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EU REGULATIONS

DIRECTIVE ON THE APPLICATION OF PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE

One decade has passed since the adoption of the Directive 2011/24/EU of the European Parliament and of the Council on the Application of Patients' Rights in Cross-border Healthcare.[2] Challenges arising from the adoption of that directive somewhat exceed the usual efforts in terms of transposition into national legislation and implementation of provisions, since in the meantime a pandemic occurred which significantly disrupted not only mobility as such but also the exercise of the rights to healthcare, especially considering a heavy burden on healthcare institutions everywhere in Europe.[3] However, it should not be ignored that this is a socially relevant act that enabled a higher degree of cohesion at the European level regarding the exercise of rights to medical assistance. Directive contains twenty-three articles, and its content will be presented in general in this text.

The introductory part stated that healthcare systems present the basic pillars of social development and connectivity, but also that Member States retain responsibility for providing better and most extensive healthcare to citizens on their territories, and that the application of regulations should not encourage treatment outside competent systems, i.e. in other Member States. In addition, this act does not extend into the sovereign right of Member States to define the scope and type of healthcare themselves. This remark is logical, bearing in mind significant

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[2] EUR-lex, consolidated text: 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, Brussels, 2011, *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011L0024-20140101*, accessed on: 30.07.2022.

[3] Miloš Petrović, „Pandemija Kovida 19: zdravstveni rizici i opsežne štetne posledice po privredne i druge tokove", *Tokovi osiguranja* 2021, br. 01, str. 70–102.

differences in the healthcare systems, as well as various traditions in different parts of the European Union. It is important to ensure clear and transparent rules that the EU citizens enjoy when moving to another Member State, which is one of the aspects that this act seeks to regulate more closely in line with the principles of access to care and other legal and ethical aspects. Aim of this Directive is to emphasize the freedom of each Member State to regulate its healthcare system and the social apparatus regarding rights to medical services on local or regional level, having in mind that they can extend such rights.

The main idea is to encourage cooperation in healthcare and improvement of patients' rights, which is defined more closely in the first article. The second article defines the relationship between other EU regulations, such as those regulating medicinal products, ethical and equal treatment, etc. The following article provides definitions of basic terms, such as "healthcare", "insured person", "cross-border healthcare", "medicine", etc. Responsibilities of the Member State providing healthcare are determined in accordance with the principles of availability, fairness, solidarity and other principles, and in accordance with its national legislation, its quality standards, but also the regulations of the Union (Article 4 Paragraph 1). Obligations of the Member State are defined in this article, while obligations of the Member State of affiliation are defined in the next provision. The sixth article prescribes the national contact points for cross-border healthcare. Reimbursement of cross-border healthcare costs is more closely defined from the seventh to the ninth article, including legal regulation of exceptions to the application of these rules.

In the next section, the Member States shall render such mutual assistance as is necessary for the implementation of this Directive, including cooperation on legal and technical and other standards (Article 10), recognition of prescriptions issued in another Member State (Article 11), European reference networks (Article 12) and treatment capacity for rare diseases (Article 13). The Directive shall closely define objectives of eHealth platform among Member States (Article 14). In addition to the administrative, technical and procedural function, this cooperation network during the current pandemic showed its practical effectiveness in terms of monitoring the vaccination and health status related to Covid-19, which made it more visible across borders.

The final section of the Directive (Articles 16 to 23) contains a more detailed definition of institutional powers and aspects of reporting on the implementation of provisions. Directive is published in the Official Journal of the European Union on 9 March 2011. The Directive became binding for the Republic of Croatia in terms of that country's accession to the Union in 2013, while the United Kingdom ceased to be bound by its provisions by leaving the EU. Scope of the Directive is in political

terms amended by the Directive 2013/64/EU regarding the amendment of the status of Mayotte with regard to the European Union.[4]

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[4] EUR-lex, Council Directive 2013/64/EU of 17 December 2013 amending Council Directives 91/271/EEC and 1999/74/EC, and Directives 2000/60/EC, 2006/7/EC, 2006/25/EC and 2011/24/EU of the European Parliament and of the Council, following the amendment of the status of Mayotte with regard to the European Union, Brussels, 2013, *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32013L0064*, accessed on: 21.07.2022.