

The EU legal framework on cross-border healthcare after the adoption of the Patients' Mobility Directive

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Abstract

This article focuses on the legal issues arising under Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. This Directive aims to facilitate the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States. The present article first examines how general EU free movement law regulates healthcare services and, in particular, medical services provided within the framework of social security systems. It then analyses the provisions of Directive 2011/24/EU regarding the systems of prior authorisation and reimbursement of cross-border healthcare and compares them with the existing framework on the coordination of social security systems and the relevant case law of the European Court of Justice.

Keywords

Directive 2011/24/EU, cross-border healthcare services, patients' mobility, social security, prior authorisation, reimbursement.

I. Introduction

*"Today is an important day for patients across the European Union. As of today, EU law in force enshrines citizens' right to go to another EU country for treatment and get reimbursed for it. From today, all EU countries should have transposed the Directive on Patients' rights in Cross-border Healthcare, adopted 30 months ago, into their National law. For patients, this Directive means empowerment: greater choice of healthcare, more information, easier recognition of prescriptions across-borders. The Directive is also good news for Europe's health systems, improving cooperation between Member States on interoperable eHealth tools, the use of health technology assessment, and the pooling of rare expertise [...]"*¹

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This statement was made on the 25th of October 2013 by the Health Commissioner, Tonio Borg, on the entry into force of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (hereinafter "Directive 2011/24/EU" or "Directive" or "Patients' Mobility Directive").² This Directive was adopted with the aim to facilitate access to safe and high-quality cross-border healthcare, to ensure patient's mobility and to promote cooperation on healthcare between Member States. Although the demand for cross-border healthcare represents only around 1% of public spending on healthcare, including cases of non-planned healthcare such as emergency care for tourists,³ this secondary legislation constitutes an important step towards the harmonisation of national rules in the relevant field, which have so far been significantly divergent, thereby causing difficulties in their application, confusion and legal uncertainty. The present article focuses on the convergence achieved by the Directive at issue in the field of cross-border healthcare. On the one hand, this convergence was much desired by the Commission in view of the important discrepancies of the national legislations. On the other hand, the Member States seemed reluctant to sacrifice their welfare structures for the accomplishment of the Internal Market. Nevertheless, a compromise was finally achieved. In order to better describe this compromise, the article first examines how healthcare services are regulated under the general EU free movement law (II) and it then analyses the provisions of Directive 2011/24/EU with emphasis on the issues of prior authorisation and reimbursement of cross-border healthcare (III).

II. Healthcare services under EU free movement law

Although the organisation of national health policies remains an exclusive competence of the Member States due to their special and sometimes sensitive nature, the operation of such policies may be subject to Treaty provisions on the Internal Market and competition. In this respect, it should be noted that the EU has a shared competence in the

University of Warsaw Journal of Comparative Law. May this be the first of many issues to come and may they provide a future basis for the evolution of constructive legal thinking.

¹ European Commission, Statement by Health Commissioner, Tonio Borg, on the entry into force of the Directive on Patients' Rights in Cross-border Healthcare, MEMO/13/932, 25/10/2013.

² 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 [2011] OJ L 88/45.

³ European Commission, Q&A: Patients' Rights in Cross-Border Healthcare, MEMO/13/918, 22/10/2013.

area of “common safety concerns in public health matters” under Article 4 (2) (k) of the Treaty on the Functioning of the European Union (hereinafter “TFEU”)⁴ and a supporting, coordinating or complementary competence in the area of “protection and improvement of human health” under Article 6 (a) TFEU. This double nature of the EU competence on public health issues is reflected in the legal basis provision of Article 168 TFEU, which first sets out the general EU objective to ensure a higher level of human health protection and then provides for three different types of measures that can be adopted in this respect.⁵ Furthermore, Article 9 TFEU, the so-called “horizontal” social clause,⁶ stipulates that all EU policies must take into account social requirements “linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health”. In addition, it must be stated that Article 35 of the Charter of Fundamental Rights protects “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”.⁷

In this chapter, we will first examine the application of the Treaty provision on the Internal Market and in particular on the freedom to provide services to healthcare services (A) and we will then proceed with a brief comment on the current system of coordination of social security (B).

⁴ Consolidated version of the Treaty on the Functioning of the European Union [2012] OJ C 326/47.

⁵ First, Article 168 (2) TFEU provides for the method of coordination through which the EU can encourage and support cooperation between the Member States in the area of public health. Second, according to Article 168 (4) TFEU, the EU, acting in accordance with the ordinary legislative procedure, may adopt (a) measures setting high standards of quality and safety for organs and substances of human origins, (b) measures in the veterinary and phytosanitary fields and (c) measures setting high standards of quality and safety for medicinal products and devices for medical use. Finally, according to Article 168 (5), the EU, acting again in accordance with the ordinary legislative procedure, may adopt *incentive* measures – excluding any harmonisation - designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol.

⁶ Opinion of the European Economic and Social Committee on ‘Strengthening EU cohesion and EU social policy coordination through the new horizontal social clause in Article 9 TFEU’ (own-initiative opinion) [2012] OJ C 24/29.

⁷ Charter of Fundamental Rights of the European Union [2012] OJ C 326/391.

A. The application of the freedom to provide services to healthcare services

Healthcare services fall within the scope of application of Article 56 TFEU on the freedom to provide services. In *Luisi and Carbone*, the European Court of Justice (hereinafter "ECJ" or "Court") confirmed that Article 56 TFEU covers both the providers and the recipients of services and that "*persons receiving medical treatment [...] are to be regarded as recipients of services*".⁸ This ruling was reaffirmed in the *Grogan* case, where the ECJ held that "*medical termination of pregnancy, performed in accordance with the law of the State in which it is carried out, constitutes a service within the meaning of Article 60 of the Treaty (Article 56 TFEU)*".⁹ The reasoning of the Court was that services are normally provided for remuneration and, in accordance with Article 57 TFEU, they fall under the scope of the provisions on the free movement of services in so far as they are not governed by the provisions relating to freedom of movement for goods, capital or persons.¹⁰ This residual character of Article 56 TFEU means that the notion of "services" covers situations which are not governed by other freedoms in order to ensure that all economic activity falls within the scope of the fundamental freedoms.¹¹ Since the "*termination of pregnancy, as lawfully practised in several Member States, is a medical activity which is normally provided for remuneration and may be carried out as part of a professional activity*",¹² it is to be considered a "service" falling under the scope of Article 56 TFEU whatever the objections on the moral plane.¹³ Consequently, the decisive criterion, which determines whether medical activities are "services" for the purposes of Article 56 TFEU, is their *economic* nature.

The Court has repeatedly held that medical services supplied for consideration fall within the scope of the provisions on the freedom to provide services and it has clarified, in *Smits and Peerbooms*, that there is no need to distinguish between care provided in a hospital

⁸ Joined Cases 286/82 and 26/83 *Graziana Luisi and Giuseppe Carbone v Ministero del Tesoro* [1984] ECR 00377, para 16.

⁹ Case C-159/90 *The Society for the Protection of Unborn Children Ireland Ltd v Stephen Grogan and others* [1991] ECR I-04685, para 21.

¹⁰ *Ibid* para 17.

¹¹ Case C-452/04 *Fidium Finanz AG v Bundesanstalt Finanzdienstleistungsaufsicht* [2006] ECR I-09521, para 32.

¹² Case C-159/90 *Grogan* (n 9) para 18.

¹³ *Ibid* para 20.

environment and care provided outside such an environment,¹⁴ and in *Stamatelaki*, that it is immaterial whether the establishment in question is public or private.¹⁵ It has further underlined that Article 56 TFEU “does not require that the service be paid for by those for whom it is performed”¹⁶ and that “the payments made by the sickness insurance funds under the contractual arrangements [...], albeit set at a flat rate, [are] the consideration for the hospital services and unquestionably [represent] remuneration for the hospital which receives them and which is engaged in an activity of an economic character”.¹⁷

Subsequently, in *Watts*, a landmark decision regarding the UK's National Health Service (NHS), the ECJ ruled that Article 56 TFEU 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”.¹⁸ However, regarding the highly controversial issue of the economic nature of the medical services provided by a NHS, the ECJ, whilst accepting the applicability of Article 56 TFEU, it nonetheless added that there was “no need in the present case to determine whether the provision of hospital treatment in the context of a national health service such as the NHS is in itself a service within the meaning of those provisions”.¹⁹ In other words, the Court seemed deliberately hesitant to rule on whether the services provided by a NHS *per se* are regarded as “services” for the purposes of Article 56 TFEU.²⁰ The aforementioned developments show that although the sector of public health – contrary to the sector of public education²¹ – has progressively been subjected to the rules of the Internal Market on the

¹⁴ Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-05473, para 53.

¹⁵ Case C-444/05 *Aikaterini Stamatelaki v NPDD Organismos Asfaliseos Eleftheron Epangelmaton (OAE)* [2007] ECR I-03185, para 22.

¹⁶ Case C-157/99 *Smits and Peerbooms* (n 14) para 57.

¹⁷ *Ibid* para 58.

¹⁸ Case C-372/04 *Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-04325, para 90.

¹⁹ *Ibid* para 91.

²⁰ Baeten R., Gekiere W. & Palm W., “Free movement of services in the EU and health care” in Baeten R., Herve T.K., Mossialos E. & Permanand G. (eds.), *Health Systems Governance in Europe* (CUP 2010) 461-508, 467; De Búrca G. & Craig P., *EU Law: Text, Cases, and Materials* (3rd edn, OUP 2011) 796.

²¹ In *Humbel*, the Court emphasised that “the essential characteristic of remuneration lies in the fact that it constitutes consideration for the service in question, and is normally agreed upon between the

freedom to provide services, the ECJ has so far avoided characterizing the healthcare of a NHS in itself as “service” within the meaning of Article 56 TFEU, in an effort to maintain a balance between the ultimate objective of the accomplishment of the Internal Market and the respect of some traditionally sensitive areas of welfare States’ competences which affect the provision of public services with significant political and societal connotations.

B. Coordination of social security

Having established early enough that medical services provided for remuneration fall within the scope of application of the Internal Market rules on freedom to provide services, in 1998 the Court went one step further and applied the freedom to provide services in the field of social security. In particular, in *Kohll*, the Court, responding to the objections raised by the Member States, held that the fact that the national rules at issue fell within the sphere of social security could not exclude the application of Article 56 TFEU.²² Whilst social security is a competence of the Member States, the latter must nonetheless exercise that competence consistently with EU law. On this basis, it ruled that the treatment provided by an orthodontist established in Germany was considered a “service” for the purposes of Article 56 TFEU and that the requirement of prior authorization for the reimbursement of the

provider and the recipient of the service”. The Court held that the national educational system did not fall within the scope of Article 56 TFEU because it was lacking the decisive element of remuneration. In this regard, the Court underlined that “*the State, in establishing and maintaining such a system, is not seeking to engage in gainful activity but is fulfilling its duties towards its own population in the social, cultural and educational fields*” and that “*the system in question is, as a general rule, funded from the public purse and not by pupils or their parents*” (Case 263/86 *Belgian State v René Humbel and Marie-Thérèse Edel* [1988] ECR 05365, paras 17-19). In *Wirth*, the Court held that “*those considerations are equally applicable to courses given in an institute of higher education which is financed, essentially, out of public funds*”, but conversely agreed with the UK that the establishments of higher education “*financed essentially out of private funds, in particular by students or their parents, and which seek to make an economic profit*” are considered “services” within the meaning of Article 56 TFEU (Case C-109/92 *Stephan Max Wirth v Landeshauptstadt Hannover* [1993] ECR I-06447, paras 16-17). Finally, in *Schwarz*, the Court reiterated that private education, which is characterized by the element of remuneration, is an economic activity falling within the scope of Article 56 TFEU (Case C-76/05 *Herbert Schwarz and Marga Gootjes-Schwarz v Finanzamt Bergisch Gladbach* [2007] ECR I-06849, para 47).

²² Case C-158/96 *Raymond Kohll v Union des caisses de maladie* [1998] ECR I-01931, para 21. See also the parallel Case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés* [1998] ECR I-01831, para 25, decided on the same day as *Kohll*, where the Court found that the requirement of a prior authorization for reimbursement of the cost of a pair of spectacles with corrective lenses purchased from an optician established in Belgium, on a prescription from an ophthalmologist established in Luxembourg, constituted an unjustified restriction on the free movement of goods under Article 34 TFEU.

treatment received, imposed by Luxembourg, constituted an unjustified restriction on the freedom to provide services.²³

However, the application of the freedom to provide services does not mean that EU law detracts from the powers of the Member States to organise their social security systems.²⁴ Indeed, social security, one of the traditional functions of the welfare State, is a particularly sensitive area,²⁵ which constitutes first and foremost a matter of the Member States. According to settled case law, *"in the absence of harmonisation at Community level, it is therefore for the legislation of each Member State to determine, first, the conditions concerning the right or duty to be insured with a social security scheme and, second, the conditions for entitlement to benefits"*.²⁶

Article 48 TFEU, the legal basis provision on social security, provides only for the coordination - and not the harmonisation - of the national legislations relating to social security combined with negative integration (i.e. prohibitions of discrimination). Coordination is one of the integration techniques used in EU secondary law, which aims at improving the interplay of national systems, rather than approaching the national legislations on the substantive level.²⁷ In essence, this means that countries are entitled to establish their own social security system, determining who is to be insured, which benefits are granted and under what conditions without any interference at EU level. The EU rules on social security coordination do not replace national systems with a single European one. However, they do provide protection for EU citizens who exercise their free movement rights.

The main legal instruments of this coordination, which is founded on the cooperation of national social security administrations, is Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security

²³ Case C-158/96 *Kohll* (n 22) para 54.

²⁴ Case C-158/96 *Kohll* (n 22) para 17; Case 238/82 *Duphar and Others v Netherlands* [1984] ECR 00523, para 16; Case C-70/95 *Sodemare and Others v Regione Lombardia* [1997] ECR I-3395, para 27.

²⁵ De la Rosa S., "The Directive on cross-border healthcare or the art of codifying complex case-law" (2012) 49 Common Market Law Review 15-46, 17.

²⁶ Case C-158/96 *Kohll* (n 22) para 18; Case 110/79 *Coonan v Insurance Officer* [1980] ECR 1445, para 12; Case C-349/87 *Paraschi v Landesversicherungsanstalt Württemberg* [1991] ECR I-4501, para 15; Joined Cases C-4/95 and C-5/95 *Stöber and Piosa Pereira v Bundesanstalt für Arbeit* [1997] ECR I-511, para 36.

²⁷ Belinger J. & Tobler C., *Essential EU Law in Charts* (HVG-ORAC, Budapest 2013) Chart 11/4. The other three integration techniques as explained in this Chart are the unified legislation, the harmonization and the mutual recognition.

systems²⁸ - which replaced the Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community²⁹ - and Regulation (EC) No 987/2009 implementing Regulation (EC) No 883/2004 (hereinafter "Regulations").³⁰ These Regulations, adopted on the basis of Article 48 TFEU, fall within the framework of the freedom of movement for workers and their main purpose is to ensure that insured persons - mainly workers - do not lose their social security protection when moving to another Member State.³¹

Despite the Court's effort not to interfere with traditional social competences of the Member States and the recognition of the legitimate aim to maintain the financial sustainability of the social security and national healthcare system, it is crucial to understand that certain core aspects of national welfare systems are undoubtedly subjected to the free movement provisions.³² The application of the Treaty provisions on the free movement to publicly funded welfare services has certainly opened the way for the adoption of Directive 2004/11/EU.

²⁸ Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems [2004] OJ L 166/1.

²⁹ Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community [1971] OJ L 149/2.

³⁰ 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 [2009] OJ L 284/1, which was later amended by Commission Regulation (EU) No 1244/2010 of 9 December 2010 amending Regulation (EC) No 883/2004 of the European Parliament and of the Council on the coordination of social security systems and Regulation (EC) No 987/2009 of the European Parliament and of the Council laying down the procedure for implementing Regulation (EC) No 883/2004 [2010] OJ L 338/35; Regulation (EU) No 465/2012 of the European Parliament and of the Council of 22 May 2012 amending Regulation (EC) No 883/2004 on the coordination of social security systems and Regulation (EC) No 987/2009 laying down the procedure for implementing Regulation (EC) No 883/2004 [2012] OJ L 149/4 and Commission Regulation (EU) No 1224/2012 of 18 December 2012 amending Regulation (EC) No 883/2004 of the European Parliament and of the Council on the coordination of social security systems and Regulation (EC) No 987/2009 of the European Parliament and of the Council laying down the procedure for implementing Regulation (EC) No 883/2004 Text with relevance for the EEA and for Switzerland [2012] OJ L 349/45.

³¹ For a detailed and comprehensive analysis of the relationship between Regulations (EC) Nos 883/2004 and 987/2009 on the coordination of social security systems and Directive 2011/24/EU on the application of patients' rights in cross border healthcare, see European Commission, Guidance note of the Commission services on the relationship between Regulations (EC) Nos 883/2004 and 987/2009 on the coordination of social security systems and Directive 2011/24/EU on the application of patients' rights in cross border healthcare, AC 246/12, 21.05.2012.

³² De Búrca G. & Craig P. (n 20) 796.

III. Cross-border healthcare services under Directive 2011/24/EU

The second chapter of the present article deals with the regulation of healthcare services under the provisions of Directive 2011/24/EU. It will first explain how the developments in the field of cross-border healthcare led to the adoption of this Directive (A) and it will then address the issues of prior authorisation and reimbursement (B).

A. The adoption of Directive 2011/24/EU

Before analysing the important substantive provisions regarding prior authorisation and reimbursement of cross-border healthcare, we will first make a brief comment on the exclusion of healthcare services from the Services Directive (1) and we will secondly examine the legal basis and the scope of Directive 2011/24/EU (2).

1. The exclusion of healthcare services from the Services Directive

From a historical perspective, as a result of their sensitive nature and their special regime, health services were excluded from the final version of the much-debated Directive 2006/123/EC of 12 December 2006 on services in the internal market (hereinafter "Directive 2006/123/EC").³³ This Directive, known as the *Bolkestein* Directive after the name of the Commissioner who introduced the initial proposal,³⁴ establishes a general legal framework promoting the exercise of the freedom of establishment for service providers and the free movement of services. Although its name is limited to services, its actual scope of application covers both the area of temporary cross-border provision of services and the area of permanent establishment of entrepreneurs or undertakings. Whilst it covers a wide range of service activities, which represent around 40 % of the EU's GDP and employment, it nonetheless excludes from its material scope, as defined in Article 2 thereof, several

³³ Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market [2006] OJ L 376/36.

³⁴ The *Bolkestein* Directive received a strong opposition and was given the name "*Frankenstein Directive*", as it was considered to be a threat to the social structures of the Member States. It is even argued that the strong opposition against the Services Directive influenced the public debate in France, a traditionally welfare state with a highly developed social protection system, and ultimately resulted in the negative vote in the national referendum concerning the Constitutional Treaty, see De Búrca G. & Craig P. (n 20) 813.

important types of services, among which “healthcare services whether or not they are provided via healthcare facilities, and regardless of the ways in which they are organised and financed at national level or whether they are public or private”.³⁵

The exclusion of healthcare services from the scope of Directive 2006/123/EC was a compromise between the Commission's objective to harmonise the national legislations in the field of services and establishment and the Member States' unwillingness to concede their competences on their welfare systems to the Union. However, despite this exclusion, the Court continued to consider healthcare services as “services” within the meaning of Article 56 TFEU. Besides, according to the *Tedeschi* principle, in the absence of secondary legislation, the relevant general Treaty provisions apply.³⁶ The application of the Treaty rules in the field of cross-border healthcare services led to important jurisprudential principles, which were ultimately codified in Directive 2011/24/EU.

2. The legal basis and the scope of Directive 2011/24/EU

Directive 2011/24/EU was adopted on the general legal basis provision of Article 114 TFEU, which confers upon the EU the power to adopt measures, in accordance with the ordinary legislative procedure, for the approximation of national legislations in fields relating to the establishment and functioning of the Internal Market. Recital 2 of its Preamble justifies the choice of this legal basis provision by referring to the aim of the Directive, which is to improve the functioning of the internal market and the free movement of goods, persons and services. Even though the Directive affects also (or even primarily) issues of public health, Article 168 TFEU was not ultimately added as a second legal basis provision, despite the political pressure exercised by the Member States.

The subject matter and scope of Directive 2011/24/EU is defined in Article 1 thereof, according to which the Directive aims at facilitating the access to safe and high-quality cross-border healthcare and promoting cooperation on healthcare between the Member States, while clarifying that this objective will be pursued in full respect of national competences in organizing and delivering healthcare. With respect to its material scope, which is defined by the combined provisions of Article 1 and 3 (a) and (e), the Directive applies to the provision of cross-border healthcare, regardless of how it is organized, delivered and financed.

³⁵ Article 2 (2) (f) of Directive 2006/123/EC.

³⁶ Case C-5/77 *Carlo Tedeschi v Denkavit Commerciale s.r.l.* [1977] ECR I-01555, para 35.

However, Article 1 (3) of the Directive explicitly excludes from its scope of application (a) services in the field of long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks,³⁷ (b) allocation of and access to organs for the purpose of organ transplants and (c) public vaccination programmes against infectious diseases which are exclusively aimed at protecting the health of the population on the territory of a Member State and which are subject to specific planning and implementation measures (with the exception of Chapter IV which refers to the cooperation between the Member States on the implementation of the Directive). Accordingly, the Directive at issue does not apply to long-term care services, organ transplants and public vaccination programmes.

B. The rules on prior authorisation and reimbursement under Directive 2011/24/EU

Turning to the more substantive questions arising under Directive 2011/24/EU, we will now address the issues of prior authorisation (1), reimbursement (2) and administrative procedures regarding cross-border healthcare (3). For this purpose, we will also compare the provisions of the Directive with the provisions of the social security Regulations in order to obtain a better understanding of this complex system.

Before starting our analysis, it should be mentioned that Directive 2011/24/EU does not distinguish between planned and unplanned healthcare but applies in principle to all care received by patients in a Member State other than the Member State of affiliation.³⁸ With regard to the unplanned healthcare, Article 2 (m) and 7 (1) of Directive 2011/24 provide that where the terms of the Regulations are met and the conditions of the Regulations are more favourable to the patient, the Regulations must be used, unless the patient explicitly requests otherwise. The application of the more favourable provisions of the Regulations is also enshrined in Recital 28 of the Preamble according to which the Directive "should not affect an insured person's rights in respect of the assumption of costs of healthcare which becomes

³⁷ The OECD has defined long-term care as the care for people needing support in activities of daily living over a prolonged period of time (OECD Report: "Long-Term Care for Older People", 2005). Long-term care services are usually provided to persons with physical or mental disabilities and the frail elderly and particular groups that need assistance in their daily life activities. They include rehabilitation, basic medical services, home nursing, social care, housing and services such as transport, meals, occupational and empowerment activities, thus also including help with instrumental activities of daily living (IADLs) (EU Report: "Long-term in the European Union", April 2008).

³⁸ European Commission, Guidance note (n 31) 3.

necessary on medical grounds during a temporary stay in another Member State according to Regulation (EC) No 883/2004". Consequently, Directive 2011/24/EU cannot be invoked in an effort to deny access to healthcare for insured persons who possess the European Health Insurance Card.³⁹ With regard to planned healthcare, the system of prior authorisation and reimbursement established by the Directive constitutes to a great extent a codification of the case law of the Court in the relevant field and will be analysed in the following paragraphs.

1. Prior authorisation for receiving cross-border healthcare

Contrary to the Regulations, which prescribe prior authorisation as a necessary requirement for receiving planned treatment in another Member State, the requirement of prior authorisation is not the rule under Directive 2011/24/EU. In particular, according to Article 8 of the Directive, the Member State of affiliation⁴⁰ may provide for a system of prior authorisation only for certain types of cross-border healthcare and only in so far as it is necessary and proportionate to the objective to be achieved and does not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients. The specific types of cross-border healthcare that may be subject to prior authorisation are listed in Article 8 (2) of the Directive and are limited to healthcare which: (i) involves overnight hospital accommodation of the patient in question for at least one night; or (ii) requires use of highly specialized and cost-intensive medical infrastructure or medical equipment; or (iii) involves treatments presenting a particular risk for the patient or the population; or (iv) is provided by a healthcare provider that could give rise to serious and specific concerns

³⁹ Under Article 19 (1) of Regulation (EC) No 883/2004, insured persons and their family members staying in a Member State other than the competent Member State are entitled to the benefits in kind which become necessary on medical grounds during their stay, taking into account the nature of the benefits and the expected length of the stay. The State of stay provides these benefits taking into account their nature and the length of the stay. The aim is that the person concerned is not compelled to return to his Member State to receive treatment before the expected end of his stay. These benefits are provided by the institution of the place of stay in accordance with the statutory conditions, procedures and rates applied by this institution, as if the beneficiaries were insured under this legislation. To benefit from these provisions, the persons concerned must submit an individual document detailing their rights issued by the competent institution of the Member State where the person is insured, known as the European Health Insurance Card (in application of Article 25 (1) of Regulation (EC) No 987/2009), directly to the treatment provider in the State of stay.

⁴⁰ According to Article 3 (c) (i) of Directive 2011/24/EU, the Member State of affiliation is the Member State competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulation (EC) No 883/2004 and (EC) No 987/2009.

relating to the quality or safety of the care. By contrast, Article 20 (1) of Regulation (EC) No 883/2004 provides that the insured persons and members of their family travelling to another Member State with the aim of receiving benefits in kind during the stay must seek an authorisation from the competent Member State.⁴¹

With respect to the possible refusal of prior authorisation, the general rule laid down in Article 8 (5) of Directive 2011/24 is that prior authorisation may not, in principle, be refused if "the patient is entitled to the healthcare in question" in the Member State of affiliation and "when this healthcare cannot be provided on its territory within a time limit which is medically justifiable". This rule constitutes a codification of the settled case law of the Court regarding the question of "undue delay". In particular, before the adoption of Directive 2011/24/EU, the Court had been called, in several occasions, to interpret Article 20 of Regulation (EC) No 883/2004, replacing Article 22 of Regulation No 1408/71 - which lays down a duty to grant the authorisation where the treatment in question is among the benefits to which the patient is entitled and where he or she cannot be given such treatment within a time-limit which is medically justifiable - in conjunction with Article 56 TFEU on the freedom to provide services.

According to the interpretation given by the Court in the cases of *Smits and Peerbooms*,⁴² *Müller-Fauré and van Riet*⁴³ and *Inizan*,⁴⁴ in order to determine whether treatment which is equally effective for the patient can be obtained without "undue delay" in the Member State of residence, the competent institution is required to have regard to all the circumstances of each specific case, taking due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history.

In *Müller-Fauré and van Riet*, Court also pointed out that, in determining whether a treatment which is the same or equally effective for the patient is available without "undue

⁴¹ In accordance with Article 1 (s) of Regulation (EC) No 883/2004, the competent Member State is the Member State in which the institution with which the person concerned is insured or from which the person is entitled to benefits is situated.

⁴² Case C-157/99 *Smits and Peerbooms* (n 14) para 104.

⁴³ Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-04509, para 90.

⁴⁴ Case C-56/01 *Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine* [2003] ECR I-12423, para 46.

delay” from an establishment on the territory of the Member State of residence, the competent institution cannot base its decision exclusively on the existence of waiting lists on that territory without taking account of the specific circumstances of the patient's medical condition.⁴⁵ The Court continued the same line of reasoning in the *Watts* case, holding that in order to be entitled to refuse the authorisation on the ground of waiting time, the competent institution must however establish that the waiting time, arising from objectives relating to the planning and management of the supply of hospital care, does not exceed the period which is acceptable in the light of an objective medical assessment of the clinical needs of the person concerned in the light of his medical condition and the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the authorisation is sought.⁴⁶ The Court also added that “*the setting of waiting times should be done flexibly and dynamically, so that the period initially notified to the person concerned may be reconsidered in the light of any deterioration in his state of health occurring after the first request for authorisation*”.⁴⁷ Consequently, in the light of this case law, it is important to underline the significance of an objective and case-by-case medical assessment of the patient's condition in order to determine whether the time limit within which an equally effective treatment can be provided in his or her own Member State is reasonable and acceptable.

Having established the rule that the Member State of affiliation is in principle obliged to grant prior authorisation if the treatment requested by the patient could not be provided on its territory without “undue delay”, the Directive then allows for further derogations from this general rule on the grounds of safety or quality considerations. In particular, according to Article 8 (6) of Directive 2011/24, the Member State of affiliation may refuse to grant prior authorisation when: (a) the patient will be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable; (b) the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question; (c) the healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety.⁴⁸ These exceptions can be reduced to the general derogation on the ground of

⁴⁵ Case C-385/99 *Müller-Fauré and van Riet* (n 43) para 92.

⁴⁶ Case C-372/04 *Watts* (n 18) para 68.

⁴⁷ *Ibid* para 69.

⁴⁸ The last derogation under Article 8 (6) (d) of the Directive, according to which the Member State of affiliation may refuse to grant prior authorisation when the healthcare can be provided on its territory

public health mentioned in Article 52 TFEU in conjunction with Article 62 TFEU. Before the adoption of the Directive, in *Stamatelaki*, the Court dismissed the argument of the Greek government that the exclusion of reimbursement of the costs occasioned in *private* hospitals in another Member State, except those relating to treatment provided to children under 14 years of age, were justified by the need to guarantee the quality of health services.⁴⁹ It based its reasoning on the principle of mutual recognition⁵⁰ and it ruled that private hospitals located in other Member States are also subject to quality controls and that doctors who operate in those establishments provide professional guarantees equivalent to those of doctors established in Greece, in particular since the adoption and implementation of Council Directive 93/16/EEC of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications.⁵¹ However, in the absence of harmonisation of quality standards in hospitals, the imposition of an automatic and unconditional trust of all private healthcare institutions is not be a “self-evident solution”.⁵² For instance, in the *French laboratories* decision, the Court recognised that France could require laboratories established in another Member State to prove that the controls of that Member State were no less strict than those applicable in France.⁵³ Due to the wide diversity in the quality of the clinical care,⁵⁴ Member States claim that strict requirements for the approval of cross-border services and frequent inspections are necessary for ensuring the quality assurance of healthcare services.⁵⁵

within a time limit which is medically justifiable stems from the general rule of Article 8 (5) of the Directive.

⁴⁹ Case C-444/05 *Stamatelaki* (n 15) para 38.

⁵⁰ The principle was first elaborated within the framework of the free movement of goods in the case 120/78 *Rewe Zentral AG v Bundesmonopolverwaltung für Branntwein* (Cassis de Dijon) [1979] ECR 649, para 14.

⁵¹ Case C-444/05 *Stamatelaki* (n 15) para 37.

⁵² Baeten R., Gekiere W. & Palm W., “Free movement of services in the EU and health care” in Baeten R., Hervey T.K., Mossialos E. & Permanand G. (eds.), *Health Systems Governance in Europe* (CUP 2010) 461-508, 484.

⁵³ Case C-496/01 *Commission v France* (French laboratories) [2004] ECR I-2351, para 74.

⁵⁴ Glinos I.A., Legido-Quigley H., McKee M. & Nolte E., Assuring the quality of health care in the European Union, WHO 2008 on behalf of the European Observatory on Health Systems and Policies.

⁵⁵ C-562/10 *Commission v Germany* (Care Insurance) [2012] n.y.r., para 33.

2. Reimbursement of the costs of cross-border healthcare

With regard to the question of reimbursement of cross-border healthcare, the general principle set out in Article 7 of Directive 2011/24/EU prescribes that the Member State of affiliation shall ensure that the costs incurred by the insured person who receives cross-border healthcare are reimbursed. This reimbursement is conditioned upon the healthcare in question being among the benefits to which the insured person is entitled in the Member State of affiliation. In practice, this means that the patient who seeks a treatment in another Member State has to pay the full cost of the treatment received directly to the healthcare provider and subsequently, he or she may ask for reimbursement only if the treatment received is covered by his or her insurance in the State of affiliation.

The fourth paragraph of Article 7 of the Directive makes an important clarification regarding the costs that are to be reimbursed: it provides that “the costs of cross-border healthcare shall be reimbursed or paid directly by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received”. This means that if the treatment received in the Member State of treatment costs more than it would have cost in the Member State of affiliation, the latter is only obliged to reimburse the amount that it would have paid should the treatment had been provided on its territory. It furthermore means that, in a reverse situation, where the treatment received in the Member State of treatment costs less than it would have cost in the Member State of affiliation, the latter is only obliged to cover the actual costs of the treatment received. This limitation of the reimbursement appears to be reasonable and consistent with the need to prevent the risk of jeopardizing the financial balance of a social security system as an overriding reason in the general interest capable of justifying a barrier to the principle of freedom to provide services and the need to protect public health which includes the objective of maintaining a balanced medical and hospital service open to all.

By contrast, in the *Vanbraekel* case,⁵⁶ which was examined under the regime established by the Regulations and the general Article 56 TFEU, the Court reached an opposite conclusion and established the “*Vanbraekel supplement*” which was later incorporated in Article 26 (7) of Regulation (EC) No 987/2009. In particular, the Court,

⁵⁶ Case C-368/98 *Abdon Vanbraekel and Others v Alliance nationale des mutualités chrétiennes (ANMC)* [2001] ECR I-05363.

whilst recognizing that Article 22 of Regulation No 1408/71 did not have the effect of requiring additional reimbursement when the system applied in the Member State in which the person concerned was insured was more beneficial,⁵⁷ it nonetheless held that this additional reimbursement was required in the light of Article 56 TFEU. The reasoning of the Court was that the lower level of cover when the person receives treatment in another Member State may deter, or even prevent, that person from resorting to providers of medical services established in other Member States and thus constitutes a barrier to freedom to provide services.⁵⁸ This barrier cannot be justified on the ground of the overriding reason in the general interest of preventing the risk of seriously undermining the financial equilibrium of the social security system or on the ground of the protection of public health under Article 62 TFEU in conjunction with Article 52 (1) TFEU.⁵⁹ It follows from the foregoing that, under Article 56 TFEU the costs are to be assumed at the most favourable tariff and therefore the wording "without exceeding the actual costs of healthcare received" of Article 7 (4) of Directive 2011/24/EU seems to be in contradiction with the "*Vanbraekel supplement*". Of course, under the same Article, it remains always possible for the Member State of affiliation to cover the full cost and may even reimburse other related costs, such as accommodation and travel costs, but this is a mere discretion and not an obligation.

It should be noted that Article 7 (9) of Directive 2011/24, which codifies the relevant case law of the Court, provides for a derogation whereby the Member State of affiliation may impose restrictions on the reimbursement on the grounds of overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of highly-quality treatment in the Member State concerned or the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.

3. Administrative procedure regarding cross-border healthcare

Finally, in accordance with Article 9 of Directive 2011/24/EU, the Member State of affiliation shall ensure that the administrative procedures regarding cross-border healthcare are based on objective, non-discriminatory criteria which are necessary and proportionate to

⁵⁷ Ibid para 37.

⁵⁸ Ibid para 45.

⁵⁹ Ibid paras 47-49.

the objective to be achieved and that the time limits are reasonable taking into account the medical condition of the patient and the urgency of the situation. The administrative procedures established by the Member States should comply not only with the requirements laid down in Article 9 of Directive 2011/24, but also with Article 47 of the Charter of Fundamental Rights, which stipulates the right to an effective judicial protection.

IV. Conclusion

Although the organisation of public health policies is considered to be one of the traditional competences of the welfare States, the societal and financial significance of cross-border healthcare services in the accomplishment of the Internal Market has subjected them to the rules on the freedom to provide services. As a result of the application of these rules, any directly or indirectly discriminatory measure or any restriction on the freedom to provide cross-border healthcare is prohibited, unless it is justified. A directly discriminatory measure – i.e. a measure which discriminates explicitly on the basis of nationality - can only be justified on the grounds of public policy, public security or public health according to Article 52 TFEU in conjunction with Article 62 TFEU. An indirectly discriminatory measure – i.e. a measure, which is not based on nationality, but which in practice affects adversely foreign providers or recipients of healthcare services - and a restriction – i.e. any national rule which has the effect of making the provision of services between Member States more difficult than the provision of services purely within one Member State and thus hinders the cross-border provision of healthcare services – can be justified not only on the grounds of public policy, public security and public health mentioned in Article 52 TFEU in conjunction with Article 62 TFEU, but also on the grounds of overriding reasons in the general interests created by the case law of the Court and later codified in Directive 2011/24/EU. In cases involving cross-border healthcare, the Member States usually invoke the need to prevent the risk of jeopardising the financial balance of their social security systems. The Court has accepted that such an overriding reason in the general interest may justify a restriction on the freedom to provide services if it complies with the fundamental principle of proportionality, which refers to the double test of suitability and necessity of the restriction in question.⁶⁰ The

⁶⁰ Case C-158/96 *Kohll* (n 22) para 42; Case C-120/95 *Decker* (n 22) para 40. Even though the Court accepted that the need to maintain the financial balance of the social security system constitutes in principle an overriding reason in the general interest capable of justifying a restriction on the freedom to provide cross-border healthcare, it nonetheless found that in this particular case the restriction was

acceptance by the Court of the possible derogation grounds is linked to the effort to maintain a balance between the subjection of healthcare services to the rules of the Internal Market and the need to respect the exercise of the traditional competences of welfare States. Directive 2011/24/EU tries to achieve this delicate balance by laying down liberal rules regarding the issues of prior authorisation and reimbursement and by allowing at the same time for important derogations for the Member States. Besides, according to Recital 4 of its Preamble, the application of the Directive should not result in patients being encouraged to receive treatment outside the Member State of affiliation. Finally, we cannot ignore that the system created by the case law of the Court and subsequently developed by Directive 2011/24/EU is quite complex and may lead to social inequalities, since "it is primarily the wealthier and better-informed European citizens who benefit from the rules".⁶¹ It remains to be seen how the Member States will implement the Directive and how the Court will interpret its provisions.

not justified, since the medical expenses incurred were to be reimbursed at exactly the same rates as those applied in Luxembourg and therefore there was no risk for the national social security system.

⁶¹ Pennings F., "The cross-border health care Directive: more free movement for citizens and more coherent EU law" (2011) 13 *European Journal of Social Security* 424 – 452, 449.