PATIENT'S RIGHTS IN CROSS-BORDER HEALTH CARE IN THE EUROPEAN UNION

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Abstract: *This Article deals with cross-border health care in the European Union. It briefly describes the history and development, but focuses mainly on the current legal framework represented by Regulation No 883/2004, and primarily Directive 2011/24 on the application of patients' rights in cross-border health care. Health care was originally the responsibility of EU member states, but the European Union has gradually gained greater power. Also the case law of the European Court of Justice started to play an important role in this field. The adoption of the Directive represented a significant change in cross-border health care and brought a dual system of reimbursement for costs of cross-border health care.*

Keywords: *cross-border health care in the EU, Directive 2011/24/EU, free movement of health service*

INTRODUCTION

Looking at the development of the European Union (EU), there has been greater mobility across member states since its creation. EU citizens are increasingly moving abroad to work, study, travel, and it consequently raises the question of social security coverage and access to health care in the host country.[1] Patients usually received health care in other member states when there was a sudden need for health care 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 health care 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 health care covers all situations different from the one when the patient is treated in a member state, where he/she is socially insured by a local health care provider who is established in that member state.[2] Therefore, free movement of patients covers both cases: when health care is provided unexpectedly while the patient is abroad, and planned cross-border health care.

Health law is considerably affected by the law of the European Union, but it was not always as such. When the European Economic Community (now European Union) was created, cross-border health care was not regulated by its founding Treaties.[3] Health care was originally exclusively the responsibility of the member states. Gradually the competence

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[1] RIEDEL, R. European patient's cross-border mobility directive: Short communication. *Public Health*. 2016, Vol. 139, p. 222.

[2] PEETERS, M. Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care. *European Journal of Health Law*. 2012, Vol. 19, No. 1, [2018]. 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).

of the European Union in public health was established and the Court of Justice of the European Union decided that health care 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. This was later largely replaced by 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 milestone in the field of cross-border health care was the adoption of Directive 2011/24 on the application of patients' rights in cross-border health care, 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 into their national law by 25 October 2013.

HISTORY AND DEVELOPMENT OF EUROPEAN UNION COMPETENCES IN HEALTH LAW

Historically speaking, health care was originally the exclusive responsibility of the member states.[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 health care 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 situation changed after the Maastricht Treaty was adopted in 1992,[7] 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, such as the prevention of diseases, health information and education.[8] This Article was later strengthened in the Treaty of Amsterdam of 1997.[9] 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.[10]

The last significant change was made by the Treaty of Lisbon of 2007.[11] Public health is now a shared competence between the EU and its member states.[12] The main objec-

[4] Article 152 (5) of the EC Treaty (now Article 168 TFEU).
[5] MOSSIALOS, E., PERMANAND, G., BAETEN, R., HERVEY, T. Health systems governance in Europe: The role of European Union law and policy. In: E. Mossialoss (ed.). *Health systems governance in Europe: the role of European Union law and policy*. Cambridge: Cambridge University Press, 2010, p. 85.
[6] Ibid.
[7] Article 129 (1) of the Maastricht Treaty.
[8] Public Health at EU level - Historical Background. *Eurocare: European Alcohol Policy Alliance* [online]. [2017-03-13]. Available at: http://www.eurocare.org/.
[9] Article 152 of the Amsterdam Treaty.
[10] HERVEY, T. K., MCHALE, J. V. *European Union health law: themes and implications*. Cambridge: Cambridge University Press. 2015, p. 39.
[11] Article 168 of the Lisbon Treaty.
[12] Article 4 (2) (k) TFEU.

tive of this provision is to strengthen cooperation and coordination between member states.[13]

The right to seek health care was also mentioned in the EU Charter of Fundamental Rights, which became legally binding since its incorporation in the Lisbon Treaty.[14] 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 Freedoms.[15,16]

DEVELOPMENT IN THE PROVISION OF CROSS-BORDER HEALTH CARE

Providing cross-border health care in the internal market

During the process of Europeanization[17] it was inevitable that national and European identities were gradually changing and these changes affected EU member states social policies.[18] The development of health and social security systems was determined by the historical, social and economic background of individual countries.[19] National health care systems were different in each member state, although they were commonly based on solidarity[20] and the principle of territoriality.[21,22]

The European Union is based on the so called 'four fundamental freedoms': free movement of goods, persons, services and capital.[23] Some national measures and mechanisms began to be viewed as potential unjustified obstacles to free movement, which is prohibited under Treaty provisions.[24]

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[13] GREER, S. L., KURZER, P. *European Union public health policy: regional and global trends*. Abingdon, Oxon: Routledge, 2013, p. 21.

[14] Ibid.

[15] Council of Europe, *European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14*, 1950.

[16] All EU member states are signatories of the Convention.

[17] Europeanization was defined by many scholars, e.g. by Ladrech [LADRECH, R. Europeanization of Domestic Politics and Institutions: The Case of France. *Journal of Common Market Studies*. 1994, Vol. 32, No. 1, pp. 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".

[18] MOSSIALOS, E., PERMANAND, G., BAETEN, R., HERVEY, T. Health systems governance in Europe: The role of European Union law and policy. In: E. Mossialoss (ed.). *Health systems governance in Europe: the role of European Union law and policy*, p 19.

[19] GEKIERE, W., BAETEN, R., PALM, W. Free movement of services in the EU and health care. In: E. Mossialoss (ed.). *Health systems governance in Europe: the role of European Union law and policy*, p. 465.

[20] 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'*, p. 2.

[21] According to the principle of territoriality, states provided social security in the time of sickness to the territory to which they had sovereignty.

[22] HERVEY, T. K., MCHALE, J. V. *European Union health law: themes and implications*, p. 73.

[23] Treaty on the Functioning of the European Union, OJ C 326.

[24] GEKIERE, W., BAETEN, R., PALM, W. Free movement of services in the EU and health care. In: E. Mossialoss (ed.). *Health systems governance in Europe: the role of European Union law and policy*, p. 461.

The jurisprudence of the European Court of Justice started to play an important role in EU law and its policy-making, including health care.[25] 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 expensive and would interfere with national rules.[26] Member states are obliged to respect these general principles of law, which help to bridge the gap left by primary and/or secondary legislation.[27]

The first important judgement – *Luisi and Carbone*[28] – 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.[29]

In *Watts*[30] judgement in 2006, the Court clarified that 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 definition.[31] 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.[32] 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.[33] A system of prior authorisation is further discussed below.

This case law, based on Article 56 TFEU (free movement of services), 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.[34]

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[25] MOSSIALOS, E., PERMANAND, G., BAETEN, R., HERVEY, T. Health systems governance in Europe: The role of European Union law and policy. In: E. Mossialoss (ed.). *Health systems governance in Europe: the role of European Union law and policy*, p. 27.

[26] GREER, S. L., SOKOL, T. Rules for Rights: European Law, Health Care and Social Citizenship. *European Law Journal*. 2014, Vol. 20, No. 1, [2017-06-08]. Available at: <http://doi.wiley.com/10.1111/eulj.12036>, pp. 78–79.

[27] The non-written sources of European law: supplementary law. In: *EUR-Lex* [online]. 2010 [2017-06-11]. Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Al14533>.

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

[29] GEKIERE, W., BAETEN, R., PALM, W. Free movement of services in the EU and health care. In: E. Mossialoss (ed.). *Health systems governance in Europe: the role of European Union law and policy*, p. 478.

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

[31] GEKIERE, W., BAETEN, R., PALM, W. Free movement of services in the EU and health care. In: E. Mossialoss (ed.). *Health systems governance in Europe: the role of European Union law and policy*, p. 468.

[32] Judgment of 16 May 2006, *Watts*, C-372/04, EU:C:2006:325, paras 37, 114.

[33] Ibid., para 63.

[34] HERVEY, T. K., MCHALE, J. V. *European Union health law: themes and implications*, p. 196.

Regulation on coordination of social security systems

Another change in this field was brought by the Regulation on coordination of social security systems. Regulation No. 1408/71 applies to employed persons and their families moving within the Community, and it was later largely replaced by Regulation No. 883/2004, which is still applicable.[35] The coordination on social security systems is the oldest legal act that protects patients' rights in EU health law and policy.[36]

Although the Regulation does not mention cross-border health care as such, it deals with the coordination of social security legislation regarding sickness benefits in kind. The Regulation is based on the principle of free movement of persons and has a dual legal base: Article 48 TFEU and Article 352 TFEU. The aim is to encourage workers' mobility providing that it is economically neutral, with regard to their social security rights.[37]

The Regulation 883/2004 applies to all EU citizens who have been covered by a social security scheme.[38] It provides conditional access to health care in other EU member states in three cases and it is applicable in cases of planned and unplanned 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 the expense of his/her home member state, usually the state where the patient works and pays social security contributions. This means that the 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.[39]

Public health insurance plays a decisive role in the prior authorisation to any planned treatment in another EU country. The procedure of granting prior authorisation to receive appropriate planned 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 aboard according to the legislation of the member state where the treatment takes place. The competent authority pays directly to the health care 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. This is the greatest impact of the Regulation in practice.

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[35] 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.

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

[37] CARRASCOSA BERMEJO, D. Cross-border health care in the EU: Interaction between Directive 2011/24/EU and the Regulations on social security coordination. *ERA Forum*. 2014, Vol. 15, No. 3, [2017-03-06]. Available at: <https://link.springer.com/article/10.1007/s12027-014-0358-8>, p. 360.

[38] This also includes the members of their families and their survivors.

[39] PALM, W., GLINOS, I. Enabling patient mobility in the EU: Between free movement and coordination. In: E. Mossialoss (ed.). *Health systems governance in Europe: the role of European Union law and policy*, pp. 514–515.

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 health care abroad, the amount of people seeking cross-border health care can increase.[40]

Nevertheless, a member state cannot refuse to grant prior authorisation when two conditions are simultaneously met: the treatment is in the basked 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/her disease.[41]

In 2014, the CJEU decided the so called *Petru case*[42] concerning the second condition of prior authorisation. The judgment was in favour of the patient by ruling that a lack of medication and basic medical supplies can result in an undue delay. It was also in favour of governments by giving them the 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.[43] 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.[44] In my opinion, the case law of the CJEU may change, although a significant change is unlikely. I agree with Frischhut and Levaggi that it might almost be 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.[45] This can be the case of an accident or a deterioration of a health condition which, without providing care, will result in the termination of stay before it was originally planned. In this case, the patient 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.[46]

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 health care providers do not know or do not apply these rules.[47]

In 2004, the 'European Health Insurance Card' was introduced by the European Commission. This card proves the entitlement to such health care and covers all the member states of the EU, plus Iceland, Lichtenstein, Norway and Switzerland.

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[40] PENNINGS, F. Cross-Border Health Care Directive: More Free Movement for Citizens and More Coherent EU Law? *European Journal of Social Security*. 2011, Vol. 13, No. 4, [2017-03-31]. Available at: <https://journals.sagepub.com/doi/pdf/10.1177/138826271101300403>, p. 428.

[41] Article 20 (2) of the Regulation 883/2004.

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

[43] FRISCHHUT, M., LEVAGGI, R. Patient mobility in the context of austerity and an enlarged EU: The European Court of Justice's ruling in the Petru Case. *Health Policy*. 2015, Vol. 119, No. 10, [2017-06-12]. Available at: <http://linkinghub.elsevier.com/retrieve/pii/S0168851015001682>, p. 1294.

[44] PENNINGS, F., VONK, G. *Research handbook on European social security law*. Edward Elgar Publishing, 2015, p. 496.

[45] Article 19 of the Regulation 883/2004.

[46] PENNINGS, F. *Cross-Border Health Care Directive: More Free Movement for Citizens and More Coherent EU Law?*, p. 427.

[47] Ibid., p. 427.

Cross-border health care in case law

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 which the Court of Justice of the EU interpreted.

Kohll[48] and Decker[49]

The beginning of parallel systems for exporting the right to medical benefits occurred by the judgments in the cases *Kohll* and *Decker*.[50] 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.[51]

In the *Kohll* case, the Court stated that the special nature of services does not remove them from the ambit of free movement rules[52]. 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.[53]

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 EU level. It also cannot be justified by the need to preserve the financial balance of the medical and hospital system of the member state.[54]

This decision does not seem so significant in contemporary terms, but it was groundbreaking considering the situation in 1998. For the first time, these two judgments intervened in national health systems, which until then were only connected through Regulation 1408/71.[55]

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.[56]

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*[57]

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

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

[50] STRBAN, G. Patient mobility in the European Union: between social security coordination and free movement of services. *ERA Forum*. 2013, Vol. 14, No. 3, [2017-03-31]. Available at: <https://link.springer.com/article/10.1007/s12027-013-0311-2 >, p. 393.

[51] GREER, S. L., KURZER, P. *European Union public health policy: regional and global trends*, p. 118.

[52] Namely Articles 59 and 60 EC (now Articles 56 and 57 TFEU).

[53] Judgment of 28 April 1998, *Kohll*, C-158/96, EU:C:1998:171, para 20, 29.

[54] BAQUERO CRUZ, J. The Case Law of the European Court of Justice on the Mobility of Patients: An Assessment. In: J. W. van de Gronden – E. Szyszczak – U. Neergaard – M. Krajewski (eds.). *Health care and EU law*. The Hague, The Netherlands: T.M.C. Asser Press, 2011, p. 82.

[55] Ibid., p. 83.

[56] DE LA ROSA, S. The Directive on cross-border health care or the art of codifying complex case law. *Common Market Law Review*. 2012, Vol. 49, p. 21.

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

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 planning, because of the use of highly specialized and cost-intensive medical infrastructure or equipment.[58]

Smits-Peerbooms[59]

This case was heard three years later and confirmed the path of the *Kohll and Decker* case. 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.[60]

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.[61] 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. The planning has to ensure that patients have sufficient and permanent access to high-quality hospital treatment.[62]

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.[63]

Vanbraekel[64]

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.[65] Therefore, the cost will be assumed at the most favourable tariff (this is known as 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, and often do not know how expensive their treatment is. Despite this, the judgment has to be perceived positively, because it promotes access to health care abroad without

[58] Ibid., paras 32, 42.
[59] Judgment of 12 July 2001, *Smits and Peerbooms*, C-157/99, EU:C:2001:404.
[60] Ibid., para 53.
[61] BAQUERO CRUZ, J. The Case Law of the European Court of Justice on the Mobility of Patients: An Assessment. In: J. W. van de Gronden – E. Szyszczak – U. Neergaard – M. Krajewski (eds.). *Health care and EU law*, p. 85.
[62] PENNINGS, F. *Cross-Border Health Care Directive: More Free Movement for Citizens and More Coherent EU Law?*, p. 432.
[63] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care*, p. 35.
[64] Judgment of the Court of 12 July 2001, *Vanbraekel*, C-368/98, EU:C:2001:400.
[65] Ibid., para 53.

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. [66]

Müller-Fauré and Van Riet[67]

The judgement of the Court is a confirmation of the previous case law concerning prior authorisation. When this decision was issued in 2003, the main principles of the cross-border health care were already established.[68] This judgment further develops the distinction between hospital services and non-hospital services stating that there is no evidence that the system of prior authorisation is necessary with respect to extramural care (non-hospital services).[69] With regards to hospital services, the Court accepted that the system is necessary and reasonable because of the need of forward planning.[70]

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. 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.[71]

DIRECTIVE 2011/24/EU ON PATIENTS' RIGHTS IN CROSS-BORDER HEALTH CARE

Directive 2011/24/EU[72] 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.[73]

Development and reasons for adopting the Directive

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 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.[74]

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[66] VAN DER MEI, A., P. *Free movement of persons within the European Community: cross-border access to public benefits*. Portland, Or.: Hart Pub., 2003, p. 311.
[67] Judgment of 13 May 2003, *Müller-Fauré and van Riet*, C-385/99, EU:C:2003:270.
[68] BAQUERO CRUZ, J. The Case Law of the European Court of Justice on the Mobility of Patients: An Assessment. In: J. W. van de Gronden – E. Szyszczak – U. Neergaard – M. Krajewski (eds.). *Health care and EU law*, p. 86.
[69] Judgment of 13 May 2003, *Müller-Fauré and van Riet*, C-385/99, EU:C:2003:270, para 93.
[70] Ibid., para 81.
[71] Ibid., para 90.
[72] 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 health care, OJ L 88 (Directive 2011/24/EU).
[73] GREER, S. L., KURZER, P. *European Union public health policy: regional and global trends*, p. 23.
[74] Ibid., pp. 23–24.

Economically poorer member states expressed their fear that the Directive could have a double disadvantage for their health system. They were concerned that the Directive would 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.[75]

Despite 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 health care costs, the financial flows were estimated higher than 1% only in border areas.[76,77]

Content and scope of application

The Directive provides an extensive legal framework for cross-border health care, mainly with rules concerning the reimbursement of costs, responsibilities of a member state of treatment,[78] as well as a member state of affiliation[79] with regard to cross-border health care and the framework for cooperation in health care. Cross-border health care covers all situations different from the one, when the patient is treated in a member state he/she is socially insured in by a local health care provider who is established in that member state.[80]

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. In addition, patients who receive unplanned medical care while staying abroad can benefit from the patients' rights stated in the Directive.[81]

The Directive is applicable to health care, regardless of how it is organised, delivered and financed.[82] There are three types of health care to which the Directive does not apply: long-term care services to support people in need of assistance in carrying out routine

[75] Ibid., p. 24.
[76] Ibid., p. 118.
[77] SZYSZCZAK, E. Patients' rights: A Lost Cause or Missed Opportunity? In: J. W. van de Gronden – E. Szyszczak – U. Neergaard – M. Krajewski (eds.). *Health care and EU law*, p. 115.
[78] Member state on whose territory health care is actually provided to the patient.
[79] Member state that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another member state.
[80] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care*, pp. 29–32.
[81] Ibid., pp. 32–33.
[82] Directive 2011/24/EU, Article 1(2).

tasks;[83] access and allocation of organs for the purpose of transplantation; and public vaccination programmes against infectious diseases.[84] These three categories, 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 their exclusion is the fear of large costs for the state of affiliation.[85]

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.[86,87]

Principally, the Directive was intended to bring clarity and legal certainty to this area, after cross-border health care became a subject of an increased litigation.[88]

Legal basis

The Directive has two legal bases: Article 114 TFEU and 168 TFEU.[89] 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.[90]

The use of public health provision (Article 168 TFEU) was justified 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*'[91]. This refers to internal market provisions. 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.[92]

The proposal of 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 justified by the Commission, which showed that even though the Court had clarified a patients' right to travel abroad to receive medical treatment, they were not actually able to exercise these rights effectively.[93]

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[83] This includes services provided by home care services, in assisted living facilities and in residential homes or housing (nursing homes).
[84] Directive 2011/24/EU, Article 1(3).
[85] PENNINGS, F. *Cross-Border Health Care Directive: More Free Movement for Citizens and More Coherent EU Law?*, p. 438.
[86] GREER, S. L., KURZER, P. *European Union public health policy: regional and global trends*, p. 23.
[87] SZYSZCZAK, E. Patients' rights: A Lost Cause or Missed Opportunity? In: J. W. van de Gronden – E. Szyszczak – U. Neergaard – M. Krajewski (eds.). *Health care and EU law*, p. 108-109.
[88] Ibid., p. 109.
[89] BORGES, D. C. L. *EU health systems and distributive justice: towards new paradigms for the provision of health care services?* Routledge, 2016, p. 147.
[90] Directive 2011/24/EU, Preamble, recital 2.
[91] Ibid., Preamble, recital 1.
[92] SZYSZCZAK, E. Patients' rights: A Lost Cause or Missed Opportunity? In: J. W. van de Gronden – E. Szyszczak – U. Neergaard – M. Krajewski (eds.). *Health care and EU law*, p. 119.
[93] Ibid., pp. 119–120.

Reimbursement of costs of cross-border health care

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.[94] In practice, a patient has to arrange treatment conditions with a health care provider and pay upfront. The patient can ask for reimbursement of costs for this treatment afterwards.[95]

The reimbursement of costs is a responsibility of the member state of affiliation.[96] 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.[97] Member states can decide to reimburse full costs in cases exceeding the reimbursement tariff in the member state of affiliation.[98] 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.[99] In addition, a member state can establish a third payer system to prevent patients having to pay all costs in advance.[100]

However, the reimbursement should not exceed the actual costs of the health care 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.[101]

Each member state has to set up a transparent mechanism for the calculation of costs of cross-border health care that must be reimbursed to patients. This mechanism has to be objective, non-discriminatory and known in advance.[102] This provision is addressed to member states that do not have reimbursement tariffs, because their patients are entitled to free health care, for example the National Health Service in Great Britain.[103]

Health care that may be subject to prior authorisation

The reimbursement of costs of cross-border health care cannot be subject to prior authorisation, with a few explicitly stated exceptions.[104]

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[94] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care*, p. 33.

[95] Na co mám nárok, pokud cestuji za zdravotní péčí. In: *Kancelář zdravotního pojištění* [online]. 18. 4. 2014 [2017-06-11]. Available at: <https://www.kancelarzp.cz/cs/pojistenci/prava-naroky-eu/narok-kategorie/cesta-za-zdrav-peci>.

[96] Directive 2011/24/EU, Article 7(1).

[97] Ibid., Article 7(4), paragraph 1.

[98] Ibid., Article 7(4), paragraph 2.

[99] Ibid., Article 7(4), paragraph 3.

[100] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care*, p. 52.

[101] STRBAN, G. *Patient mobility in the European Union: between social security coordination and free movement of services*, p. 400.

[102] Directive 2011/24/EU, Article 7(6).

[103] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care*, p. 35.

[104] Directive 2011/24/EU, Article 7(8).

Firstly, health care 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.[105] Member states have to notify the Commission about categories of health care which they qualify as subjects to planning requirement.[106]

The second exception is treatment that presents a particular risk for the patient or the population.[107] This provision can be interpreted broadly and its application depends on how member states implement it into their national law.[108]

The third exception is health care provided by a health care provider that could cause concerns regarding the quality or safety of the care. This does not apply to health care which is subject to EU legislation ensuring a minimum level of safety and quality.[109] As in the second exception, the impact of this provision depends on how it is implemented in national law. It is not entirely clear to what extent member states can question the quality and safety of health care provided in different member states. As confirmed in the *Stamatelaki case,*[110] reimbursement of cross-border health care cannot be refused solely for the reason that the treatment was provided in a private hospital.[111]

Each member state has to publish which health care requires a prior authorisation and all relevant information about the prior authorisation system.[112]

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.[113] 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.[114]

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.[115] 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.[116] Member states can

[105] Ibid., Article 8(2)a.
[106] Ibid., Article 8(2), paragraph 2.
[107] Ibid., Article 8(2)b.
[108] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care,* p. 38.
[109] Directive 2011/24/EU, Article 8(2)c.
[110] Judgment of 19 April 2007, *Stamatelaki,* C-444/05, EU:C:2007:231.
[111] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care,* p. 38.
[112] Directive 2011/24/EU, Article 8(7).
[113] STRBAN, G. *Patient mobility in the European Union: between social security coordination and free movement of services,* p. 401.
[114] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care,* p. 52.
[115] Directive 2011/24/EU, Article 8(6)a.
[116] Ibid., Article 8(6)b.

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.[117] For example, this can imply a situation when a health care provider is not entitled to the right to practice.[118] The final case is when the health care 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.[119] This refusal cannot be based only on the existence of waiting lists.[120] The phrases "within a reasonable time" or "within a time limit, which is medically justifiable" display a vague time period, but one related to a patient's specific medical condition and can be derived from the ECJ case law.[121]

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, health care for which authorisation was given according to the rules of the Regulation 883/2004 (based on the free movement of persons). Secondly, health care 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).[122,123]

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.[124] The rights under these two instruments cannot be used simultaneously; thus double reimbursement is clearly forbidden.[125] The Directive specifies that it applies without prejudice to the Regulation.[126]

The Directive gives priority to the Regulation. It explicitly states that when conditions of the Regulation are met, a prior authorisation will be granted pursuant to that Regulation unless the patient requests otherwise.[127] 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.

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[117] Ibid., Article 8(6)c.
[118] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care*, p. 39.
[119] Directive 2011/24/EU, Article 8(6)d.
[120] Ibid., Preamble, Recital 43.
[121] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care*, p. 39.
[122] PENNINGS, F. *Cross-Border Health Care Directive: More Free Movement for Citizens and More Coherent EU Law?*, p. 134.
[123] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care*, p. 40.
[124] Directive 2011/24/EU, Preamble, Recital 30.
[125] CARRASCOSA BERMEJO, D. *Cross-border health care in the EU: Interaction between Directive 2011/24/EU and the Regulations on social security coordination*, p. 364.
[126] Directive 2011/24/EU, Article 2(m).
[127] Ibid., Article 8(3).

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.[128]

Furthermore, the distinction between these systems is complicated for the majority of patients. This interplay between social security coordination and the law on economic freedoms makes the application of the right to cross-border health care reasonably complex.[129]

The question that 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) health care providers (not related to public health care system).[130]

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.[131]

The Directive expressly states that a member state is not obliged to reimburse costs of health care provided by health care 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.[132] 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 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.[133]

Furthermore, the dual legal system also seems problematic in terms of reimbursement of costs of cross-border health care. 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.[134]

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[128] CARRASCOSA BERMEJO, D. *Cross-border health care in the EU: Interaction between Directive 2011/24/EU and the Regulations on social security coordination*, p. 365.

[129] STRBAN, G. *Patient mobility in the European Union: between social security coordination and free movement of services*, p. 406.

[130] Ibid., pp. 403–404.

[131] Ibid., pp. 403–404.

[132] Directive 2011/24/EU, Article 1(4).

[133] STRBAN, G. *Patient mobility in the European Union: between social security coordination and free movement of services*, p. 404.

[134] Ibid., p. 405.

There are a few situations when only the Regulation applies. First, the Regulation can apply in relation to health care received in some third countries[135]. 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.[136] Finally, if an insured person becomes a resident in another member state, reimbursement rights under the Directive are no longer applicable, because residence is not considered as a cross-border situation.[137]

An advantage of the Directive is that, compared to the Regulation, in most member states access to each health care provider is only possible under the Directive. Under the Regulation, the patients' choice of health care provider is limited.[138]

The distinction in requirements for reimbursement is as follows. Under the Regulation, prior authorisation is only required for planned health care, irrespective of whether the treatment is in a hospital or not. Unplanned health care 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.[139]

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.[140]

One of the most important rights is the right of patients to receive information. The right to information can be divided into two categories. Firstly, patients are 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 health care, prices, authorisation or registration status of a health care provider and his insurance cover.[141]

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.[142]

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[135] Non-EU member states.
[136] Directive 2011/24/EU, Article 1(3).
[137] CARRASCOSA BERMEJO, D. *Cross-border health care in the EU: Interaction between Directive 2011/24/EU and the Regulations on social security coordination,* p. 367.
[138] Ibid., p. 366.
[139] Ibid., p. 372.
[140] HERVEY, T. K., MCHALE, J. V. *European Union health law: themes and implications*, p. 189.
[141] Directive 2011/24/EU, Article 4(2)a,b.
[142] Ibid., Article 4(5).

According to the European Commission's survey,[143] most EU citizens feel ill-informed about health care and reimbursement rights they are entitled to in another EU country. Information provided to patients is considered too complex, incomplete and often only in a foreign language. Information is provided in national contact points for cross-border health care, which member states are obliged to designate.[144]

Patients also have right not to be discriminated which was derived from the general prohibition on discrimination on the basis of nationality of the Treaty on the Functioning of the European Union, and applies to all patients from other member states.[145] Nevertheless, a member state can adopt measures in order to ensure sufficient and permanent access to a health care service on its territory. These measures have to be justified by overriding reasons of general interest and must be publicly available in advance.[146] Simply put, member states can adopt these measures only when the access of their own patients to their health care service is jeopardised due to a disproportionate inflow of foreign patients.[147] Furthermore, fees of health care for foreign patients have to be the same as for domestic patients.[148]

The right to transparent complaints procedure includes a patients' right to a mechanism to seek remedies if they suffer harm arising from the health care received.[149]

The 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.[150]

Furthermore, 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.[151]

National contact points

Member states have to designate at least one national contact point for cross-border health care which should consult with patient organisations, health care providers and health insurers.[152] Their task is to facilitate the exchange of information among other contact points, and cooperate with them and the Commission.[153] The biggest benefit for patients is represented by the obligation of national contact points to inform about health care providers, patients' rights, the complaints procedure and the mechanism for seeking remedies.[154]

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[143] *Special Eurobarometer 425 "Patients' rights in cross-border health care in the European Union": Report. 2015.* Available at: http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_425_sum_en.pdf, p. 10–15.
[144] Directive 2011/24/EU, Article 6.
[145] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care,* p. 54.
[146] Directive 2011/24/EU, Article 4(3).
[147] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care,* p. 44.
[148] Directive 2011/24/EU, Article 4(4).
[149] Ibid., Article 4(2)c.
[150] Ibid., Article 4(2)e.
[151] Ibid., Article 4(2)f.
[152] Ibid., Article 6(1).
[153] Ibid., Article 6(2).
[154] Ibid., Article 6(3).

In many member states, the national contact point is the institution that has been collecting information on cross-border heath care, which might be the existing contact point for social security coordination.[155] 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 health care insurer or in independent bodies.[156]

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.[157]

Cooperation in health care

The Directive governs six areas of possible cooperation of member states: mutual assistance and cooperation, recognition of prescriptions issued in another member state, European reference network, rare diseases, eHealth, and cooperation on health technology assessment.[158]

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 health care may be the most efficient way for organising health services.[159] This cooperation may concern joint planning, mutual recognition of procedures or standards, interoperability of respective national information and communication technology systems.[160] This provision is expected to improve the quality of health care services across EU member states. The lack of harmonisation of quality and safety standards may be problematic in this respect. In my opinion, the improvement will be gradual and relatively slow.

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.[161]

The difference in approaches in member states was challenged in the *Grogan case*[162]. 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

[155] STRBAN, G. *Patient mobility in the European Union: between social security coordination and free movement of services*, p. 402.
[156] *Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border health care: COM(2015) 421 final*. Brussels, 2015. Available at: https://ec.europa.eu/health//sites/health/files/cross_border_care/docs/2015_operation_report_dir201124eu_en.pdf, p. 8.
[157] Directive 2011/24/EU, Article 6(5).
[158] Ibid., Articles 10-15.
[159] Ibid., Article 10(1)(3).
[160] Ibid., Preamble, Recital 50.
[161] HERVEY, T. K., MCHALE, J. V. *European Union health law: themes and implications*, p. 91.
[162] Judgment of the Court of 4 October 1991, *Grogan*, C-159/90, EU:C:1991:378.

and abortion is only allowed when it is necessary to save a mother's life.[163] The CJEU confirmed that abortion constitutes a 'service' 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 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-hierarchal.[164]

There is also considerable ethical discourse concerning the right to reproduce, especially the question to who should the technology be available. There are also significant differences in donor anonymity, waiting times and costs of treatment, which may play a decisive role in couple decisions.[165]

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.[166]

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.

Implementation of the Directive

A directive is one of the 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.[167]

Directive 2011/24/EU was due to be transposed by member states by 25 October 2013.[168] 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.[169]

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[163] Irish Constitution, Article 40.3.3.
[164] HERVEY, T. K., MCHALE, J. V. *European Union health law: themes and implications*, p. 92.
[165] Ibid., pp. 91–92.
[166] Ibid., p. 95.
[167] Treaty on the Functioning of the European Union, OJ C 326, Art. 288.
[168] Directive 2011/24/EU, Article 21, p. 3.
[169] *Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border health care.*

As a result, there is a much broader legal framework for cross-border health care. The Directive does not only provide a reimbursement system for the costs of cross-border health care, but it also provides patients' rights that are not related to cross-border care. The Directive reaches beyond patient mobility and influences European health care systems as a whole. This therefore affects all European patients, not only those crossing borders.[170]

Member states and European Union institutions did not expect an enormous increase of patients crossing borders to receive health care abroad when adopting the Directive. Patients generally prefer to be treated close to where they live, because they find health care satisfying at home 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.[171]

This assumption proved to be correct; according to a Commission survey conducted in 2015, patient flows for health care abroad under the Directive are low.[172]

Member states could use their discretionary powers and choose a different form and methods to implement the Directive. The Directive requires the Commission to draw up a report on the operation of the Directive by 25 October 2015, and every three years thereafter.[173] 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.[174]

Prior authorisation

A system of prior authorisation has been implemented by 21 member states.[175] Some of these have introduced legislation enabling them to set up this system at a later date, if they find it necessary.[176]

14 member states used both the 'overnight stay' and the 'highly specialised' care criteria for requiring prior authorisation. None of these countries, which have used the 'overnight stay' criterion, specified which treatment is covered by this criterion. Nine of the 14 member states identified 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 has not been elucidated by national authorities.[177]

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[170] PEETERS, M. *Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Health care*, p. 51.

[171] *Special Eurobarometer 425 "Patients' rights in cross-border health care in the European Union": Report. 2015*, p. 9.

[172] *Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border health care*, p. 7.

[173] Directive 2011/24/EU, Article 20(1).

[174] *Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border health care*, p. 3.

[175] Not by Austria, the Czech Republic, Estonia, Finland, Lithuania, the Netherlands and Sweden.

[176] *Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border health care*, p. 17.

[177] Ibid., p. 5.

Reimbursement

The ways in which member states have transposed the Directive could be considered as limiting reimbursement. For example, three member states require any patient seeking reimbursement for cross-border health care to demonstrate why it is medically necessary for the particular episode of health care to be received in another country.[178] 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 to access specialist health care. These referrals are also required when patients wish to be reimbursed for this health care 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.[179]

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.[180]

CONCLUSION

Cross-border health care has become a more prominent phenomenon in the European Union. Health law is a 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.

Health care was originally the exclusive responsibility of member states. These competences were strengthened over time and public health is now a shared competence between the EU and the member states. This historical development is crucial to understanding the issue of cross-border health care.

The development in the provision of cross-border health care 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 jurisprudence of the European Court of Justice started to play an important role in EU law and its policy making. 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.

The adoption of the Directive 2011/24/EU on patients' rights in cross-border health care represents an important change in providing cross-border health care. Through its

[178] Ibid., p. 6.
[179] Ibid., p. 6.
[180] Ibid., p. 6.

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 considered too complicated for the majority of patients.

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 health care 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 across all EU member states.