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CERTIFIED TRANSLATION FROM POLISH

Journal of laws 2012,159

2015.08.28 amended Journal of laws 2015.1163 art. 1 There are subsequent versions of the text

ACT

of 6 November 2008 on

Patients' Rights and Patients' Rights Ombudsman

(consolidated text)

Chapter 1

General provisions

Art. 1. The Act specifies:

1) patients' rights;

- 2) rules regarding access to medical documentation;
- 3) obligations of operators providing health services related to patients' rights;
- 4) mode for appointing, removing and the powers of the Patients' Ombudsman;
- 5) proceedings in cases of practices infringing collective patients' rights;
- 6) rules and procedure for determining compensation and redress for medical events.
- Art. 2. Respecting patients' rights set out in the Act is the responsibility of public authorities competent in the field of health, the National Health Fund, the providers of health services, medical professionals and others involved in providing health services.
 - Art. 3. 1. The following terms, as used in this Act, shall mean:
- 1) real guardian a person being a guardian, performing constant care of a patient who, due to age, health or mental state, needs such care, but having no such statutory obligation;
- 2) informant a spouse, a relative or a next of kin to the second degree in a straight line, a legal representative, a person remaining in cohabitation or a person designated by a
- 3) health care professional a person performing a medical profession, referred to in Art. 2 paragraph 1 point 2 of the Act of 15 April 2011 On medical activity (Journal of Laws No. 112, item 654, No. 149, item 887, No. 174, item 1039, No. 185, item 1092);
- 4) patient a person asking for granting health services or benefiting from health services provided by the entity providing health care services or a health care professional;
- 5) health care service provider an entity performing medical activities referred to in Art. 2 paragraph 1 point 5 of the Act of 15 April 2011 On medical activity;
- 6) health service health services referred to in Art. 2 paragraph 1 point 10 of the Act of 15 April 2011 On medical activity;

- 7) (repealed).
- 2. Whenever the Act mentions about a physician, it is also understood as a dentist and a paramedic in the scope resulting from the provisions of the paramedic profession.
- **Art. 4.** 1. In case of a culpable violation of patients' rights, the court may award the injured an adequate sum in pecuniary compensation and redress for the damage suffered, pursuant to art. 448 of the Civil Code.
- 2. In the event of a culpable violation of a patient's right to die in peace and dignity, the court may, at the request of a spouse, relatives or related by affinity to the second degree in a straight line or a legal representative, award an appropriate amount of money for their specified social purpose, pursuant to art. 448 of the Civil Code.
- 3. The provision of paragraph 1 shall not apply to culpable violation of patient's rights in cases of:
- 1) storing valuables in a depository of an entity carrying out therapeutic medical activities as stationary and 24-hour health care services;
- 2) information about the type and scope of health services provided by the providers of health care services;
- 3) access to medical documentation regarding his medical condition;
- 4) reporting adverse reactions to medicinal products.
- **Art. 5.** Head of an entity providing health services or a physician authorized by him may limit the use of patients' rights in the event of an epidemic threat or because of the health safety of patients, and in the case of the rights referred to in Art. 33 paragraph 1, also due to the organizational capacity of the entity.

Patient's right to health services

- **Art. 6.** 1. A patient has the right to health services conforming to the requirements of current medical knowledge.
- 2. A patient has the right, in limited opportunities of providing appropriate health services, to a transparent, objective procedure for accessing these services, based on medical criteria.
- 3. A patient has the right to request from the physician/nurse providing health services to:
- 1) in the case of a physician, consult another physician or convene a medical council;
- 2) in the case of a nurse (midwife), consult another nurse (midwife).
- 4. A physician may refuse to convene a medical council or consult another doctor, if he considers that the request referred to in paragraph 3 is unfounded.
- 5. The request referred to in paragraph 3, and the refusal referred to in paragraph 4 shall be recorded in a medical documentation.
- 6. The provisions of paragraphs 4 and 5 shall apply to a nurse (a midwife) consulting another nurse (midwife).
- **Art. 7.** 1. A patient has the right to immediate provision of health services because of the threat to health or life.
- 2. In the case of childbirth, a patient is entitled to receive health services associated with the childbirth.



Art. 8. A patient has a right to health services provided with due care by the providers of health services in conditions corresponding to those set out in separate regulations for technical and sanitary requirements. Granting health services individuals pursuing medical professions shall be guided by the principles of professional ethics laid down by competent self-governments of health professions.

Chapter 3

Patient's right to information

- Art. 9. 1. A patient has the right to information about their health condition.
- 2. A patient, including a minor, who is over 16 years old, or his legal representative shall be entitled to obtain from a physician understandable information about the patient's health condition, diagnosis, the proposed and possible methods of diagnosis and treatment, foreseeable consequences of their application or omissions, the results of treatment, and prognosis.
- 3. A patient or his legal representative has the right to consent to providing the information referred to in paragraph 2 to others.
- 4. A patient has the right to request a physician not to give him the information referred to in paragraph 2.
- 5. After obtaining the information referred to in paragraph 2, a patient has the right to express his opinion in this regard to the physician.
- 6. In the case referred to in Art. 31 paragraph 4 of the Act of December 5, 1996 on Professions of doctor and dentist (Journal of Laws of 2011 No. 277, item 1634, No. 291, item 1707 and 2012, item 95), a patient has the right to request the physician to give him the full scope of the information referred to in paragraph 2.
- 7. Patient minors, younger than 16 years old, are entitled to obtain the information referred to in paragraph 2 in the scope and form needed for the proper diagnostic or therapeutic procedure.
- 8. A patient, including a minor, who is over 16 years old, or his legal representative shall be entitled to obtain understandable information about the care and nursing from a nurse, a midwife.
- **Art. 10.** In the case referred to in Art. 38, paragraph 1 of the Act of December 5, 1996 on Professions of doctor and dentist, a patient, his legal representative or a real guardian has the right to a sufficiently advanced notice of the physician's intention to withdraw from the patient's treatment and the physicians' indication a possibility of obtaining health services at another physicians' or an entity providing health services.
- **Art. 11.** 1. A patient has the right to information on the patients' rights set out in this Act and other provisions, taking into account the limitations of those rights set out in these provisions. A health service provider provides this information in a written form, by placing it in his facility, in a public place.
- 2. Paragraph 1, the second sentence shall not apply to individual medical practice, individual specialized medical practices, individual practices of nurses, midwives and specialist practices of individual nurses, midwives performed solely at the place of call.
- 3. In the case of a patient unable to move, the information referred to in paragraph 1 shall be provided in a manner enabling becoming acquainted with it in the room where the patient resides.

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Art. 12. A patient has the right to be informed of the nature and scope of health services provided by the entity providing health services, including the preventive health programs financed from public funds, carried out by that entity. The provisions of Art. 11 paragraph 1, the second sentence and paragraph 3 shall apply accordingly.

Chapter 3a

The right to report adverse reactions to medicinal products

Art. 12a. A patient or his legal representative or a real guardian has the right to report an adverse reaction of a medicinal product to those performing medical profession, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocides or the entity responsible for placing the medicinal product on the market, in accordance with the Act of 6 September 2001 - Pharmaceutical law (Journal of Laws of 2008 No. 45, item 271, as amended).

Chapter 4

Patient's right to confidentiality of information related to him

- **Art. 13.** A patient has the right to confidentiality of the persons performing medical profession, including those providing health services, of the information related to him and obtained in connection with the exercise of the medical profession.
- **Art. 14.** 1. In order to implement the law referred to in Art. 13, persons exercising medical professions are obliged to keep the information related to the patient, especially to the patients' health condition, confidential.
 - 2. The provision of paragraph 1 does not apply, where:
- 1) separate legislation provides so;
- 2) confidentiality may constitute a danger to the life or health of the patient or of others;
- 3) a patient or his legal representative consents to the disclosure of confidential information;
- 4) there is a need to pass the necessary information about the patient related to the provision of health services to other persons performing medical professions, involved in providing the services.
- 2a. The provision of paragraph 1 also does not apply to proceedings before the provincial committee for the adjudication of medical events, referred to in Art. 67e paragraph 1.
- 3. Persons performing medical profession, except for the cases referred to in paragraph 2, points 1-3 and paragraph 2a, are related to professional secrecy even after the patient's death.

Chapter 5

Patient's right to consent to health services

Art. 15. The provisions of this chapter shall apply to a consent to providing health services or refusing such consent, if provisions of separate legislation do not provide otherwise.



- **Art. 16.** A patient has the right to consent to providing specific health services or refuse such consent after obtaining information to the extent specified in Art. 9.
- **Art. 17.** 1. A patient, including a minor, who is over 16 years old, has the right to consent to carrying out an examination or to provide other health services by a physician.
- 2. A legal representative of a minor patient, a person completely incapacitated or incapable of informed consent, has the right to give the consent referred to in paragraph 1. In the absence of a legal representative, a real guardian is entitled to give such consent in relation to an examination.
- 3. A minor patient who is over 16 years of, a legally incapacitated person or a patient who is mentally ill or mentally retarded, but featuring a sufficient recognition, has the right to object to the provision of health services, despite the consent of a statutory representative or a real guardian. In this case, powers of a guardianship court are required.
- 4. The consent and the objection referred to in paragraphs 1-3 can be expressed verbally or through a behavior of the persons referred to in those provisions which clearly indicates a willingness to undergo the procedures proposed by a physician or a lack of such a will.
- **Art. 18.** 1. In the case of a surgery or the use of methods of treatment or a diagnosis posing an increased risk to a patient, the consent referred to in Article 17, paragraph 1 shall be expressed in writing. Article 17, paragraphs 2 and 3 shall apply to such a consent or objection.
- 2. Prior to the consent given in the manner specified in paragraph 1, a patient has the right to obtain information referred to in Article 9, paragraph. 2.
 - 3. The provisions of Article 17, paragraphs 2-4 shall apply mutatis mutandis.
- **Art. 19.** Rules of performing examinations or providing other health services by a physician, despite the lack of consent or objection, referred to in Art. 17 and 18 shall be determined by Art. 33 and Art. 34, paragraph 6 of the Act of December 5, 1996 on Professions of doctor and dentist.

The right to respect patient's privacy and dignity

- **Art. 20.** 1. A patient has the right to have his privacy and dignity respected, in particular at the time of having health services provided.
- 2. The right to dignity includes the right to die in peace and dignity. Patients in terminal conditions have the right to have health care providers alleviate their pain and other suffering.
 - Art. 21. 1. An informant can be present during providing health services.
- 2. A medical professional providing health services to a patient may refuse the presence of an informant during providing health services in the case of a likelihood of an epidemic threat or due to the safety of the health of the patient. Such a refusal shall be recorded in medical documentation.
- **Art. 22.** 1. In order to implement the law referred to in Art. 20, paragraph 1, a medical professional has an obligation to act in a manner that respects the privacy and dignity of a patient.

- 2. Medical professionals, other than those providing health services, take part in providing these services only if it is necessary due to the type of the service or due to the performance of control activities on the basis of the provision of medical activity. Participation, as well as the presence of other persons, requires the consent of a patient and if a patient is a minor, a completely incapacitated person or a person incapable of informed consent, his legal representative, and the medical professional, providing health care services.
- 3. Articles 13 and 14 shall apply mutatis mutandis to the persons referred to in paragraph 2, second sentence.

Patient's right to medical documentation

- **Art. 23.** 1. A patient has the right of access to the medical documentation concerning his health condition and the health care services provided to him.
- 2. The data contained in the medical documentation is protected under this Act and other regulations.
- **Art. 24.** 1. In order to implement the law referred to in Art. 23, paragraph 1, the entity providing health services shall keep, store and share medical documentation in the manner prescribed in this chapter and ensure protection of the data contained in the documentation.
 - 1a. Medical documentation shall be carried out in an electronic form.
- 2. Physicians, nurses and midwives are authorized to receive and process the data contained in the medical documentation referred to in Art. 25.
 - Art. 25. Medical documentation contains at least:
- 1) determination of a patient, enabling the establishment of his identity:
 - a) surname and first name (s),
 - b) date of birth,
 - c) gender indication,
 - d) address of the place of residence,
 - e) social security number, if it has been issued in the case of a newborn mother's social security number and, in the case of people who have their social security number not issued the type and number of their identity document,
 - f) if the patient is a minor, a completely incapacitated or a person incapable of informed consent – the surname and first name (s) of a legal representative and the address of his place of residence;
- 2) identification of the entity providing health services with an indication of the organizational unit in which the services were provided;
- 3) description of the patient's health or health services provided to him;
- 4) date of development.
- **Art. 26.** 1. The entity providing health services provides medical documentation to a patient or his legal representative, or a person authorized by the patient.
- 2. After a patient's death, the right to access his medical documentation is granted to a person authorized by the patient during his life.



- 3. The entity providing health services also provides access to medical documentation to:
- 1) providers of health services, if the documentation is necessary to ensure continuity of health services;
- 2) public authorities, the National Health Fund, bodies of the self-government of health professionals and national and regional consultants, to the extent necessary for the performance of the tasks of those entities, in particular, control and surveillance;
- 2a) entities referred to in Art. 119 paragraphs 1 and 2 of the Act of 15 April 2011 On medical activity, to the extent necessary to carry out inspections on behalf of the minister responsible for health issues;
- 3) the minister responsible for health issues, courts, including disciplinary courts, prosecution services, court physicians and professional liability ombudsmen, in connection with their proceedings;
- 4) bodies and institutions authorized under separate laws where the examination was conducted at their request;
- 5) old-age pension authorities and teams issuing decisions on disability in connection with investigations conducted by them;
- 6) operators keeping records of medical services, to the extent necessary to keep the records:
- 7) insurance companies, with the consent of a patient;
- 7a) medical committees subordinate to the minister responsible for internal affairs, military medical committees and medical committees of the Internal Security Agency or the Intelligence Agency, subordinate to the Heads of the relevant Agency;
- 8) a physician, a nurse or a midwife in connection with the conduct of an assessment procedure of an entity providing health services under the provisions on accreditation in health care, to the extent necessary to carry it out;
- 9) a regional committee for adjudication of medical events, referred to in Art. 67e paragraph 1, in terms of the procedure conducted;
- 10) heirs, in terms of a procedure before a regional committee for the adjudication of medical events, referred to in Art. 67e paragraph 1;
- 11) persons exercising control activities pursuant to art. 39 paragraph 1 of the Act of 28 April 2011 on Information system in health care (Journal of Laws No. 113, item 657 and No. 174, item 1039) to the extent necessary to carry them out.
- 4. Medical documentation can be also made available to a higher education facility or a research institute to be used for scientific purposes, without disclosing the names and other personally identifiable information of the person to whom it relates.

Art. 27. Medical documentation is made available:

- 1) to be reviewed, including databases in terms of health, in the headquarters of the entity providing health services;
- 2) to draw up its extracts, duplicates or copies;
- 3) through the issuance of an original confirmation of receipt and subject to a return after use, if an authorized body or entity requests access to the originals of the documentation.
- **Art. 28.** 1. A fee may be charged for sharing medical documentation in a manner specified in Art. 27 paragraph 2 by an entity providing health services.



- 2. Paragraph 1 does not affect the powers of disability facilities defined in Art. 77, paragraph 5 of the Act of 13 October 1998 on Social Insurance System (Journal of Laws of 2009 No. 205, item 1585, as amended) and Art. 121, paragraph 2 of the Act of 17 December 1998 On pensions from the Social Insurance Fund (Journal of Laws of 2009 No. 153, item 1227, as amended).
- 2a. The charges referred to in paragraph 1 shall not be charged in the case of sharing medical documentation in connection with proceedings before a regional committee for adjudication of medical events, referred to in Art. 67e, paragraph 1.
- 3. The fees for sharing medical documentation specified in Art. 27, paragraph 2 shall be fixed by an entity providing health services.
 - 4. The maximum fee for:
- 1) one page of an extract or a copy of a medical documentation must not exceed 0.002 of the average remuneration in the previous quarter, from the first day of the month following the announcement by the Central Statistical Office in the Official Journal of the Republic of Poland "Polish Monitor", pursuant to Art. 20, point 2 of the Act of 17 December 1998 On old-age and disability pensions from the Social Insurance Fund;
- 2) one page of a copy of a medical documentation must not exceed 0.0002 of the average remuneration referred to in paragraph 1;
- 3) issuing an extract, a copy or an electronic copy of a medical documentation on a medium, if the entity performing the medical activity keeps medical documentation in an electronic form must not exceed 0.002 of the average remuneration referred to in paragraph 1.
- **Art. 29.** 1. The entity providing health services keeps medical documentations for a period of 20 years from the end of the calendar year of the last entry, with the exception of:
- a medical documentation in the case of a patient's death as a result of an injury or a poisoning, to be kept for a period of 30 years from the end of the calendar year of the death;
- 2) X-ray images stored outside a patient's medical documentation, to be kept for a period of 10 years from the end of the calendar year in which the image was captured;
- 3) referrals for examinations or physicians' referrals which are stored for a period of 5 years from the end of the calendar year in which the service being the subject of the referral was provided;
- 4) medical documentation concerning children up to the age of 2 years old, to be kept for 22 years.
- 2. After the period mentioned in paragraph 1, an entity providing health services, shall destroy medical documentations in a way that prevents identification of the patients concerned.
- 3. After the expiry of the periods referred to in paragraph 1, handling medical documentations being archival materials within the meaning of the Act of 14 July 1983 on National Archival Resources and Archives (Journal of Laws of 2011 No. 123, item 698 and No. 171 item 1016), shall be subject to the regulations issued pursuant to Art. 5 paragraphs 2 and 2b of this Act.
- **Art. 30.** 1. The minister responsible for health, after consulting the Supreme Council of Nurses and Midwives and the National Council laboratory diagnosticians, shall determine, by a regulation, the types and extent of medical documentations, how they are processed and the models of certain types of medical documentations, in particular, a model book of a child's health, taking into account the types of entities providing health services and the



need to ensure the right of access to medical documentations, its diligent performance, data protection and protection of information on the health condition of a patient and uniform models of medical documentations being essential to a rapid and effective delivery of health services.

- 2. The Minister responsible for Internal Affairs, the Minister of Justice, in consultation with the minister responsible for health, and after consulting the Supreme Medical Council, the Supreme Council of Nurses and Midwives and the National Council laboratory diagnosticians, and the Minister of National Defense, in consultation with the minister responsible for health issues, after consulting the Medical Council of Military Medical Association, each within their own sphere of action, shall determine, by a regulation, the types and extent of medical documentations, how they are processed and the models of certain types of medical documentations, in particular, a model book of a child's health, taking into account the types of entities providing health services and the need to ensure the right of access to medical documentations, its diligent performance, data protection and protection of information on the health condition of a patient and uniform models of medical documentations being essential to a rapid and effective delivery of health services.
- **Art. 30a.** The provisions of Art. 26-29 and the regulations issued pursuant to art. 30 apply to entities that keep and make available medical documentations after the cessation of the provision of health services by the entity providing health services.

Chapter 8

Patient's right to object to the opinion or the judgment of a physician

- **Art. 31.** 1. A patient or his legal representative may object to the opinion or judgment referred to in Art. 2, paragraph 1 of the Act of December 5, 1996 on Professions of doctor and dentist, if the opinion or judgement affects the rights or obligations of the patient under the law.
- 2. The objection shall be submitted to the Medical Committee acting at the Patient Rights' Ombudsman, through the Patient Rights' Ombudsman within 30 days from the date of the opinion or judgment of the adjudicating physician.
- 3. The objection must be justified, including an indication of the provision in the law which gives rise to the rights or obligations referred to in paragraph 1.
- 4. In the event of a failure to comply with paragraph 3, the objection is returned to the person who filed it.
- 5. The Medical Committee, basing on medical documentation and, if necessary, after examining the patient, shall give a judgement immediately, but no later than within 30 days from the date of filing the objection.
- 6. The Medical Committee issues a judgement by an absolute majority of votes in the presence of the full composition of that committee.
 - 7. There can be no appeal to the Medical Committee's decision.
- 8. The provisions of the Code of Administrative Procedure shall not apply to the proceedings before a Medical Committee.
- 9. Paragraphs 1-8 do not apply in the case of appeal proceedings in respect of opinions and judgments, governed by separate regulations.



- **Art. 32.** 1. The Medical Committee shall consist of three physicians appointed by the Patient Rights' Ombudsman from the list referred to in paragraph 2, including two of the same specialty as the physician who issued the opinion or the judgement referred to in Article 31, paragraph 1.
- 2. National consultants, in consultation with the relevant regional consultants, draw up a list of physicians in the given medical field who may be members of the Medical Committee once a year on or before March 30.
- 3. By virtue of participation in a Medical Committee, a physician is entitled to remuneration established by the Patient Rights' Ombudsman.
- 4. Operating expenses of the Medical Committee are financed from the state budget, part of which is at the disposal of the Patient Rights' Ombudsman.
- 5. The minister responsible for health, after consulting the Supreme Medical Council, shall determine, by regulation, the modus operandi of the Medical Committee, taking into account the efficiency of the implementation of patient rights.

Patient's right to respect for privacy and family life

- **Art. 33.** 1. A patient of a medical entity performing stationary and 24-hour medical activities under the provisions on medical activity has the right to personal, telephone or correspondence contact with others.
 - 2. A patient has the right to refuse contact with the persons mentioned in paragraph 1.
 - Art. 34. 1. A patient has the right to an extra nursing care.
- 2. The extra nursing care referred to in paragraph 1 is understood as the care that does involve the provision of health services, including the care exercised over a patient in terms of pregnancy, childbirth and postpartum.
- **Art. 35.** 1. A patient bears the costs of the rights referred to in Art. 33, paragraph 1 and Art. 34, paragraph 1, if the implementation of these rights results in costs incurred by the medicinal entity performing stationary and 24-hour medical activities under the provisions on medical activity.
- 2. The fee to compensate for the costs referred to in paragraph 1 shall be established by the head of the entity, taking into account the actual costs of the rights referred to in Art. 33, paragraph 1 and Art. 34, paragraph 1.
- 3. Information about the fee referred to in paragraph 2 and how it is determined is public and available at the premises of the entity referred to in paragraph 1.

Chapter 10

Patient's right to pastoral care

- **Art. 36.** A patient staying in a medical entity carrying out stationary and 24-hour medical activities under the provisions on medical activity has a right to pastoral care.
- **Art. 37.** In case of health deterioration or a threat to life, the entity referred to in Art. 33, paragraph 1 is obliged to allow a patient to contact a priest.



Art. 38. The medicinal entity bears the costs of the rights of the patient referred to in Articles 36 and 37, unless otherwise provided by the law.

Chapter 11

Patient's right to deposit valuables

- **Art. 39.** A patient staying in a medical entity carrying out stationary and 24-hour medical activities under the provisions on medical activity has the right to deposit valuables. The costs of implementing this law shall be borne by the entity, unless otherwise provided by the law.
 - Art. 40. The minister responsible for health matters shall establish, by a regulation:
- 1) the scope of the list of items to be deposited,
- 2) the method of securing deposited objects,
- 3) the manner and conditions for keeping and storing a deposit book
- bearing in mind ensuring a proper implementation of the patient right referred to in Art. 39.

Chapter 12

Patient rights' ombudsman

- **Art. 41.** In order to protect the patients' rights defined in this Act and other regulations a Patient Rights' Ombudsman is established, hereinafter referred to as the "Ombudsman".
- **Art. 42.** 1. The Ombudsman is the central organ of the government administration competent in matters concerning the protection of patients' rights set out in this Act and other regulations.
 - 2. The Prime Minister supervises the activities of the Ombudsman.
- 3. The Ombudsman performs his duties through the Office of the Patient Rights' Ombudsman, hereinafter referred to as the "Office ".
 - Art. 43. 1. The Ombudsman can be a person who fulfills the following criteria:
- 1) he/she has at least a university degree and a master's degree or its equivalent;
- 2) he/she has not been finally sentenced for a crime committed intentionally;
- 3) the condition of his/her health enables proper exercise of the function of the Ombudsman;
- 4) he/she has the knowledge and experience which guarantee the proper exercise of the function of the Ombudsman.
 - 2. The Ombudsman cannot:
- 1) hold any other position except for the position of a professor of a higher education entity, perform any other professional activities;
- 2) belong to a political party;
- 3) perform public activities incompatible with the duties and the dignity of his office.
- **Art. 44.** 1. The Ombudsman is appointed by the Prime Minister from among persons selected through an open and competitive recruitment.



- 2. Information about a vacancy for the position of the Ombudsman shall be announced by placing an advertisement in a public place at the headquarters of the Office and in the Public Information Bulletin referred to in the Act of 6 September 2001 on Access to Public Information (Journal of Laws No 112, item 1198, as amended) and the Public Information Bulletin of the Prime Minister's Office. The advertisement should include:
- 1) the office name and address;
- 2) the position determination;
- 3) requirements relating to the position, under the law;
- 4) the scope of the tasks to be performed;
- 5) indication of the required documents;
- 6) date and place for the submission of documents;
- 7) information on the recruitment methods and techniques.
- 3. The time referred to in paragraph 2, point 6 may not be less than 10 days from the date of the publication of the advertisement in the Public Information Bulletin of the Prime Minister's Office.
- 4. Recruitment for the position of the Ombudsman shall be conducted by a team appointed by the minister responsible for health, composed of at least three people whose knowledge and experience warrant selecting the best candidates. The course of recruitment shall include assessments of professional experience, knowledge necessary to perform the tasks in the Office for which the recruitment is carried out and managerial skills.
- 5. The assessment of the knowledge and managerial skills referred to in paragraph 4 can be performed on behalf of the team by a person who is not a member of the team but is qualified to perform such an assessment.
- 6. Members of the team and the person referred to in paragraph 5 have a duty to keep the information on persons applying for the position obtained in the course of recruitment confidential.
- 7. In the course of the recruitment, the team selects no more than three candidates to be presented to the Prime Minister.
- 8. The recruitment conducted shall be followed by a report prepared by the team and including:
- 1) the office name and address;
- 2) description of the position for which the recruitment took place and the number of candidates;
- 3) the names and addresses of no more than the top three candidates in order of the fulfillment of the requirements specified in the advertisement;
- 4) information about the methods and techniques of recruitment;
- 5) reasons for the selection of either of the candidates or reasons for not selecting any;
- 6) the team members.
- 9. The result of the recruitment shall be announced immediately by placing information in the Public Information Bulletins referred to in paragraph 2. The information on the recruitment results shall include:
- 1) the office name and address;
- 2) description of the position for which the recruitment took place;
- 3) the names of the candidates selected and their place of residence within the meaning of the Civil Code or information about not selecting any candidate.
- 10. Placing the vacancy advertisement and the results in the Public Information Bulletin of the Prime Minister's Office is free of charge.
- **Art. 45.** The Ombudsman is dismissed by the Prime Minister. The Ombudsman fulfills his/hers duties until the appointment of a successor.



- **Art. 46.** 1. The Ombudsman performs his tasks with the assistance of no more than two deputies.
- 2. Prime Minister shall appoint and dismiss Deputy Ombudsmen at the request of the Ombudsman.
 - 3. The Deputy Ombudsman shall be a person that meets the following criteria:
- 1) he/she has at least a university degree;
- 2) he/she has not been finally sentenced for a crime committed intentionally;
- 3) his/her health condition enables the proper exercise of the functions of the Deputy Ombudsman;
- 4) he/she has the knowledge and experience which guarantee the proper exercise of the function of the Deputy Ombudsman.
- 4. One of the deputies of the Ombudsman is obliged to have at least a university degree in medical science and a master's degree or its equivalent.
 - 5. The Deputy Ombudsman cannot:
- 1) hold any other position, except for being a professor of higher education, nor perform any other professional activities;
- 2) belong to a political party;
- 3) perform public activities incompatible with the duties and the dignity of the Office.

Art. 47. 1. The scope of activities of the Deputy Ombudsman includes:

- 1) conducting proceedings in cases of practices infringing collective rights of patients;
- 2) conducting proceedings under Art. 50-53;
- 3) performing activities in the civil cases referred to in Art. 55;
- 4) developing and submitting to the Council of Ministers draft laws relating to the protection of patients' rights;
- 5) applying to competent organs for legislative initiative or the issuance or amendment of legislation for the protection of patients' rights;
- 6) development and production of publications and educational programs promoting awareness of the protection of patients' rights;
- cooperation with public authorities in order to ensure that patients adhere to their rights, in particular the minister responsible for health;
- 8) providing the competent public authorities, organizations and institutions, and selfgovernments of medical professions with assessments and proposals to ensure effective protection of patients' rights;
- 9) cooperation with non-governmental organizations, social and professional organizations the statutory objectives of which include the protection of patients' rights;
- 10) analysis of patients' complaints in order to identify the risks and areas of the health care system in need of repair;
- 11) performing other tasks specified in the law or ordered by the Prime Minister.
- 2. The bodies and institutions to which the Ombudsman applied, as set out in paragraph 1, points 5 and 8 are obliged to respond to such applications within 30 days of their receipt.
- **Art. 48.** The Ombudsman can request the Civil Rights' Ombudsman or the Children Rights' Ombudsman for Children to take measures within their competence.
- **Art. 49.** The Ombudsman and the Deputy Ombudsman cannot carry out activities incompatible with the duties of their Offices.
- **Art. 50.** 1. The Ombudsman commences an investigation if he/she becomes aware of information at least making a violation of patients' rights probable, including in particular:
- 1) identification of the applicant;
- 2) identification of the patient whose rights are concerned;
- 3) brief description of the facts.



- 2. The application addressed to the Ombudsman is free of charge.
- 3. The ombudsman can commence an investigation on its own initiative, taking into account in particular the obtained information at least making violation of patients' rights probable.
 - **Art. 51.** The Ombudsman, having reviewed the application addressed to him, can:
- 1) take up the case,
- 2) only instruct the applicant on the legal measures that he or the patient is entitled to,
- 3) refer the case according to its jurisdiction,
- 4) not take up the case,
- notifying the applicant and the patient concerned.
 - **Art. 52.** 1. In the case referred to in Art. 51, point 1, the Ombudsman can:
- 1) independently conduct an investigation;
- 2) request competent authorities, in particular regulators, prosecutors, state, professional or social control, in accordance with their competences to examine the case or part thereof.
- 2. Conducting the proceedings referred to in paragraph 1, point 1, the Ombudsman has the right to:
- 1) examine, even without any notice, any matter on the spot;
- demand clarification or presentation of files of each case dealt with by the supreme and central state administration bodies, state administration bodies, bodies of NGOs, social and professional organizations and the bodies of organizational units with legal personality, as well as local government bodies and local government organizational units and local government health professions;
- 3) request information on the status of the case carried out by courts and a prosecutor's office and other law enforcement authorities and request examination of court and prosecutors' records at their offices and the records of other law enforcement bodies, after an investigation and its settlement;
- 4) order expertise and opinions.
- 3. The Ombudsman shall refuse to disclose the names and other personal information of a patient, including those for public authorities, if he/she deems it necessary to protect the rights of the patient, unless otherwise provided by the law.
 - Art. 53. 1. Following a clarifying investigation, the Ombudsman can:
- 1) explain to the applicant and to the patient at issue that he/she found no violation of patients' rights;
- direct a petition to the authority, organization or institution in which he/she found a violation of patients' rights; such a petition cannot affect the independence of the judiciary;
- 3) refer to the parent body of the entity referred to in paragraph 2 with an application for the use of the measures provided for in the law.
- 2. In the case referred to in paragraph 1, point 1, the Ombudsman also informs the entity providing health services concerned with the alleged infringement of patients' rights about finding no violation of patients' rights.
- 3. In the case referred to in paragraph 1, point 1, the applicant is entitled to request a reexamination of the case. Art. 127 § 3 of the Code of Administrative Procedure shall apply mutatis mutandis.
- 4. The petition referred to in paragraph 1, point 2, includes the Ombudsman formulated opinions or conclusions as to how the case was settled and can demand disciplinary proceedings or impose official sanctions.





- 5. The body, organization or institution to which such a petition was addressed, as referred to in paragraph 1, point 2, are obliged immediately, but no later than within 30 days, to inform the ombudsman of the actions taken or the position taken. If the Ombudsman does not share the position, he/she cab apply to the competent authority with a motion to apply the measures provided for in the law.
- **Art. 54.** To the extent not covered by Art. 49-53, the proceedings conducted by the Ombudsman are subject to the provisions of the Code of Administrative Procedure.
- **Art. 55.** In the case of civil cases concerning violations of patients' rights set out in this Act and other regulations, the Ombudsman can, at his own initiation or after an application:
- 1) request an initiation of proceedings,
- 2) participate in the ongoing proceedings
- with a prosecutor's rights.
- **Art. 56.** The Psychiatric Patient Rights' Ombudsmen referred to in the Act of 19 August 1994 on Mental health protection (Journal of Laws of 2011 No. 231, item 1375) are employees of the Office and perform their tasks with the help of this Office.
- **Art. 57.** The Office organization and its specific mode of action is determined by the statute under a regulation of the Prime Minister.
- **Art. 58.** 1. The Ombudsman annually submits to the Council of Ministers, no later than on 31 July of the following year, a report on abiding patient rights on the territory of poland.
- 2. The Council of Ministers submits the report referred to in paragraph 1, along with its position on this report, to the Polish Parliament, no later than on 31 August of the following year.

Proceedings in cases of practices infringing collective patients' rights

- Art. 59. 1. A practice infringing collective patients' rights is understood as:
- 1) unlawful concerted action or failure to act of health service providers,
- 2) organizing, contrary to the provisions on resolving labor disputes, as confirmed by a final court decision, a protest action or a strike by the strike organizer
- aimed at deprivation patients of their rights or restricting these rights, especially in order to achieve financial gain. The sum of individual rights is not a collective patient right.
 - 2. It is forbidden to exercise practices infringing collective patients' rights.
- 3. Protection of collective patients' rights provided for in the Act does not preclude protection under other laws, in particular the provisions on unfair competition, regulations on competition and consumer protection, and provisions concerning combating unfair commercial practices.
- **Art. 60.** A party to the proceedings is anyone who applies for a decision on practices infringing collective patients' rights or against whom proceedings have been commenced on the application of such a practice. Applicants for a decision on practices infringing collective patient rights are subject to the provisions of Art. 50, paragraphs 1 and 2.



- **Art. 61.** 1. In proceedings concerning the application of practices infringing collective patints' rights, the Ombudsman has the right to demand documents and any information regarding the circumstances of practices for which there is reasonable suspicion that they have the nature of practices infringing collective patients' rights, no later than 30 days from the date of the receipt of the request.
 - 2. The request referred to in paragraph 1 should contain:
- 1) indication of the scope of information;
- 2) indication of the purpose of the request;
- 3) indication of the time limit for providing information;
- 4) instruction about sanctions for failure to provide information or providing false or misleading information.
- 3. Everyone has the right to submit in writing on his own initiative or at the request of the Ombudsman clarifications relating to the relevant circumstances of the violation of patients' rights.
- **Art. 62.** The Ombudsman issues an order to initiate proceedings on practices infringing collective patients' rights and notifies the parties.
- **Art. 63.** 1. The Ombudsman shall refuse, by a decision, to initiate proceedings if the act or omission clearly does not fulfill the conditions laid down in Art. 59, paragraph 1 or if the applicant for a decision recognizing the practice as infringing collective patient rights fails to provide prima facie evidence of depriving patients of their rights or limiting such rights.
- 2. The ombudsman can refuse to issue a decision, initiate proceedings, if he deems it justified.
- **Art. 64.** 1. In the event that the Ombudsman issues a decision to identify a practice as infringing collective patients' rights, he orders the abandonment of it or points actions necessary to remove the effects of the infringement of collective patient rights, setting deadlines for their adoption. The decision is immediately enforceable.
- 2. The Ombudsman's decision referred to in paragraph 1 can impose on the entity providing health services or the organizer of a strike an obligation to file, within the determined time, information on the progress of the actions necessary to refrain from practices infringing collective patients' rights or to remove the effects of the infringement of collective patient rights.
- 3. The decision referred to in paragraph 1 shall not be issued, if the entity providing health services or the organizer of a strike stopped the practice referred to in Art. 59, paragraph 1.
- 4. In the case referred to in paragraph 3, the Ombudsman shall issue a decision recognizing the practice as infringing collective patients' rights and declare its discontinuity.
- 5. The burden of proving the circumstances referred to in paragraph 3 rests on the entity providing health services or the organizer of a strike.
- **Art. 65.** The Ombudsman's decisions are final. In the absence of the provisions of this Chapter and Chapter 14 regulating proceedings concerning practices infringing collective patients' rights, the provisions of the Administrative Code shall be in force.
 - **Art. 66.** 1. The Ombudsman's decision can be appealed to the administrative court.
 - 2. The administrative court shall review the complaint immediately.



Art. 67. No investigation shall be initiated on the application of practices infringing collective patients' rights, if a year elapsed after the end of the year in which such practices were discontinued.

Chapter 13a

Rules and procedure for determining compensation and redress for medical events

- **Art. 67a.** 1. The provisions of this chapter shall apply to infecting a patient with a biological pathogen, a bodily harm or health impairment of a patient or a patient's death following a non-compliance with the current medical knowledge in the case of:
- 1) a diagnosis, if it resulted in an inappropriate treatment or delayed an appropriate treatment, contributing to the development of the disease,
- 2) treatment, including surgery,
- 3) the use of a medicinal product or a medical device
- hereinafter referred to as a "medical event".
- 2. The provisions of this Chapter shall apply to medical events resulting from the provision of health services in a hospital, under the provisions on medical activity.

Art. 67b. 1. In the case of:

- 1) the infection, bodily harm or health impairment referred to in Art. 67a, paragraph 1 a patient or his legal representative may submit a request to establish a medical event,
- 2) the death, referred to in Art. 67a, paragraph 1 a request to establish a medical event can be submitted by a patient's heirs
- hereinafter referred to as "the applicant entities".
- 2. Proceedings before a regional committee for the adjudication of medical events referred to in Art. 67e, paragraph 1:
- are suspended in the case of proceedings pending in connection with the same event for professional liability of the person performing the medical profession or criminal proceedings relating to an offense;
- 2) shall not be commenced and any commenced shall be discontinued when a case for compensation or redress in cash has been finally judged in connection with the same event or there are pending civil proceedings in this case.
- 3. In the event of termination of the proceedings referred to in paragraph 2, point 1, the proceedings before the regional committee for the adjudication of medical events, referred to in Art. 67e, paragraph. 1, shall be ex officio.
- **Art. 67c.** 1. An application to establish a medical event, hereinafter referred to as an "application", shall be submitted to a regional committee for adjudication on medical events with jurisdiction over the seat of the hospital.
- 2. The application must be filed within one year from the date on which the applicant entity learned of the infection, injury or health or death of a patient, as referred to in Art. 67a., paragraph 1, but the time cannot be longer than 3 years from the date of the event resulting in the infection, bodily harm or health impairment or the death of a patient.
- 3. Submission of an application which resulted in a regional committee for adjudication of medical events, referred to in Art. 67e, paragraph 1, issued a judgement on a medical event, interrupts the time limits for bringing claims specified in the provisions of the Civil Code arising from the events covered by the application.
- 4. In case of a patient death, as referred to in Art. 67a., paragraph 1, the period referred to in paragraph 2 does not run until the end of the succession proceedings.





Art. 67d. 1. The application includes:

- 1) patient information:
 - a) first name and surname,
 - b) date of birth,
 - c) social security number or the series and number of an identity document, if applicable;
- 2) name and surname of a legal representative, if applicable;
- 3) names and surnames of all the heirs, if applicable;
- 4) indication which of the heirs represents the others in the proceedings before the regional committee for the adjudication of medical events referred to in Art. 67e, paragraph 1, if applicable;
- 5) address for service;
- 6) data of the medicinal entity running the hospital:
 - a) company,
 - b) registered address and the address of the hospital, if applicable;
- 7) justification for the application containing become real events which resulted in an infection, bodily harm, health impairment or a patient death referred to in Art. 67a., paragraph 1, as well as damage to property or pecuniary;
- 8) indication of whether the application's subject is an infection, a bodily harm, a health impairment or a patient death referred to in Art. 67a., paragraph 1;
- 9) proposal for the amount of compensation and redress, not higher than that specified in Art. 67k, paragraph 7.
 - 2. The application shall include:
- 1) prima facie evidence of circumstances indicated in the application;
- 2) a proof of payment of the fee referred to in paragraph 3;
- 3) a decision on the acquisition of inheritance in the case referred to in Art. 67b., paragraph 1, point 2 and a power of attorney to represent the other heirs in the event of an application submitted by at least one of them.
- 3. Submission of an application is subject to a fee of 200 PLN. The fee shall be credited towards the costs of the proceedings before a regional committee for the adjudication of medical events.
- 4. The fee referred to in paragraph 3 is payable on account of the competent regional office.
- 5. An incomplete or improperly paid application is returned to the applicant without a review.
- 6. A complete and duly paid application shall be immediately, by a regional committee for adjudication of medical events referred to in Art. 67e, paragraph 1, transferred to the head of the entity running the medicinal hospital, the activity of which is referred to in the application, and the insurer referred to in Art. 67i, paragraph 2, point 2. The head of the entity and the insurer shall present their position within 30 days of the receipt of the application and evidence in support of the position. Failure to present a position constitutes acceptance of the application on the circumstances indicated therein, and the proposed amount of compensation and redress.
- **Art. 67e.** 1. Regional committees for the adjudication of medical events are established, hereinafter referred to as "regional committees". The seat of regional committees is the seat of the competent regional governor office.
- 2. Performing tasks of a regional committee does not constitute exercising powers of an official authority.



- 3. A regional committee consists of 16 members, including:
- 8 members holding at least a university degree and a master's degree or its equivalent in a medical science who performed a medical profession for at least five years or have a doctoral degree in a medical science,
- 2) 8 members holding at least a university degree and a master's degree in legal sciences who were employed at positions related to the use or creation of the law for at least 5 years or hold a doctoral degree in the field of legal sciences
- who have knowledge of patients' rights and enjoy full civil rights.
 - 4. Members of a regional committee cannot persons:
- 1) finally sentenced for an intentional crime or an intentional tax crime;
- 2) finally sentenced for a punishment of professional or disciplinary liability;
- 3) with a legally binding decision on a penal measure specified in Art. 39, point 2 or 2a of the Penal Code.
 - 5. From among the members of a regional committee:
- 1) 14 members are appointed by a regional governor, whereas:
 - a) 4 members are persons appointed from among candidates proposed by the professional associations of doctors, dentists, nurses and midwives and laboratory diagnosticians, established in the region,
 - b) 4 members are persons appointed from among candidates proposed by local professional advocacies and a self-government of legal advisers, established in the region,
 - c) 6 members are persons appointed from among candidates proposed by social organizations operating in the region for the benefit of patients' rights;
- one member is appointed by each, the minister responsible for health and Patient Rights' Ombudsman.
- 6. The entities referred to in paragraph 5, paragraph 1 shall provide and the minister responsible for health and the Patient Rights' Ombudsman appoint candidates for members of a regional committee not later than 6 months before the expiry of the term of office of a provincial committee and, if a member of a regional committee is dismissed before the end of the term within the deadline set by a regional governor.
- 7. The term of the regional committee is 6 years. Where a member of a regional committee is dismissed before the end of the term under paragraph 9, the term of the office of a member appointed in the place shall expire on the date of expiry of the term of office of the regional committee.
- 8. The provisions of paragraphs 6 and 7 shall apply mutatis mutandis in the case of a death of a member of a regional committee.
- 9. A member of a regional committee is dismissed before the end of the term by the authority which appointed him/her, in the case of:
- 1) resignation;
- 2) illnesses permanently preventing performance of the duties;
- 3) circumstances specified in Art. 67g, paragraph 1;
- 4) failure to submit the declaration referred to in Article 67g, paragraph 4;
- 5) circumstances referred to in paragraph 4;
- 6) evading the performance of the duties of a regional committee member or their improper performance.
- 10. The employer of a person appointed to be a member of a regional committee is informed on the fact and the dates of the committee's meetings.
- 11. The work of the regional committee is run by a chairman 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.

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- 12. The date of the first meeting of a regional committee is determined by a regional governor. The first meeting, until the election of a Chairman referred to in paragraph 11, is chaired by a member of the regional committee appointed by the governor.
- 13. Regional committees operate pursuant to regulations adopted by themselves, whereas:
- 1) resolutions of a regional committee are taken by a simple majority of votes, unless otherwise provided in the law;
- 2) in the case of an equal number of votes, the chairman's vote is decisive;
- 3) no member of a regional committee can abstain from voting;
- 4) meetings of a regional committee are minuted.

Art. 67f. 1. Regional committees have jurisdiction with a 4-seat composition.

- 2. An adjudication panel of a regional committee, hereinafter referred to as an "adjudicating panel" shall be designated by the chairman of a regional committee according to the order of receipt of applications to establish a medical event from the alphabetical list of the members of a regional committee, and 2 members of the panel meet the requirements referred to in Art. 67e, paragraph 3, point 1 and 2 members of the panel meet the requirements referred to in Art. 67e, paragraph, 3, point 2. Any derogation of this order is allowed only for the reasons specified in Art. 67g, paragraph 2.
- 3. The panel is headed by a chairman. The term of the first meeting of the panel and its chairman is designated by a regional committee chairman.
- **Art. 67g.** 1. Members of an adjudication panel, their spouses, descendants and ascendants in a straight line cannot be:
- 1) owners, employees or people cooperating with the entity running the hospital or the insurer referred to in Art. 67i, paragraph 2, and members of the authorities of that entity or insurer;
- 2) members of organs and persons employed in the creating entity in the meaning of the provisions on medical activity, if the entity established a non-entrepreneur medicinal entity who runs the hospital referred to in Art. 67i, paragraph2, point 1;
- 3) holders of shares representing more than 10% of the share capital in commercial companies that run the hospital referred to in Art. 67i, paragraph 2, point 1, and the insurer referred to in Art. 67i, paragraph 2, point 2.
 - 2. A member of a panel shall be excluded from proceedings in cases in which:
- he/she is the entity applicant or is with the entity in such a legal relation that the outcome of the proceedings before a regional committee has an impact on its rights and obligations;
- 2) is with the applicant entity in such a personal relationship that it raises doubts as to his impartiality;
- 3) the applicant entity is his spouse, relative or relative by marriage in a straight line, a side relative to the fourth degree and a lateral relative to the second degree;
- 4) the applicant entity is related to him by way of an adoption, a custody or a guardianship;
- 5) was or is a proxy or a legal representative of the applicant entity.
- 3. Reasons for exclusion of a member of an adjudication panel also last after termination of a marriage, an adoption, a guardianship or a custody.
- 4. Prior to an appointment to the adjudication panel, members of a regional committee make a statement about the absence of circumstances referred to in paragraph 1 and 2, a "conflict of interest statement".

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- 5. Members of a provincial committee are bound to keep the patient information obtained during the proceedings before the committee secret, including the period after leaving the committee.
- 6. The provisions of paragraphs 1-5 shall also apply to non-members of a regional committee that the committee commissioned a review to.
- 7. The minister responsible for health matters shall establish, by a regulation, a model declaration of interests with a view to obtaining full information about the circumstances referred to in paragraphs 1 and 2.

Art. 67h. 1. Members of an adjudication panel are entitled to:

- 1) remuneration in the amount not exceeding 430 PLN for participation in the meeting;
- 2) reimbursement of travel costs in the amount and on the terms specified in regulations issued pursuant to art. 77⁵ § 2 of the Labour Code;
- 3) dismissal from work on the day of the committee meeting, without retaining the right to remuneration.
- 2. The amount referred to in paragraph 1, point 1, is subject to adjustment, taking into account the average annual growth rate of wages in the government sector, adopted in the Budget Act.
- 3. Activities of a regional committee are financed from the state budget, from the part in the disposal of the competent regional governor. The amount of remuneration referred to in paragraph 1, point 1 shall be established by a relevant regional governor.
- **Art. 67i.** 1. The purpose of the proceedings before a regional committee is to determine whether the event which resulted in a property or non-pecuniary damage, was a medical event.
- 2. The meeting of a regional committee, except for the part of a meeting during which a voting and a ruling are held, can be attended by the entity applicant and a representative if:
- 1) the head of the medicinal entity running the hospital the activity of which is involved in the application to establish a medical event;
- 2) the insurer with which the medicinal entity running the hospital identified in paragraph 1 concluded the policy set out in the regulations on medical activity.
- 3. The date of the meeting shall be notified to the applicant and the manager of the medicinal entity running the hospital and the insurer referred to in paragraph 2. The notice shall be served at least 7 days before the meeting.
 - 4. In order to issue a judgement, a regional committee can call for clarification:
- 1) the applicant entity;
- 2) the manager of the medicinal entity running the hospital the activity of which is related in the application;
- 3) those who perform medical profession in the medicinal entity running the hospital and others who were its employees or were otherwise related to it in the period in which, according to the application, the medical event took place or those who were indicated in the application as people who could possess information relevant to the case pending before a regional committee;
- 4) the insurer referred to in Art. 67i, paragraph 2, point 2;
- Calls shall be served at least 7 days prior to the date of the meeting.
- 5. During proceedings, a regional committee considers the evidence presented by the applicant and the manager of the medicinal entity running the hospital the activity of which is related to in the applicant and the insurer referred to in Art. 67i, paragraph 2, point 2. A regional committee can also, within the procedure:





- request the documentation kept by the medicinal entity running the hospital, including medical documentation;
- 2) carry out an investigation in the medicinal entity running the hospital;
- 3) visits the premises and facilities of the hospital.
- 6. The actions referred to in paragraph 5, points 2 and 3, shall be subject to a protocol drawn up and signed by the members of the regional committee and individuals involved in these actions. Refusal or inability of signing the protocol shall be stated in it.
- 7. If ascertaining circumstances which are important for the judgment requires special knowledge, a regional committee consults a doctor in the medical field from the list referred to in Article 32, paragraph 2, or a regional consultant in the field of medicine, pharmacy or other applicable in the field of health.
- **Art. 67j.** 1. A regional committee, after a deliberation, issues, in writing, a decision on a medical event or a lack of it, with a justification.
- 2. A regional committee shall issue the decision referred to in paragraph 1 no later than within 4 months from the date of filing the application.
- 3. A decision of a regional committee is taken by a majority of at least 3/4 of the votes in the presence of all the members of the adjudicating panel.
- 4. A decision of a regional committee is drawn up in two copies signed by all of the members of the adjudicating panel. A member of a panel who disagreed with the majority can express a different opinion and must justify it in writing in time for a preparation of a justification of the verdict within the period referred to in paragraph 5.
- 5. The chairman of the adjudicating panel at the regional committee meeting during which the judgment was issued, shall announce its contents, citing the main reasons for the decision. A justification shall be prepared within 7 days from the date of issuing the decision.
 - 6. The decision and the reasons shall be delivered to:
- 1) the applicant entity,
- 2) the head of the medicinal entity running the hospital and the insurer referred to in Art. 67i, paragraph2
- not later than within 7 days from the date of the expiry of the period referred to in paragraph 5.
- 7. The head of the medicinal entity running a hospital and the insurer referred to in Art. 67i, paragraph 2 are entitled to submit to a regional committee a reasoned request for a retrial within 14 days of the service of the decision and the reasons to the applicant.
- 8. An application for a retrial is considered by a regional committee within 30 days of its receipt. Considering the application cannot involve a member of the panel who participated in the issue of the contested decision. The provisions of paragraphs 1, 3-6 and Art. 67g-67i shall apply.
- 9. A regional Committee shall notify the entities entitled to apply for a retrial on the expiry of the deadline referred to in paragraph 7.
- **Art. 67k.** 1. Within the scope regulated by this Act, the insurer is bound by the decision of a regional committee.
 - 2. The insurer, via a provincial commission, within 30 days from the date of:
- 1) the receipt of the notice referred to in Art. 67j, paragraph 9,
- 2) the delivery of the judgment of a regional committee about a medical event issued due to an application for a retrial
- shall submit a proposal of compensation or redress to the applicant. The proposal cannot be higher than the maximum amount of compensation and redress referred to in paragraph 7.



- 3. Where an insurer fails to submit a proposals of compensation within the period referred to in paragraph 2, the insurer is obliged to pay the amount specified in the application, not higher than that specified in paragraph 7.
- 4. In the case referred to in paragraph 3, a regional committee shall issue a certificate which states that an application to establish a medical event was filed, the amount of compensation or redress, and the failure to propose the compensation and redress referred to in paragraph 3. This certificate shall be enforceable. The provisions of Chapter II of Title I of Part Three of the Code of Civil Procedure shall apply.
- 5. An applicant, within 7 days from the date of the receipt of the proposal referred to in paragraph 2, files, via a regional committee, a declaration of its acceptance or rejection to the insurer.
- 6. Apart from the declaration of acceptance of the proposal referred to in paragraph 2, an applicant shall submit a statement waiving all claims for monetary damages for any harm that may result from the event recognized by a regional committee as a medical event in respect of damage revealed after the date of filing the application. A statement made by an heir representing other heirs, as referred to in Art. 67d, paragraph 2, point 3 is effective against the others.
- 7. The maximum benefit amount (compensation and redress) arising from one medical event for one patient in the case:
- 1) infection, bodily harm or health impairment amounts to 100,000 PLN,
- patient death amounts to 300,000 PLN.
- 8. In the case referred to in paragraph 6, the compensation and redress offered by the insurer is enforceable. The provisions of Chapter II of Title I of Part Three of the Code of Civil Procedure shall apply.
- 9. Presentation by the insurer of the proposal referred to in paragraph 2 or the payment of his compensation or redress, does not imply recognition of a claim for the purposes of his investigation in civil proceedings.
- 10. Paragraphs 1-9 and the regulations issued under paragraph 11, to the extent that relate to the insurer, apply to the medicinal entity running the hospital concerned:
- 1) exhaustion of the sum insured for all medical events in the hospital the effects of which are covered by the insurance policy referred to in Art. 25, paragraph 1, point 2 of the Act of 15 April 2011 on medical activity, or a failure to conclude it;
- 2) the payment of benefits under medical events pursuant to Art. 25, paragraph 1e, point 1 of the Act of 15 April 2011 on medical activity.
- 11. The minister responsible for health, after consulting the Supreme Medical Council, the Supreme Council of Nurses and Midwives, the National Council of laboratory diagnosticians and the Polish Chamber of Insurance shall determine, by a regulation, the detailed scope and conditions for establishing the amount of the benefit referred to in paragraph 7, and its amount for one patient for each type of a medical event, taking into account the need to ensure protection of the interests of the patient and the need for transparency in the setting of the amount.
- **Art. 67I.** 1. The applicant entity can withdraw the application to establish a medical incident up to the decision following a request to reconsider the case, as referred to in Art. 67j, paragraph 8.
- 2. A regional committee discontinues proceedings considering the application to determine a medical event in the following cases:
- 1) as referred to in paragraph 1;
- 2) applicant's death;



- 3) revocation of the power of attorney, as referred to in Art. 67d, paragraph 2, point 3.3. Costs of the proceedings before a regional committee shall be born by:
- 1) the applicant entity in the case of a decision about the lack of a medical event;
- 2) the medicinal entity running a hospital in the case of a decision confirming a medical event;
- 3) the insurer in the case referred to in Art. 67k, paragraph 3.
- 4. The amount of the costs shall be determined by a regional commission in the decision. An amount equivalent to the costs shall be paid to the account of a competent regional office.
 - 5. The costs of proceedings before a regional committee represent:
- 1) the fee referred to in Art. 67d, paragraph 3;
- 2) reimbursement of travel and accommodation costs and lost earnings or income of the persons called by a regional committee;
- 3) remuneration for an opinion development.

Proceeds from the costs constitute the revenue of the state budget.

- 6. Expenses related to the service of calls and other writings of a regional committee and refunded fees are not charged to the entity applicant, the medicinal entity running a hospital and the insurer.
- 7. The minister responsible for health matters shall establish, by a regulation, a lump-sum amount of individual costs in the proceedings before a regional committee, with the aim of balancing the interests of patients and hospitals.
- **Art. 67m.** 1. An applicant entity, a medical entity running a hospital and an insurer can, within 30 days from the day of:
- 1) ineffective expiry of the deadline referred to in Article 67j, paragraph7,
- 2) the receipt of a decision issued as a result of an application for a retrial, as referred to in Art. 67j, paragraph 8
- bring an action against unlawfulness of a regional committee's decision. Such an action can be based only on infringement of provisions relating to proceedings before a regional committee.
- 2. Such a complaint shall, within 30 days of its receipt, be judged on by a regional committee composed of 6 members. The provisions of Art. 67c, paragraph 1, Art. 67f, paragraphs 2 and 3, and Art. 67g, 67h and Art. 67j, paragraph. 8, the second sentence, shall apply mutatis mutandis.
- **Art. 67n.** Declarations of interests, protocols and decisions with the reasons shall be kept by a regional governor for 10 years.
- **Art. 67o.** To the extent not regulated by the provisions of Art. 67a-67m, proceedings before a regional committee are subject to Art. 50, 51, 53 1 , 102, 131, 133-143, 150, 156, 157-158, 162, 164-172, 173-174, art. 180 § 1 point 1 and 3, art. 181 point 2, art. 206 § 1, art. 207 § 1, art. 210-213, 216, 217, 224, 225, 227-237, 240-242, 244-257, 258-273, 277, 280-289, 299-300, 316, 350, 353, 424 5 and 424 8 -424 12 of the Code of Civil Procedure.



Penalty payments

- **Art. 68.** The Ombudsman imposes, by a decision, a penalty payment of 500,000 PLN on an entity providing health services or an organizer of a strike in the absence of the actions set out in the decision referred to in Art. 64, paragraph 1, within the period specified in it.
- **Art. 69.** The Ombudsman imposes, by a decision, a penalty payment of 50,000 PLN on an entity requested in the event of not providing, at the Ombudsman's request, documents and information referred to in Art. 61.
- **Art. 70.** Determining the amount of the penalty payments referred to in Articles 68 and 69 shall take into account, in particular, the duration, extent and circumstances of violations of the law and also previous violations of the law.
- **Art. 71.** 1. The funds derived from the penalty payments referred to in Art. 68 and 69 constitute income of the state budget.
- 2. A penalty payment shall be subject to collection under the provisions on administrative enforcement proceedings.

Chapter 15

Final provision

Art. 72. This Act shall enter into force on the date specified in the Act - regulations implementing the Act on Patients' Rights and Patients' Rights Ombudsman, the Law on Accreditation of Healthcare and the Law of consultants in health care.

Repertory A No. 1037 / 2015

I, the undersigned, Sylwia Tomczyk M.A., a Sworn Translator entered in a register of sworn translators kept by the Minister of Justice under no. TP/1553/05, do hereby certify that the above translation is consistent with the Polish original document.

Pszów 09.11.2015

