Considerations regarding Directive 2011/24/EU on the application of patients' rights in cross-border healthcare in EU member states

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Abstract

The free movement of persons is one of the four fundamental freedoms recognized and regulated at the European Union level. The definition and implementation of all existing policies and actions at European level, regardless of the scope, have as their focal point a high level of health protection. Under the conditions of the extension of the right to healthcare of the persons, at the level of the European Union, it is intended to ensure the access of every person to healthcare based on the latest scientific discoveries. The adoption in 2011 of Directive No. 24 is an important step in respecting patients' rights in cross-border healthcare, with important consequences both for the health of patients and for the health systems in the Member States.

Keywords: *healthcare, cross-border, rights, patients***.**

JEL Classification: K32

1. Introduction

The purpose of Directive 2011/24/EU on patients' rights in cross-border healthcare[2] is to facilitate access to high-quality and safe healthcare in another Member State of the European Union. European regulations promote cross-border healthcare cooperation between Member States in the interest of the European citizens with prescriptions, digital health (eHealth), rare diseases, as well as medical technology assessments.

For the application of patients' rights in cross-border healthcare, health systems are central to ensuring a high level of social protection, contributing to both social cohesion and social justice, with an important role in sustainable development. These systems are based on a set of operating principles necessary to ensure a high level of health protection and to ensure patients confidence in cross-border healthcare.

Cross-border healthcare is defined as *healthcare provided or prescribed in a Member State other than the Member State of affiliation* and may be granted to the insured persons[3] of the EU Member States under the terms of the Directive in compliance with national provisions in the field.

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[2] Published in JO L 88, 4.4.2011.

[3] Insured person' means: persons, including members of their families and their survivors, who are covered by Article 2 of Regulation (EC) No 883/2004 and who are insured persons within the meaning of Article 1(c) of that Regulation; and nationals of a third country who are covered by Regulation

European regulations lay down rules to facilitate access to safe and high-quality healthcare, respecting the competences that the States have in organizing and delivering medical services and healthcare.

2. Responsibilities of the EU Member State where the treatment is performed

Member States' responsibilities for cross-border healthcare are shared. The Directive lays down responsibilities of the Member States in which the treatment is performed[4] and responsibilities of the Member States of affiliation.[5] The Member States where treatment is performed shall provide cross-border healthcare in accordance with the legislation of that State, with the quality and safety standards and guidelines established both at the level of the European Union and at Member State level.

Member States providing cross-border healthcare have the obligation to inform the patient, at his request, on the standards and guidelines regarding the quality and safety of medical services, as well as on those regarding the supervision and assessment of the healthcare providers[6]; information should regard the providers of medical services who are covered by these guidelines, as well as the accessibility of hospitals for people with disabilities. Healthcare providers are required to assist patients in making informed choices about treatment options, availability, quality and safety of healthcare provided. Also, while respecting the principle of transparency, healthcare providers issue clear invoices and inform the patient about prices, insurance, and other means of personal or collective protection with regard to professional liability.

There is an obligation for healthcare providers to provide patients with transparent complaint procedures and mechanisms by which patients can seek compensation for damages caused by injuries resulting from the healthcare services they receive, in compliance with national law. In the Member States providing treatment there must be professional liability insurance schemes or any guarantee or similar means appropriate to the nature and level of risk for the treatments provided.

(EC) No 859/2003 or Regulation (EU) No 1231/2010, or who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits.

[4] Art. 3 letter d) „Member State of treatment' means the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established.

[5] 'Member State of affiliation' means: for persons referred to the Member State that is competent to grant to the insured person a prior authorization to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009;for persons referred to the Member State that is competent to grant to the insured person a prior authorization to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010. If no Member State is competent according to those Regulations, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State.

[6] 'healthcare provider' means any natural or legal person or any other entity legally providing healthcare on the territory of a Member State.

States must ensure the right to privacy by observing the provisions on personal data processing. Patients receiving treatment are entitled to the medical record of that treatment in electronic or printed format and should have access to a copy of this file, also subject to national measures on personal data protection.

Cross-border healthcare should be provided to all patients in other countries, respecting the principle of non-discrimination on the basis of nationality. However, the Member State of treatment, when there are reasons of general interest, such as ensuring sufficient and permanent access to a range of high-quality treatments or where there is a desire to control costs or to avoid wasting human resources, technical or financial, may adopt measures on treatment designed to ensure sufficient and permanent access to healthcare on its territory. Measures are limited to what is necessary and proportionate and do not constitute a means of arbitrary discrimination and must be made public. Member States are required to ensure that healthcare providers within their territory will apply to patients the same range of medical care fees as to the patients in their own Member States in a similar medical situation or to set prices in accordance with objective and non-discriminatory criteria if there are no comparable prices for native patients. European legislation allows healthcare providers to set their own prices, but they should not discriminate against patients in other Member States. Member States may also choose to provide information in languages other than those of the Member State concerned.

3. Responsibilities of the Member State of affiliation

The Member State of affiliation shall ensure the conditions for the reimbursement of costs of cross-border healthcare. It should also provide mechanisms for informing patients at their request of their rights in that Member State, in particular as regards the terms and conditions for the reimbursement of costs, as well as the procedures for assessing and determining those rights, and the conditions under which they may be entitled to compensation when they consider that their rights have been infringed. There is an obligation to ensure remote access to the patient's file that has received cross-border healthcare or to receive a copy of the file in compliance with the personal data protection provisions. If the patient has been provided with cross-border healthcare and further medical monitoring is required, the same medical monitoring that the patient would have benefited from on his or her territory should be made available.

According to Directive 2011/24/EU, it is the Member State of affiliation that has the obligation to ensure the reimbursement of the costs incurred by an insured person if cross-border healthcare is among the rights to which he/she is entitled. However, there are exceptions to these provisions. Thus, in the first instance, if the Member State has recognized the right to sickness benefits for pensioners and members of their families residing in the territory of another State, then the Member State shall provide healthcare at its own expense during the stay of these persons on its territory under the same conditions as for domestic patients. Another situation is that where healthcare does not require prior authorization and is granted in the

territory of a Member State that is ultimately responsible for the reimbursement of costs. In this case the costs are borne by that State.

The affiliation state determines the healthcare services for which the insured person is entitled to reimbursement of costs and their level, regardless of where the healthcare is provided.[7] It is imperative to have transparent costing mechanisms for cross-border healthcare based on objective and non-discriminatory criteria known and applied in the state of affiliation at all levels (local, regional, national). The conditions for reimbursement of the costs incurred by the insured person are the same in the case of healthcare provided by telemedicine.

4. National contact points for cross-border healthcare

In order to achieve the best possible conditions of access to cross-border healthcare, national contact points are designated in the Member States of the European Union. They have the obligation to consult with patient organizations, healthcare providers and health insurers; on request, they have to provide patients with contact details of national points in other Member States. At the same time, they are required to provide patients with data on service providers, including their restrictions on the conduct of their professional activities, procedures and mechanisms for redress, the legal and administrative options available to settle disputes, including for damages suffered in cross-border healthcare.

5. Prior authorization

The Directive sets out the conditions under which medical assistance may be subject to prior authorization. The Member State of affiliation may establish a prior authorization system for the purpose of reimbursing the cost of cross-border healthcare. This system, including its criteria and their enforcement, as well as the individual decisions to deny prior authorization must be limited only to what is necessary and proportionate to the objective to be achieved and can not constitute a means of arbitrary discrimination or an unjustified obstacle to free movement of patients. It concerns medical assistance which is subject to planning requirements to ensure sufficient and permanent access to a range of high-quality treatments in the Member State concerned, or the need to control costs or to avoid waste of resources, and it requires either the patient's hospitalization for at least one night or the use of specialized or expensive medical infrastructure or equipment. Prior authorization is required when healthcare involves treatments of particular risk to the patient or the population, or when healthcare is provided by a healthcare provider that could raise concerns about the quality or safety of care, with the exception of healthcare that

[7] The level of costs reimbursed is equal to the level of costs that would have been borne by the Member State of affiliation if healthcare had been provided in its territory. In certain circumstances, if the total cost of cross-border healthcare is higher, the Member State may decide to fully cover them. The state may also decide to reimburse accommodation, travel or additional costs for people with disabilities, provided there is documentation that specifies these costs.

provides a minimum level of safety and quality in the European Union, in which case it is necessary to notify the Commission.

The patient receives prior authorization for cross-border healthcare on request, the Member State of affiliation having the obligation to verify the fulfilment of the conditions. If a patient is in a difficult situation, being suspected of having a rare disease, he may request prior authorization, in which case there is a possibility of clinical evaluation by experts in the field. If there are no experts in the affiliation state or the expert's opinion is not conclusive, the Member State of affiliation may request scientific advice.

Under no circumstances may the Member State of affiliation refuse to grant prior authorization if the patient is entitled to it and if healthcare cannot be provided on its territory within a reasonable medical term. This is done by taking into account the objective medical assessment of the patient's state of health, the history and evolution of the disease, the severity of the pain or the nature of the patient's disability at the time of the introduction or renewal of the patient's request.

The Member State of affiliation may refuse to grant prior authorization when the patient may be exposed to a safety risk that cannot be considered acceptable; when the general public is exposed with a reasonable degree of certainty; when healthcare is provided by a healthcare provider generating serious concerns about compliance with standards and guidelines on quality of healthcare and patient safety, regardless of whether standards or guidelines are set by laws or regulations or by accreditation systems established by the Member State of treatment; when the necessary healthcare can be provided within the Member State territory within a reasonable time and by taking into account the patient's state of health and the likely evolution of the disease. The Member State of affiliation may make publicly available the types of pre-authorized healthcare as well as any other relevant information.

6. Cooperation in the field of healthcare

Directive 2011/24/EU contains a series of provisions on the need for cooperation and mutual assistance between EU Member States on medical prescriptions, on the development of European reference networks, on the development of diagnostic and treatment capacity for rare diseases, e-health and medical technology assessment. All these are aimed at providing high-quality cross-border healthcare and the insured person's access to optimal diagnosis and treatment procedures for the patient's state of health.

7. Transposition of Directive 2011/24/EU in Romania

Directive 2011/24/EU on patients' rights in cross-border healthcare has been transposed into the Romanian law by Law no. 95/2006 on health reform, republished, as amended and supplemented, art. 901-922. Internal law regulations follow the objectives and directions established by European regulations, facilitating access to

safe and high-quality cross-border healthcare. At the same time, cooperation is promoted in the field of health care between the health systems in Romania and the EU Member States.

The application of the legal rules is done in a unitary manner without regard to the organization, operation and financing of healthcare providers. Long-term care services for people in need of help in carrying out their routine, daily duties are excluded from cross-border healthcare; the treatment of patients requiring isolation or compulsory hospitalization and the treatment of persons serving custodial sentences in the penitentiary hospital; as well as those who need medical care and palliative care at home. Cross-border healthcare is also excluded in case of organ allocation and organ transplantation as well as population vaccination programs against infectious diseases designed to protect population health, which are subject to specific planning and implementation measures.

The Romanian State grants cross-border healthcare taking into account the principles of universal access to good quality healthcare, solidarity and in accordance with national healthcare legislation and safety standards, as well as with the quality and safety standards that hospitals have to meet in order to obtain operating sanitary authorization.

The national contact point exists and works alongside the National Health Insurance House and has the following tasks: consultation with patient organizations, specialized structures in the Ministry of Health, healthcare providers and health insurers; collaborating with the other National Contact Points and with the European Commission; providing patients with contact details of national contact points in other EU Member States, on request; information on healthcare providers and their restrictions on the conduct of their professional activities; information on patients' rights, procedures and mechanisms for repairing damages and for settling disputes; the terms and conditions of reimbursement of costs and the procedures for assessing and determining those rights.

Internal provisions fully translate the patients' rights under European regulations on the reimbursement of the costs of cross-border healthcare, as well as the obligations of healthcare providers in the field. The non-observance of the obligations imposed on the healthcare providers constitutes contravention and is sanctioned with fines between 500-5000 Lei, the limits of which are permanently updated by Government decisions.

Reimbursement of costs for cross-border healthcare is done in Romania through health insurance houses. The methodology for reimbursement of prices/tariffs representing the equivalent of cross-border healthcare is established by Government Decision. Law no. 95/2006 provides for the obligation of the health insurance funds to communicate in writing, within the term stipulated by law and with the indication of the legal basis, the rejection of the insured's claims regarding the reimbursement of the equivalent of the cross-border healthcare. The insured can challenge the decision of the health insurance fund on the rejection or on the reimbursement level of the cross-border healthcare services provided by the health insurance funds, under the law of administrative contentious. After the reply to the

appeal or the expiration of the deadline for responding, the insured person may address the administrative contentious court.

National legislation provides for the medical assistance subject to prior authorization under the same conditions as the relevant European Directive, establishing that the type of cross-border healthcare is established by Government Decision. Prior authorization applications submitted by an insured person are reviewed by health insurance funds under the same conditions as the claims for reimbursement of costs for cross-border healthcare. Appeals of the insured to the health insurance funds' rejection of the application are made within 15 days of the date of acknowledgment, and their reply will be given within 15 days from the date of filing the appeal. In the event of unfavourable settlement, the insured person may address the administrative litigation court.

With regard to cooperation in the field of healthcare, medical prescriptions, European reference networks, diagnosis and treatment for rare diseases, telemedicine and e-health, the national legislation sets out tasks for the Ministry of Health. This facilitates cooperation between European health systems, supports the development of reference networks, cooperates with other Member States to develop diagnostic and treatment capacity for rare diseases and in the case of eHealth, participates in EU meetings and voluntary activities, which connect the EU authorities and voluntary network activities, linking national authorities and bodies responsible for health technology assessment.

8. Implementation of Directive 2011/24/EU into the national law of the Member States

In 2018, the European Commission made a report[8] on the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

According to this report, cross-border mobility at the European Union level increased slightly between 2015 and 2018, driven by the improvement of citizens' information on their right to access to cross-border healthcare and, on the other hand, by the collaboration of the European institutions and Member States on the coordination of social security systems and health systems with regard to medical recommendations, digital health system, rare diseases and medical technology assessments.

According to the report, Directive 2011/24/EU has had a positive impact on the legal certainty and clarity of information for both domestic and cross-border patients. The launch of the European Reference Network[9] has led to a positive

[8] Brussels, 21.9.2018COM(2018), https://eur-lex.europa.eu/legal-content/RO/TXT/HTML/?uri=CELEX:52018DC0651&from=RO, consulted on 1.10.2018.

[9] The European Reference Network is a virtual, voluntary cross-border network bringing together healthcare providers across Europe. Its purpose is to diagnose and treat patients suffering from rare and complex illnesses that require highly specialized care. This network is not directly accessible to patients, but to healthcare providers who recommend them to the relevant network. Its operation began in 2017. Until 2018, 165 committees have been set up.

change in the provision of cross-border healthcare at a high quality level accessible to EU citizens. Five years after the implementation of European regulations, cross-border patient flows are stable, being largely determined by cultural and geographical proximity. From the financial point of view, it is considered that there was no major impact on the budgets of the health systems.

Concerning the number of requests for prior authorization in the period 2015-2017, the Commission's report indicates their steady increase since 2015, reaching a double number of applications and approvals of prior authorization in 2017, compared to 2015. However, patients were faced with problems regarding reimbursement systems, the use of prior authorization, administrative requirements and the charge of the costs of patients entering the states of treatment.

Concerning the costs of cross-border healthcare, states are allowed to limit the application of the rules on reimbursement of the cost of cross-border healthcare on grounds of general interest but without discrimination. Problems have been found to reimburse the cost of cross-border healthcare in the case of primary care from private or non-contracted healthcare providers compared to the level of reimbursement in the public healthcare system or contracted healthcare providers. There are three states that use a lower reimbursement level as a benchmark for reimbursing the cost of cross-border healthcare.[10]

The European Commission's report highlights that although Member States have the possibility to reimburse the costs of cross-border healthcare, subject to prior authorization, such an option is not recommended to be used excessively because it would constitute a restriction on the free movement of services.[11] Six Member States (the Czech Republic, Estonia, Finland, Lithuania, the Netherlands, Sweden and Norway have not opted to introduce prior authorization, leaving this to the patients' choice.

The European Commission recommends that Member States make available to citizens the list of short-term medical services that are subject to prior authorization and that the treatments are sufficiently well-established.

As regards the administrative procedures for reimbursement, the report notes that they are based on objective and non-discriminatory criteria. Some requirements have been removed in some countries to support citizens. Some states requested citizens to have the certified translation of their medical documentation for reimbursement. This is considered an obstacle to the free movement of services, as the cost of translation in some countries could be higher than the cost of the medical service.

Under the directive, healthcare providers must provide patients in other countries with the same range of fees as for domestic patients in a comparable

[10] Case C-372/04 Watts. http://curia.europa.eu/juris/liste.jsf?language=en&num=C-372/04, consulted on 1.10.2018.

[11] Case C-205/99, Analir and others, Rec. 2001, p. I-1271, paragraph 38 http://curia.europa.eu/juris/documents.jsf?language=RO& critereEcli=ECLI:EU:C:2001:107, consulted on 1.10.2018; case C-157/99 Smits v. Peerbooms, paragraph 90 http://curia.europa.eu/ juris/liste.jsf?language =en&num=C-157/99.

medical situation. If there is no comparable price for domestic patients, there is an obligation for suppliers to charge a price calculated in accordance with objective, non-discriminatory criteria. The Commission's report highlights that Member States can set comparable prices on the basis of an objective and non-discriminatory methodology. In connection with the financial implications for reimbursements granted in 2016, 65,000,000 EUR have been spent for healthcare with and without prior authorization.

In 2018, the European Commission adopted a proposal to ensure the sustainability of EU cooperation in the field of medical technology assessment. Cooperation in the field of medical technology aims to make innovative technologies available to European citizens in the health sector.

9. Conclusions

Cross-border healthcare is an important step in ensuring and respecting the right to health of insured persons. The provisions of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare has made progress in creating the conditions for an "internal health market" by creating the means of cooperation and coordination of health systems, and by linking them to innovative technologies. The transposition and implementation of this directive at the level of the EU Member States has had a positive impact on the access of insured persons to quality and safe health services and implicitly on their health status.

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