

Directive on the application of patients' rights in cross-border healthcare

(Dyrektywa transgraniczna w sprawie stosowania praw pacjentów w
transgranicznej opiece zdrowotnej)

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Abstract – The present article describes the main premises emerging from the Directive of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare such as the regulation of access to healthcare services for the citizens of the EU Member States and the main tasks and the functioning of National Contact Points which were established by the said Directive. The paper introduces briefly the administrative procedures concerning rendering and receiving health care services within the limits of cross-border health care – both from the perspective of the Member State of affiliation and the Member State of treatment.

Key words - European Union, National Contact Points, guaranteed health care services.

Streszczenie – Praca opisuje główne założenia wynikające z Dyrektywy Parlamentu Europejskiego i Rady Unii Europejskiej z dnia 9 marca 2011 roku w sprawie stosowania praw pacjentów w transgranicznej opiece zdrowotnej, do których zalicza się regulowanie dostępu do opieki zdrowotnej dla obywateli krajów członkowskich Unii Europejskiej oraz główne zadania i sposób funkcjonowania powołanych wyżej wspomnianą dyrektywą Krajowych Punktów Kontaktowych. Opisane zostały procedury administracyjne obowiązujące przy udzielaniu oraz pobieraniu świadczeń zdrowotnych w ramach transgranicznej opieki zdrowotnej - zarówno ze strony państwa ubezpieczającego danego obywatela, jak i państwa świadczącego te usługi.

Słowa kluczowe - Unia Europejska, Krajowe Punkty Kontaktowe, gwarantowane świadczenia zdrowotne.

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I. INTRODUCTION

In joining the European Union on May 1, 2004, Poland undertook to comply with the common European Union (EU) rights and obligations and to enforce EU legal acts. The membership of Poland in the EU constitutes a major opportunity and provides Polish citizens with a rich source of benefits, such as being entitled to healthcare services outside their Member State of affiliation without bearing any additional financial burdens.

Health of the citizens is an essential priority for the European Union that has been implemented through a variety of programmes and initiatives, such as the Second (2008-2013) and Third Health Programme (2014-2020) [1,2].

The EU aims to increase the cost-effectiveness of healthcare systems as well as invest in health via health promotion programmes and seeks to reduce social inequali-

ties, particularly those emerging from inequalities in health and access to health care [3].

When considering the main aims of the European Commission in the field of public health, the following may be found, among others: to increase its cost-effectiveness, exercise supervision over potential global health threats and create health policy on the basis of scientific data [4].

A directive is an example of legal instruments existing in the EU. It requires the Member States to implement particular legal provisions set out in a particular regulation in order to achieve the final legal status in all Member States. The Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (Official Journal of the European Union, L 88/45 as amended) focuses on providing safety and high-quality health services in all Member States. It is of particular importance not only for its scale, but also because of the geopolitical situation. The Directive addresses, among others, medical tourism and draws attention to the patients' rights and availability of medical treatment outside their home country. No additional fee is required for healthcare services, which, in fact, excluded patients from the process of cost settlement for healthcare treatment – this obligation falls on insurers (public or private). Healthcare services delivered in the Member States constitute a unique component of a goods and services market as they address people, i.e. patients, and services provided by healthcare facilities are of particular importance as they involve human life.

Aim

The aim of the present paper is to describe the Directive of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare that offers free movement of patients between Member States. It also analyses the role of particular countries in cross-border treatment in the context of contemporary challenges that Europe is facing.

II. CROSS-BORDER DIRECTIVE

The Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare hereinafter referred to as the cross-border directive was developed and adopted by the European Parliament and Council, entered into force on 25 October 2013 and it was supposed to address concerns arising from the cooperation between particular Member States in the field of the movement of patients and medical services [5].

The Directive aimed to facilitate the access by EU citi-

zens to medical services in all Member States, without interfering in their autonomy in terms of the organisation and scope of delivery of medical care as well as its financing. It is worth emphasizing that it was not the Directive's intention to encourage patients to seek treatment abroad.

III. ACCESS TO HEALTHCARE

The scope of the guaranteed medical services is independent from the Member State in which treatment is provided. This concerns both planned treatment and unforeseen medical treatment that becomes necessary during a temporary stay in another EU country. The cross-border directive does not apply to the following services: preventive vaccination programmes, long-term care services, and organ transplantation.

A patient may decide to seek treatment outside the Member State of affiliation in a number of cases. These include not only highly specialised medical procedures or treatment methods not available in the Member State of affiliation, but also better quality of medical care and the presence of family members in the Member State of treatment.

IV. RESPONSIBILITIES OF THE MEMBER STATE OF TREATMENT AND THE MEMBER STATE OF AFFILIATION

The Member State providing healthcare services should take into account the principles of universalism, equity, and solidarity. The Directive requires the Member States to respect its provisions, regardless of the internal legislation of the Member States.

These provisions include, for instance, an obligation to ensure the protection of personal data of patients and to provide certain bodies with access to medical records in order to ensure, among others, continuity of care. Patients have the access to medical records containing information on their health, diagnosis, examination results, and reports on treatment provided at every stage of therapy.

The Member State of treatment is required to treat all patients equally. Patients from outside the Member State of treatment should not be discriminated against or privileged with regard to domestic patients.

A key action of the Member State of affiliation is to ensure that the costs incurred by a patient who receives cross-border healthcare are reimbursed. Mechanisms for reimbursement of costs should be transparent and available to all patients concerned. It is the Member State of affiliation that is supposed to ensure good health of citizens, also by

granting authorisation to receive treatment abroad.

Providing health insurance to their citizens, the Member States commit themselves to reimburse costs of cross-border healthcare. As was already pointed out, only the benefits that fall within the scope of the basket of guaranteed medical services apply to reimbursement. The level of reimbursement is set according to the prices applied in the Member State of affiliation. The Member State of affiliation may also decide to reimburse accommodation and travel costs, or extra costs which persons with disabilities might incur. For the purpose of reimbursement of costs of cross-border healthcare, it is necessary to provide any documentation of the costs incurred by a patient.

The Member States may set limits for reimbursement of costs incurred to ensure sufficient and continuous access to high-quality healthcare and to control costs.

The Act of 27 August 2004 on health care services financed from public funds (Journal of Laws 2004 No. 210 item 2135 as amended) constitutes the basis for applying for reimbursement of costs of cross-border healthcare for a Polish patient. The Act specifies the cost to be reimbursed – it cannot exceed the actual costs incurred by a healthcare provider. The amount of reimbursement is calculated by converting the expenditure (indicated on a medical bill) using the average currency exchange rate announced by the National Bank of Poland applicable on the issue date. In Poland, a Regional Branch of the National Health Fund is the institution responsible for calculating the actual amount of reimbursement and for payment.

National Contact Points (Polish: Krajowe Punkty Kontaktowe, KPK) were established to provide patients with direct information on cross-border healthcare. National Contact Points provide information to patients residing in a Member State for treatment as well as to those planning to seek healthcare abroad.

National Contact Points provide information on a profile of healthcare providers, standards of treatment in selected healthcare facilities, procedures related to administrative formalities concerning cross-border healthcare, and others.

V. ADMINISTRATIVE PROCEDURES FOR CROSS-BORDER HEALTHCARE

Criteria for granting authorisation for treatment in another Member State shall be: transparent, justified, and publicly available and they cannot hinder the free movement of persons within the European Union. Authorisation for cross-border treatment is granted on the basis of the following recommendations:

- an objective medical assessment of the patient's medical condition,
- the history and probable course of the patient's illness, and
- the degree of the patient's pain.

In addition, the EU Member States have the right to draw up a list of medical services that are subject to prior authorisation when provided in another Member State. The list aims, among others, to improve cost control in order to avoid any waste of financial, technical and human resources. These benefits include overnight hospital accommodation and a procedure requiring highly specialised and cost-intensive medical equipment. Prior authorisation may also be necessary if a planned treatment poses a substantial risk for the patient or the population.

For the list of medical services subject to prior authorisation by the managing director of a regional branch of the National Health Fund Polish citizens may refer to the Regulation of the Minister of Health of 4 November 2014 on the list of healthcare services requiring prior authorisation by the managing director of a regional branch of the National Health Fund (pursuant to Article 42e (1) of the Act of 27 August 2004 on healthcare services financed from public funds [6,7]. Apart from several highly specialised procedures, prior authorisation is needed for treatment requiring at least a 24-hour hospital stay and treatment within drug prescription programmes.

Prior authorisation for cross-border treatment shall not be granted to patients who could be exposed to threats, posing a greater risk than a potential benefit for the patient during treatment abroad. Prior authorisation shall also not be granted to patients applying for cross-border treatment that can be delivered on the territory of a Member State of affiliation within a time limit that is medically justifiable (on the basis of the patient's medical condition and individual course of illness).

The authorisation for cross-border treatment shall not be granted if the population is exposed to a health risk and there is doubt as to the quality of medical services delivered by a healthcare provider. There is a rule that at the time of granting authorisation for cross-border treatment, the Member State of affiliation shall ensure that the cost incurred by the patient is reimbursed irrespective of the amount of payment.

The EU Member States provide their citizens with an access to administrative procedures regarding the reimbursement of costs of healthcare received in another Member State. These procedures should be objective and non-discriminative as well as easily accessible.

The Member States are also required to set out a time

limit for reviewing a request for cross-border healthcare. When considering the request, Member States shall take into account not only the specific medical condition, but also the urgency of the procedure. Each clinical case needs an individual approach, having regard to the decision-making criteria established beforehand by the Member State.

In accordance with the cross-border directive, a prescription issued for a medicinal product, authorised to be marketed on the territory of a Member State, should be dispensed irrespective of the country where the prescription was issued. Pharmacists may refuse to dispense a medicinal product if they are concerned with the patient's health or have legitimate doubts about the authenticity, content or comprehensibility of an individual prescription. The recognition of prescriptions issued in a Member State other than that of affiliation does not affect either the national management of medicinal products (particularly the prescription and distribution of drugs) or decisions to dispense generics or substitutes. The level of reimbursement shall not depend on the fact in which Member State the prescription has been issued.

The Member State of affiliation shall take all necessary measures to recognise prescriptions in order to ensure continuity of treatment (of course, in the event when a medicinal product prescribed or a medical device is available on the territory of the Member State of affiliation).

The assumptions of the directive on the application of patients' rights in cross-border healthcare contributed to the development of measures enabling a health professional to verify the authenticity of a prescription (whether a person issuing a prescription is a member of a regulated health profession entitled to do so as well as whether the correct prescription format is used). It is also recommended to use the international non-proprietary name and the dosage of medicinal products in order to ensure patient safety and allow pharmacists to choose an appropriate medicine (or a substitute) of the correct chemical composition.

VI. CONCLUSION

The present paper aimed to provide an insight into the content of the Directive of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. Based on the main premises of the said Directive, the paper presented, among others, regulations on the access to healthcare services, responsibilities of Member States of treatment and administrative procedures regarding delivering healthcare in another Member State than that of affiliation.

National Contact Points were established under the Directive to serve as the main source of information and support for patients: those who go to another Member State in order to receive treatment as well as those who have already received treatment. For instance, National Contact Points provide information on a profile of healthcare providers, support in undergoing administrative procedures related to cross-border healthcare and a list of standards of treatment in selected healthcare facilities.

When it comes to the administrative procedures for cross-border healthcare, it is also important to remember to receive an authorisation for treatment in another Member State than that of affiliation. The granting of an authorisation is subject to three recommendations: an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, and the degree of the patient's pain. The Regulation of the Minister of Health of 4 November 2014 on the list of healthcare services requiring prior authorisation by the managing director of a regional branch of the National Health Fund is the document that Polish citizens may refer to when it comes to obtaining authorisation for certain medical services.

As EU legislation, the said Directive shall provide guidelines for the Member States to follow the regulations and organise cross-border healthcare. The Directive covers a number of issues related to delivering healthcare by the Member States, providing recommendations designed to develop uniform and coherent procedures for delivering and receiving medical services in the EU countries.

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