New legal regulations on current medical problems

Nowe regulacje prawne dotyczące aktualnych problemów medycznych

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- legislation
- medical experiment
- vaccination against COVID-19
- data protection

ABSTRACT

The article consists of three parts showing the changes that took place in the health care law in 2021. The main goal was to discuss those legislative changes that, according to the authors, are innovative and in the future will have a significant impact on the shape of the entire health care system in Poland.

SŁOWA KLUCZOWE:

- legislacja
- eksperyment medyczny
- szczepienia przeciw COVID-19
- ochrona danych

STRESZCZENIE

Artykuł składa się z trzech części ukazujących zmiany, jakie nastąpiły w przepisach prawa w ochronie zdrowia w 2021 r. Podstawowym celem było omówienie tych zmian legislacyjnych, które zdaniem Autorów są innowacyjne a w przyszłości będą miały istotny wpływ na kształt całego systemu ochrony zdrowia w Polsce.

Introduction

The intensive development of modern medical and biotechnological techniques around the world poses modern man to questions that could not have arisen a few years ago. These radical changes are also taking place in Polish medicine. It is a breakthrough moment for the legal order, encouraging numerous studies and studies in this field.

In this publication, we took up three issues that were key to Polish legislation in 2021. First, the subject of the medical experiment and changes to the Act on the Professions of Physicians and Dentists. In this case, on the one hand, we see recognition for new technologies and their great potential in medicine, which is clearly visible in research on therapies and medical experiments, and on the other hand, there is a need to protect patients and introduce compulsory insurance for a medical experiment. Vaccination against COVID-19 shows us that new therapies are crucial also in prophylaxis. This is the second area where legal regulations have changed significantly. Vaccination against COVID-19 is a new challenge for medical personnel. It seems right to say that new medical knowledge (e.g., on preventive vaccinations based on new technologies) should be passed on to society not only by scientists, but also by practitioners, i.e., medical professionals, who are obliged to constantly improve their qualifications and competences. The third issue concerns an attempt to solve one of the problems of the health service, which was revealed with all its might during the COVID-19 pandemic – how to safely convey information about a patient to his relatives, in closed hospital wards.

Patient protection in the regulation of medical experiments

The analysis of the challenges posed by the Polish legislator in the development of medicine would not be complete if the legal regulations covering the medical experiment are disregarded. Amendment to the Act of December 15, 1996 on the professions of a doctor and dentist [hereinafter: Medical Act, Polish Law (1)] made by the Act of July 16, 2020 amending the act on the professions of doctor and physician and some other acts (2) significantly changed the regulations governing the principles of conducting a medical experiment. At the outset, it should be noted that, in the opinion of the project initiator, the amendment of these standards was necessary due to the fact that the then provisions on the medical experiment did not reflect its actual course, while maintaining the patients' rights, including with particular emphasis on pregnant women, prohibition of conducting experiments on a conceived child, soldier, incapacitated person, deprived of liberty (3).

These changes included both the amendment to the already functioning solutions (including the information obligation towards the participant of the experiment, competences to perform the function of the experiment director), as well as the introduction of new regulations, among which it is worth mentioning the obligation to insure the civil liability of the experiment, introducing groups of entities that are not they may be participants in research experiments (conceived child, incapacitated person, soldier, person deprived of liberty or detained), prohibiting financial gratuities and the possibility of conducting a therapeutic experiment

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without the required consent. Due to the volume of the publication in question, a detailed analysis of the new considerations will be limited to two very significant changes – the extension of the information obligation in relation to the legal status before the amendment and the new, previously unknown in Polish legislation, obligation to insure the experiment.

The issues of the information obligation in the case of conducting a medical experiment have been regulated by the legislator in Art. 24 u.z.l. and they differ significantly from the obligation to inform the patient (or his statutory representative) on general principles, regulated in Art. 31 of this act. This provision clearly indicates that it is the doctor who provides the patient or his representative with accessible information in a specific scope. Meanwhile, in Art. 24 u.z.l. it has not been specified who is directly responsible for providing the required information before agreeing to participate in a medical experiment, but there is no doubt that the doctor in charge of the experiment will be responsible for providing it. This information should be received not only by the person subjected to the experiment, but also (pursuant to Art. 25 of the Act on Civil Procedure) who may be directly affected by its effects. However, the legislator did not explain the status of this person. Another significant difference is, for example, the requirement to provide information about the experiment in two forms – oral and written.

The most important, however, are the differences in the scope of information provided, which now, after the amendment, has become very wide and definitely goes beyond the typical issues related to the use of a specific medical procedure. The regulations in force so far assumed the obligation to inform the person subjected to the experiment about the goals, methods and conditions of its conduct, as well as the expected benefits, risks and the possibility of withdrawing from the continuation of the experiment at every stage.

In the current legal status, the information obligation has been extended to the presentation of the full plan of the proposed experiment, presentation of the scope and duration of individual procedures, as well as the discussion of the nuisance and health risks associated with participation in this experiment. It has become a requirement to discuss the so-called adverse events, including how you respond to them. Importantly, the legislator unequivocally ordered to provide explanations and answer questions or raised doubts. In addition, the information obligation now also covers the discussion of measures taken to ensure respect for the participant's private life and the confidentiality of his personal data, as well as the rules of access to information relevant to the participant, obtained during its implementation, and to its general results. In addition, the participant of the experiment has the right to information on any foreseen further uses of its results, data and biological material collected during the experiment, including its use for commercial purposes. Separate issues are the rules for the payment of compensation in the event of damage and the source of financing a medical experiment. Finally, the participant of the experiment should obtain information on the rules of access to the experimental treatment after the end of participation in the therapeutic experiment, if it turns out that the experiment brought benefits to his health, as well as on the possibilities and rules of access to another therapeutic experiment, if it can benefit the participant's health.

Before starting a medical experiment, the participant should also be informed about his rights and about the protection guaranteed by law, in particular about his right to refuse to grant consent and to withdraw consent at any time, without giving a reason and without negative legal consequences in the form of any discrimination, including the right to healthcare. In a situation where the immediate interruption of the medical experiment could endanger the life or health of the participant, the person conducting the medical experiment is also required to inform him/her about this fact.

Reliably provided information is important for the legal effectiveness of the consent of the person subjected to the experiment. It is worth noting that the legislator has clarified the obligation to obtain consent also from a minor who has reached the age of 13. (and not as it was before: "if the minor is over 16 years of age or under 16 and is able to expressly express an opinion on his participation in the experiment, his consent is also required"). This change does not mean lowering the age, but only clarifying it. Therefore, the obligation to provide information in the above-mentioned scope will also materialize to a person consenting to participate in a medical experiment, if he or she is 13 years of age or older. It is also worth noting that similar competences to self-determination of a minor who turned 13 years of age (and thus a similar right to information prior to consent) was previously also included in the regulations on termination of pregnancy (4) or tissue collection (5).

The obligation for the entity conducting the medical experiment to conclude a third party liability insurance agreement applies to both types of medical experiment (6) – research [aimed at broadening medical knowledge – Article 21 (3) of the Act] and therapeutic [consisting in the introduction of new or only partially tested diagnostic, treatment or prophylactic methods in order to achieve direct benefits for the health of the sick person – Article 21 (2) uzl]. The addressee of the competence regulated in art. 23c u.z.l. is the entity carrying out the medical experiment. Despite the fact that the legislator used the term "subject conducting the experiment" and not "medical entity", it cannot be assumed that a medical experiment, the director of which can only be a doctor, was conducted in an entity that does not conduct medical activity. The consequence of the above is the de facto imposition of a new financial obligation on medical entities. While research experiments can also be carried out by research institutes operating in the field of medical sciences or health sciences, the place of conducting therapeutic experiments will be primarily a medical entity, most often a hospital. Therefore, it is impossible not to notice that the practical implementation of this obligation may limit the number of medical experiments, especially therapeutic ones, aimed at helping the participant of the experiment, when the methods used so far are ineffective or their effectiveness is insufficient. These experiments are not research studies and will therefore not be financial (including insurance) from the research subsidy. Hospitals in financial difficulties may refuse to conduct therapeutic experiments due to a lack of funds to cover the cost of insurance.

The conclusion of the insurance contract is undoubtedly an additional protection of the interests of the participant in the experiment and the person who may be directly affected by the effects of the experiment. Payment of compensation in the event of a failed experiment may allow the cost of additional treatment or adaptation of the living environment to the new health situation. It is doubtful, however, to recognize that the introduction of the insurance obligation contributed to the implementation of the patient's

rights, rather to securing his possible needs. In practice, the subject task of the entity conducting the experiment may contribute to increasing the positive opinion of the society about medical experiments, and thus – greater openness to participation in them.

Vaccinations COVID-19 as an example of expanding the competences and independence of medical personnel

The Centers for Disease Control and Prevention (CDC) in Atlanta regularly publishes a list of ten great achievements in the field of public health. In the 20th century, one of the first places was vaccination, which contributed to: fighting smallpox; elimination of poliomyelitis in the Americas; control of measles, rubella, tetanus, diphtheria, Haemophilus influenzae type b and other infectious diseases in the United States and other parts of the world (7). The COVID-19 pandemic has shown us that today, in the 21st century, threats related to infectious diseases dominate, and that preventive vaccinations help reduce or significantly eliminate the risk of contracting them. Since the time of Edward Jenner, who used vaccinia to vaccinate humans against smallpox, vaccination has been known to elicit a specific immune response to the antigens contained in the vaccine in order to prevent the vaccinated person from contracting an infectious disease (8).

The legal act defining the types of preventive vaccinations and regulating the rules of carrying out vaccinations and their financing is the Act of 5 December 2008 on the prevention and combating of infectious diseases and infections in humans (9). This law also addresses the issue of COVID-19 vaccination. The necessity to carry out a large number of vaccinations against COVID-19 in as many people as possible in the shortest possible time resulted in changes in the regulations, consisting in extending the group of people entitled to qualify and perform vaccinations to other medical professions and students of medicine and nursing. By the Act of January 21, 2021 on special solutions related to the prevention, counteraction and combating of COVID-19, other infectious diseases and emergencies caused by them, and some other acts, regulations were introduced in this area, which are to apply during the period of epidemic threat and state the epidemic announced due to COVID-19 (10).

As with any preventive vaccination, vaccination against COVID-19 is preceded by a qualifying examination. The basis for the eligibility of an adult to be vaccinated against COVID-19 is to conduct a targeted pre-vaccination screening interview, focused on the questions in the initial screening interview questionnaire before vaccinating an adult against COVID-19 (11). The questionnaire should be completed before visiting a vaccination center. It consists of introductory questions regarding possible exposure to the SARS-CoV-2 virus and questions about health. The answers to these questions are the basis for qualification for vaccination against COVID-19. In addition, a person who intends to be vaccinated against COVID-19 signs two declarations at the end of the questionnaire: one is about consenting to the vaccination against COVID-19, and the other is about receiving information about this vaccination.

Until April 9, 2021, the qualifying examination was conducted by a doctor. After this date, not only doctors, but also dentists, nurses, midwives, paramedics, school hygienists and laboratory diagnosticians, pharmacists and physiotherapists, after completing theoretical training (available on the CPME website), have the right to perform the examination (12). In addition, students of the last two years of medical studies and the last year of first-cycle studies in nursing may qualify for vaccination against COVID-19 under the supervision of a doctor, dentist, nurse, midwife, medical assistant, paramedic or school hygienist and upon presentation of a document confirming possession of qualification skills for vaccination issued by the university providing this education.

Medical personnel who qualify adults to be vaccinated against COVID-19 make a decision on vaccination based on the analysis of the answers to the above-mentioned questions, questionnaire and health assessment of the person to be vaccinated (general well-being and health, verification of body temperature, possibly additional follow-up interview if necessary). In exceptional circumstances, a qualification by a doctor is required. This happens in two situations. First, when the answers to the health questionnaire require a more detailed interview or standard medical examination. Secondly, in connection with the commencement of vaccination against COVID-19 in younger children (5-11 years old), the legislator requires that, before vaccination, the qualifying examination in children under 15 years of age is carried out by a doctor with valid professional license (including a trainee doctor) (13).

Doctors, dentists, nurses, midwives, paramedics and paramedics are entitled to vaccinate. They can also be performed by physiotherapists, pharmacists, school hygienists and laboratory diagnosticians, however, after completing the following courses: theoretical (e-learning course conducted by the Medical Center of Postgraduate Education) and practical (including learning to administer the vaccine in the form of intramuscular injection and the ability to act in the event of a sudden allergic reaction or other life-threatening condition after vaccination).

There is no doubt that the changes in the qualifications and implementation of vaccinations against COVID-19 only confirmed the professional independence of medical professions other than physicians. For many years, medical professions such as nurses, midwives, physiotherapists and pharmacists were not independent professions. The physician played the main and dominant role, which resulted from the adopted model of care focused mainly on diagnosis and treatment, as well as the medical education system, and thus responsibility. Although the role of the doctor in the system is leading (14), at present, the model of educating other medical professions is very similar to the regulations that determine the education of a doctor. These people also have higher education and constantly have to improve their professional qualifications, and are also responsible for their actions.

Providing information about the patient in the light of the current guidelines of the President of the Office for Personal Data Protection and the Patient's Rights Ombudsman

The SARS-CoV-2 virus pandemic has made informing about the patient's health via ICT systems or communication systems a common practice among medical entities and medical professionals. However, this process was not accompanied by any general campaign informing about the principles of safe – from the point of view of legal protection, transfer of information containing sensitive medical data and personal data. The answer to this information gap

may be the "Guidelines on the implementation by authorized persons of the right to remote information about the patient's health" (15) prepared jointly by the Patient Ombudsman and the President of the Office for Personal Data Protection. The content of the document clearly indicates that it is to constitute a set of officially recommended recommendations on procedures and solutions enabling in practice the safe implementation of the right to obtain information about the patient's health, taking into account the principles resulting from the regulation of personal data protection in entities providing health services.

The guidelines have been divided into general and detailed ones, devoted to such issues as creating appropriate technical conditions and defining detailed rules of conduct when providing information on the patient's health to third parties. The guidelines also refer, in separate parts, to the principles of remote contact with a person authorized by a conscious patient and – which most often raises the most doubts about the issue of obtaining information by a third party about the health of a patient who, due to his or her health condition, could not submit an appropriate authorization to provide information about your health condition and provided health services.

The authors of the guidelines emphasize that none of the applicable provisions of the Act of November 6, 2008, on the rights of patients and the Patient's Rights Ombudsman (16) does not prohibit distance communication, pointing out at the same time that this form of communication should be carried out with respect to the principles of law, professional experience and common sense.

The guidelines, in a detailed part, also emphasize that both the relatives of the patient as well as people from outside this circle, but authorized by the patient, have the right to obtain information about their health condition, and providing information to one of the authorized persons does not release the entity from the obligation to provide such information to other authorized persons, if the patient has indicated several such persons.

Due to the need to protect particularly sensitive personal data (health data), providing this information, especially in the form of remote communication, requires different precautionary principles than in the case of personal contact. Importantly, the guidelines already in the first paragraphs indicate that it is unacceptable to use employees' private equipment for this type of contact. It seems that such recommendations are a cliché, and often, especially in the case of small individual medical practices, the telephone assigned to the facility is also the private equipment of the facility owner – which leads to a number of risks related to, for example, inadequate securing of the equipment, transporting the device, theft, connecting with unsecured public networks, processing of redundant personal data for the facility, etc. In each case, informing about the patient's health condition should be preceded by the fact that the person providing the information becomes convinced that he or she has contact with the patient's relatives or a person authorized by him. However, the method of verifying the identity of the person contacting remotely should be adequate to the statutory requirement imposing the obligation to provide information without undue delay. Thus, the authors of the guidelines find it unacceptable to use excessively complex methods of verifying the identity of persons applying for information, especially those resulting in a delay in providing information. The choice of the proposed solution (including the type of questions asked in the case of an unconscious patient) should be individually adjusted (e.g., to the patient's age, type of disease). It seems that the first solution proposed by the authors of Wrawych, i.e., the system of codes established between the facility, the patient and the patient's family, may not be effective, for example in wards where elderly people are hospitalized, who will not be able to remember and provide the family with the number assigned to them, e.g., in the admission book of the facility, even in the event of assistance from the facility staff. The authors of W Guidelines also indicate special signs, including a tattoo, as one of the questions that may be used to verify the caller in the event that the patient is unconscious. It seems that in the age of social media and the desire to share the details of private life with Internet users, this information can be surprisingly easily available on-line, so it should also be used with caution. As it seems, the catalog of questions indicated by the authors of W tells may also include questions about, for example, prior hospitalization in the facility (of course, if it took place) and its details (e.g., the department where the patient was staying), the issuer of the identity card the patient (if the facility has this type of document), and if the patient has been transferred from another facility, you can ask about the details of his stay in the previous facility. An individual approach to each case, taking into account the specific situation and circumstances in which the patient was admitted to the medical entity, should also be manifested in the fact that the scope of information provided by medical personnel should depend on the situation and individual inquiry of the person contacting the medical entity. The guidelines also emphasize the special importance of the mechanisms of informing about the health condition of patients in the event of a visit ban, which excludes direct contact of the person interested in obtaining information with a doctor. The guidelines recommend the implementation of appropriate procedures for the provision of data on the patient's health via remote communication channels and familiarization with these procedures for medical and administrative personnel. The implementation of these procedures should, however, be preceded by a risk analysis made by the personal data administrator. Particular attention should be paid to the application of appropriate technical and organizational measures, ensuring an appropriate and risk-appropriate level of security of the processed data, taking into account their specific category.

The guidelines directly indicate the need to conduct a risk analysis, i.e., a process known from the General Data Protection Regulation, the elements of which are provided for in Art. 35 GDPR (17), allowing, among others on the identification of sources of threat, indication of the effects (understood as negative consequences for the patient in connection with the implementation of the threat) and their size, as well as the degree of probability of their occurrence (understood as the chance of realizing the threat). Consequently, the calculated risks will allow the selection of appropriate technical, organizational or IT measures, the use of which will ensure the security of data processing (in this case also data of special sensitive categories). Again, it is important that the authors of the guidelines leave no illusions about the need to conduct this type of analysis, however, this requirement applies to all processes where the risk to the rights and freedoms of data subjects (in this case, patients) is high – and in the discussed process, this risk will have such an attribute in the light of the UODO Guidelines on the list of data processing operations requiring an impact assessment. (18) The guidelines do not expressly express (it is indicated that appropriate security measures are ensured) about the need to ensure the confidentiality conditions for providing this type of information.

Therefore, in this case, it is unacceptable, for example, to provide information outside the doctor's office, in the corridor, in conditions where the information may be read by other patients and other people. It is equally important to emphasize the authors of the guidelines that the standards or internal procedures for the provision of information at a distance must be fully known to the staff. Only then, in the context of awareness, it will allow for safe data processing, as it is well known that the most common cause of data leaks is the employee, it can be concluded that the above-mentioned principles will be implemented and the data will be processed safely.

The guidelines should be particularly appreciated as an initiative aimed at solving one of the major problems of health care in the time of a pandemic and as an attempt to show a path to reconcile, it would seem, two contradictory values – on the one hand, maximizing the health safety of patients related to, inter alia, with isolation, including from family members, and on the other hand, the need for families to obtain information about the health of their relatives. It should also be emphasized that the guidelines do not contain an exhaustive catalog of methods allowing to identify the entitlement to receive information about the health condition of patients by persons contacting a medical facility by means of remote communication. One of the main goals of the guidelines is to indicate to medical entities such a method of verifying the identity of the person awaiting information on the patient's health, which will allow them to act in accordance with the provisions on the protection of personal data, and, as a result, to protect themselves against possible liability for unlawful processing of these data.

Conclusions

Discussion of the legal challenges in Polish medicine of the 21st century required reference to the legal changes caused by the global SARS-CoV-2 virus pandemic and the COVID-19 disease. During a pandemic, the importance of a medical experiment, including clinical trials, is even more noticeable not only for the medical community. For this reason, the discussion of the amendments to the Act on the Professions of Physician and Dentist covered the extension of the information obligation for the participant of the experiment and the introduction of the obligation to insure against civil liability. The above issues are the key to obtaining a safe and effective remedy for COVID-19 disease. It is important not only to test drugs and vaccines in accordance with the procedures, but also to introduce them to the market and create the possibility of quick access to the preparation. Hence, the legal and organizational challenge for the health care system was to expand the competences of medical professions in order to conduct qualification tests and perform preventive vaccinations against COVID-19. Moreover, in a pandemic, it was not easy to reconcile the safety of patients and their families with organizational changes in healthcare entities. In practice, this meant that informing about the patient's health via ICT systems or communication systems by medical professionals has become a common practice. In the times of the pandemic, the major problems presented in the article required showing not only the theoretical perspective that boils down to the assessment of legal regulations, but also the practical aspects taking into account the introduction of these changes.

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