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**Patient's rights in cross-border health care in the
European Union**

Master thesis

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Iva Čípová

V Praze dne 29. 6. 2017

I hereby declare that I have written this master thesis on my own; all the sources and literature have been duly cited and this master thesis has not been used to obtain any other or the same academic degree.

Iva Čípová

In Prague on 29 June 2017

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List of abbreviations

EU – European Union

CJEU – Court of Justice of the European Union

TFEU – Treaty on the Functioning of the European Union

ECHR - Convention for the Protection of Human Rights and Fundamental Freedoms

NCP – National Contact Point

HIB – Health Insurance Bureau

Introduction

Looking at the development of the European Union, there has been greater mobility across member states since the EU was created. EU citizens are increasingly moving abroad to work, study, travel, and it consequently raises the question of social security coverage and access to healthcare in the host country.¹ Patients usually received healthcare in other member states when there was a sudden need for healthcare during a stay abroad. Eventually, patients became more informed and wanted to knowingly cross borders and seek medical treatment in other member states. The reasons for planning healthcare abroad can be different: the health care does not exist or is forbidden in a patient's member state, or the medical provider in another member state provides better quality health care, or the waiting time is shorter.

Cross-border healthcare covers all situations different from the one when the patient is treated in a member state, where he/she is socially insured in by a local healthcare provider who is established in that member state.² Therefore, free movement of patients nowadays covers both cases: when healthcare is provided unexpectedly while the patient is abroad, and planned cross-border healthcare.

Health law is considerably affected by the law of the European Union, but it was not always like that. When the European Union was created, cross-border healthcare was not regulated by its founding Treaties³. Healthcare was originally exclusively the responsibility of the member states, because health systems were different in each member state and interference in these systems was (and still is) politically sensitive. Gradually the competence of the European Union in public health was established and the Court of Justice of the European Union for the first time decided that healthcare could be considered as a service according to the TFEU. An improvement was achieved by Regulation No 1408/71 on the application of social security schemes to employed persons and their families moving within the Community, which was later replaced by

¹ RIEDEL, Rafal. European patient's cross-border mobility directive: Short communication. *Public Health*. 2016(139), 222-223, p. 222.

² PEETERS, Mick. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Healthcare*. DOI: 10.1163/157180912X615158. ISBN 10.1163/157180912X615158. Available at: <http://booksandjournals.brillonline.com/content/10.1163/157180912x615158>, p. 29.

³ Treaty Establishing the European Coal and Steel Community (1951), Treaty Establishing the European Economic Community (1957), Treaty Establishing the European Atomic Energy Community (1957), Treaty on European Union (1992).

Regulation No 883/2004, which is still applicable. Nevertheless, for many years this field was regulated mainly by case law of the Court of Justice of the European Union.

A landmark in the field of cross-border healthcare was the adoption of Directive 2011/24 on the application of patients' rights in cross-border healthcare, which was adopted after years of political negotiations. The Directive was approved on 9 March 2011 and all member states were obliged to implement it in their national law by 25 October 2013.

European health law is an interesting yet complex field. This thesis will therefore be focused only on a part of it, solely concerning cross-border health care in the European Union.

I became more familiar with this topic while studying in Antwerp under the Erasmus+ programme, where I attended the International and European Health Law course taught by professor Lierman. I have chosen the topic because it is not only a theoretical abstract topic, but it also has a practical impact on patients from all European Union countries.

The aim of the master thesis is to thoroughly analyse the current legal framework with a focus on patients' rights, examine the impact of the Directive, explain an issue of overlap between the Directive and Regulation, and evaluate the transposition of the Directive in the Czech Republic. To achieve this aim, it is necessary to examine the topic with respect to the historical and political development of the European Union and to the case law of the European Court of Justice.

The main sources used are books edited by prof. Mossialos and prof. van de Gronden, articles written by prof. Pennings and Mr. Peeters, case law of the ECJ, and documents issued by the EU, which provide valuable information about the current situation. Given the fact that there are not many resources written in Czech language, the master thesis is primarily based on foreign literature.

This thesis is based on standard methods of master thesis elaboration. The method of analysis is predominant and methods of description and synthesis are used as complementary methods.

The thesis is divided into four chapters. First of which concerns European Union competences in health law, explaining the history of incorporating health law provisions into the Treaty on the Functioning of the European Union, as it is called today. This

historical development is important for understanding the issue of cross-border healthcare.

The second chapter is mainly focused on the important case law of the ECJ, concerning patients' rights. Although initially I will discuss the development in providing cross-border health care, specifically the relation between cross-border health care and the internal market, and the change brought by Regulation on coordination of social security systems. I will also briefly explain the differences in health insurance systems of the member states and the specifics of cross-border commuters.

In the third part of the thesis, Directive 2011/24/EU on patients' rights in cross-border healthcare is discussed. This chapter explains development and reasons for adopting the Directive, and analyses specific articles of the Directive and their impact. An important part of this chapter is to examine the relation between the Directive and the Regulation.

The final chapter deals with cross-border healthcare in the Czech Republic, mainly with the implementation of the Directive into the Czech legal system, information to patients, and the reimbursement system.

This thesis is based on the legal status of the day 29 June 2017.

1. European Union competences in health law

1.1. History and development of European Union competences in health law

Historically speaking, healthcare was originally the exclusive responsibility of the member states, as explicitly stated in Article 152 (5) of the EC Treaty (now Article 168 TFEU).⁴ Reasons for this legislation were clear: national interests, political sensitivity, and a huge diversity of health care systems in each member state.⁵

Even though national healthcare systems officially fell outside EU law, its elements, like financing and delivery, were directly affected by EU law. Other areas of EU law had unintended effects on the health care system too.⁶

The earliest mention of EU health law can be, according to some experts, found in the law of the Common Agricultural Policy and was focused on food safety. Others hold the view that EU health law is narrower and focuses primarily on patients, health professionals and the healthcare system. In their view, legislation of health law began with the social security position of workers moving for work between six original member states. According to this legislation, these workers and members of their families were entitled to access health care systems in other member states.⁷

The situation changed by adopting the Maastricht Treaty in 1992⁸, when a degree of legal competence in the area of public health protection was given to the European Commission for the first time. This competence was limited to topics of general interest, like prevention of diseases, health information and education.⁹ This Article was strengthened and renumbered as Article 152 in the Treaty of Amsterdam of

⁴ MOSSIALOS, Elias, PERMANAND, Govin, BAETEN, Rita and HERVEY, Tamara. Health systems governance in Europe: The role of European Union law and policy. In MOSSIALOS, Elias, ed. *Health systems governance in Europe: the role of European Union law and policy*. Cambridge: Cambridge University Press, 2010. Health economic, policy and management. ISBN 978-0-521-74756-1, p. 4.

⁵ *Ibid.*, p. 85.

⁶ *Ibid.*

⁷ HERVEY, Tamara K. and Jean V. MCHALE. *European Union health law: themes and implications*. Cambridge: Cambridge University Press. 2015. Law in context. ISBN 978-1-107-01049-9, p. 31-32.

⁸ Article 129 (1) of the Maastricht Treaty.

⁹ Public Health at EU level - Historical Background. *Eurocare: European Alcohol Policy Alliance* [online]. [cit. 2017-03-13]. Available at: <http://www.eurocare.org/>.

1997.¹⁰ In the contrast with Art. 129(1) of the Maastricht Treaty, which established that *‘the Community shall contribute towards ensuring a high level of human health protection’*¹¹, Art. 152 of the Amsterdam Treaty stated that *‘a high level of health protection shall be ensured in the definition and implementation of all Community policies and activities’*¹². Competences in health law were still entrusted to member states, because harmonisation was excluded and these provisions were weak in comparison to other EU policies. Despite these issues, most EU health lawyers consider this as a major step for health law to become an important aspect of EU law.¹³

The last significant change was made by the Treaty of Lisbon of 2007. The provision concerning health protection was renumbered again in the Lisbon Treaty as Article 168.¹⁴ This provision gives the EU competences in (public) health. Public health is a shared competence between the EU and its member states¹⁵ and according to Article 6 (a) TFEU the Union shall have competence to carry out actions to support, coordinate or supplement protection and improvement of human health of the member states. This means that member states exercise their competence to the extent that the EU has not exercised its competence, and to the extent that the EU has decided to cease exercising its competence.¹⁶ The main objective of this provision is to strengthen cooperation and coordination between member states.¹⁷

The right to seek healthcare was also mentioned in the EU Charter of Fundamental Rights, which became legally binding since its incorporation in the Lisbon Treaty.¹⁸ Article 35 clarifies that *‘everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices’*¹⁹.

¹⁰ SZYSZCZAK, Erika. Patients’ rights: A Lost Cause or Missed Opportunity?. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS. *Health care and EU law*. The Hague, The Netherlands: T.M.C. Asser Press, 2011. ISBN 9789067047272, p. 105.

¹¹ Article 129 (1) of the Maastrich Treaty.

¹² Article 152 of the Amsterdam Treaty.

¹³ HERVEY, Tamara K. and Jean V. MCHALE, supra note 7, p. 39.

¹⁴ Ibid, p. 42.

¹⁵ Article 4 (2) (k) TFEU.

¹⁶ NEERGAARD, Ulla. EU Health Care Law in a Constitutional Light: Distribution of Competences, Notions of ‘Solidarity’, and Social Europe’. In VAN DE GRONDEN, Johan, supra note 10, p. 23.

¹⁷ GREER, Scott L. and Paulette KURZER. *European Union public health policy: regional and global trends*. Abingdon, Oxon: Routledge, 2013. Routledge advances in European politics, 90. ISBN 9780203077245, p. 21.

¹⁸ Ibid., p. 21.

¹⁹ European Union, *Charter of Fundamental Rights of the European Union*, 26 October 2012, 2012/C 326/02, Art. 35.

A legal competence for the EU in areas of health law was limited. As a result, the Commission has also coordinated an EU health policy using soft governance techniques.^{20,21}

It should be noted that Article 114 TFEU contains the general internal market legal base and paragraph 3 of this Article requires that the harmonisation measure adopted must guarantee a high level of protection of human health.^{22,23}

Cross-border health care is generally based on the right to access to health care which was enshrined, even though on a more general level, in the Convention for the Protection of Human Rights and Fundamental Freedoms²⁴. This Convention was drafted in 1950 by the Council of Europe and established the European Court of Human Rights.²⁵ Over the years, many actions brought before the European Court of Human Rights have concerned health and health care. For example, the right to life in Article 2 ECHR has been used in actions concerning abortion, the right to die and liability of health professionals. Article 3, which prohibits inhuman or degrading treatment, has been used in cases concerning expulsion of ill people and forcible medical intervention or treatment. Article 8, on the right to respect of private and family life, has been used extensively in the context of access to personal medical records and confidentiality of personal information concerning health.^{26,27}

²⁰ For example a communication, an action programme and others.

²¹ SZYSZCZAK, Erika. Patients' rights: A Lost Cause or Missed Opportunity?. In VAN DE GRONDEN, Johan, supra note 10, p. 113.

²² Health has many definitions depending on which point of view is considered. The classic medical definition describes health as the 'absence of disease' which emphasises adequate functioning of the human body. The widely recognised definition was established in the Constitution of the World Health Organisation: '*health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*'.

²³ NEERGAARD, Ulla. EU Health Care Law in a Constitutional Light: Distribution of Competences, Notions of 'Solidarity', and Social Europe'. In VAN DE GRONDEN, Johan, supra note 10, p. 23-24.

²⁴ Council of Europe, *European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14*, 1950, ETS 5, available at: <http://www.refworld.org/docid/3ae6b3b04.html>.

²⁵ The European Convention on Human Rights. *European Court of Human Rights* [online]. [cit. 2017-06-08]. Available at: <http://www.echr.coe.int/pages/home.aspx?p=basictexts>.

²⁶ MCHALE, Jean. Fundamental rights and health care. In MOSSIALOS, Elias, ed., supra note 4, p. 286.

²⁷ Factsheet - Health. *European Court of Human Rights* [online]. 2017 [cit. 2017-06-08]. Available at: http://www.echr.coe.int/Documents/FS_Health_ENG.pdf.

2. Development of providing cross-border health care

2.1. Health care and health insurance systems of the member states

All European Union member states have established public or collective health care and insurance systems to which their citizens are compulsorily affiliated. These systems differ in each state, but they can generally be divided into social insurance systems and national health services.²⁸

In a social health insurance scheme, the law determines the categories of persons who are compulsory insured, the insurance premiums to be paid, the benefit package, and the rules governing the administration of the system. The whole population is compulsorily insured in most countries. Nevertheless, in some states only the majority population is covered by the insurance schemes.²⁹

A further distinction in social health insurance scheme can be made between systems, based on the principle of reimbursement and systems based on the benefits-in-kind principle. The principle of reimbursement means that patients are entitled to the payment of costs of medical care. In practice, patients pay money directly to the medical practitioner, and they are reimbursed afterwards by their sickness fund. According to the benefits-in-kind principle, patients are entitled to obtain health care from doctors who are directly paid by the competent health insurance institutions.³⁰

The national health services are usually funded out of tax revenues and offer medical services to almost the entire population in accordance with the principle of benefits-in-kind. Generally, national health services systems are more centralised than social insurance systems.³¹

²⁸ VAN DER MEI, Anne Pieter. *Free movement of persons within the European Community: cross-border access to public benefits*. Portland, Or.: Hart Pub., 2003. ISBN 1-84113-288-8, p. 223-224.

²⁹ Ibid., p. 224.

³⁰ Ibid., p. 224.

³¹ Ibid., p. 224-225.

2.2. Providing cross-border health care in the internal market

During the process of Europeanization³² it was inevitable that national and European identities were gradually changing and these changes affected EU member states social policies.³³ The development of health and social security systems was determined by the historical, social and economic background of individual countries.³⁴ National health care systems were different in each member state, although they were commonly based on solidarity³⁵ and the principle of territoriality.³⁶ According to the principle of territoriality, states provided social security in the time of sickness to the territory to which they had sovereignty.³⁷

The European Union is based on the so called ‘four fundamental freedoms’: free movement of goods, persons, services and capital.³⁸ These forms of mobility gradually increased and extended into all sectors of EU law. Some national measures and mechanisms began to be viewed as potential unjustified obstacles to free movement, which is prohibited under Treaty provisions.³⁹

The jurisprudence of the European Court of Justice started to play an important role in EU law and its policy-making, including health care.⁴⁰ The CJEU has developed a complex framework of intertwining principles which are used to evaluate the member states' rules regulating the area of patient mobility, and also indirectly, national rules on access to socially covered health care in general. However, the Court has not established concrete standards of health-care access. An installation of these standards would be

³² Europeanization was defined by many scholars, e.g. Ladrech [Ladrech, R. (1994), ‘Europeanization of Domestic Politics and Institutions: The Case of France’, *Journal of Common Market Studies*, 32:1, 69-88]: *‘Europeanization is an incremental process reorienting the direction and shape of politics to the degree that EC political and economic dynamics become part of the organizational logic of national politics and policy-making’*.

³³ MOSSIALOS, Elias, PERMANAND, Govin, BAETEN, Rita and HERVEY, Tamara. Health systems governance in Europe: The role of European Union law and policy. In MOSSIALOS, Elias, ed., supra note 4, p 19.

³⁴ GEKIERE, Wouter, BAETEN, Rita and PALM, Willy. Free movement of services in the EU and health care. In MOSSIALOS, Elias, ed., supra note 4, p. 465.

³⁵ Stjernø in *Solidarity in Europe: The History of an Idea* defines solidarity as *‘the preparedness to share resources by personal contribution to those in struggle or in need and through taxation and redistribution organised by the state’*.

³⁶ HERVEY, Tamara K. and Jean V. MCHALE, supra note 7, p. 73.

³⁷ STRBAN, Grega. Patient mobility in the European Union: between social security coordination and free movement of services. *ERA Forum* [online]. 2013, 14(3), 391-407 [cit. 2017-03-31]. DOI: 10.1007/s12027-013-0311-2. ISSN 16123093, p. 393.

³⁸ Treaty on the Functioning of the European Union, OJ C 326.

³⁹ GEKIERE, Wouter, BAETEN, Rita and PALM, Willy. Free movement of services in the EU and health care. In MOSSIALOS, Elias, ed., supra note 4, p. 461.

⁴⁰ MOSSIALOS, Elias, PERMANAND, Govin, BAETEN, Rita and HERVEY, Tamara. Health systems governance in Europe: The role of European Union law and policy. In MOSSIALOS, Elias, ed., supra note 4, p. 27.

expensive and would interfere with national rules.⁴¹ These general principles of law developed by the Court are part of EU law and member states are obliged to respect them. The general principles help to bridge the gap left by primary and/or secondary legislation.⁴²

It was not clear whether providing health care constituted providing services. Services are defined by Article 57 (ex Article 50 EC) as any activities ‘*where they are normally provided for remuneration, in so far as they are not governed by the provisions relating to freedom of movement for goods, capital and persons*’⁴³. The first important case involving health care was *Luisi and Carbone*⁴⁴. Decided in 1984, it established tourists, business travellers, students and patients as ‘recipients of services’, who can travel to another member state to receive medical treatment.⁴⁵ The economic nature of health care services was therefore acknowledged by the Court for the first time.⁴⁶ This decision was surprising, because payments within national health systems were not generally considered as ‘remuneration’. Health care under a national health system was thus not counted as a ‘service’ within EU law.⁴⁷

In *Watts*⁴⁸ judgement in 2006, the Court clarified that Article 56 TFEU (ex Article 49 EC) applies where a patient ‘*receives medical services in a hospital environment for consideration in a Member State other than her State of residence, regardless of the way in which the national system with which that person is registered and from which reimbursement of the cost of those services is subsequently sought operates*’⁴⁹. In other words, the economic nature of the health service does not depend on the specific type of statutory cover or the specific type of health service. The provision of health care is therefore considered a service activity under the TFEU

⁴¹ GREER, Scott L. and Tomislav SOKOL. Rules for Rights: European Law, Health Care and Social Citizenship. *European Law Journal* [online]. 2014, 20(1), 66-87 [cit. 2017-06-08]. DOI: 10.1111/eulj.12036. ISSN 13515993. Available at: <http://doi.wiley.com/10.1111/eulj.12036>, p. 78-79.

⁴² The non-written sources of European law: supplementary law. *EUR-Lex: Access to European Union law EUR-Lex Access to European Union law* [online]. 2010 [cit. 2017-06-11]. Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3A114533>.

⁴³ Treaty on the Functioning of the European Union, OJ C 326, Art. 57.

⁴⁴ Judgment of 31 January 1984, *Luisi and Carbone v. Ministero dello Tesoro*, C-286/82, EU:C:1984:35.

⁴⁵ *Ibid.*, para 16.

⁴⁶ GEKIERE, Wouter, BAETEN, Rita and PALM, Willy. Free movement of services in the EU and health care. In MOSSIALOS, Elias, ed., *supra* note 4, p. 466.

⁴⁷ HERVEY, Tamara K. and Jean V. MCHALE, *supra* note 7, p. 195.

⁴⁸ Judgment of 16 May 2006, *Watts*, C-372/04, EU:C:2006:325.

⁴⁹ *Ibid.*, para 90.

definition.⁵⁰ The Court also confirmed that national authorities are entitled to implement a system of waiting lists and can require prior authorisation for medical treatment abroad when it is justified by maintaining financial balance.⁵¹ On the other hand, national authorities cannot refuse to grant prior authorisation if treatment is not available on their territory within an acceptable time, depending on medical circumstances of a specific case.⁵² A system of prior authorisation is further discussed below.

The application of free movement rules in the field of health care is not unconditional.⁵³ Member states are allowed to create exceptions to free movement under the condition that they are non-discriminatory and justified in the public interest. This justification is composed of two tests: a necessity test and a proportionality test. The necessity test means that a member state has to prove that the measure is ‘*objectively necessary for ensuring the attainment of a public interest objective*’⁵⁴. The proportionality test states the need to prove the measure does not exceed what is necessary to attain the objective and that the same result cannot be achieved by a less restrictive rule.⁵⁵ Member states have to provide evidence that the public interest objective would be jeopardised by the non-application of a restrictive measure. Member states have to meet a relatively high burden of proof.⁵⁶

This case law, based on Article 56 TFEU, improved the position of patients under the Regulation on coordination of social security systems. Article 56 TFEU is a part of primary and directly effective Treaty law and gives rights to individuals which are enforceable in the national courts and cannot be removed by legislation.⁵⁷

2.3. Cross-border commuters

Cross-border commuters (sometimes called cross-border or frontier workers) are people who work in one EU member state, but live in another and return there daily, or

⁵⁰ GEKIERE, Wouter, BAETEN, Rita and PALM, Willy. Free movement of services in the EU and health care. In MOSSIALOS, Elias, ed., supra note 4, p. 468.

⁵¹ *Watts*, supra note 48, paras 37, 114.

⁵² *Ibid.*, para 63.

⁵³ GEKIERE, Wouter, BAETEN, Rita and PALM, Willy. Free movement of services in the EU and health care. In MOSSIALOS, Elias, ed., supra note 4, p. 507.

⁵⁴ *Ibid.*, p. 478.

⁵⁵ *Ibid.*, p. 478.

⁵⁶ *Ibid.*, p. 507.

⁵⁷ HERVEY, Tamara K. and Jean V. MCHALE, supra note 7, p. 196.

at least once a week. Generally, they are subject to the laws of both countries. The laws of the country where they work cover employment and income taxes and most security rights. The laws of the country where they live cover property taxes and most other taxes and residence formalities.⁵⁸

Cross-border commuters are entitled to full health care in both countries. A right to full medical treatment⁵⁹ in the state where a cross-border commuter lives is not automatic; he/she has to ask the insurance institution, where he/she is insured in, for a form S1 (ex form E106). This institution has to assess whether a commuter resides in another EU member state. By granting this form, the commuter is entitled to full health care in both countries.⁶⁰

Non-employed family members of cross-border commuters are also entitled to full health care both countries and necessary health care in other EU member states.⁶¹ There is an exception if a cross-border commuter works in Denmark, Finland, Croatia, Iceland, Ireland, Norway, Sweden and Great Britain. In this case, a commuter's non-employed family members are entitled only to necessary medical care in the state where the commuter is insured in.⁶²

2.4. Regulation on coordination of social security systems

Historically speaking, the coordination on social security systems is the oldest legal act that protects patients' rights in EU health law and policy.⁶³ Social security entitlements are based on TFEU provisions of the freedom of movement for workers⁶⁴ and the freedom of establishment⁶⁵. That means that no discrimination on the grounds

⁵⁸ Cross-border commuters. *EUROPA: Your Europe* [online]. 2017 [cit. 2017-06-08]. Available at: http://europa.eu/youreurope/citizens/work/work-abroad/cross-border-commuters/index_en.htm.

⁵⁹ Full medical treatment means a treatment to which patients insured under the legislation of the state concerned are entitled to - they are subject to the same access conditions, the same form of payment. (VAN DER MEI, Anne Pieter, supra note 28, p. 240.).

⁶⁰ Na co mám nárok, pokud jsem pracovník, bydlící v jiném členském státě EU. *Kancelář zdravotního pojištění* [online]. 2014 [cit. 2017-06-09]. Available at: <http://www.kancelarzp.cz/cs/pojistenci/prava-naroky-eu/narok-kategorie/prac-zije-jinde-eu>.

⁶¹ Evropská unie: Přeshraniční pracovník - pendler. *Česká průmyslová zdravotní pojišťovna* [online]. [cit. 2017-06-09]. Available at: <https://www.cpzp.cz/eu/index.php?id=1098>.

⁶² Rozsah péče hrazené z vašeho zdravotního pojištění. *EUROPA: Zdraví* [online]. 2017 [cit. 2017-06-09]. Available at: http://europa.eu/youreurope/citizens/health/when-living-abroad/health-insurance-cover/index_cs.htm.

⁶³ Regulations apply not only to nationals of the EU, but also in Iceland, Liechtenstein, Norway and Switzerland.

⁶⁴ Article 45 TFEU.

⁶⁵ Article 49 TFEU.

of nationality is permitted in terms of employment or establishment rights. Secondary legislation extended this principle to discrimination with respect to social advantages.⁶⁶

Although the Regulations on coordination of social security systems do not mention cross-border healthcare as such, they deal with the coordination of social security legislation regarding sickness benefits in kind. The Regulations are based on the principle of free movement of persons and have dual legal base: Article 48 TFEU and Article 352 TFEU. Their aim is to encourage workers' mobility providing that it is economically neutral, with regard to their social security rights.⁶⁷

2.4.1. Regulation 1408/71

EC Regulation 1408/71 was originally intended to establish entitlements in each member state of residence for people moving to another member state, or for migrant workers and their families working and living in another member state.⁶⁸

The scope of the Regulation was extended in 2003 to include non-EU nationals who are affiliated to a social security scheme within the EU.⁶⁹ On 1 May 2010, the Regulation was replaced by Regulation 883/2004, implemented by Regulation 987/2009/EC⁷⁰ and amended by Regulation 988/2009/EC⁷¹, which replicates the personal scope of Regulation 1408/71 in Article 2. Regulation 1408/71 continues to apply in Norway, Iceland, Liechtenstein and Switzerland until the current agreements with EEA and Switzerland are amended. Until the European Council reaches an agreement on the extension of the new regulations, it also applies to nationals of non-EU countries, legally resident in the territory of the EU.⁷²

⁶⁶ HERVEY, Tamara K. and Jean V. MCHALE, *supra* note 7, p. 189.

⁶⁷ CARRASCOSA BERMEJO, Dolores. Cross-border healthcare in the EU: Interaction between Directive 2011/24/EU and the Regulations on social security coordination. *ERA Forum* [online]. 2014, 15(3), 359 - 380 [cit. 2017-03-06]. DOI: 10.1007/s12027-014-0358-8. ISSN 18639038, p. 360.

⁶⁸ PALM, Willy and GLINOS, Irene. Enabling patient mobility in the EU: Between free movement and coordination. In MOSSIALOS, Elias, ed., *supra* note 4, p. 514-515.

⁶⁹ PENNING, Frans. The Draft Patient Mobility Directive and the Coordination Regulations of Social Security. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, *supra* note 10, p. 134.

⁷⁰ Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems, OJ L 284.

⁷¹ Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009 amending Regulation (EC) No 883/2004 on the coordination of social security systems, and determining the content of its Annexes, OJ L 284.

⁷² Coordination of social security systems: Frequently Asked Questions - Regulations. *European Commission: Employment, Social Affairs & Inclusion* [online]. [cit. 2017-06-12]. Available at: <http://ec.europa.eu/social/main.jsp?catId=857&intPageId=983&langId=en>.

However, the provisions of the Regulation 1408/71 relevant to sickness benefit in kind remained essentially the same in the case of planned health care.⁷³

2.4.2. Regulation 883/2004

Contrary to the previous Regulation, which was limited to employed and self-employed persons, this new framework applies to all EU citizens who have been covered by a social security scheme. This also includes the members of their families and their survivors.⁷⁴

The Regulation provides conditional access to health care in other EU member state in three cases. Firstly, when a patient has moved to another member state to work or conduct business (or is a family member of such person), he/she has the right to access the health system of the host member state. Secondly, when a patient requires care which is medically necessary during a temporary stay abroad. Thirdly, when a patient receives prior authorisation to receive treatment abroad, although this is only considered in exceptional cases.⁷⁵ It is clear that the first two mentioned cases represent unplanned health care, while the third case illustrates planned health care.

The general rule is that if a patient falls under the scope of the Regulation and meets its conditions, he/she is covered as though he/she was insured in the member state where he/she is treated, but at expense of his/her home member state – usually the state where the patient works and pays social security contributions. Practically, this means that this patient is entitled to the same benefit package, tariffs, and the statutory reimbursement conditions and formalities as local patients in the state in which treatment occurs. This system is considered to be a so called ‘safety net’, providing a minimum guarantee for citizens to use their right to free movement.⁷⁶

The procedure of granting prior authorisation to receive appropriate treatment in another member state is regulated by Article 20 of the Regulation. According to this Article, when a patient receives a prior authorisation from the competent institution in the member state he/she is insured in, he/she is entitled to receive treatment abroad according to the legislation of the member state where the treatment takes place. The

⁷³ PENNINGGS, Frans. Cross-Border Health Care Directive: More Free Movement for Citizens and More Coherent EU Law, The [article]. *European Journal of Social Security* [online]. 2011, 13(4), 424 [cit. 2017-03-31]. ISSN 13882627, p. 426.

⁷⁴ *Ibid.*, p. 426.

⁷⁵ HERVEY, Tamara K. and Jean V. MCHALE, *supra* note 7, p. 193.

⁷⁶ PALM, Willy and GLINOS, Irene. Enabling patient mobility in the EU: Between free movement and coordination. In MOSSIALOS, Elias, ed., *supra* note 4, p. 514-515.

competent authority pays directly to the healthcare provider in another member state. The patient is viewed as if he/she was insured in the member state of treatment. An obvious advantage for the patient is in most cases he/she will not be obliged to pay (usually a large amount) in advance.

Member states often hesitate to grant prior authorisation, because they are afraid of higher costs connected with the treatment abroad. These costs may be higher, and by allowing citizens to receive healthcare abroad, the amount of people seeking cross-border healthcare can increase.⁷⁷

Nevertheless, a member state cannot refuse to grant prior authorisation when two conditions are simultaneously met: the treatment is in the basket of reimbursable treatment of the member state of affiliation, and the treatment cannot be given in the member state of affiliation within a reasonable period of time, taking into account the current medical condition of the specific patient and the probable course of his disease.⁷⁸

The CJEU in 2014 decided so called *Petru case*⁷⁹ concerning the second condition of a prior authorisation. Elena Petru was a Romanian national who suffered from a serious cardiovascular disease and needed open heart surgery.⁸⁰ Romania's health service refused her application to have the surgery performed in Germany.⁸¹ She went to have the operation anyway and subsequently she sued for reimbursement on the grounds of inadequate hospital establishment and infrastructure in Romania.⁸² A regional court in Romania referred the case to the ECJ for a preliminary ruling.⁸³ The CJEU came to the conclusion that *'an authorization cannot be refused where it is because of a lack of medication and basic medical supplies and infrastructure that the hospital treatment concerned cannot be provided in good time in the insured person's Member State of residence. The question whether that is impossible must be determined by reference to all the hospital establishments in that Member State that are capable of providing the treatment in question and by reference to the period within which the treatment could be obtained in good time'*.⁸⁴

⁷⁷ PENNINGGS, Frans, supra note 73, p. 428.

⁷⁸ Article 20 (2) of the Regulation 883/2004.

⁷⁹ Judgment of 9 October 2014, *Petru*, C-268/13, EU:C:2014:2271.

⁸⁰ *Ibid.*, para 9.

⁸¹ *Ibid.*, para 11.

⁸² *Ibid.*, paras 10,12.

⁸³ *Ibid.*, para 17.

⁸⁴ *Ibid.*, para 36.

In previous cases⁸⁵, the Court has re-affirmed the principle of prior authorisation, but it has also restricted the notion of undue delay. In *Petru case*, the CJEU decided both in favour of the patient by ruling that also a lack of medication and basic medical supplies can result in an undue delay. The judgement was also in favour of governments, by giving them possibility to evaluate all the hospital establishments in their territory that are capable of providing the treatment in question, not only the ones in the area where the patient lives.⁸⁶

The question was made pursuant to Regulation 1408/71, but because in-hospital care is involved in this case, the question would also arise under the Directive 2011/24. This case did not make it easier for patients to obtain prior authorisation and it may now challenge the role of patient mobility across member states.⁸⁷ In my opinion, the case law of the CJEU can change in the future, although a significant change is unlikely. I agree with Frischhut and Levaggi that it might be almost impossible for patients to prove that treatment they need was not available in other hospitals in their country.

Patients have a right to health care when it becomes necessary during a stay in another member state.⁸⁸ In this case, the person has not travelled abroad to receive treatment, but as a consequence of an accident, he/she is entitled to health care as a patient under EU law on an emergency basis. It is not necessary to receive an authorisation by an institution in his/her home country. The costs of the treatment are paid for by the patient's home country.⁸⁹

The application of this provision is usually not problematic, although there was a discussion about the meaning of the phrase 'when medical care becomes necessary'. Another practical issue is that sometimes healthcare providers do not know or do not apply these rules.⁹⁰

⁸⁵ Judgment of 12 July 2001, *Smits and Peerbooms*, C-157/99, EU:C:2001:404; Judgment of 5 October 2010, *Elchinov*, C-173/09, EU:C:2010:581.

⁸⁶ FRISCHHUT, Markus and Rosella LEVAGGI. Patient mobility in the context of austerity and an enlarged EU: The European Court of Justice's ruling in the *Petru Case*. *Health Policy* [online]. 2015, 119(10), 1293-1297 [cit. 2017-06-12]. DOI: 10.1016/j.healthpol.2015.07.002. ISSN 01688510. Available at: <http://linkinghub.elsevier.com/retrieve/pii/S0168851015001682>, p. 1294.

⁸⁷ PENNINGGS, Frans and Gijsbert VONK. *Research handbook on European social security law*. Edward Elgar Publishing, 2015. ISBN 9781782547327, p. 496.

⁸⁸ Article 19 of the Regulation 883/2004.

⁸⁹ PENNINGGS, Frans, supra note 73, p. 427.

⁹⁰ *Ibid.*, p. 427.

In 2004, the ‘Europe Health Insurance Card’ was introduced by the European Commission. This card proves the entitlement to such healthcare and covers all the member states of the EU, plus Iceland, Lichtenstein, Norway and Switzerland.⁹¹

One main advantage of the Regulation compared to the Directive is that patients do not have to make a payment in advance, because they can benefit from the third party payer system of the country of treatment.⁹² This procedure will be further explained below.

In practice, it is sometimes difficult to distinguish if planned healthcare should be reimbursed according to Regulation or Directive rules.

2.5. Cross-border health care in case law

The Court of Justice of the EU has not only interpreted the Regulation, but has also relied on the Treaty provisions for enabling cross-border healthcare.⁹³ Some important judgments of the Court were already mentioned above.

2.5.1. *Kohll*⁹⁴ and *Decker*⁹⁵

The beginning of parallel systems for exporting the right to medical benefits occurred by the judgments in the cases *Kohll* and *Decker*.⁹⁶ This joint decision, issued by the CJEU in 1998, affected patient mobility within the European Union. It was significant in that sense, that EU internal market law was applied to health care. In other words, the Court determined that health was part of the internal market and therefore patients should not be prevented from seeking care in another member state.⁹⁷

Mr. Kohll and Mr. Decker were both citizens of Luxembourg who crossed borders for healthcare purposes; Mr. Kohll took his daughter to Germany to receive a dental treatment and Mr. Decker bought a pair of glasses in Belgium. Afterwards they asked their health insurance fund for reimbursement of their costs. Their request was refused, arguing that according to Luxembourg legislation, a prior authorisation is required in order to obtain reimbursement. The Court ruled that the prior authorisation

⁹¹ HERVEY, Tamara K. and Jean V. MCHALE, supra note 7, p. 191-192.

⁹² PALM, Willy and GLINOS, Irene. Enabling patient mobility in the EU: Between free movement and coordination. In MOSSIALOS, Elias, ed., supra note 4, p. 516.

⁹³ STRBAN, Grega, supra note 37, p. 395.

⁹⁴ Judgment of 28 April 1998, *Kohll*, C-158/96, EU:C:1998:171.

⁹⁵ Judgment of 28 April 1998, *Decker*, C-120/95, EU:C:1998:167.

⁹⁶ STRBAN, Grega, supra note 37, p. 393.

⁹⁷ GREER, Scott L. and Paulette KURZER, supra note 17, p. 118.

requirement for the reimbursement of costs of health care in another member state was an infringement on free movement rules, specifically free movement of services in the case of dental treatment and the free movement of goods in the case of buying glasses.⁹⁸

In the *Kohll* case, the Court stated that the special nature of services does not remove them from the ambit of free movement rules, namely Articles 59 and 60 EC (now Articles 56 and 57 TFEU).⁹⁹ According to this judgment, the service of the orthodontist, provided for remuneration, must be regarded as a service within the meaning of Article 57 TFEU, which expressly refers to activities of the professions.¹⁰⁰

The Court stated that a condition of prior authorisation cannot be justified for reasons related to the quality and accessibility of medical services, because the access to the profession has been harmonised at European Union level. It also cannot be justified by the need to preserve the financial balance of the medical and hospital system of the member state.¹⁰¹ The Court came to the conclusion that justification of prior authorisation was not established in this case.¹⁰²

This decision does not seem so significant in contemporary terms, but considering the situation in 1998, it was groundbreaking. For the first time, these two judgments intervened in national health systems, which until then were only connected through Regulation 1408/71.¹⁰³

Nevertheless, this new approach initiated by the Court was criticised by many member states, which were afraid that this change might have a negative impact on the financial stability of their health insurance system.¹⁰⁴

After the successful litigation of *Kohll* and *Decker*, many patients followed their example when asking for reimbursement of costs. The Court later ruled in *Commission v. France*¹⁰⁵ that a requirement of prior authorization for reimbursing medical services abroad could be justified in the case of hospital care or non-hospital care with a need for

⁹⁸ PEETERS, Miek, supra note 2, p. 34.

⁹⁹ *Kohll*, supra note 94, para 20.

¹⁰⁰ *Ibid.*, para 29.

¹⁰¹ BAQUERO CRUZ, Julio. The Case Law of the European Court of Justice on the Mobility of Patients: An Assessment. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, supra note 10, p. 82.

¹⁰² *Kohll*, supra note 94, para 53.

¹⁰³ BAQUERO CRUZ, Julio. The Case Law of the European Court of Justice on the Mobility of Patients: An Assessment. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, supra note 10, p. 83.

¹⁰⁴ DE LA ROSA, Stéphane. The Directive on cross-border healthcare or the art of codifying complex case law. *Common Market Law Review*. 2012(49), 15-46. ISSN 0165-0750, p. 21.

¹⁰⁵ Judgment of 5 October 2010, *Commission v France*, C-512/08, EU:C:2010:579.

planning, because of the use of highly specialized and cost-intensive medical infrastructure or equipment.¹⁰⁶

2.5.2. *Smits-Peerbooms*¹⁰⁷

This case was heard three years later and confirmed the path of the Kohll and Decker case. It concerns reimbursement of hospital treatment costs.

Mrs. Geraets-Smits, a Dutch national, suffered from Parkinson's disease. She received treatment in Germany and the reimbursement of the expenses was subsequently refused. The institution explained that a similar treatment existed in her home country and there was no additional advantage or medical necessity in the treatment provided in Germany.¹⁰⁸

Mr. Peerbooms, also a Dutch national, fell into a coma after a road accident. He was given special intensive therapy using neurostimulation in a clinic in Austria. This technique was used only experimentally at two medical centres in the Netherlands, and was available only for patients under the age of 25. Mr. Peerbooms was older so he would not have received such treatment in the Netherlands. The request to pay for the costs of the treatment was rejected based on similar reasons as in the case of Mrs. Smits: adequate treatment existed in the Netherlands, the treatment was not considered as 'normal' in the Netherlands and there was no scientific evidence of its effectiveness.¹⁰⁹

The Court of Justice confirmed that medical activities fall within the scope of Article 57 TFEU and there is no need to distinguish in this regard between care provided in a hospital and non-hospital care.¹¹⁰

Nevertheless, the Court distinguished between intramural (in-hospital) and extramural (out-of-hospital) services, considering conditions for prior authorisation. For intramural services, the requirement of prior authorisation may be warranted if it satisfies the principle of proportionality. For extramural services, this requirement would constitute a breach of the Treaty.¹¹¹ A good planning system is necessary for determining the number of hospitals, their geographical distribution, the mode of their organisation, their equipment, and the nature of the medical services they are offering.

¹⁰⁶ Ibid., paras 32, 42.

¹⁰⁷ Judgment of 12 July 2001, *Smits and Peerbooms*, C-157/99, EU:C:2001:404.

¹⁰⁸ Ibid., paras 25, 26.

¹⁰⁹ Ibid., paras 31 - 39.

¹¹⁰ Ibid., para 53.

¹¹¹ BAQUERO CRUZ, Julio. The Case Law of the European Court of Justice on the Mobility of Patients: An Assessment. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, supra note 10, p. 85.

The planning has to ensure that patients have sufficient and permanent access to high-quality hospital treatment.¹¹²

In order to ensure that a system of prior authorisation is compatible with the principle of proportionality, the Court interpreted two conditions imposed by the Dutch system. For a treatment to be considered ‘normal’, it has to be normal according to the state of ‘international medical science and medical standards generally accepted at international level’. Prior authorisation ‘*can be refused on the ground of lack of medical necessity only if the same or equally effective treatment can be obtained without undue delay at an establishment having a contractual arrangement with the insured person's sickness insurance fund*’¹¹³.

The Court requires that prior authorisation be based on objective non-discriminatory criteria which are known in advance. The authorisation procedure has to be easy accessible and guarantee medical treatment within reasonable time.¹¹⁴

2.5.3. *Vanbraekel*¹¹⁵

Mrs. Vanbraekel suffered from bilateral gonarthrosis. She wanted to undergo an operation in France to avoid the long waiting lists in Belgian hospitals. Her request for authorisation was refused because she did not submit an opinion of a Belgian university professor saying that the operation would be performed under better medical conditions in France than in Belgium. Nonetheless, Mrs. Vanbraekel had the operation performed in a French hospital, and subsequently asked for reimbursement in Belgium.¹¹⁶

The necessity of the hospital treatment in France was approved and she therefore had a right to be reimbursed. The question raised was if she should be reimbursed according to rules of Belgium or according to rules of the state of treatment, which were less generous than Belgian regulation.¹¹⁷ According to Regulation 1408/71, Mrs. Vanbraekel should have been reimbursed according to French national rules. The Court decided that the lower level of reimbursement according to the rules of the state of treatment (considering that the treatment received is the same) may deter patients from seeking medical treatment in other member states. This rule therefore constitutes a

¹¹² PENNINGGS, Frans, *supra* note 73, p. 432.

¹¹³ *Smits and Peerbooms*, *supra* note 107, para 108.

¹¹⁴ PEETERS, Miek, *supra* note 2, p. 35.

¹¹⁵ Judgment of the Court of 12 July 2001, *Vanbraekel*, C-368/98, EU:C:2001:400.

¹¹⁶ *Ibid.*, paras 11-14.

¹¹⁷ BAQUERO CRUZ, Julio. The Case Law of the European Court of Justice on the Mobility of Patients: An Assessment. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, *supra* note 10, p. 83-84.

potential barrier to free movement of services and there are no overriding reasons which could justify it.¹¹⁸

The importance of this case lies in the interpretation of Article 22(1)(c) and (i) of Regulation 1408/71. This provision has to be interpreted as meaning, if an insured person received medical treatment in another member state, where the costs are lower than in the state of insurance, he/she is entitled to additional reimbursement.¹¹⁹ Therefore, the cost will be assumed at the most favourable tariff (this is known at the ‘*Vanbraekel supplement*’).

This decision can be problematic from the point of view of patient awareness. Especially for persons insured under a benefit in kind scheme, who do not receive medical bills directly, often do not know how expensive their treatment is. Despite this, this judgment has to be perceived positively, because it promotes access to health care abroad without imposing any additional financial costs on member states and their sickness funds. There is still one obstacle to cross-border health care – the costs of travelling and accommodation are usually not covered.¹²⁰

2.5.4. *Müller-Fauré and Van Riet*¹²¹

Ms. Müller-Fauré and Ms Van Riet were both Dutch residents who sought reimbursement for non-hospital costs of medical treatment abroad. Ms. Müller-Fauré received dental treatment while she was on holiday in Germany. Ms. Van Riet underwent an arthroscopy in a Belgian hospital. The Dutch mutual sickness insurance fund refused reimbursement. The Court had to decide if the Dutch prior authorisation system is compatible with EU law.¹²²

The judgement of the Court is a confirmation of the previous case law concerning this matter. When this decision was issued in 2003, the main principles of the cross-border health care were already established.¹²³ This judgment further develops the distinction between hospital services and non-hospital services, while admitting that *‘the distinction between hospital services and non-hospital services may sometimes*

¹¹⁸ *Vanbraekel*, supra note 115, paras 45, 50.

¹¹⁹ *Ibid.*, para 53.

¹²⁰ VAN DER MEI, Anne Pieter, supra note 28, p. 311.

¹²¹ Judgment of 13 May 2003, *Müller-Fauré and van Riet*, C-385/99, EU:C:2003:270.

¹²² *Ibid.*, paras 20- 27.

¹²³ BAQUERO CRUZ, Julio. The Case Law of the European Court of Justice on the Mobility of Patients: An Assessment. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, supra note 10, p. 86.

*prove difficult to draw*¹²⁴. The Court found no evidence that the system of prior authorisation is necessary with respect to extramural care (non-hospital services).¹²⁵ As regards to hospital services, the Court accepted that the system is necessary and reasonable because of the need of forward planning.¹²⁶

Authorisation to receive treatment in another member state may be refused only if the same, or an equally effective, treatment can be obtained without undue delay. The Court was asked to interpret the meaning of this term.¹²⁷ It decided that *,a refusal to grant prior authorisation which is based not on fear of wastage resulting from hospital overcapacity but solely on the ground that there are waiting lists on national territory for the hospital treatment concerned, without account being taken of the specific circumstances attaching to the patient's medical condition*¹²⁸, is an unjustified restriction. All the circumstances of each specific case have to be considered, namely the patient's medical condition at the time when authorisation is sought, the degree of pain, the nature of the patient's disability and his/her medical history.¹²⁹

2.5.5. *Inizan*¹³⁰

This judgement can be seen as a confirmation of the previous case law of the CJEU with regard to free movement of health services.¹³¹

Ms. Inizan, a French citizen, sought a package of multidisciplinary pain treatment in a German hospital.¹³² Her request for reimbursement was refused, finding that prior authorisation was only given if equally effective treatment could not be carried out in France without undue delay. In this case, equivalent treatment was available in France.¹³³

The Court confirmed that the prior authorization rule would be a restriction on the freedom to provide and receive services.¹³⁴ However, this rule, in the case of

¹²⁴ *Müller-Fauré and van Riet*, supra note 121, para 75.

¹²⁵ *Ibid.*, para 93.

¹²⁶ *Ibid.*, para 81.

¹²⁷ *Ibid.*, paras 34-35.

¹²⁸ *Ibid.*, para 92.

¹²⁹ *Ibid.*, para 90.

¹³⁰ Judgment of 23 October 2003, *Inizan*, C-56/01, EU:C:2003:578.

¹³¹ NEERGAARD, Ulla. EU Health Care Law in a Constitutional Light: Distribution of Competences, Notions of 'Solidarity', and Social Europe'. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, supra note 10, p. 31.

¹³² *Inizan*, supra note 130, para 7.

¹³³ *Ibid.*, para 11.

¹³⁴ *Ibid.*, para 54.

hospital treatment, can be justified under three conditions.¹³⁵ It has to be based on objective non-discriminatory criteria, based on a procedural system which is easily accessible, and subject to judicial review.¹³⁶

The Court was also asked whether Article 22 of Regulation 1408/71 is valid, in light of the application of Article 49 EC to free movement of patients. In short, this Article remains valid, because it helps to facilitate the free movement of patients by granting additional rights to those available under Article 49 EC (now Article 56 TFEU).¹³⁷

2.5.6. *Stamatelaki*¹³⁸

Mr. Stamatelakis, a Greek national, sought medical care in a private hospital in the UK.¹³⁹ His home social security institution denied reimbursement on the basis of Greek law, which does not reimburse treatments in private hospitals abroad if a patient is over 14 years of age. According to Greek law, patients are reimbursed only if they are treated in private hospitals in Greece.¹⁴⁰

The Court found that Article 49 EC (now Article 56 TFEU) precludes legislation, such as Greek one, which excludes all reimbursement of the cost of treatment provided in private hospitals in another member state, except those relating to treatment to children younger than 14 years old.¹⁴¹ The Court puts emphasis on *‘the absolute terms, with the exception of the case of children under 14 years of age, of the prohibition laid down by the Greek legislation are not appropriate to the objective pursued, since measures which are less restrictive and more in keeping with the freedom to provide services could be adopted, such as a prior authorisation scheme which complies with the requirements imposed by Community law and, if appropriate, the determination of scales for reimbursement of the costs of treatment’*.¹⁴² The Court also emphasised, that private hospitals in other member states than Greece are subject to

¹³⁵ Ibid., para 56.

¹³⁶ Ibid., para 57.

¹³⁷ HERVEY, Tamara K. and Jean V. MCHALE. *Health law and the European Union*. New York: Cambridge University Press, 2004. Law in context. ISBN 9780521605243, p. 132-133.

¹³⁸ Judgment of 19 April 2007, *Stamatelaki*, C-444/05, EU:C:2007:231.

¹³⁹ Ibid., para 9.

¹⁴⁰ Ibid., para 11.

¹⁴¹ Ibid., para 38.

¹⁴² Ibid., para 35.

quality controls and that doctors established in other member states provide professional guarantees equivalent to doctors established in Greece.¹⁴³

2.5.7. *Elchinov*¹⁴⁴

Mr. Elchinov, a Bulgarian citizen, underwent treatment in a specialist clinic in Germany, because such treatment was not available in Bulgaria.¹⁴⁵ The Bulgarian health illness fund refused to reimburse the cost of hospital treatment.¹⁴⁶ The essential question referred to the Court was whether social security systems are obliged to cover foreign medical treatments which are not offered by domestic health care systems.¹⁴⁷

The Court decided that an application for prior authorisation cannot be refused on the ground that a treatment method is not available in the state of residence of the insured person. This refusal would constitute a restriction within the scope of the second subparagraph of Article 22(2) of Regulation 1408/71.¹⁴⁸ The competent institution is required to give the patient the authorisation necessary for the reimbursement of the cost of that treatment, when the alternative treatment, which can be given without undue delay in the member state of his residence, is not equally effective.¹⁴⁹

By this decision, the Court considerably broadened the interpretation of Article 22(2) of Regulation 1408/71 and facilitated the access of patients to high-quality and advanced medical care. On the other hand, this broad interpretation can have serious financial consequences for member states with less advanced domestic treatments, if a lot of patients decide to receive the most advanced medical treatment abroad.

2.6. Summary

This chapter was started with an explanation of differences in health insurance systems of the member states in general. This distinction is important for understanding how the system of cross-border health care works.

Each EU member state has established its own health and social security system. Its development was affected by the historical, social and economical circumstances.

¹⁴³ Ibid., paras 36, 37.

¹⁴⁴ Judgment of 5 October 2010, *Elchinov*, C-173/09, EU:C:2010:581.

¹⁴⁵ Ibid., para 12.

¹⁴⁶ Ibid., para 14.

¹⁴⁷ SOKOL, Tomislav. Rindal and Elchinov: An (Impending) Revolution in EU Law on Patient Mobility? *Croatian Yearbook of European Law and Policy*. 2010(6), 167-208, p. 197.

¹⁴⁸ *Elchinov*, supra note 144, para 62.

¹⁴⁹ Ibid., para 67.

The jurisprudence of the European Court of Justice started to play an important role in EU health law in the 1980s. The first important judgement¹⁵⁰ established the economic nature of health care services for the first time. Health care services are considered economic services and are therefore fully subject to the free movement of services rules. They must be provided for remuneration, regardless of the way in which the national health system operates. Nevertheless, the application of free movement rules in the field of health care is not unconditional. Member states are allowed to create exception under the condition that they are non-discriminatory and justified in the public interest.

Nowadays, member states cannot freely organise their health systems completely as desired. They have to take into account that patients are free to travel to other member states to obtain health care. Furthermore, in many instances patients may be free to request the financing of the medical treatment from the state where they are insured. On the other hand, member states can, under certain circumstances, demand a prior authorisation. While organising the health system, member states should consider that health providers are possible to deliver health services to a wider group of patients than their own nationals.¹⁵¹

Another change in this field was brought by the Regulation on coordination of social security systems. This Regulation protects patients' rights in EU health law and policy, and it is applicable in cases of planned as well as unplanned healthcare.

The most important part of this chapter is case law of the European Court of Justice. Patients can rely not only on the before mentioned Regulation, but also on directly applicable free movement of services rules laid down in primary law.

One of the first important decisions affecting patient mobility within the EU was judgment the joint decision *Kohll* and *Decker*. It was significant in that sense, that EU internal market law was applied to health care.

Patients have to obtain prior authorisation to receive health care abroad. This rule naturally applies only for cases of planned care. The costs of healthcare will be reimbursed according to the tariff of the state, which is more beneficial for the patient.¹⁵² The Court distinguished between care provided in a hospital and non-hospital care. The requirement of prior authorisation is necessary only for hospital treatment

¹⁵⁰ *Luisi and Carbone v. Ministero dello Tesoro*, supra note 44.

¹⁵¹ NEERGAARD, Ulla. EU Health Care Law in a Constitutional Light: Distribution of Competences, Notions of 'Solidarity', and Social Europe'. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, supra note 10, p. 35.

¹⁵² *Vanbraekel*, supra note 115.

because of the need of forward planning in order to maintain a balanced medical and hospital service.¹⁵³ In conclusion, the case law of the CJEU improved the position of patients in cross-border health care and facilitated greater access to health care.

¹⁵³ *Smits and Peerbooms*, supra note 107.

3. Directive 2011/24/EU on patients' rights in cross-border health care

Directive 2011/24/EU of 9 March 2011 applies to individual patients who decide to seek health care in a member state different from their home country. It can be considered as a first attempt to collectivize and codify patients' rights and also member states' responsibilities.¹⁵⁴

3.1. Development and reasons for adopting the Directive

The political need for creating a directive on patient mobility emerged during the process of adopting the Services Directive 2006/123¹⁵⁵, in which the European Parliament excluded healthcare from the scope of application. This was because that healthcare was not considered suitable for this kind of directive.¹⁵⁶

When the Directive was introduced by the European Commission in 2008, the draft faced objections from governments of the member states and also from a majority of members of the European Parliament. Member states were worried that the proposal was going too far and that unrestricted freedom of mobility for patients and health services would lead to a loss of control over health budgets. Despite their objections, the Directive was approved by the European Parliament in January 2011 after a complex political procedure of almost six years.¹⁵⁷

The objectives of the Directive were to: provide clear rules and reliable information to patients regarding access and reimbursement for healthcare received in another EU country; to provide patients with the highest quality healthcare when travelling abroad; and to ensure EU countries work closer together in the interest of patients.¹⁵⁸

Member states were naturally divided during negotiations into two groups who held different views. Smaller and economically poorer member states expressed their

¹⁵⁴ GREER, Scott L. and Paulette KURZER, *supra* note 17, p. 23.

¹⁵⁵ Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ L 376.

¹⁵⁶ PEETERS, Miek, *supra* note 2, p. 30.

¹⁵⁷ GREER, Scott L. and Paulette KURZER, *supra* note 17, p. 23-24.

¹⁵⁸ *Special Eurobarometer 425 "Patients' rights in cross-border healthcare in the European Union": Report. 2015.* ISBN 978-92-79-47894-9, p. 3.

fear that the Directive could have a double disadvantage for their health system. They were also concerned that the Directive may cause a large outflow of patients and medical specialists to other member states and a simultaneous influx of patients from wealthier member states. This situation would cause an under-supply for the domestic population (because patients from wealthier countries are much more profitable for domestic providers), but domestic patients would hardly be able to seek treatment in expensive health care systems, because providers in these countries are to be remunerated according to the fee schedule in the poorer countries. Wealthier member states insisted on a strict application of the prior authorization procedure wherever possible and appropriate.¹⁵⁹

From a political point of view, the final version of the Directive can be seen as a compromise *'trying to find the balance between the respect for the ECJ jurisdiction, the respect for the right (and obligation) of member states to organise, run and manage their health care systems, and the right of patients' hoping for more harmonisation, clarity and legal certainty*¹⁶⁰. The future role of the ECJ in health care will depend on how and to what extent member states transpose the directive into their national law.¹⁶¹

The proposal was also seen as discriminatory. Opponents said the advantages of providing cross-border health care can only be used by patients who have knowledge of their EU rights, have enough financial means to travel abroad for treatment, and stay abroad for some period to receive treatment. It was also argued that this system was unfair towards chronically ill patients and the long-term sick who require longer and probably more complex forms of treatment.¹⁶²

Despite all of these doubts, the number of EU patients travelling between member states to seek health care abroad was estimated as low, according to the Commission's consultation on health services. The assumption was that only 1% of all expenses in health care (including health care unexpected during holidays abroad) will be used on cross-border healthcare costs, the financial flows were estimated higher than 1% only in border areas.^{163,164}

¹⁵⁹ GREER, Scott L. and Paulette KURZER, supra note 17, p. 24.

¹⁶⁰ Ibid., p. 25.

¹⁶¹ Ibid., p. 25.

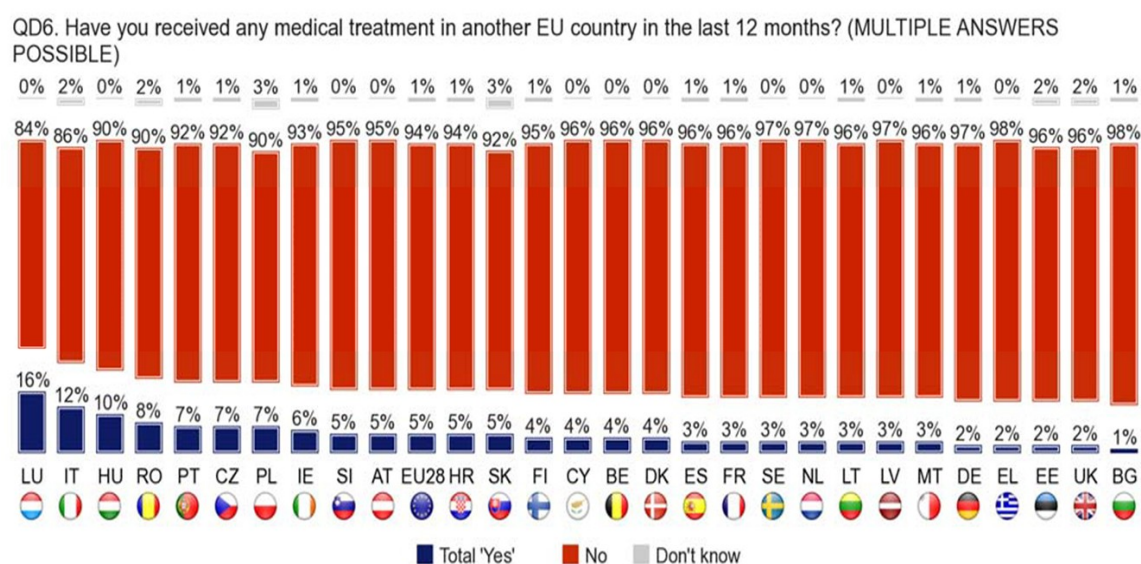
¹⁶² SZYSZCZAK, Erika. Patients' rights: A Lost Cause or Missed Opportunity?. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, supra note 10, p. 111.

¹⁶³ GREER, Scott L. and Paulette KURZER, supra note 17, p. 118.

¹⁶⁴ SZYSZCZAK, Erika. Patients' rights: A Lost Cause or Missed Opportunity?. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, supra note 10, p. 115.

In 2015, a report called ‘Patients’ rights in cross-border healthcare in the European Union’ was published. This survey was requested by the European Commission, Directorate-General for Health and Consumers (SANCO) and coordinated by Directorate-General for Communication. In terms of the proportion of Europeans who said that they had actually received medical treatment in another Member State, there was relatively little difference from one EU country to another, according to this survey.¹⁶⁵

Chart 1: European Union citizens receiving medical treatment in another EU country



Source: *Special Eurobarometer 425 “Patients’ rights in cross border healthcare in the European Union”*: Report. 2015. ISBN 978-92-79-47894-9.

3.2. Content and scope of application

The Directive provides an extensive legal framework for cross-border healthcare, mainly with rules concerning the reimbursement of costs of cross-border health care, responsibilities of a member state of treatment,¹⁶⁶ as well as a member state of affiliation¹⁶⁷ with regard to cross-border healthcare and the framework for cooperation in healthcare. Cross-border healthcare covers all situations different from

¹⁶⁵ *Special Eurobarometer 425 “Patients’ rights in cross-border healthcare in the European Union”*: Report. 2015, supra note 158.

¹⁶⁶ Member state on whose territory healthcare is actually provided to the patient.

¹⁶⁷ Member state that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another member state.

the one, when the patient is treated in a member state he/she is socially insured in by a local healthcare provider who is established in that member state.¹⁶⁸

Cases concerning situations of planned patient mobility, such as the *Kohll* and *Decker* cases, can be considered as predecessors of the Directive. Nevertheless, the Directive does not have to be limited to planned patient mobility. Also patients who receive unplanned medical care while staying abroad can benefit from the patients' rights stated in the Directive.¹⁶⁹

The Directive is applicable to healthcare, regardless of how it is organised, delivered and financed.¹⁷⁰ In Article 1(3), there are three categories to which the Directive does not apply to. Firstly, there are long-term care services to support people in need of assistance in carrying out routine tasks. This includes services provided by home care services, in assisted living facilities and in residential homes or housing (nursing homes).¹⁷¹ The Directive is also not applicable to the access and allocation of organs for the purpose of transplantation and public vaccination programmes against infectious diseases.¹⁷²

These three types of healthcare, excluded from the scope of the Directive, have not yet been dealt in the case law of the CJEU on Article 56 TFEU. The only reason for excluding these three categories is the fear of large costs for the state of affiliation.¹⁷³

3.3. Aims of the Directive

The aim of the Directive has been (i) to promote the idea of a borderless European health care market, (ii) to provide clarity and certainty as to the application of free movement principles to health services, (iii) to specify the rights of consumers and patients' in terms of quality and safety standards, (iv) to create an EU set of procedural rights and guarantees for patients seeking health care abroad, (v) to provide a framework for cooperation between member states on cross-border health care.^{174,175}

¹⁶⁸ PEETERS, Miek, *supra* note 2, p. 29-32.

¹⁶⁹ PEETERS, Miek, *supra* note 2, p. 32-33.

¹⁷⁰ 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, OJ L 88 (Directive 2011/24/EU), Article 1(2).

¹⁷¹ *Ibid.*, Preamble, recital 14.

¹⁷² *Ibid.*, Article 1(3).

¹⁷³ PENNING, Frans, *supra* note 73, p. 438.

¹⁷⁴ GREER, Scott L. and Paulette KURZER, *supra* note 17, p. 23.

¹⁷⁵ SZYSZCZAK, Erika. Patients' rights: A Lost Cause or Missed Opportunity?. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, *supra* note 10, p. 108-109.

Generally, the reason for proposing the Directive concerning such a sensitive field for member states was to bring clarity and legal certainty to this area, because cross-border health care became a subject of an increased litigation.¹⁷⁶

3.4. Legal basis

The Directive has two legal bases – Article 114 TFEU and 168 TFEU.¹⁷⁷ The initial proposal of the Directive was based upon the internal market legal base of Article 114 TFEU and this Article constitutes a main legal basis, as stated in recital 2 of the Directive.¹⁷⁸

The use of public health provision (Article 168 TFEU) was justified mainly by the fact that ‘*a high level of human health protection is to be ensured also when the Union adopts acts under other Treaty provisions*’¹⁷⁹. That in this case means internal market provisions.¹⁸⁰ Moreover, Article 114(3) TFEU requires that when a harmonisation measure is adopted, it must guarantee a high level of protection of human health, in particular taking into account any new development based upon scientific fact.¹⁸¹

The proposal of the Article 114 TFEU as a single legal base was criticised due to its explicit linkage to the free movement right to health care services as an economic right. It was but justified by the Commission, which showed that even though the Court had clarified patients’ rights to travel abroad to receive medical treatment, patients were not actually able to exercise these rights effectively. The Committee of Regions also supported the use of a joint legal basis, combining Article 114 TFEU and Article 168 TFEU, which was eventually adopted. As a result, many objectives of the Directive are incompatible with the prohibition of harmonisation stated in Article 168 TFEU.¹⁸²

¹⁷⁶ Ibid., p. 109.

¹⁷⁷ BORGES, Danielle da Costa Leite. *EU health systems and distributive justice: towards new paradigms for the provision of health care services?*. ISBN 9781315628301, p. 147.

¹⁷⁸ Directive 2011/24/EU, supra note 170, Preamble, recital 2.

¹⁷⁹ Ibid., Preamble, recital 1.

¹⁸⁰ BORGES, Danielle da Costa Leite, supra note 177, p. 147.

¹⁸¹ SZYSZCZAK, Erika. Patients’ rights: A Lost Cause or Missed Opportunity?. In VAN DE GRONDEN, Johan [AND OTHERS] a EDITORS, supra note 10, p. 119.

¹⁸² Ibid., p. 119-120.

3.5. Reimbursement of costs of cross-border healthcare

3.5.1. General principles for reimbursement of costs

The provisions of the Directive concerning reimbursement of costs are essentially a codification of the *Kohll-Decker* case law.¹⁸³

In practice, a patient has to arrange treatment conditions with a health care provider and pay upfront. Afterwards, the patient can ask for reimbursement of costs for this treatment.¹⁸⁴

The reimbursement of costs is a responsibility of the member state of affiliation.¹⁸⁵ The costs of cross-border health care are reimbursed up to the level of costs that would have been assumed by the member state, if this health care is provided in its territory, but only up to the actual costs of health care received.¹⁸⁶ Member states can decide to reimburse full costs in cases when these costs exceed the reimbursement tariff in the member state of affiliation.¹⁸⁷ However, the Directive explicitly states that a member state can also reimburse other related costs, such as accommodation and travel costs, or extra costs for persons with disabilities.¹⁸⁸ In addition, a member state can set up a third payer system to prevent patients having to pay all costs in advance.¹⁸⁹

However, the reimbursement should not exceed the actual costs of the healthcare received. That means that enrichment of the patient with the so-called *Vanbraekel supplement*, which had to be paid even when the actual costs in the state of treatment were lower than reimbursement tariffs in the state of affiliation, is prohibited.¹⁹⁰

Each member state has to set up a transparent mechanism for the calculation of costs of cross-border healthcare that must be reimbursed to patients. This mechanism has to be objective, non-discriminatory and known in advance.¹⁹¹ This provision is addressed to member states that do not have reimbursement tariffs, because their

¹⁸³ PEETERS, Miek, supra note 2, p. 33.

¹⁸⁴ Na co mám nárok, pokud cestuji za zdravotní péčí. *Kancelář zdravotního pojištění* [online]. 2010 [cit. 2017-06-11]. Available at: <https://www.kancelarzp.cz/cs/pojistenci/prava-naroky-eu/narok-kategorie/cesta-za-zdrav-peci>.

¹⁸⁵ Directive 2011/24/EU, supra note 170, Article 7(1).

¹⁸⁶ Ibid., Article 7(4), paragraph 1.

¹⁸⁷ Ibid., Article 7(4), paragraph 2.

¹⁸⁸ Ibid., Article 7(4), paragraph 3.

¹⁸⁹ PEETERS, Miek, supra note 2, p. 52.

¹⁹⁰ STRBAN, Grega, supra note 37, p. 400.

¹⁹¹ Directive 2011/24/EU, supra note 170, Article 7(6).

patients are entitled to health care for free, for example Great Britain with its National Health Service.¹⁹²

3.5.2. *Healthcare that may be subject to prior authorisation*

The reimbursement of costs of cross-border healthcare cannot be subject to prior authorisation with a few explicitly stated exceptions.¹⁹³

Firstly, healthcare which is subject to planning requirements and involves overnight hospital accommodation for at least one night, or requires use of highly specialised and cost-intensive medical infrastructure or medical equipment.¹⁹⁴ Member states have to notify the Commission about categories of healthcare which they qualify as subjects to planning requirement.¹⁹⁵

The second exception is treatment that presents a particular risk for the patient or the population.¹⁹⁶ This provision can be interpreted broadly and its application depends on how member states implement it into their national law.¹⁹⁷

The third exception is healthcare provided by a healthcare provider that could cause concerns relating to the quality or safety of the care. This does not apply to healthcare which is subject to EU legislation ensuring a minimum level of safety and quality.¹⁹⁸

As in the second exception, the impact of this provision depends on how member states implement it in their national law. From this provision, it is not entirely clear to what extent member states can question the quality and safety of healthcare provided in different member states. As confirmed in the *Stamatelaki case*¹⁹⁹, reimbursement of cross-border healthcare cannot be refused solely for the reason that the treatment was provided in a private hospital.²⁰⁰ Looking at the reference to EU legislation ensuring a minimum level of safety and quality, it is not clear which legislation in particular it is. According to Peeters, it seems that the reference is related

¹⁹² PEETERS, Miek, supra note 2, p. 35.

¹⁹³ Directive 2011/24/EU, supra note 170, Article 7(8).

¹⁹⁴ Ibid., Article 8(2)a.

¹⁹⁵ Ibid., Article 8(2), paragraph 2.

¹⁹⁶ Ibid., Article 8(2)b.

¹⁹⁷ PEETERS, Miek, supra note 2, p. 38.

¹⁹⁸ Directive 2011/24/EU, supra note 170, Article 8(2)c.

¹⁹⁹ *Stamatelaki*, supra note 138.

²⁰⁰ PEETERS, Miek, supra note 2, p. 38.

to possible future European legislation which could provide a minimum harmonisation of quality and safety criteria of medical services.²⁰¹

Each member state has to publish which healthcare requires a prior authorisation and all relevant information about the prior authorisation system.²⁰² For example, the Czech Republic has not used the option to set up a system of prior authorisation.

Nevertheless, the prior authorisation system was drafted as an exception to the rule and it has to be construed narrowly by member states. Prior authorisation should be restricted to what is necessary and proportionate to the objective to be achieved.²⁰³ The European Commission can sue a member state to the CJEU if the list of prior authorisation rules is not consistent with free movement principles.²⁰⁴

3.5.3. Refusal of prior authorisation

The possibility of a member state refusing to grant prior authorisation is limited to four cases. Firstly, this concerns a situation when a treatment would constitute a safety risk for a patient. This risk has to be determined by a clinical evaluation with reasonable certainty.²⁰⁵ The second case is a safety risk for the population when the general public would be exposed with reasonable certainty to a substantial safety hazard.²⁰⁶ Member states can also refuse prior authorisation when there are serious or specific concerns about the health care provider relating to the quality of care and patient safety.²⁰⁷ For example, this can imply a situation when a healthcare provider is not entitled to the right to practice.²⁰⁸ The last case of refusing to grant a prior authorisation is when the healthcare can be provided on a territory of a state within a reasonable timeframe. The competent institution has to take into consideration the current health condition of a patient and probable development of the illness.²⁰⁹ This refusal cannot be based only on the existence of waiting lists.²¹⁰ The phrases “within a reasonable time” or “within a time limit, which is medically justifiable” display a vague

²⁰¹ Ibid., p. 38.

²⁰² Directive 2011/24/EU, supra note 170, Article 8(7).

²⁰³ STRBAN, Grega, supra note 37, p. 401.

²⁰⁴ PEETERS, Miek, supra note 2, p. 52.

²⁰⁵ Directive 2011/24/EU, supra note 170, Article 8(6)a.

²⁰⁶ Ibid., Article 8(6)b.

²⁰⁷ Ibid., Article 8(6)c.

²⁰⁸ PEETERS, Miek, supra note 2, p. 39.

²⁰⁹ Directive 2011/24/EU, supra note 170, Article 8(6)d.

²¹⁰ Ibid., Preamble, Recital 43.

time period, but one related to a patient's specific medical condition and can be derived from the ECJ case law.²¹¹

3.6. Relation between the Directive and the Regulation

As a result of adopting the Directive, a dual system of reimbursement for costs of cross-border care came into existence. Firstly, healthcare for which authorisation was given according to the rules of the Regulation 883/2004 (based on the free movement of persons). Secondly, healthcare for which no authorisation was given, but which had to be reimbursed on the basis of the Treaty provisions, now codified in Directive 2011/24 (based on the free movement of services/goods).^{212,213}

It was decided that the system of the Regulation will remain effective alongside the Directive. The existence of two alternative procedures is explicitly mentioned in the Directive, stating that either the rules in the Directive apply, or the Regulation applies.²¹⁴ The rights under these two instruments cannot be used simultaneously; thus double reimbursement is clearly forbidden.²¹⁵ The Directive specifies that it applies without prejudice to the Regulation.²¹⁶

The Directive gives priority to the Regulation. It explicitly states that when conditions of Regulation are met, a prior authorisation will be granted pursuant to that Regulation unless the patient requests otherwise.²¹⁷ Practically, it means if the Regulation has more beneficial rules for patients, it will have priority. If not, the patient can request for the Directive to be applied.

When a patient chooses the path of the Directive, he/she leaves the framework of the social security law and enters the law of the internal market. At that moment, his/her status as a socially insured person changes into the position of an economic subject – a consumer. He/she will have to pay for the costs of healthcare in advance, according to local tariffs. This patient will again be treated as a socially insured person when

²¹¹ PEETERS, Miek, *supra* note 2, p. 39.

²¹² PENNING, Frans, *supra* note 73, p. 134.

²¹³ PEETERS, Miek, *supra* note 2, p. 40.

²¹⁴ Directive 2011/24/EU, *supra* note 170, Preamble, Recital 30.

²¹⁵ CARRASCOSA BERMEJO, Dolores, *supra* note 67, p. 364.

²¹⁶ Directive 2011/24/EU, *supra* note 170, Article 2(m).

²¹⁷ *Ibid.*, Article 8(3).

submitting his/her application for reimbursement of medical treatment to the social security institution in his/her home country.²¹⁸

It is possible to combine both systems in practice. For example, a patient can attend a practitioner for prior consultation under the Directive without prior authorisation (and then obtain reimbursement of costs). Once the treatment or the surgery procedure required has been established, he/she can ask for a prior authorisation under the Regulation and get reimbursement for this.²¹⁹

Furthermore, the distinction between these two systems is very complicated for the majority of patients. This dual system is complex and not easy to understand. This interplay between social security coordination and the law on economic freedoms made the application of the right to cross-border healthcare reasonably complex.²²⁰

The question which arises is: when it is more beneficial for a patient to choose the application of the Directive over the more traditional social security coordination system? The Regulation is generally preferable, because no advance payments are necessary and there is possibility for the coverage of travel and accommodation costs. For example, the choice of the Directive is suitable for ambulatory treatment, for a more efficient treatment method, or for treatment with private (non-contracted) healthcare providers (not related to public healthcare system).²²¹

In this situation, a so-called reverse discrimination may occur. When a European Union citizen is staying in his/her member state and he/she is in a purely internal legal situation, the European Union law cannot be used. Only the national law of the member state concerned can be used which may be less beneficial for the patient than the European Union law.²²²

The Directive expressly states that a member state is not obliged to reimburse costs of healthcare provided by healthcare providers established on its own territory if those providers are not part of the social security system or public health system of that member state.²²³ As a result, this situation may have a negative impact on the legal position of a person whose treatment is limited to purely internal situations. In his article, Strban examines what could be the solution of this situation. He does not find

²¹⁸ STRBAN, Grega, *supra* note 37, p. 403.

²¹⁹ CARRASCOSA BERMEJO, Dolores, *supra* note 67, p. 365.

²²⁰ STRBAN, Grega, *supra* note 37, p. 406.

²²¹ *Ibid.*, p. 403-404.

²²² *Ibid.*, p. 403-404.

²²³ Directive 2011/24/EU, *supra* note 170, Article 1(4).

this kind of reverse discrimination in accordance with the European Union law and national law of member states. The CJEU has already recognised rights based on the European Union citizenship without any movement within the Union. Reverse discrimination might also be in contradiction with national laws of EU member states prohibiting discrimination.²²⁴

Furthermore, the dual legal system also seems problematic in terms of reimbursement of costs of cross-border healthcare. The member states responsible for reimbursement under these two legal instruments might be different, since the member state responsible under the Regulation and under the Directive may not always be the same.²²⁵

Strban concludes that harmonisation of these two systems would be beneficial, although he asks more questions than he provides answers for. He misses the consistent social policy of the European Union which would regulate patients' mobility issues in one legal instrument, which would be understandable to an average patient.²²⁶

There are a few situations when only the Regulation will apply. First, the Regulation can apply in relation to healthcare received in some third countries²²⁷. This is possible, because of the external dimension of social security coordination. Secondly, the Regulation covers treatment which is explicitly excluded from the material scope of the Directive. This is for long-term care, organ transplants and public vaccination programmes.²²⁸ Finally, if an insured person becomes a resident in another member state, reimbursement rights under the Directive are not longer applicable, because residence is not considered as a cross-border situation.²²⁹

One of the advantages of the Directive is that, compared to the Regulation, in most member states access to each healthcare provider is only possible under the Directive. Under the Regulation, the patients' choice of healthcare provider is limited.²³⁰

²²⁴ STRBAN, Grega, *supra* note 37, p. 404.

²²⁵ *Ibid.*, p. 405.

²²⁶ *Ibid.*, p. 406.

²²⁷ Non-EU member states.

²²⁸ Directive 2011/24/EU, *supra* note 170, Article 1(3).

²²⁹ CARRASCOSA BERMEJO, Dolores, *supra* note 67, p. 367.

²³⁰ *Ibid.*, p. 366.

Table 1: Overview Directive 2011/24 vs. Regulation 883/2004

	Legal basis	Entitlement to reimbursement 1. Need for prior authorisation 2. Grounds for refusal of authorisation	Applicable rules (including reimbursement tariffs)
Regulation 883/2004	Free movement of persons Art. 48 TFEU + Art. 352 TFEU	1. always need for prior authorisation 2. authorisation cannot be refused if: - treatment is in the basket of MS of affiliation and - patient is in need of treatment that cannot be given within reasonable time in MS of affiliation	MS of treatment – MS of affiliation pays directly through third payer system
Directive 2011/24	Free movement of services/goods Art. 114 TFEU + Art. 168 TFEU	1. only need for prior authorisation in case of: - hospital/non-hospital care (with planning) - safety risk for patient - safety risk for population - concerns about healthcare provider 2. authorisation can only be refused in case of: - safety risk for patient - safety risk for population - concerns about healthcare provider - treatment can be provided within reasonable time in MS of affiliation	MS of affiliation – MS of affiliation reimburses costs (unless the MS has installed a third payer system), possibly also extra costs (e.g. travel and accommodation costs)

Source: PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Healthcare*. DOI: 10.1163/157180912X615158. ISBN 10.1163/157180912X615158. Available at: <http://booksandjournals.brillonline.com/content/10.1163/157180912x615158>, p. 42.

The distinction in requirements for reimbursement is as follows. Under the Regulation, prior authorisation is only required for planned healthcare, irrespective of whether the treatment is in a hospital or not. Unplanned healthcare does not require prior authorisation. On the other hand, under the Directive, prior authorisation should be the exception, not the rule. When implementing the Directive, member states can establish requirements which might be considered as obstacles to free movement of services, only if they are justified by overriding reasons of general interest.²³¹

Table 2: Reimbursement under the Regulation and the Directive

	Regulation		Directive
	Unplanned	Planned	
Purpose of the journey	Temporary stay non-related to healthcare	Healthcare	Irrelevant
Healthcare coverage provided	Medically-necessary case during the stay	Complete healthcare	Complete healthcare
Basket of services	MS of treatment	Competent MS	MS of affiliation
Prior authorisation	No	Yes	Depends on implementation
Issued by	-	Competent authorising MS	MS of affiliation
Payment procedure	Standard procedure in MS of treatment	Standard procedure in MS of treatment	Upfront payment by the patient
Reimbursement procedure	Reimbursement between institutions Reimbursement to patient in case of upfront payment	Reimbursement between institutions Reimbursement to patient in case of upfront payment	Upfront payment by the patient Reimbursement to patient
Extent of the reimbursement	Tariff of the MS of treatment	Tariff of the MS of treatment	Tariff of the MS of affiliation

Source: CARRASCOSA BERMEJO, D. Cross-border healthcare in the EU: Interaction between Directive 2011/24/EU and the Regulations on social security coordination, p. 378.

²³¹ CARRASCOSA BERMEJO, Dolores, supra note 67, p. 372.

3.7. Patients' rights in the Directive

Patients' rights are strongly individuated, focused on the central value of patient choice and concerned with the enforcement of individual rights. Very little attention is paid to patients' rights as a collective phenomenon as part of national health systems. This aspect of patients' rights is embraced by the coordination of social security entitlements.²³²

3.7.1. *Right to receive information*

One of the most important rights in the system of cross-border healthcare is the right of patients to receive information. Right to information can be divided into two categories. Firstly, patients entitled to receive information on standards and guidelines on quality and safety in the state of treatment and information about reimbursement in the state of affiliation. Secondly, the rights aim to provide all the information needed to help patients make an informed choice. When making an informed choice, the patients require information about: treatment options, availability, quality and safety of the healthcare, prices, authorisation or registration status of a healthcare provider and his insurance cover.²³³

The Directive does not affect national law on language use, therefore member states can provide information in other languages, but they are not obliged to do so.²³⁴ For example, the Health Insurance Bureau in the Czech Republic also provides information in English.

According to the European Commission's survey²³⁵, most EU citizens feel ill-informed about healthcare and reimbursement rights they are entitled to in another EU country. Information provided to patients is too complex, incomplete and often only in a foreign language.

²³² HERVEY, Tamara K. and Jean V. MCHALE, supra note 7, p. 189.

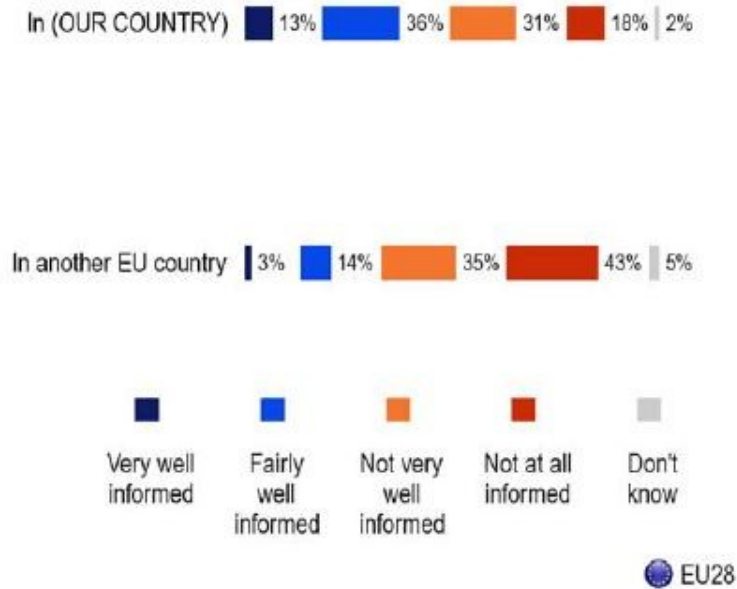
²³³ Directive 2011/24/EU, supra note 170, Article 4(2)a,b.

²³⁴ Ibid., Article 4(5).

²³⁵ *Special Eurobarometer 425 "Patients' rights in cross-border healthcare in the European Union"*: Report. 2015, supra note 158.

Chart 2: Awareness of patients regarding the right to be reimbursed

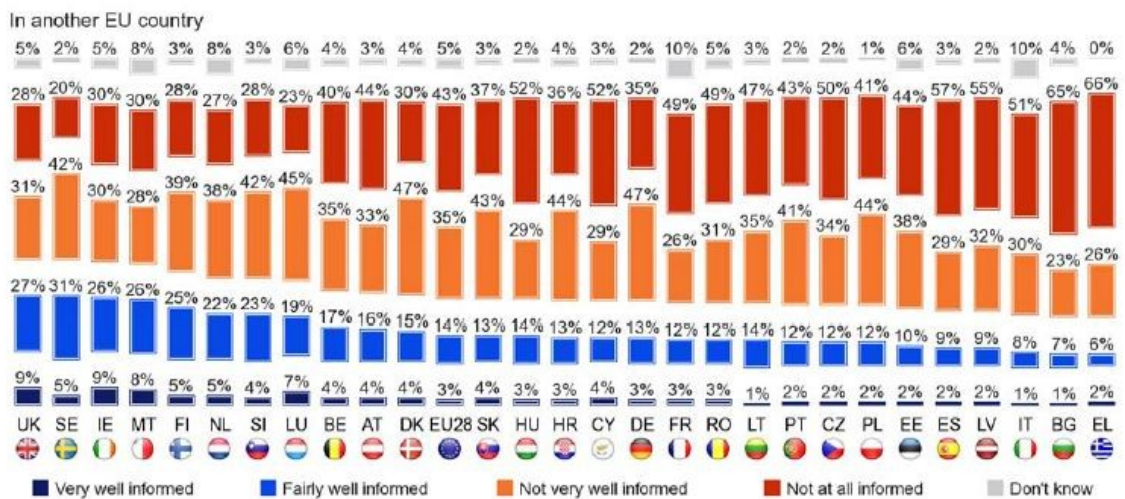
QD1. Overall, to what extent do you think that you are well informed about what healthcare you have the right to get reimbursed for...?



Source: *Special Eurobarometer 425 "Patients' rights in cross border healthcare in the European Union": Report. 2015.* ISBN 978-92-79-47894-9.

Chart 3: Awareness of patients regarding the right to be reimbursed (in MS)

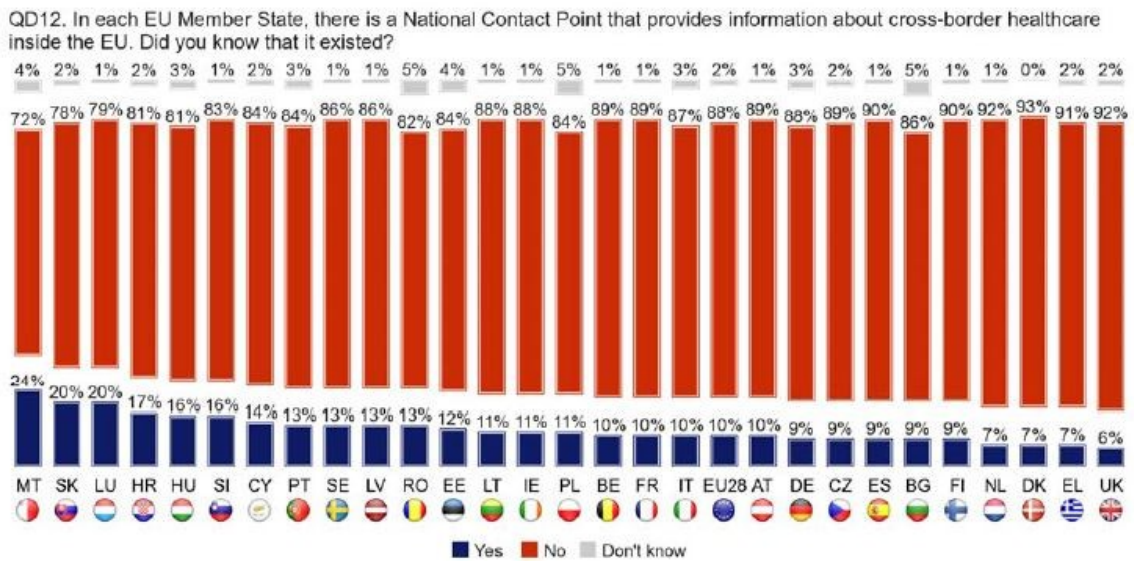
QD1.2. Overall, to what extent do you think that you are well informed about what healthcare you have the right to get reimbursed for...?



Source: *Special Eurobarometer 425 "Patients' rights in cross border healthcare in the European Union": Report. 2015.* ISBN 978-92-79-47894-9.

Information is provided in national contacts points for cross-border healthcare, which member states are obliged to designate.²³⁶ Nevertheless, the survey showed that only one European in ten knew of the existence of national contact points providing information about cross-border healthcare inside the EU. This figure may seem low, but given the fact that only 5% of Europeans experienced EU cross-border healthcare, it seems rather logical.²³⁷

Chart 4: Awareness of patients regarding national contact points



Source: *Special Eurobarometer 425 “Patients’ rights in cross border healthcare in the European Union”*: Report. 2015. ISBN 978-92-79-47894-9.

3.7.2. Right not to be discriminated

This right was derived from the general prohibition on discrimination on the basis of nationality of the Treaty, and applies to all patients from other member states.²³⁸ Nevertheless, a member state can adopt measures concerning access to healthcare in order to ensure sufficient and permanent access to a healthcare service on its territory. These measures have to be justified by overriding reasons of general interest and must be publicly available in advance.²³⁹ In other words, member states can adopt these measures only when the access of their own patients to their healthcare

²³⁶ Directive 2011/24/EU, supra note 170, Article 6.

²³⁷ *Special Eurobarometer 425 “Patients’ rights in cross-border healthcare in the European Union”*: Report. 2015, supra note 158.

²³⁸ PEETERS, Miek, supra note 2, p. 54.

²³⁹ Directive 2011/24/EU, supra note 170, Article 4(3).

service is jeopardised due to a disproportionate inflow of foreign patients.²⁴⁰ Furthermore, fees of healthcare for foreign patients have to be the same as for domestic patients.²⁴¹

3.7.3. Right to transparent complaints procedure

This right includes a patients' right to a mechanism to seek remedies if they suffer harm arising from the healthcare received.²⁴²

3.7.4. Right to privacy

Right to privacy has to be considered with respect to the processing of personal data, as found in the EU Charter of Fundamental Rights, Article 8, and Directive 95/46/EC.²⁴³

3.7.5. Right to receive a medical record of treatment

Patients who received medical treatment abroad are entitled to receive a written or electronic medical record of this treatment in order to ensure continuity of care.²⁴⁴

3.8. National contact points

Member states have to designate at least one national contact point for cross-border healthcare which should consult with patient organisations, healthcare providers and health insurers.²⁴⁵ Their task is to facilitate the exchange of information among other contact points, and cooperate with them and the Commission.²⁴⁶ The biggest benefit for patients is represented by the obligation of national contact points to inform about healthcare providers, patients' rights, the complaints procedure and the mechanism for seeking remedies.²⁴⁷

In many member states, including the Czech Republic, the national contact point is the institution that already exists, and has been collecting information on cross-border health care, which might be the existing contact point for social security coordination.²⁴⁸

²⁴⁰ PEETERS, Miek, *supra* note 2, p. 44.

²⁴¹ Directive 2011/24/EU, *supra* note 170, Article 4(4).

²⁴² *Ibid.*, Article 4(2)c.

²⁴³ *Ibid.*, Article 4(2)e.

²⁴⁴ *Ibid.*, Article 4(2)f.

²⁴⁵ *Ibid.*, Article 6(1).

²⁴⁶ *Ibid.*, Article 6(2).

²⁴⁷ *Ibid.*, Article 6(3).

²⁴⁸ STRBAN, Grega, *supra* note 37, p. 402.

Some member states have different national contact points for incoming and outgoing patients. Some NCPs are based in the Ministry of Health, while others are located in the healthcare insurer or in independent bodies.²⁴⁹

The information provided by the national contact point should be easily accessible, available by electronic means and in a format accessible to people with disabilities.²⁵⁰

3.9. Cooperation in healthcare

The Directive governs six areas of possible cooperation of member states: mutual assistance and cooperation²⁵¹, recognition of prescriptions issued in another member state²⁵², European reference networks²⁵³, rare diseases²⁵⁴, eHealth²⁵⁵, and cooperation on health technology assessment²⁵⁶.

3.9.1. Mutual assistance and cooperation

This provision is necessary for the implementation of the Directive. It concerns cooperation on standards and guidelines on quality and safety, and the exchange of information. Cooperation is especially important in border regions, where providing cross-border healthcare may be the most efficient way for organising health services.²⁵⁷ This cooperation may concern joint planning, mutual recognition of procedures or standards, interoperability of respective national information and communication technology systems.²⁵⁸ This provision is expected to improve the quality of healthcare services across EU member states. Problematic in this respect may be the lack of harmonisation of quality and safety standards. In my opinion, the improvement will probably be gradual and relatively slow.

²⁴⁹ *Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare: COM(2015) 421 final*. Brussels, 2015.

²⁵⁰ Directive 2011/24/EU, *supra* note 170, Article 6(5).

²⁵¹ *Ibid.*, Article 10.

²⁵² *Ibid.*, Article 11.

²⁵³ *Ibid.*, Article 12.

²⁵⁴ *Ibid.*, Article 13.

²⁵⁵ *Ibid.*, Article 14.

²⁵⁶ *Ibid.*, Article 15.

²⁵⁷ *Ibid.*, Article 10(1)(3).

²⁵⁸ *Ibid.*, Preamble, Recital 50.

3.9.2. Recognition of prescriptions

Member states have to recognise prescriptions for medicinal products issued in another member state if these products are authorised to be marketed on their territory.²⁵⁹

3.10. Ethically controversial treatment

A range of areas of health law, particularly those concerning human reproduction and end-of-life decision making, are subject to significantly different approaches in EU member states. Access to abortion, assisted reproduction or end-of-life decisions differ widely across European states.²⁶⁰

Considering abortion, national abortion law is very strict in Malta and Ireland. Abortion is illegal in Malta, and only allowed when it is necessary to save a mother's life in Ireland. In contrast, abortion is available on many grounds and medical termination of pregnancy is covered under the national health system in most member states.²⁶¹

The difference in approaches in member states was challenged in the *Grogan case*²⁶². This case dealt with information distribution regarding abortion services abroad by a students' union at an Irish university. Irish Constitution protects the right of life of the unborn and abortion is only allowed when it is necessary to save a mother's life.²⁶³ The CJEU confirmed that abortion constitutes a 'service' in the sense of Article 56 TFEU. At the same time, the CJEU decided that a link between the actions of the Irish students' union and medical clinics providing termination of pregnancy abroad was 'too tenuous' for the prohibition of distributing information to constitute a restriction on free movement of services.²⁶⁴ Therefore, the Irish rule that restricts advertising by a body unconnected with a service provider is no restriction in the sense of Article 56 TFEU.

This judgment clarified doubts about how the principles of EU free movement law intervene with ethical principles, especially those enshrined in national constitutional law. Most member states embodied abortion rules and other sensitive

²⁵⁹ Ibid., Article 11(1).

²⁶⁰ HERVEY, Tamara K. and Jean V. MCHALE, supra note 7, p. 91.

²⁶¹ Ibid., p. 91-92.

²⁶² Judgment of the Court of 4 October 1991, *Grogan*, C-159/90, EU:C:1991:378.

²⁶³ Irish Constitution, Article 40.3.3.

²⁶⁴ *Grogan*, supra note 262, para. 24.

ethical principles into constitutional texts. The EU's constitutional law has to be considered in examining how far EU law and national law are in a hierarchical relationship. Most of the opinions are inclined to the fact that the relationship between the EU's constitutional rules and those of member states are non-hierarchical.²⁶⁵

There is also considerable ethical discourse concerning the right to reproduce, especially the question to who should the technology be available. For example, the regulatory structures concerning fertility treatment are significantly less restrictive in Belgium. That is why many patients from other countries have been seeking fertility treatment in the country. In some states, this kind of treatment is only available to couples who meet specific conditions. In some, egg or embryo donations or surrogate motherhood is restricted. There are also significant differences in donor anonymity, waiting times and costs of treatment, which may play a decisive role in couple decisions.²⁶⁶

There has not been any other EU health law litigation involved, although reproductive tourism, abortion tourism and death tourism is on the rise. The *Diane Blood* case²⁶⁷ can be considered as a partial exception. Although the case involves EU law, it was only considered by the national court. Mrs. Blood sought to use sperm collected from her recently deceased husband while he was critically ill. The removal and subsequent use was found illegal, because he had not given explicit consent to the taking of his sperm. Mrs. Blood sought to have the sperm exported in order to allow her to receive treatment in Belgium where this treatment is permitted. This export was refused and subsequently Mrs. Blood argued this refusal breached Article 56 TFEU as it restricted the free movement of services. The English Court of Appeal confirmed that rules on free movement of services are applicable on the export of the sperm. National rules cannot prevent citizens to seek treatment in a member state where it is accepted. Nevertheless, the legality of the removal or the storage of the sperm was not an issue before the court. Afterwards, the decision was reconsidered according to the courts judgement, and the export of the sperm was authorised. Mrs. Blood subsequently gave birth to two sons.

²⁶⁵ HERVEY, Tamara K. and Jean V. MCHALE, supra note 7, p. 92.

²⁶⁶ Ibid., p. 91-92.

²⁶⁷ R v. Human Fertilisation and Embryology Authority Ex P. Blood; Court of Appeal, Civil Division, 6 February 1997.

Although there has been increased discussion of the possible impact of EU free movement law on the ethical dimension of national health care provisions, there is still considerable limitation on its scope. Member states can no longer control which types of treatment their patients access and where. Unfortunately, the financial situation of patients may make a difference. For a woman living in Ireland who wants to have an abortion, it means she will have to pay the costs of travelling and possible accommodation abroad.²⁶⁸

In my opinion, member states should be allowed to protect their national law concerning ethical principles which are traditional on their territory. Potential harmonisation should not go that far to implement uniform rules in each state. Nevertheless, to preserve and protect EU free movement rules, citizens of each member state should be free to travel abroad to seek health care services which are not available or even illegal in their home country.

3.11. Implementation of the Directive

A directive is one of legal acts of the European Union. It is binding upon each member state to which it is addressed, but it leaves the choice of form and methods to the national authorities. Directives have to be implemented in national legislation in accordance with the procedures of the individual member state.²⁶⁹ The implementation of the Directive in the Czech Republic is further discussed below.

Directive 2011/24/EU was due to be transposed by member states by 25 October 2013.²⁷⁰ Infringement proceedings were launched against 26 member states on the grounds of a late or incomplete notification of such measures. These infringements only related to the completeness of transposition measures without examining if member states transposed the Directive correctly.²⁷¹

As a result, there is a much broader legal framework for cross-border healthcare. The Directive does not only provide a reimbursement system for costs of cross-border healthcare, but also provide patients' rights that are not related to cross-border care. The Directive reaches beyond patient mobility and influences European healthcare systems

²⁶⁸ HERVEY, Tamara K. and Jean V. MCHALE, *supra* note 7, p. 95.

²⁶⁹ Treaty on the Functioning of the European Union, OJ C 326, Art. 288.

²⁷⁰ Directive 2011/24/EU, *supra* note 170, Article 21.

²⁷¹ *Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare*, *supra* note 249.

in their whole. This therefore affects all European patients, not only those crossing borders.²⁷²

Member states and European Union institutions did not expect an enormous increase of patients crossing borders to receive healthcare abroad when adopting the Directive. Patients generally prefer to be treated close to where they live. The reasons are obvious: patients find the healthcare they can receive at home satisfying and feel more comfortable to be treated in their own country close to their family. Language may be a significant barrier for some patients and some are afraid of not being reimbursed.²⁷³

This assumption proved to be correct; according to a Commission survey conducted in 2015, patient flows for healthcare abroad under the Directive are low.²⁷⁴

Member states could use their discretionary powers and choose a different form and methods to implement the Directive. Article 20(1) of the Directive requires the Commission to ‘draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council’²⁷⁵ by 25 October 2015, and every three years thereafter. The first report was published on 4 September 2015 and showed the current state of transposing the Directive in different member states, as explained below.²⁷⁶

3.11.1. Prior authorisation

A system of prior authorisation has been implemented by 21 member states (not by Austria, the Czech Republic, Estonia, Finland, Lithuania, the Netherlands and Sweden). Some of these have introduced legislation enabling them to set up this system at a later date, if they find it necessary.²⁷⁷

²⁷² PEETERS, Miek, *supra* note 2, p. 51.

²⁷³ *Special Eurobarometer 425 “Patients’ rights in cross-border healthcare in the European Union”*: Report. 2015, *supra* note 158.

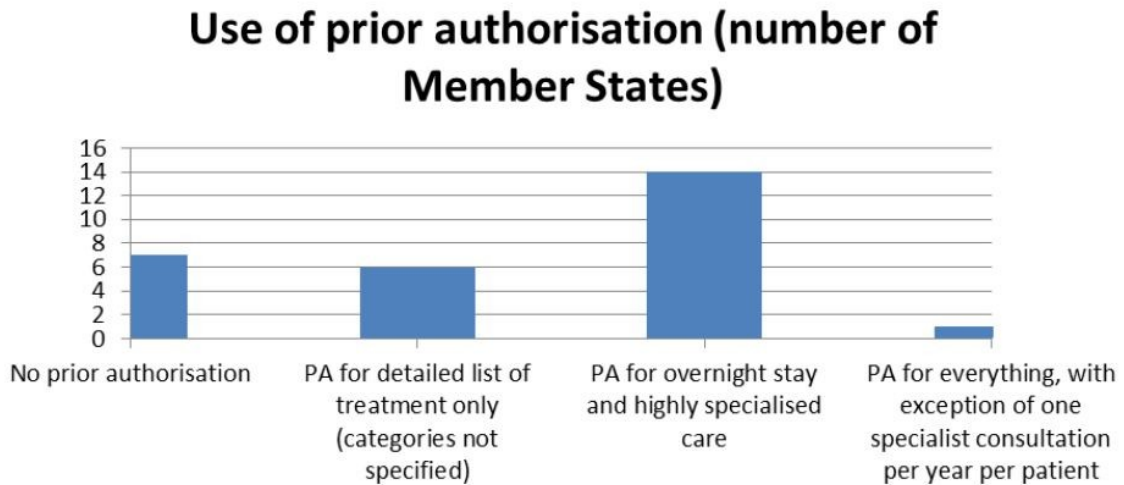
²⁷⁴ *Commission report on the operation of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare*, *supra* note 249.

²⁷⁵ Directive 2011/24/EU, *supra* note 170, Article 20(1).

²⁷⁶ *Commission report on the operation of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare*, *supra* note 249.

²⁷⁷ *Ibid.*

Chart 5: Use of prior authorisation (number of member states)



Source: *Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare: COM(2015) 421 final*. Brussels, 2015.

14 member states used both the 'overnight stay' and the 'highly specialised' care criteria for requiring prior authorisation. Neither of these countries, which have used the 'overnight stay' criterion, specified which treatment is covered by this criterion. Nine of the 14 member states set out which treatments they consider to meet the 'highly specialised' criterion, whilst five have not.

It is therefore unclear for patients in these 14 member states exactly which treatment is subject to prior authorisation, since the use of at least one of these criteria - and sometimes both - has not been elucidated by national authorities.²⁷⁸

3.11.2. Reimbursement

Member states are entitled to limit the application of the rules on reimbursement of cross-border healthcare for overriding reasons of general interest. However, such limitations have to be necessary and proportionate, and do not constitute a means of arbitrary discrimination or an unjustified obstacle to free movement. Furthermore, member states are required to notify the Commission of any decision to introduce limitations under the Directive.

Although the Commission confirmed that it has received no specific notifications in its report, some of the ways in which member states have transposed the

²⁷⁸ *Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare*, supra note 249.

Directive could be considered as limiting reimbursement. For example, three member states require any patient seeking reimbursement for cross-border healthcare to demonstrate why it is medically necessary for the particular episode of healthcare to be received in another country.²⁷⁹ It is questionable whether this is in line with the principle of patient free movement, and with the criteria set out in Articles 7(9) and 7(11) of the Directive.

Alongside this, twelve member states require patients to obtain a referral from a general practitioner or family doctor in order to access specialist healthcare. It means that these referrals are also required when patients want to be reimbursed for this kind of healthcare in another member state. This requirement seems to be in conflict with the principle of mutual recognition of qualifications, according to which member states should recognise decisions about clinical need and appropriateness provided by an equivalent professional in another member state.²⁸⁰

Another provision, which might be contrary to the aim of the Directive, is the one requiring patients to provide a sworn translation of invoices. This provision was adopted by four member states (one of them even requiring patients to get all documents certified by their consul in the country of treatment).²⁸¹

3.11.3. *Recognition of prescription*

Article 11 of the Directive gives effect to the principle of mutual recognition of medical prescriptions between member states. The Commission can adopt practical measures to support such recognition.

Most of these measures were addressed in the Implementing Directive 2012/52/EU²⁸², which established a list of common elements to be included in cross-border prescriptions.

The deadline for the transposition of the Implementing Directive was 25 October 2013, the same for the transposition of Directive 2011/24/EU. 21 member states either failed to make the deadline or transposed the Implementing Directive incompletely,

²⁷⁹ Ibid.

²⁸⁰ Ibid.

²⁸¹ Ibid.

²⁸² Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State, OJ L 356.

which led to infringement proceedings.²⁸³ All of these infringement cases were closed on the grounds of subsequent transposition by the member states concerned.²⁸⁴

3.12. Summary

The adoption of the Directive represents a significant change in cross-border healthcare. Patients' awareness of their rights, have to a greater extent increased since the entitlements of patients were stated only in the CJEU case law. In short, the Directive was prepared as a response to the case law of the CJEU. Its aim was to solve the situation when some preliminary rulings about healthcare reimbursement claims were refused, because they lacked the prior authorisation prescribed by the Regulation.²⁸⁵

By adopting the Directive, a dual system of reimbursement for costs of cross-border health care came into existence. Patient mobility in the European Union is therefore based on two legal systems, social security coordination respecting diversity of national social security systems provided by the Regulation, and economic freedoms of free movement of goods and services provided by the Directive. This dual system is complex and the distinction between them is extremely complicated for the majority of patients.

Nevertheless, the Directive brings much more than 'just' patient mobility. It establishes an improvement in quality and safety, patients' rights, and cooperation between member states.

Given the freedom member states have in transposing directives, the actual influence of the Directive on healthcare systems of member states depends on how they transposed the Directive into their national law.

As described in Chapter 3.11, some member states have implemented the Directive fully and are making an effort to promote patients' rights to cross border healthcare. There are a number of member states that implemented the Directive in a way not beneficial for patients. In many cases, it is not clear which treatment is subject

²⁸³ *Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare*, supra note 249.

²⁸⁴ Two infringement proceedings were pending as of 1 July 2015, when the Commission Report was drawn up. Nevertheless, in these two cases, the member states concerned committed to addressing the outstanding issues.

²⁸⁵ CARRASCOSA BERMEJO, Dolores, supra note 67, p. 361.

to prior authorisation. Sometimes lower reimbursement tariffs than those used in the home member state are applied and some states created burdensome administrative requirements to deter patients.²⁸⁶

As surveys have showed, the number of citizens who are informed about their general rights to reimbursement is extremely low. And even where citizens are aware of their rights, there are a number of member states where it is complicated for patients to find out more about how to use these rights in practice. I believe that this situation will gradually improve through the implementation of the Directive, which will cause a rise in a number of patients crossing borders to receive health care in other member states. Considering the special nature of health services, mainly patients suffering from rare diseases and patients in border regions will use the advantages of cross-border health care.

The Directive has largely been accepted positively by the academic community and experts. Some authors drew attention to significant shortcomings of the Directive. Some of them are not sure if it is in the interest of the member states to have an open healthcare market. Considering upfront payments and possible risk of additional costs, it is possible that the access to cross-border health care will not be available to everyone, but only to more informed, mobile and wealthier patients.²⁸⁷ There is also one specific problem related to implementation. The member states may differ in the way of implementing the Directive and inconsistent implementation may cause a legal risk for a patient seeking health care abroad.²⁸⁸

Despite all these shortcomings published by critics of the Directive, I consider its adoption as a positive step, which has brought many advantages for patients from all EU member states.

²⁸⁶ Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, supra note 249.

²⁸⁷ STRBAN, Grega, supra note 37, p. 406.

²⁸⁸ GREER, Scott L. Avoiding another directive: the unstable politics of European Union cross-border health care law. *Health Economics, Policy and Law* [online]. 2013, 8(04), 415-421 [cit. 2017-06-11]. DOI: 10.1017/S1744133112000424. ISSN 1744-1331. Available at: http://www.journals.cambridge.org/abstract_S1744133112000424, p. 420.

4. Cross-border health care in the Czech Republic

4.1. Health insurance system in the Czech Republic

The Czech public health insurance system is based on obligatory participation of insured persons. There is no possibility of voluntary participation. Every person is insured individually, there are no derived rights (for example ‘family insurance’ does not exist in the Czech system).

The Czech health insurance system is administered by seven health insurance companies.²⁸⁹ Each citizen can choose in which health insurance company he/she wants to be registered, because each provide different benefits for patients.

Health insurance companies conclude contracts with health care providers. The conditions set in these individual contracts can be partly different for each health care provider. A healthcare provider can make a contract with more than one or even with all of the health insurance companies. On the other hand, a provider can choose not to have contract with any health insurance company.²⁹⁰

Health care costs are paid to each contracted provider directly by the health insurance company (patient does not need to pay any part of the cost to provider).²⁹¹

4.2. Implementation of the Directive

A directive is one of legal acts of the European Union. It is binding upon each member state to which it is addressed, but it also leaves the choice of form and methods to the national authorities. Directives have to be implemented in national legislation in accordance with the procedures of the individual member state. This section discusses only the implementation of the Directive, because a regulation has general application; it is binding in its entirety and directly applicable in all member states.²⁹²

All EU member states were obliged to implement the Directive 2011/24 by 25 October 2013.²⁹³

²⁸⁹ The biggest one is the General Health Insurance Company (in Czech Všeobecná zdravotní pojišťovna), which covers approximately 60% of the population.

²⁹⁰ Only a very small percentage of health care providers chose this option.

²⁹¹ Health insurance system in CZ. *Kancelář zdravotního pojištění* [online]. 2016 [cit. 2017-06-21]. Available at: <https://www.kancelarzp.cz/en/links-info-en/health-insurance-system-in-cz>.

²⁹² Treaty on the Functioning of the European Union, OJ C 326, Art. 288.

²⁹³ Directive 2011/24/EU, supra note 170, Article 21.

In the Czech Republic, the first part of the Directive was implemented in the Health Services Act No. 372/2011 Coll.,²⁹⁴ in the section concerning health services.²⁹⁵ Given the unstable political situation which led to early parliamentary elections in 2013, the part of the Directive concerning reimbursement for health care services consumed in another member state of the European Union was implemented later by the Act No. 60/2014 Coll.²⁹⁶ This changed the Public Health Insurance Act No. 48/1997 Coll.²⁹⁷ and other connected Acts. This Act was published in the Collection of Laws of the Czech Republic (in Czech *Sbírka zákonů*) on 7 April 2014 and came into force on 22 April 2014 (except for one paragraph).²⁹⁸ The Czech Republic therefore implemented the Directive after the transposition deadline. Fortunately, there was no legal consequence for the Czech Republic. By failing to adopt the Directive in the transposition period, the Czech Republic exposed itself to the risk of initiating proceedings for breach of the Treaty under Art. 258, possibly Art. 260 of the Treaty on the Functioning of the European Union and, a risk of financial sanctions.²⁹⁹

The Public Health Insurance Act in certain respects also reflected Regulation No. 883/2004 on the coordination of social security systems and Regulation No. 987/2009 laying down detailed rules for applying Regulation No. 883/2004.³⁰⁰

This Act modifies and expands the rights of patients who decide to seek healthcare services in another member state of the European Union. It primarily concerns reimbursement for receiving healthcare services in another EU member state, and a national contact point providing information on receiving these services in other EU member states and administrative procedures.³⁰¹

The content of the Directive is divided into two categories: rules of obligatory implementation and rules of facultative implementation. One of the obligatory rules is the new principle of reimbursement of costs. According to this principle, the amount

²⁹⁴ Act No. 372/2011 Coll., on health services and the terms and conditions for providing of such services, as amended (Act on Healthcare Services).

²⁹⁵ Explanatory report to Act No. 372/2011 Coll., on Health Services (Parliamentary Press No. 405/0), p. 107.

²⁹⁶ Act No. 60/2014 Coll. amending Act No. 48/1997 Coll., on public health insurance and other related laws, as amended.

²⁹⁷ Act No. 48/1997 Coll., on public health insurance and on the amendment of some other related laws, as amended (Public Health Insurance Act).

²⁹⁸ Novela zákona o veřejném zdravotním pojištění. *Právní rádce: Newsletter*. 2014(09), 2.

²⁹⁹ Government proposal amending the Act No. 48/1997 Coll., on public health insurance and on the amendment of some other related laws, as amended, Parliamentary Press No. 10/0, part 1/6. Available at: <http://www.psp.cz/sqw/text/tiskt.sqw?O=7&CT=10&CT1=0>.

³⁰⁰ Novela zákona o veřejném zdravotním pojištění, supra note 298.

³⁰¹ *Ibid.*

reimbursed for health care provided in another member state will be the same as the amount that would be paid by a health insurance company for health care provided in the Czech Republic. Other parts of the Directive which are obligatory to implement is provision regarding national contact points providing information to patients and provision setting up an administrative procedure. A provision concerning prior authorisation is not obligatory to implement.³⁰²

4.3. Information to patients in the Czech Republic

The Health Insurance Bureau (in Czech Kancelář zdravotního pojištění) is designated as a national contact point on the basis of Art. 14 of Public Health Insurance Act No. 48/1997 and EU Directive 24/2011 on Patients' Rights in Cross-Border Healthcare. From the legal point of view, the HIB is an association of all Czech public health insurance companies. The HIB is the successor of the Centre for International Reimbursement (in Czech Centrum mezistátních úhrad), which was founded in 2001 and whose name has been changed from 2016.³⁰³

The HIB has to publish general information about possibilities of using health care services in other member states on its official website.³⁰⁴ It also has to provide concrete information upon a request of patients.³⁰⁵

The information obligation does not apply solely to the HIB. According to sec. 14c (6) of the Public Health Insurance Act, health care providers and health insurance companies are required to provide information on a request of the HIB.

The draft law, which was consulted with health insurance companies and the Centre for Interstate Reimbursement (now Health Insurance Bureau), was submitted in five different variants from which one was chosen. The Ministry of Health or health insurance companies were considered as other possible national contact points. I consider the choice of the HIB as a national contact point as a good option, because this institution was already providing reimbursement for costs of health care according to Regulation 883/2004, Implementing Regulation 987/2009 and international agreements (mostly bilateral) and it was also providing information to patients. Therefore this

³⁰² Explanatory report to Act No. 48/1997 Coll., on public health insurance (Parliamentary Press No. 10/0), p. 9-10.

³⁰³ O nás: Kancelář ZP. *Kancelář zdravotního pojištění* [online]. [cit. 2017-03-18]. Available at: https://www.kancelarzp.cz/cs/onas/role_cmu.

³⁰⁴ Section 14c (2) of the Public Health Insurance Act.

³⁰⁵ Section 14c (3) of the Public Health Insurance Act.

solution does not burden the state budget in comparison with other possible alternatives.³⁰⁶

The Ministry of Health was the supervising authority responsible for implementing the Directive.³⁰⁷

4.4. Prior consent

The Czech Republic has not set up a system of prior consent.³⁰⁸ More specifically, the government may determine cross-border health care by government decree, for which a prior consent is necessary in order to receive reimbursement. This decree will be issued when required according to available statistics.³⁰⁹

Cross-border health care can be subject to prior consent only in two cases. Firstly, when it includes planned treatment for which time limits are set and which require hospital accommodation or highly specialised and cost-intensive medical equipment. Secondly, concerning treatment presenting a particular risk for the patient or the population.³¹⁰

The system of prior consent would ensure the stability of health system, but on the other hand it would impose a financial burden on patients. Since the number of citizens seeking health care services abroad was decreasing slightly, and there was no reason to expect a large increase of this number, the system of prior consent was not considered necessary.³¹¹

This solution is therefore a compromise between two approaches. Patients are not unnecessarily burdened, but if the stability of health system is threatened by the increased number of requests for reimbursement, the government can issue a decree imposing a prior consent on before mentioned health care.³¹²

³⁰⁶ Explanatory report to Act No. 48/1997 Coll., supra note 302.

³⁰⁷ Government proposal amending the Act No. 48/1997 Coll., supra note 299.

³⁰⁸ The Public Health Insurance Act uses different terminology for the Directive and for the Regulation. A term 'prior consent' is used when talking about the Directive, a term 'prior authorisation' in connection with the Regulation.

³⁰⁹ Explanatory report to Act No. 48/1997 Coll., supra note 302, p. 18.

³¹⁰ Section 14b (1) of the Public Health Insurance Act.

³¹¹ Explanatory report to Act No. 48/1997 Coll., supra note 302, p. 18.

³¹² Ibid.

The request for prior consent would have to be submitted before receiving cross-border health care. The prior consent would be given by health insurance company where the patient is registered.³¹³

The health insurance company can refuse to grant the prior consent in four cases established in sec. 14b (4). This paragraph essentially takes over the legal framework established in Article 8 (6) of the Directive. Reasons for refusal are: (i) the patient would be exposed to an unacceptable patient-safety risk; (ii) the use of cross-border health care could result in a significant threat to public health; (iii) health care provided by a health care provider raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety; (iv) health care can be provided on the territory of the Czech Republic within a time limit established by the Government Decree on local and time availability of health services.

The Ministry of Health notifies the European Commission regarding health care services subject to prior consent.³¹⁴

While assessing the patient's request for a prior consent, the health insurance company has to consider whether conditions for granting prior authorisation under coordination regulations are met. If so, the health insurance company has to inform the patient about benefits of coordination regulations. It is at the discretion of the patient if he/she wants prior authorisation under the Regulation or prior consent within the meaning of the Directive.³¹⁵

In spite of criticising the overlaps between the Directive and Regulation rules in the previous chapter, I believe that the relation between these rules is clearly stated in Czech legislation.

Decisions of health insurance companies explained in this chapter are according to sec. 53 (1) subject to general rules on administrative proceedings.³¹⁶

In conclusion, the Czech Republic has chosen a pro-European approach of liberalisation of cross-border health care. In principle, the transposition has extended the scope of the Czech health insurance system for all providers established in the EU, regardless if the provider is contractual or non-contractual, hospital or out-of-hospital, state or non-state.

³¹³ Section 14b (3) of the Public Health Insurance Act.

³¹⁴ Section 14b (2) of the Public Health Insurance Act.

³¹⁵ Section 14b (5) of the Public Health Insurance Act.

³¹⁶ Act No. 71/1967 Coll. and Act No. 500/2004 Coll.

There are critics of this system who do not find the current legal framework suitable. Mr. Švec, director of the HIB, considers the total unilateral liberalization of providing cross-border health care as an unbalanced step that will limit the control and regulation of the healthcare system in the Czech Republic.³¹⁷

4.5. Reimbursement of costs of cross-border health care

The aim of the Public Health Insurance Act is to clearly and comprehensibly determine the system of reimbursement of costs of cross-border health care. The right to be reimbursed for the costs of cross-border health care has been extended.

The Act defines conditions under which the costs incurred by an insured person for planned cross-border health care will be reimbursed to the patient.

The Act also covers some rules of Regulation 883/2004 and Regulation 987/2009 in order to clearly distinguish them from implemented rules of the Directive.³¹⁸

4.5.1. Planned health care

A reimbursement of costs of cross-border health care based on the Directive will be provided to an insured person upon his/her request. The costs will be reimbursed only up to the level of costs of health care if it was provided in the territory of the Czech Republic. If the reimbursement of cross-border health care is subject to prior consent, the reimbursement would be provided only if prior consent was granted.³¹⁹ It is therefore a system of additional reimbursement. Patients have to pay for the costs of cross-border health care upfront and afterwards they will be reimbursed at their request. The calculation of reimbursement costs is based on the relevant legislation in force at the date of issuing the accounting document for the healthcare provided in another member state.³²⁰ The disadvantage of this system is that it is not possible to precisely determine in advance what will be the extent of the health care provided and what the

³¹⁷ ŠVEC, Ladislav. V uvolnění přeshraniční péče na celém území EU jsme nejevropštější. Petra Klusáková. Zdravotnictví a medicína [online]. 7. 4. 2014. [cit. 2017-06-20]. Available at: http://zdravi.euro.cz/clanek/v-uvolneni-preshranicni-pece-na-celem-uzemi-eu-jsme-nejevropstejsi-474858?seo_name=mlada-fronta-noviny-zdravi-euro-cz.

³¹⁸ Explanatory report to Act No. 48/1997 Coll., supra note 302, p. 9.

³¹⁹ Section 14 (3) of the Public Health Insurance Act.

³²⁰ Section 14a of the Public Health Insurance Act.

cost of the reimbursement will be, but patients have the option to ask their health insurance company about approximate costs of health care.

If a patient obtains prior authorisation according to the Regulation, the reimbursement system is different. The procedure of obtaining prior authorisation is initiated at the request of a patient. The health insurance company where the patient is registered is considered the competent institution. If the insurance company decides to grant the prior authorisation it issues a S2 form, which is necessary to submit to an institution in the state of treatment. This authorisation can be granted for health in all EU and EFTA³²¹ countries.³²² Insured persons are entitled to the same treatment as citizens of the state of treatment. In most cases, health care is paid by health insurance companies in the state of treatment. These insurance companies will additionally charge the costs through the HIB to a Czech health insurance company.^{323,324}

The third option of planned health care is granting prior consent according to sec 16 of the Public Health Insurance Act. This consent has to be given by an inspection doctor, except when there is a risk of delay. It is given only exceptionally, when the health care is not covered in the Czech Republic and receiving such health care is the only option for the patient. In this case, costs of health care are paid directly to a foreign health provider by Czech health insurance company.³²⁵

4.5.2. *Unplanned health care*

Czech citizens are entitled to access to medically necessary healthcare during a temporary stay in any of the EU member states, as well as: Iceland, Liechtenstein, Norway, and Switzerland. This right is based on the European health insurance card. Patients have the access to health care under the same conditions and at the same cost as people insured in that country.³²⁶

The system of reimbursement is similar to planned health care according to Regulation 883/2004. Patients can either ask for reimbursement from the national

³²¹ European Free Trade Association - Norway, Switzerland, Iceland, and Liechtenstein.

³²² Explanatory report to Act No. 48/1997 Coll., supra note 302, p. 34.

³²³ An exception is some health care segments in countries (Belgium, Luxembourg, France), where local patients first pay to the doctor themselves and subsequently ask for reimbursement.

³²⁴ Vycestování se souhlasem pojišťovny. *Kancelář zdravotního pojištění* [online]. 2016 [cit. 2017-06-21]. Available at: <https://www.kancelarzp.cz/cs/vycestovani-zdr-pece/cz-poj-do-zahr/vycestovani-souhl-pojistovny>.

³²⁵ Ibid.

³²⁶ European Health Insurance Card. *Europa: Employment, Social Affairs & Inclusion* [online]. 2017 [cit. 2017-06-21]. Available at: <http://ec.europa.eu/social/main.jsp?catId=559>.

institution while still in the country and get reimbursement directly there, or ask for reimbursement from their Czech health insurance company when they return home. Expenses will be reimbursed according to the rules and rates of the country where the treatment was received. So patients will either be reimbursed for the full cost of the treatment, or they will have to pay the patient's fee according to the rules of the country where they were treated.³²⁷

4.6. Summary

The Directive was fully implemented into the Czech legal system on 7 April 2014. Patients therefore have been using the benefits of the new legal framework for more than three years.

The number of requests for consent to travel to receive health care in EU countries is slightly increasing each year. The proportion of cases in the total number is less than 1 % (206 requests in 2016, 181 in 2015, 148 in 2014). The percentage of applications granted decreased compared to previous years (67 % in 2016, 58 % in 2015, 66 % in 2014, but around 95 % in previous years).³²⁸

It is interesting to compare the number of Czech patients receiving health care abroad (111 cases in 2016, 91 in 2015) and patients from EU member states receiving health care in the Czech Republic (1.111 cases in 2016³²⁹, 1086 in 2015). The Czech Republic is therefore more a provider of cross-border health care than a consumer. This may be because there is a high level of quality and relatively good availability of health care in the Czech Republic. Meanwhile, when comparing these numbers to statistics in previous years, the number is more or less the same.³³⁰

The amended Public Health Insurance Act provides more options for patients and it extends the range of rights of patients. Despite the appropriate and understandable implementation of the Directive, I am afraid that the overall system of providing cross-border health care is still unclear for patients. Information for patients is provided by the Health Insurance Bureau and individual health insurance companies, eventually also by health care providers itself.

³²⁷ Unplanned healthcare: payments and reimbursements. *Europa: Health* [online]. 2017 [cit. 2017-06-21]. Available at: http://europa.eu/youreurope/citizens/health/unplanned-healthcare/payments-reimbursements/index_en.htm.

³²⁸ Statistical Yearbook of the Health Insurance Bureau for 2016, 2015, 2014.

³²⁹ 750 patients from Slovakia.

³³⁰ Statistical Yearbook of the Health Insurance Bureau for 2016, 2015, 2014.

Looking at the statistics, the impact of the Directive on cross-border health care in the Czech Republic has not been vast. Czech patients do not use the right on cross-border health care in other member states to a large extent under the Directive. This is due to the large financial costs which patients are required to pay upfront. These costs are subsequently reimbursed, but often only partially. The use of cross-border planned health care is more a choice for wealthier and more mobile patients.

Conclusion

Cross-border health care has become a more prominent phenomenon in the European Union. This master thesis looks at this phenomenon with a focus on patients' rights. Health law is complex field and considering its specific nature in comparison with other EU policies, it was not easy for the European Union to create an effective legal framework.

The aim of my master thesis was to analyse the current legal framework with a focus on patients' rights. To achieve this goal, I aimed to evaluate the impact of the Directive; I explained the relation between the Directive and Regulation and evaluated the transposition of the Directive in the Czech Republic.

In the first chapter, the European Union competences in health law were outlined. It was necessary to explain the history of incorporating health law provisions into the Treaty on the Functioning of the Union. The most important provision is Article 168 TFEU, which gives the EU competences in public health. Nevertheless, competences of the EU in the area of health law are not limited to Article 168; we can also find them in other EU policies. This historical development is key to understanding the issue of cross-border health care.

The second chapter is devoted to the development in the provision of cross-border health care and its relation to the principles of the internal market of the EU. This development was influenced by the case law of the European Court of Justice. As explained, health care services are considered economic services and are therefore fully subject to the free movement of services rules. Another change in this field was brought by the Regulation on coordination of social security systems, which protects patients' rights in EU health law and policy. The most important part of this chapter is case law of the CJEU. The case law shaped and strengthened patients' rights to access health care in other EU member states. Patients can rely not only on the Regulation, but also on directly applicable free movement of services rules laid down in primary law.

In the third chapter, Directive 2011/24/EU on patients' rights in cross-border health care is discussed. This chapter contains development and reasons for adopting the Directive and analysis of specific articles of the Directive and their practical impact. The adoption of the Directive represents an important change in providing cross-border

health care. By its adoption, a dual system of reimbursement for the cost of cross-border health care came into existence. Patient mobility in the EU is currently based on two legal systems, one provided by the Regulation and one by the Directive. Nevertheless, the relation between the Directive and the Regulation is complex and the distinction between the rights provided by each of them is complicated for the majority of patients. Mention is also devoted to the implementation of the Directive in individual member states.

The last chapter represents cross-border healthcare in the Czech Republic. The Directive was fully implemented into the Czech legal system in the Public Health Insurance Act No. 48/1997 Coll., which came into force on 22 April 2014. The Health Insurance Bureau was designated as a national contact point whose obligation is to provide and publish information to patients. The Czech Republic is one of the few member states that have not set up a system of prior consent. The government may determine cross-border health care subject to prior consent by government decree when required according to available statistics. The last section of the chapter explains how the reimbursement system works in practice; the system is different for planned and unplanned health care. As this chapter shows, the Czech Republic has therefore chosen an open approach of liberalisation of cross-border health care, which can possibly lead to financial destabilization of the whole public health insurance system.

The adoption of the Directive, combined with established case law, brought positive changes targeting harmonisation and better access to health care for all European Union citizens. It is important to mention that there are still problems remaining. From the perspective of patients, I see the complexity of the current legal system as a primary concern. This is where cross-border healthcare is covered by two distinct sets of EU legislation (the Directive and the Regulation), which is difficult to distinguish by an average patient. Another problematic area is the ethically controversial treatment and the lack of harmonisation of quality and safety standards. In addition, information provided is often incomplete or only in a foreign language.

Regardless of these criticisms, I consider the adoption of the Directive as a positive step, which has brought many advantages for patients from all EU member states.

This master thesis comprehensively evaluates the issue of cross-border health care, offers a summary of actual problems and their possible solution, which I consider

as the main contribution. For this reason, I believe that I fulfilled the aim of the thesis mentioned in the introduction.

Teze v českém jazyce

Úvod

Při pohledu na vývoj Evropské unie je zřejmé, že její občané stále častěji cestují do zahraničí za prací, studiem a zážitky. Tento fenomén následně vyvolává otázky týkající se sociálního zabezpečení a přístupu ke zdravotní péči v hostitelské zemi. Dříve pacienti využívali zdravotní péče v zahraničí zpravidla v případě náhlých onemocnění nebo úrazů. Postupně se díky větší informovanosti a možnostem zvyšoval zájem vycestovat za zdravotní péčí do zahraničí. Důvodem může být to, že zdravotní péče ve státě pacientova bydliště neexistuje nebo je zakázaná, nebo že zdravotní péče v zahraničí je kvalitnější nebo čekací doba je kratší.

Mezníkem v poskytování přeshraniční zdravotní péče bylo přijetí Směrnice o uplatňování práv pacientů v přeshraniční zdravotní péči (dále pouze „Směrnice“), která byla přijata 9. března 2011 po několikaletém politickém vyjednávání.

Cílem této práce je komplexně zanalyzovat současnou právní úpravu se zaměřením na práva pacientů, zhodnotit vliv Směrnice, vysvětlit problematiku vztahu mezi Směrnicí a Nařízením o koordinaci systémů sociálního zabezpečení (dále pouze „Nařízení“) a zhodnotit implementaci Směrnice v České republice. K dosažení tohoto cíle je nutné vysvětlit tuto problematiku s ohledem na historický a politický vývoj Evropské unie a na judikaturu Soudního dvora Evropské unie (dále pouze „SDEU“).

Tato diplomová práce je po obsahové stránce rozdělena do čtyř kapitol. První z nich se zabývá pravomocemi Evropské unie v oblasti zdravotnictví a vysvětluje historii začlenění ustanovení týkající se zdravotnického práva do Smlouvy o fungování Evropské unie (dále pouze „SFEU“).

Druhá kapitola upravuje vývoj poskytování přeshraniční zdravotní péče. Na začátku kapitoly jsou obecně popsány systémy zdravotnictví v členských státech EU a problematika poskytování přeshraniční zdravotní péče na vnitřním trhu Evropské unie. Zásadní část představuje popis tzv. koordinačních nařízení upravující přeshraniční zdravotní péči a judikatury Soudního dvora EU s ohledem na práva pacientů.

Třetí kapitola analyzuje Směrnici 2011/24/EU o uplatňování práv pacientů v přeshraniční zdravotní péči. Tato kapitola vysvětluje vývoj a důvody pro přijetí Směrnice a obsahuje právní analýzu jednotlivých ustanovení Směrnice a jejich přínos. Důležitou částí je popis vztahu mezi Směrnicí a Nařízením.

Poslední kapitola pojednává o přeshraniční zdravotní péči v České republice, hlavně o implementaci Směrnice do českého právního řádu, o problematice náhrad nákladů za přeshraniční zdravotní péči a o informovanosti pacientů v České republice.

1. Pravomoci Evropské unie v oblasti zdravotnictví

Zdravotní péče byla původně výlučnou pravomocí členských států. Důvody pro tuto úpravu byly zřejmé: národní zájmy, politická citlivost této problematiky a velká rozmanitost systémů zdravotní péče v jednotlivých členských státech.

Situace se změnila přijetím Maastrichtské smlouvy v roce 1992, kdy byla Evropské komisi poprvé svěřena pravomoc v oblasti ochrany veřejného zdraví. Tato pravomoc byla omezena na oblast veřejného zájmu, jako je prevence nemocí, informace o zdraví a vzdělávání. Tato pravomoc byla posílena v Amsterdamské smlouvě. Pravomoci v oblasti zdravotnického práva byly i nadále svěřeny členským státům, protože harmonizace byla vyloučena a tato ustanovení byla ve srovnání s ostatními politikami EU slabá. Další významná změna byla provedena Lisabonskou smlouvou. Ochrana lidského zdraví byla zakotvena v článku 168 SFEU. V současnosti je veřejné zdraví sdílenou pravomocí Evropské unie a členských států a hlavním cílem je posílení spolupráce a koordinace mezi členskými státy.

Přeshraniční zdravotní péče je v podstatě posílení práva na přístup ke zdravotní péči, které bylo upraveno, byť spíše v obecnější rovině, v Úmluvě o ochraně lidských práv a základních svobod. V průběhu let se mnoho žalob předložených Evropskému soudu pro lidská práva týkalo zdravotnictví a zdravotní péče. Např. práva na život v článku 2 se pacienti dovolávali v žalobách týkajících se potratů, práva na smrt a odpovědnosti zdravotnických pracovníků. Článek 3, který zakazuje nelidské nebo ponižující zacházení, se dovolávalo v případech nuceného vyhoštění nemocných pacientů a násilných lékařských zásahů nebo léčby. Článek 8 upravující právo na respektování soukromého a rodinného života byl široce využíván v souvislosti s přístupem ke zdravotnické dokumentaci a důvěrnosti osobních údajů týkajících se zdraví.

2. Vývoj poskytování přeshraniční zdravotní péče

Vývoj systémů zdravotnictví byl ovlivněn historickými, společenskými a ekonomickými okolnostmi. Tyto systémy se liší v jednotlivých členských státech, ale obecně je lze rozdělit na systémy sociálního pojištění, které jsou založeny na povinném zdravotním pojištění, a systémy národních zdravotních služeb, které jsou obvykle financovány z daňových příjmů.

Judikatura SDEU začala hrát důležitou roli od osmdesátých let. V *Luisi and Carbone* SDEU poprvé kvalifikoval zdravotní služby jako služby ve smyslu ustanovení čl. 60 SES (nyní ustanovení čl. 57 SFEU) a uznal tak jejich ekonomickou povahu. Zdravotnické služby jsou považovány za ekonomické služby, a proto se na ně plně vztahují pravidla o volném pohybu služeb. Musí být poskytovány za úplatu bez ohledu na způsob fungování národního zdravotního systému. Nicméně uplatňování pravidel volného pohybu v oblasti zdravotní péče není bezpodmínečné. Členské státy mohou vytvářet výjimky za podmínky, že jsou nediskriminační a odůvodněné ve veřejném zájmu.

Přeshraniční pracovníci, někdy také nazývaní pendleři, jsou lidé, kteří dojíždí za prací do jiné země EU, než ve které bydlí, ale domů se vrací minimálně jednou týdně. Tito pracovníci mají nárok na plnou zdravotní péči v obou zemích.

První právní úpravou, která ochraňovala práva pacientů v oblasti zdravotnictví, bylo Nařízení 1408/71 o uplatňování systémů sociálního zabezpečení. Toto Nařízení bylo později nahrazeno nařízením stejného názvu, pod číslem 883/2004. Nařízení stanoví podmíněný přístup ke zdravotní péči v jiném členském státě EU ve třech případech. Za prvé, pokud se pacient přestěhoval do jiného členského státu kvůli práci nebo podnikání (nebo je rodinným příslušníkem takové osoby), má právo na přístup do zdravotního systému hostitelského členského státu. Za druhé, když pacient potřebuje péči, která je lékařsky nezbytná během dočasného pobytu v zahraničí. Třetím případem je, pokud pacient obdrží předchozí povolení k léčbě v zahraničí. Jak vyplývá z výše uvedeného, první dva uvedené případy představují neplánovanou zdravotní péči, třetí případ je péče plánovaná.

Pro plánovanou zdravotní péči v jiném členském státě je nutné předchozí povolení. Toto povolení je upraveno v článku 20 Nařízení. Pokud pacient splní podmínky stanovené v Nařízení, má nárok na stejnou zdravotní péči jako pojištěnci toho státu, kde je léčen. Náklady jsou hrazeny jeho domovským státem, to je obvykle ten stát, kde pacient pracuje a platí pojištění. Členský stát nemůže odmítnout udělit toto povolení, pokud jsou splněny dvě podmínky: zdravotní péče patří mezi dávky stanovené právními předpisy v členském státě, kde má pacient bydliště; a léčba je v tomto členském státě nedostupná v lékařsky obvyklé

lhůtě, s přihlédnutím k zdravotnímu stavu pacienta a pravděpodobnému průběhu jeho nemoci.

Nejdůležitější částí této kapitoly je judikatura Soudního dvora EU. SDEU nejen interpretoval jednotlivá ustanovení koordinačních nařízení, ale také zakotvil práva pacientů cestujících za zdravotní péči z jednoho členského státu do jiného, kteří se nyní mohou spoléhat také na přímo aplikovatelná ustanovení primárního práva o volném pohybu služeb.

Zásadní význam z hlediska poskytování přeshraniční zdravotní péče mají rozhodnutí *Kohll a Decker*. SDEU v nich označil zdravotní péči za službu, která podléhá aplikaci principů volného pohybu v rámci vnitřního trhu EU. Podle *Vanbraekel* budou náklady zdravotní péče uhrazeny podle sazebníku státu, který je pro pacienta výhodnější. V *Smits and Peerbooms* SDEU rozlišil mezi nemocniční zdravotní péčí a péčí poskytovanou ambulantně. Požadavek předchozího povolení je nutný pouze u péče poskytované v nemocnici kvůli potřebě systematického plánování za účelem zajištění trvalé dostupnosti kvalitní nemocniční péče.

Závěrem lze říci, že judikatura SDEU posílila postavení pacientů v přeshraniční zdravotní péči a usnadnila přístup k ní.

3. Směrnice o uplatňování práv pacientů v přeshraniční zdravotní péči

Směrnice se vztahuje na jednotlivé pacienty, kteří se rozhodnou vyhledat zdravotní péči v jiném členském státě, než ve kterém jsou pojištěni. Cílem směrnice je stanovit pravidla pro usnadnění přístupu k přeshraniční zdravotní péči v rámci EU, zajistit mobilitu pacientů v souladu se zásadami stanovenými Soudním dvorem a podpořit spolupráci v oblasti zdravotní péče mezi členskými státy. Úpravu systémů zdravotnictví ale Směrnice nechává na odpovědnosti členských států.

Návrh Směrnice byl představen Evropskou komisí v roce 2008 a od začátku čelil námitkám vlád členských států. Ty se obávaly, že neomezená možnost mobility pacientů a zdravotnických služeb povede ke ztrátě kontroly nad rozpočty ve zdravotnictví. Navzdory těmto námitkám byla Směrnice schválena Evropským Parlamentem v lednu 2011.

Přijetí této Směrnice představuje významnou změnu v přeshraniční zdravotní péči. Směrnice byla vypracována jako reakce na judikaturu SDEU, vycházelo se

především z předběžných rozhodnutí o žádostech o náhradu nákladů na zdravotní péči, které byly odmítnuty, protože neměly předchozí povolení předepsané Nařízením.

Směrnice má duální právní základ – ustanovení článku 114 SFEU a článku 168 SFEU. Cílem čl. 114 SFEU je zlepšení podmínek pro vytvoření a fungování vnitřního trhu, účelem čl. 168 SFEU je zajištění ochrany veřejného zdraví.

Směrnice se vztahuje na poskytování zdravotní péče bez ohledu na to, jak je organizována, poskytována a financována. Pouze tři kategorie služeb jsou vyloučeny z působnosti Směrnice: služby v oblasti dlouhodobé péče, přidělování orgánů a přístup k nim za účelem transplantace a programy očkování proti nakažlivým nemocem.

Náhradu nákladů za přeshraniční zdravotní péči zajišťuje členský stát, v němž je pacient pojištěn. Náklady uhradí jen do výše nákladů, které by sám převzal, pokud by zdravotní péče byla poskytnuta na jeho území, maximálně ale do výše skutečných nákladů na čerpanou zdravotní péči. Členský stát se může rozhodnout uhradit náklady v plné výši, případně také uhradit další související náklady, jako jsou ubytování a cestovní výdaje.

Náhrada nákladů na přeshraniční zdravotní péči nesmí být, až na tři výjimky, podmíněna udělením předchozího povolení. První výjimkou je zdravotní péče, která vyžaduje plánování a zahrnuje pobyt pacienta v nemocnici alespoň na jednu noc, nebo vyžaduje vysoce specializované přístrojové nebo zdravotnické vybavení. Druhou výjimku představuje léčba, která znamená zvláštní riziko pro pacienta nebo obyvatelstvo. Třetí výjimkou je zdravotní péče poskytovaná poskytovatelem, u kterého mohou v jednotlivých případech vyvstat vážné a konkrétní obavy ohledně kvality nebo bezpečnosti péče. Každý členský stát je povinen zveřejnit, jaká zdravotní péče podléhá předchozímu povolení.

Členský stát může odmítnout udělit předchozí povolení ve čtyřech případech. První dva z nich představuje situace, kdy by léčba představovala bezpečnostní riziko pro pacienta nebo pro širokou veřejnost. Stát také může odmítnout udělit povolení v případě poskytovatele, který vzbuzuje vážné a konkrétní obavy ohledně dodržování standardů a pokynů týkajících se kvality zdravotní péče a bezpečnosti pacienta. Posledním případem je, pokud lze zdravotní péči poskytnout na území členského státu ve lhůtě, která je lékařsky odůvodnitelná. Musí být ale zohledněn současný zdravotní stav a pravděpodobný průběh nemoci každého dotyčného pacienta.

Přijetím Směrnice vznikl také dvojí systém úhrady nákladů za přeshraniční zdravotní péči. Směrnice ponechala Nařízení č. 883/2004 v platnosti a stanovila, že se použije buď Směrnice, nebo Nařízení. Práva vyplývající z těchto dvou systémů nelze využít současně, pacientovi tedy nemohou být uhrazeny náklady dvakrát, podle Směrnice i podle Nařízení.

Směrnice stanovila prioritu aplikace Nařízení. Pokud jsou tedy splněny podmínky stanovené v Nařízení, udělí se předchozí povolení podle tohoto Nařízení, nepožádá-li pacient o jiný postup. V praxi to znamená, že pokud bude Nařízení příznivější pro pacienta, bude mít přednost. Pokud ne, může pacient požádat o uplatnění Směrnice. V tomto případě ale musí zaplatit náklady zdravotní péče předem a později požádat o proplacení nákladů stát, ve kterém je pojištěn.

Tento duální systém je složitý a rozdíl mezi jednotlivými nároky je pro většinu pacientů velmi komplikovaný. Výhodou Nařízení pro pacienta je, že nemusí platit za zdravotní péči předem a posléze žádat o náhradu nákladů. Volba směrnice je pro pacienta vhodná v případě ambulantní léčby nebo v případě léčby soukromými poskytovateli zdravotní péče. Ve většině členských států je přístup ke všem poskytovatelům zdravotní péče možný pouze podle Směrnice, podle Nařízení je výběr poskytovatelů zdravotní péče omezen.

Jak ukázaly průzkumy, počet občanů, kteří jsou si vědomi svých nároků na náhradu nákladů za přeshraniční zdravotní péči, je velmi nízký. I když občané vědí o svých právech, existuje řada členských států, v nichž je pro pacienty obtížné zjistit více informací, jak těchto práv v praxi využít. Domnívám se, že tato situace se bude postupně zlepšovat díky Směrnici, která v budoucnu způsobí částečný nárůst počtu pacientů překračujících hranice za účelem čerpání zdravotní péče v jiném členském státě. Avšak s přihlédnutím ke zvláštní povaze zdravotnických služeb budou využívat výhody přeshraniční zdravotní péče převážně pacienti v příhraničních oblastech a pacienti trpící vzácnými onemocněními.

Směrnice ale přinesla více než „jen“ mobilitu pacientů. Zavádí také zlepšení kvality a bezpečnosti, práva pacientů, a spolupráci členských států.

Každý členský stát určí jedno nebo více vnitrostátních kontaktních míst pro přeshraniční zdravotní péči. Tato vnitrostátní kontaktní místa usnadňují poskytování informací a úzce spolupracují navzájem a s Evropskou komisí, poskytují také pacientům kontaktní údaje o vnitrostátních kontaktních místech v jiných členských státech.

Největším přínosem je povinnost vnitrostátních kontaktních míst informovat pacienty o poskytovatelích zdravotní péče, o jejich právech, o postupech pro podávání stížností a o možnostech urovnání sporů.

Vzhledem ke svobodě, kterou mají členské státy při transpozici směrnic, bude skutečný vliv Směrnice na zdravotní systémy členských států záviset na tom, jak Směrnici transponovali do svého vnitrostátního práva. Směrnice měla být transponována členskými státy do 25. října 2013.

Řada oblastí zdravotnického práva, zejména těch, které se týkají lidské reprodukce a „end-of-life decisions“, jsou předmětem výrazně odlišných přístupů v členských státech EU. Přístup k potratům, asistované reprodukci nebo tzv. „end-of-life decisions“ se v evropských státech značně liší. Tato problematika vyvolala diskusi o možném dopadu práva EU v oblasti volného pohybu na etickou dimenzi vnitrostátních právních předpisů. Členské státy mohou eticky kontroverzní léčbu na svém území zakázat nebo podmínit. Ale v důsledku vývoje vnitřního trhu EU nemohou bránit svým občanům v přístupu k této léčbě v jiném členském státě.

Směrnice byla akademickou komunitou a odborníky přijata převážně pozitivně. Někteří autoři upozorňovali na významné nedostatky Směrnice, někteří z nich si nejsou jistí, zda je v zájmu členských států mít otevřený trh zdravotní péče. Vzhledem k nutnosti plateb předem a možnému riziku dodatečných nákladů je možné, že přístup k přeshraniční zdravotní péči nebude možný pro každého, ale pouze pro pacienty, kteří jsou mobilnější, informovanější a bohatší. Existuje také jeden specifický problém týkající se implementace. Členské státy se mohou ve způsobu provedení směrnice lišit a případná nekonzistentní implementace může způsobit právní riziko pro pacienty, kteří vyhledají zdravotní péči v zahraničí.

Přes všechny tyto zmíněné nedostatky považuji přijetí směrnice za pozitivní krok, který přinesl mnoho výhod pro pacienty všech členských států EU.

4. Přeshraniční zdravotní péče v České republice

Směrnice obecně je jedním z právních aktů Evropské unie. Směrnice je závazná pro každý stát, kterému je určena, pokud jde o výsledek, jehož má být dosaženo, přičemž volba formy a prostředků se ponechává vnitrostátním orgánům. Směrnice musí být transponována do právního řádu jednotlivých členských států ve stanovené lhůtě.

Všechny členské státy byly povinny implementovat Směrnici do svého právního řádu s účinností od 25. října 2013.

V České republice byla první část Směrnice transponována do zákona č. 372/2011 Sb., o zdravotních službách a podmínkách jejich poskytování, v části, která se týká zdravotních služeb. Vzhledem k nestabilní politické situaci, která vedla k předčasným volbám do Poslanecké sněmovny v roce 2013, byla část Směrnice týkající se náhrady nákladů na přeshraniční zdravotní péči transponována později, zákonem č. 60/2014 Sb. Tímto byl změněn zákon č. 48/1997 Sb., o veřejném zdravotním pojištění a další související zákony; a byl zveřejněn ve Sbírce zákonů 7. dubna 2014 s účinností od 22. dubna 2014. Česká republika tedy transponovala Směrnici až po uplynutí transpoziční lhůty, čímž se vystavila riziku peněžních sankcí ze strany EU.

Zákon o veřejném zdravotním pojištění rozšiřuje práva pacientů, kteří se rozhodnou vyhledat zdravotní služby v jiném členském státě Evropské unie. Novela konkrétně obsahuje především náhradu nákladů za čerpané zdravotní služby v jiných členských státech EU, vnitrostátní kontaktní místo poskytující informace v oblasti čerpání zdravotních služeb v členských státech a správní postupy upravující pravidla pro čerpání zdravotních služeb.

Kancelář zdravotního pojištění (do roku 2016 Centrum mezistátních úhrad) je vnitrostátním kontaktním místem pro přeshraniční zdravotní služby poskytované za přímou úhradu ve smyslu ustanovení § 14 zákona č. 48/1997 Sb. a Směrnice 24/2011 o uplatňování práv pacientů v přeshraniční zdravotní péči. Kancelář musí zveřejňovat obecné informace vztahující se k možnostem čerpání zdravotních služeb v jiném členském státě, má také povinnost poskytovat konkrétní informace na žádost pacientů.

Česká republika je jedním z mála členských států, které nezavedly systém předchozího souhlasu. Vláda může nařízením vymezit hrazené přeshraniční služby, u nichž je poskytnutí náhrady nákladů podmíněno udělením předchozího souhlasu. Nařízení vlády a v něm uvedené konkrétní hrazené služby se vydá až ve chvíli, kdy bude podle dostupných statistických údajů možné určit, zda je regulace skutečně potřebná. Toto řešení je kompromisem mezi dvěma přístupy. Na jednu stranu nepřiměřeně nezatěžuje pacienty nutností získání předchozího souhlasu a posiluje jejich právo na svobodnou volbu poskytovatele zdravotních služeb a zdravotnického zařízení. Na druhou stranu toto řešení umožňuje okamžité zakotvení institutu předchozího

souhlasu při ohrožení stability systému zdravotního pojištění. Česká republika tedy zvolila otevřený proevropský přístup a rozhodla se přeshraniční zdravotní péči velmi liberalizovat. Touto právní úpravou se v podstatě rozšířila věcná působnost veřejného zdravotního pojištění na všechny poskytovatele v rámci celé EU bez ohledu na to, zda se jedná o péči ambulantní či nemocniční, státní či nestátní, smluvní či nesmluvní.

System náhrady nákladů za přeshraniční zdravotní péči je odlišný pro plánovanou a neplánovanou zdravotní péči. Pokud pacient obdrží plánovanou zdravotní péči na základě Směrnice, náhrada nákladů bude poskytnuta pouze do výše stanovené pro úhradu konkrétní péče na území České republiky. Jedná se o systém dodatečné náhrady, pacient musí zaplatit všechny náklady spojené se zdravotní péčí v zahraničí předem a následně požádat o náhradu těchto nákladů. Pokud pacient získá předchozí povolení podle Nařízení, nebude sám hradit žádné náklady. Zdravotní péče bude uhrazena zdravotní pojišťovnou ve státě ošetření, která následně tyto náklady přeúčtuje české zdravotní pojišťovně, u které je pacient registrován. Poslední možností je získání předchozího souhlasu revizního lékaře, je-li poskytnutí přeshraničních zdravotních služeb jedinou možností pro pojištěnce. V tomto případě jsou náklady hrazeny zahraničnímu poskytovateli přímo zdravotní pojišťovnou.

Čeští pojištěnci mají během dočasného pobytu v zemích EU, na Islandu, v Lichtenštejnsku, Norsku a Švýcarsku, nárok na nezbytnou lékařskou péči ve státním lékařském zařízení. Zdravotní péče je poskytována na základě Evropského průkazu zdravotního pojištění a musí být poskytnuta za stejných podmínek a za stejnou cenu jako lidem pojištěným v dané zemi.

Množství žádostí o souhlas s vycestováním za zdravotní péčí do zemí EU se každým rokem mírně zvyšuje. Při porovnání počtu případů na plánovanou zdravotní péči poskytovanou českým pojištěncům v EU a evropským pojištěncům v ČR je zřejmé, že Česká republika je spíše poskytovatelem než konzumentem přeshraniční plánované péče. To je pravděpodobně dáno kvalitou a relativně dobrou dostupností zdravotní péče.

Novela zákona implementující Směrnici přinesla více možností pro pacienty a rozšířila rozsah jejich práv. Navzdory přehledné právní úpravě se obávám, že celkový systém poskytování přeshraniční zdravotní péče je pro pacienty stále nepřehledný. Dopad Směrnice na přeshraniční zdravotní péči v České republice tedy nebyl obrovský, čeští pacienti tohoto práva nevyužívají ve velké míře. Důvodem jsou podle mého názoru velké finanční náklady, které jsou pacienti povinni zaplatit předem a až následně

požádat o jejich náhradu. Čerpání přeshraniční zdravotní péče je možností spíše pro bohatší a mobilnější pacienty.

Závěr

Přeshraniční zdravotní péče se v rámci Evropské unie stává stále rozšířenějším fenoménem. Tato diplomová práce se tímto tématem zabývá se zaměřením na práva pacientů. Zdravotnické právo je složitou oblastí a vzhledem ke své zvláštní povaze ve srovnání s ostatními politikami EU nebylo pro Evropskou unii snadné vytvořit účinný právní rámec.

Cílem této práce bylo analyzovat současnou právní úpravu se zaměřením na práva pacientů. K dosažení tohoto cíle bylo nutné zhodnotit vliv Směrnice, vysvětlit problematiku vztahu mezi Směrnicí a Nařízením a zhodnotit implementaci Směrnice v České republice.

V první kapitole byly popsány pravomoci Evropské unie v oblasti zdravotnictví. Bylo nezbytné vysvětlit historii začlenění ustanovení týkající se zdravotnického práva do Smlouvy o fungování Evropské unie. Nejvýznamnějším ustanovením je ustanovení článku 168 SFEU, který udělil Evropské unii pravomoc v oblasti veřejného zdraví. Veřejné zdraví je nyní sdílenou pravomocí Evropské unie a členských států. Tento historický vývoj je důležitý pro pochopení problematiky přeshraniční zdravotní péče.

Druhá kapitola je věnována vývoji poskytování přeshraniční zdravotní péče a jejímu vztahu s principy vnitřního trhu EU. Tento vývoj byl ovlivněn judikaturou Soudního dvora EU. Jak bylo vysvětleno, zdravotní služby jsou považovány za ekonomické služby a plně tedy podléhají pravidlům volnému pohybu pravidel služeb. Další změnu v této oblasti přineslo Nařízení o koordinaci systémů sociálního zabezpečení. Nejvýznamnější částí této kapitoly je judikatura SDEU. Judikatura v průběhu let formovala a posílila práva pacientů na přístup ke zdravotní péči v ostatních členských státech EU. Pacienti se tak mohou spoléhat nejen na nařízení, ale i na přímo aplikovatelná pravidla volného pohybu služeb stanovená v primárním právu.

Třetí kapitola upravuje Směrnici 2011/24/EU o uplatňování práv pacientů v přeshraniční zdravotní péči. Tato kapitola vysvětluje vývoj a důvody pro přijetí Směrnice a obsahuje právní analýzu jednotlivých ustanovení Směrnice a jejich praktický přínos. Zmiňuje také kritické názory týkající se nedostatků právní úpravy.

Poslední kapitola pojednává o přeshraniční zdravotní péči v České republice, především o implementaci Směrnice do českého právního řádu, o problematice náhrad nákladů a o fungování systému úhrad v praxi.

Přijetí Směrnice ve spojení se zavedenou judikaturou přineslo pozitivní změny směřující k harmonizaci a lepší přístup ke zdravotní péči pro všechny občany Evropské unie. Je důležité zmínit, že v oblasti přeshraniční zdravotní péče stále existují nevyřešené problémy. Za největší problém z pohledu pacientů považují složitost současné právní úpravy, kdy je přeshraniční zdravotní péče upravena dvěma různými předpisy Evropské unie (Směrnicí a Nařízením), která je pro běžného pacienta těžko rozlišitelná.

Přes všechny nedostatky považují přijetí směrnice za pozitivní krok, který přinesl mnoho výhod pro pacienty všech členských států EU.

Za hlavní přínos této diplomové práce považují, že komplexně hodnotí problematiku přeshraniční zdravotní péče, poskytuje přehled aktuálních problémů a jejich možné řešení. Z tohoto důvodu věřím, že jsem splnila cíl práce stanovený v úvodu.

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Abstract

The subject-matter of this master thesis is cross-border healthcare in the European Union. It describes the history and development, but focuses mainly on the current legal framework represented by Regulation No 883/2004, and mainly Directive 2011/24 on the application of patients' rights in cross-border health care.

The aim of the master thesis is to thoroughly analyse the current legal framework with a focus on patients' rights, to examine the impact of the Directive, to explain an issue of overlap between the Directive and Regulation, and to evaluate the transposition of the Directive in the Czech Republic. To achieve this aim, it is necessary to examine the topic with respect to the historical and political development of the European Union and to the case law of the European Court of Justice.

The thesis is divided into four chapters. First of which concerns European Union competences in health law, explaining the history of incorporating health law provisions into the Treaty on the Functioning of the European Union, as it is called today. This historical development is important for understanding the issue of cross-border healthcare.

The second chapter is mainly focused on the important case law of the ECJ concerning patients' rights. Although initially I will discuss the development in providing cross-border health care, specifically the relation between cross-border health care and the internal market, and the change brought by Regulation on coordination of social security systems.

In the third part of the thesis, Directive 2011/24/EU on patients' rights in cross-border healthcare is discussed. This chapter explains development and reasons for adopting the Directive and analyses specific articles of the Directive and their impact.

The final chapter deals with cross-border healthcare in the Czech Republic, mainly with the implementation of the Directive into the Czech legal system, information to patients, and the reimbursement system.

The conclusion contains the summary of the thesis. The adoption of the Directive represents a significant change in cross-border healthcare. Despite some shortcomings, the Directive has brought many advantages for patients from all EU member states and it can be seen as a positive step in providing cross-border healthcare.

Abstrakt

Tématem této diplomové práce je přeshraniční zdravotní péče v Evropské unii. Popisuje historii a vývoj a především se zaměřuje na stávající právní rámec představovaný Nařízením 883/2004 a Směrnicí 2011/24 o uplatňování práv pacientů v přeshraniční zdravotní péči.

Cílem této práce je komplexně zanalyzovat současnou právní úpravu se zaměřením na práva pacientů, zhodnotit vliv Směrnice, vysvětlit problematiku vztahu mezi Směrnicí a Nařízením a zhodnotit implementaci Směrnice v České republice. K dosažení tohoto cíle je nutné vysvětlit tuto problematiku s ohledem na historický a politický vývoj Evropské unie a na judikaturu Soudního dvora Evropské unie.

Tato diplomová práce je po obsahové stránce rozdělena do čtyř kapitol. První z nich se zabývá pravomocemi Evropské unie v oblasti zdravotnictví a vysvětluje historii začlenění ustanovení týkající se zdravotnického práva do Smlouvy o fungování Evropské unie, jak je dnes nazývána. Tento historický vývoj je důležitý pro porozumění problematice přeshraniční zdravotní péče.

Druhá kapitola upravuje vývoj poskytování přeshraniční zdravotní péče. Na začátku kapitoly jsou obecně popsány systémy zdravotnictví v členských státech EU a problematika poskytování přeshraniční zdravotní péče na vnitřním trhu Evropské unie. Zásadní část představuje popis tzv. koordinačních nařízení upravující přeshraniční zdravotní péči a přehled judikatury Soudního dvora EU s ohledem na práva pacientů.

Třetí kapitola analyzuje Směrnici 2011/24/EU o uplatňování práv pacientů v přeshraniční zdravotní péči. Tato kapitola vysvětluje vývoj a důvody pro přijetí Směrnice a obsahuje právní analýzu jednotlivých ustanovení Směrnice a jejich přínos. Důležitou částí je popis vztahu mezi Směrnicí a Nařízením.

Poslední kapitola pojednává o přeshraniční zdravotní péče v České republice, hlavně o implementaci Směrnice do českého právního řádu, o problematice náhrad nákladů za přeshraniční zdravotní péči a o informovanosti pacientů v České republice.

V závěru je provedeno shrnutí obsahu diplomové práce. Přijetí Směrnice představuje významnou změnu v poskytování přeshraniční zdravotní péče. Přes všechny nedostatky přinesla Směrnice mnoho výhod pro pacienty všech členských států EU a lze ji považovat za pozitivní krok při v oblasti přeshraniční zdravotní péče.

Název práce a klíčová slova / Title and key words

Název práce v českém jazyce:

Práva pacientů v přeshraniční zdravotní péči v Evropské unii

Klíčová slova:

Přeshraniční zdravotní péče v EU

Směrnice 2011/24/EU

Volný pohyb zdravotních služeb

Title in English:

Patient's rights in cross-border health care in the European Union

Key words:

Cross-border health care in the EU

Directive 2011/24/EU

Free movement of health services