order of requests to determine a medical event, whereas two members of the adjudicating panel should be appointed from the group of physicians and two from the group of lawyers. The works of the panel are coordinated by its chairman. Date of the first meeting of the panel and its chairman are appointed by the chairman of the Commission.

The Act defines the grounds of revoking members of Commission before the end of term (Art. 67e paragraph 9 of the Act), it also regulates who cannot become a member of the adjudicating panel, provides for the exclusion of a Commission member from the panel (Art. 67g of the Act) and defines the principles of remuneration and reimbursement of expenses incurred by members of Commission (Art. 67h of the Act).

4.2. *Functioning of Commissions*

The purpose of the proceedings of Commission is to determine whether the event, as a consequence of which material or non-material damage has occurred, was a medical event, within the abovemetioned meaning. In case of positive decision of the Commission, the applicant may request claim from damages incurred (material) and pain and suffering compensation (non-material). The Act does not provide for the other means of satisfying patient's claims, such as awarding pensions, frequently more attractive for the patient, which should be assessed negatively.

In case of infection, bodily injury or detriment of health of the patient, in person or through their legal representative, may apply for determination of a medical event, and in case of patient's death the request may be submitted by their heirs.

Request to determine a medical event is submitted to the Commission competent to the seat of a hospital. Entities entitled to submit such a request must do that within a year from the day they learned about infection, bodily injury or detriment of health or death of a patient; however this period cannot be longer than 3 years from the date of the event which resulted in infection, bodily injury, detriment of health or death of a patient.

The claim, under warning of its return, must contain patient's details (with PESEL number or number of identity document), other applicant's data, correspondence address, details of a healthcare entity managing the hospital, justification of the claim including substantiated event which was the cause of infection, bodily injury, detriment of health or death of a patient, and the resulting material or non-material damage, as well as indication whether the subject of application is the infection, bodily injury, detriment of health or death of a patient, and proposal of the amount of compensation and redress, not higher than specified in the Act. The application shall be accompanied by evidence of substantiating circumstances specified in the claim, as well as confirmation of payment (200 zloty).

A complete and paid application is immediately forwarded by the Commission to the head of healthcare entity managing the hospital, the activity of which was the basis for a claim, and the insurer. Head of this entity and the insurer present their position within 30 days from the receipt of the application together with evidences that support their point. Failure to present the point constitutes the acceptance of a claim in relation to circumstances indicated therein and the proposed amount of compensation and redress.

For the purpose of adjudication the Commission may summon person submitting the claim and the head of the healthcare entity managing the hospital, as well as subjects who performed medical profession in healthcare entity managing the hospital and other persons and insurer to be heard.

The commission adjudicates on the basis of gathered evidence provided by the applicant, representative of the hospital to which it relates, insurer and presented on Commission's request medical records of healthcare entity, testimony of witnesses, examination of hospital rooms and equipment, and if circumstances important for adjudication require any special information, the Commission consults medical expert in a certain field of medicine or regional consultant.

After deliberation and voting, the Commission issues a written decision on the medical event or lack of it, with justification. This decision cannot be issued later than 4 months of filing a request.

The chairman of adjudicating panel at the meeting of Commission, on which the decision was issued, announces its content citing the main reasons of decision. Within 7 days from the date of decision a justification is prepared and both documents are sent to the parties. The parties are entitled to submission of a reasoned request for reconsideration within 14 days from the day of receipt of the decision and justification. Such a request should be considered by the Commission within 30 days from receipt. Reconsideration of the request cannot be conducted by members of the panel, who participated in the issue of the contested decision.

The insurer is bound by the decision of Commission and based on it presents to the applicant a proposal of compensation and redress. This proposal cannot be higher than the maximum amount of compensation and redress defined in the Act. If the insurer does not provide within the expected time a proposal of compensation and redress, he is obliged to pay the amount requested by the applicant. In this case the Commission issues a certificate that confirms submission of application for medical event, the amount of compensation or redress and the fact of failure of the insurer's proposal. Such a certificate is an executor entitlement, on the basis of which one can apply for enforcing a claim by a bailiff.

If however the insurer offers compensation or redress, the applicant within 7 days from the date of receipt of the proposal makes a statement, also through the Commission, of acceptance or rejection. In case of acceptance of the insurer's proposal, the applicant submits with declaration of acceptance of proposal statement waiving all claims for monetary damages for the harm suffered that might result from the events

considered by the Commission a medical event for damages which revealed up to the date of filing request.

The maximum value of the benefit (compensation and redress) due to one medical event for one patient is

1) in case of infection, bodily harm or health disorder of the patient – 100,000 zloty,
2) in case of death of a patient – 300,000 zloty.

The parties are also entitled to extraordinary appellate measure for Commission's decisions in the form of complaint to consider a Commission ruling as inconsistent with law (Art. 67m of the Act). Such a complaint might be submitted by the parties within 30 days of ineffective expiry date of reconsideration request or within 30 days of decision given on the basis of reconsideration request. Such a complaint can only be based on violation of the provisions relating to the proceedings of Commission. In case of a complaint, the Commission shall decide within 30 days of its receipt, in an extended six-person composition.

5. Conclusions

1. A broadly understood medical activity cannot be carried out without the risk of error or unforeseen medical events associated with procedures or medicines used, hence the need to ensure possibility of fast and possibly easy damages claims.
2. After a year of operation of the Commission it should be concluded that the appointment of Commissions did not increase the number of damage claims against hospitals, which was feared by the medical society and assumed by the authors of the amended Act. According to data collected by the Ombudsman of Patient's Rights, up to 30 November 2012 the Commission received 331 applications. The most were reported in Voivodeships: Masovian (45 applications), Silesian (38), Lesser Poland (35) and Pomeranian (29). By the end of November 2012 all Commissions have issued a total of 82 decisions, 26% of applications submitted in this period were returned due to incompleteness, lack of payment, failure to comply with formal requirements (e.g. no substantiation of medical event or lack of amount or subject of request). Claims were also returned because it concerned events prior to January 1, 2012. About 84% of the applications submitted related to bodily injury, detriment of health or hospital infection, 16% of applications were associated with patient's death. Amounts of claims were widely varied. For example, in Lodz Voivodeship in case of bodily injury the minimum claim was 4000 zloty, and maximum 100,000 zloty. Two cases in Lodz Voivodeship related to infections (80,000 zloty and 100,000 zloty), and 4 applications pertained to the death of hospitalized subjects (in 1 of these cases the amount of claim was 100,000 zloty, and in 3 cases – 300,000 zloty).[11]
3. The Commissions were appointed as a quasi-judicial body, mediation and conciliation, although their status is not entirely clear.
4. The proceedings before Commission is not as simple as the legislator had assumed and in many ways it is unreadable and complicated for the potential applicant. Incidental references to the specific rules of civil procedure also raise question of interpretation.
5. There are also differences in functioning of different Commissions due to the fact that each of them has created an individual, independent rules of operation. Hence the conclusion, that in order to prevent such procedures, detailed rules of functioning of Commissions should be in future legalized by regulation and not left to the discretion of the adjudicating bodies themselves.
6. Amendments to the Act on the appointment of the Commission should be assessed positively, although more detailed analysis can conclude that the introduced provisions are often illogical, too general, vague and not entirely fulfilling their role. Hence, further work on the proposed changes of the Act is still required.

Conflict of interest

None declared.

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