The relationship between the Regulations on the coordination of social security systems and the Directive on the application of patients' rights in cross-border healthcare

(Language: English)

Written by Gabriella Berki (ed), Francesco Costamagna, Nicolas Rennuy and Grega Strban
January – 2023

EUROPEAN COMMISSION

Directorate-General for Employment, Social Affairs and Inclusion
Directorate E — Labour Mobility
Unit E2 — Social security coordination

European Commission
B-1049 Brussels

The relationship between the Regulations on the coordination of social security systems and the Directive on the application of patients' rights in cross-border healthcare

(Language: English)

Directorate-General for for Employment, Social Affairs and Inclusion

2023

Manuscript completed in January 2023

Luxembourg: Publications Office of the European Union, 2023

PDF ISBN 978-92-68-00710-5 doi: 10.2767/92066 KE-05-23-077-EN-N

Table of Contents

1. Executive summary 7

2. Introduction 10

2.1. Context 10

2.2. Objective of the report 11

2.3. Scope of the report 12

2.4. Structure of the report 12

3. Analysis of the relationship between the two EU legal instruments on cross-border healthcare 13

3.1. Objectives of the EU instruments on cross-border healthcare 13

3.2. Legal bases of the EU instruments on cross-border healthcare 15

3.3. Scope 17

3.3.1. Personal scope 17
3.3.2. Material scope 20

3.4. Different types of healthcare abroad 25

3.4.1. Unplanned/necessary cross-border healthcare 26
3.4.2. Planned cross-border healthcare 28
3.4.3. Residence in another Member State 32

3.5. Reimbursement of medical costs 40

4. Provision of clear information on cross-border healthcare 44

4.1. Information provision for patients on the Regulations and the Directive – state of play 44

4.2. Information obligations under the Directive and the Regulations 45

4.3. Sources of information on cross-border healthcare 48

4.3.1. National healthcare authorities 48
4.3.2. National contact points 48
4.3.3. Healthcare providers 49

4.4. Tools to improve informed decision-making 49

5. Access to cross-border telemedicine under the Regulations and the Directive 51

5.1. Introduction 51

5.2. Scenarios for planned healthcare 51

5.3. Some comments 59

6. Conclusions and recommendations 61

1. Executive summary

After almost a decade of applying the Cross-Border Healthcare Directive 2011/24/EU, this report revisits some outstanding issues regarding cross-border healthcare in the EU, such as the relationship between the Social Security Coordination Regulations and the Directive, clear and comprehensive information provision to patients and the challenges of cross-border telemedicine services.

While the above legal instruments – the Directive and the Regulations – coexist and create a complementary system, the rules are sometimes very complex and difficult for the institutions and healthcare providers to apply and for the citizens to understand. The Regulations and the Directive overlap in terms of personal and material scope but are not identical. Hence, to ensure that persons seeking healthcare abroad receive healthcare within the EU based on the instrument that is most advantageous to them, the rules must be clear and applied in a coherent way.

This report consists of three substantive chapters. After the introduction, Chapter 3 deals with the analysis of the relationship between the Social Security Coordination Regulations and the Directive – within the EU legal framework. This in-depth analysis focuses on the objectives, the legal bases and the scope of the two instruments. Additionally, the rules on the different types of healthcare abroad are scrutinised, with separate subchapters dedicated to unplanned/necessary cross-border healthcare, planned treatments, and the situation surrounding the insured person's place of residence.

In Chapter 3, it is concluded that:

- The two sets of acts pursue by and large the same general objective, but differ in their specific objectives, their legal bases and their inner logic.
- Although there is no hierarchy between the two legal tools, their relationship remains complex and not easily understood by patients or service providers.
- Recent case law has shed welcome light on the concept of 'insured person'. There remain questions as to the meaning of the concept of 'family members'.
- The material scope of the Regulations and the Directive overlap to a large extent. Questions continue to be raised with regards to long-term care, unplanned care, medical assistance and public vaccination programs.
- In relation to the latter, it is argued that these are in principle subject to the Regulations, but they fall out of the Directive's scope.
- The lack of distinction between unplanned and planned care under the Directive is somewhat problematic as it may bring about paradoxical results in cases of unforeseen need for healthcare in situations where the treatment in question is subject to prior authorisation. However, different opinions emerge on this issue.
- The undue influence (whether intentional or not) of patient choice by health care providers must be overcome by patient education and monitoring measures.
- Prior authorisation is the main rule under the Regulations, while it is an exception under the Directive.
- The Court of Justice of the European Union has identified some situations where the patient is entitled to have the costs reimbursed even without a properly issued

prior authorisation, provided that all the other conditions for cross–border health care services are met.

- Under both sets of rules, the most controversial issue concerning the decision to grant or refuse the authorisation is whether an equally effective treatment can be given in the home Member State.

- The position of non-residents breaks down in a multitude of complex scenarios, not all of which are covered by the Directive.

The safeguarding of the cross-border healthcare rights is dependent upon the awareness by the patient of what those rights are and when and how they can be invoked. However, it has been repeatedly reported that the European patients do not feel well informed about their cross-border healthcare rights. In Chapter 4, entitled 'Provision of clear information on cross-border healthcare', the information obligations under both the Regulations and the Directive are examined, the sources of information on cross-border healthcare are mapped and tools to support better informed decision making are discussed.

In Chapter 4, it is concluded that:

- The Directive contains an extensive set of information obligations that must be met by the Member State of affiliation and the Member State of treatment.

- National authorities responsible for cross-border healthcare issues, national contact points, healthcare providers and patient organisations all play a distinctive role in information provision and patient education.

- Although several EU measures aim to provide patients with clear and coherent information, further initiatives seem to be necessary.

- It is recommended to make a greater use of the existing tools, to continue exploiting the full potential of the network of national contact points, to help both patient organisations and healthcare providers to fulfil their roles as essential information sources for patients and finally, to give larger publicity to these issues, including through social media platforms.

In Chapter 5, access to cross-border telemedicine under the Regulations and the Directive is addressed. The Covid-19 pandemic has increased the use of telemedicine, prompting renewed calls for the design of a stronger and clearer regulatory framework. Reimbursement of the costs related to the cross-border recourse to telemedicine is one of the aspects to be clarified. To this end, this chapter sets out, in the case of planned health care, a number of scenarios.

In Chapter 5, it is concluded that:

- The regulation of cross-border telemedicine remains patchy, despite its surging practical importance due to technological innovation and the Covid-19 pandemic.

- Telemedicine lacks statutory definition at European level.

- The application of the Regulations and the Directive to telemedicine ought to be clarified.

- The place of professional-to-professional telemedicine in European law remains unclear. The Directive does not seem to be designed for such scenarios but might apply regardless.

- A thorny issue is the compatibility with European law of the requirement that healthcare be provided in person rather than by telemedicine.

- A recurring issue is whether connected treatments are to be considered separately or together. While a joint analysis seems most problematic, a separate analysis might not be free from complications either.

- The common assumption that telemedicine falls outside the scope of Article 20 of Regulation (EC) No 883/2004 can prove false. The Regulations apply in full where a person travels to a Member State to obtain telemedicine there.

- A further unresolved point is the impact of the free movement of services on the access to telemedicine.

- Telemedicine leaves many questions open.

Chapter 6 summarises conclusions and recommendations of this report.

2. Introduction

2.1. Context

Within the EU legal order, two sets of legal instruments provide for access to healthcare treatment in another Member State and guarantee the reimbursement thereof by that State: the Social Security Coordination Regulations (EC) Nos 883/2004 and 987/2009 (hereinafter 'the Social Security Coordination Regulations) [1] and the Cross-Border Healthcare Directive 2011/24/EU (hereinafter 'the Cross-Border Healthcare Directive).[2]

While the two sets of instruments coexist and create a complementary system, the rules are sometimes very complex and difficult to apply and for healthcare providers and citizens to understand. The Regulations and the Directive overlap in terms of personal and material scope but are not identical. Hence, to ensure that persons seeking healthcare abroad receive cross-border healthcare within the EU based on the instrument that is most advantageous, the rules have to be clear and applied in a coherent way.

One of the main aims of the Cross-Border Healthcare Directive is to clarify its relationship with the existing legal framework of European social security coordination.[3] However, most recently, the public consultation conducted as part of the evaluation of the Directive[4] revealed that, in particular, patients and patient organisations perceived the Directive *as less than optimally effective in creating legal certainty and clarity over patients' rights*. Insufficient and unclear information on the rights and obligations attaching to the provision of cross-border healthcare, diverging interpretations of the relevant rules and uncertainty over the level of reimbursement were among the issues cited. Gaps in information for patients about their rights together with financial burdens are considered as the most important issues related to cross-border healthcare.[5]

The Cross-Border Healthcare Directive underlines that

> 'this Directive should not affect an insured person's rights in respect of the assumption of costs of healthcare which becomes necessary on medical grounds during a temporary stay in another Member State according to [the Social Security Coordination Regulations]. In addition, this Directive should not affect an insured person's right to be granted an authorisation for treatment in another Member State where the conditions provided for by [the Social Security Coordination Regulations] are met […].
>
> It is appropriate to require that also patients who seek healthcare in another Member State in other circumstances than those provided for in [the Social Security Coordination Regulations] should be able to benefit from the principles of free movement of patients, services and goods in accordance with the TFEU and with this Directive. Patients should enjoy a guarantee of assumption of the costs of that healthcare at least at the level as would be provided for the same

[1] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems and 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. *Cf.* also Regulation (EU) 1231/2010 extending Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 to nationals of third countries who are not already covered by these Regulations solely on the ground of their nationality.

[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.

[3] Cross-Border Healthcare Directive, Article 1 (1).

[4] Commission staff working document accompanying the document Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, Staff Working Document ('SWD') (2022) 200 final.

[5] SWD(2022) 200 final, p. 18.

> healthcare, had it been provided in the Member State of affiliation. This should fully respect the responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevent any significant effect on the financing of the national healthcare systems.
>
> For patients, therefore, the two systems should be coherent; either this Directive applies or the Union regulations on the coordination of social security systems apply.
>
> Patients should not be deprived of the more beneficial rights guaranteed by the Union Regulations on the coordination of social security systems when the conditions are met. Therefore, any patient who requests an authorisation to receive treatment appropriate to his condition in another Member State should always be granted this authorisation under the conditions provided for in the Unions regulations when the treatment in question is among the benefits provided for by the legislation in the Member State where the patient resides and when the patient cannot be given such treatment within a time limit that is medically justifiable, taking account of his current state of health and the probable course of the condition. However, if a patient instead explicitly requests to seek treatment under the terms of this Directive, the benefits which apply to reimbursement should be limited to those which apply under this Directive. Where the patient is entitled to cross-border healthcare under both this Directive and Regulation (EC) No 883/2004, and the application of that Regulation is more advantageous to the patient, the patient's attention should be drawn to this by the Member State of affiliation'.[6]

Consequently, although there is no hierarchy between the two legal instruments, in cases where they could both be applicable, priority is given to the Social Security Coordination Regulations, the only exception being where the patient explicitly requests otherwise. However, in practice, their relationship is more complex and is the cause of much uncertainty for patients.

In 2012, a Guidance note on the relationship of the Cross-Border Healthcare Directive and the Social Security Coordination Regulations was adopted by the Administrative Commission for the coordination of social security systems. It aimed at ensuring the coherent application of the Regulations and the Directive by the Member States with regard to social security aspects which are covered by both instruments, and at guiding Member States when transposing Directive 2011/24/EU. In light of the developments which have taken place in the past decade, both on EU and national levels with relation to cross-border healthcare, it is timely to revisit some of the most burning issues in this field.

2.2. Objective of the report

The main objective of this report is to provide a thorough analysis of the relationship between the Social Security Coordination Regulations and the Cross-Border Healthcare Directive. The report focuses on both the differences and similarities of the two instruments in various cross-border healthcare situations. The report seeks to address how the patients' informed choices in these situations could be better supported. The report also addresses the issue of telemedicine as it has become central to the provision of healthcare in recent years.

[6] Cross-Border Healthcare Directive, Recitals 28-31.

2.3. Scope of the report

This report approaches the topic from a supranational perspective. As the relationship between the Regulations and the Directive has been widely discussed ever since the Directive was adopted, the aim of this report is to draw attention to those questions which have not so far been addressed and to other issues that have arisen since the adoption of the Directive, for example, raised by the case-law of the Court of Justice of the EU (CJEU).

Without mapping the current national rules and their practical application, this report seeks to shed light on the most pressing issues within the framework of the EU legislation. Possible solutions and recommendations are also formulated from this angle.

2.4. Structure of the report

Considering the above-mentioned objectives and limitations, the report consists of six parts. After the executive summary, the introduction specifies the context of the report, its objective, scope, and structure. The first of the three substantive chapters deals with the analysis of the relationship between the Social Security Coordination Regulations and the Directive – based on the EU legal framework. This in-depth analysis focuses on the objectives, the legal bases and both the personal and material scope of the two instruments. Additionally, the rules on various types of healthcare abroad are scrutinised, thus separate subchapters are dedicated to unplanned/necessary cross-border healthcare, planned treatments, and the situation where the residence of an insured person is in another Member State. Within Chapter 4, the provision of clear information on cross-border healthcare and the information obligations under both the Social Security Coordination Regulations and the Directive are examined, the sources of information on cross-border healthcare are mapped and tools to improve informed decision making are discussed. In Chapter 5, access to cross-border telemedicine under the Regulations and the Directive is addressed. Finally, Chapter 6 summarises the conclusions and provides recommendations.

3. Analysis of the relationship between the two EU legal instruments on cross-border healthcare

3.1. Objectives of the EU instruments on cross-border healthcare

Although cross-border healthcare law may encompass many aspects of organising, financing and delivering healthcare, in the present paper the notion of EU cross-border healthcare law is limited to two instruments, i.e., the Social Security Coordination Regulations and the Cross-Border Healthcare Directive. Although their general objectives might be the same (or at least very similar), that is to facilitate various forms of free movement in the EU, more specific objectives are discernible in the two instruments.

Health is one of the most precious human values. It influences the existence and development of every individual and the society as a whole. Its importance is even more obvious when lost or impaired. Sickness and injury are a part of any individual's life and are constantly present in our society, as shown, for example by the latest crisis arising out of the Covid-19 pandemic. Consequently, the general objective of EU cross-border healthcare law is to provide the highest attainable standard of health[7] to persons moving within the Union.

However, the specific objective of the Social Security Coordination Regulations is to guarantee freedom of movement of workers and other economically active persons (such as self-employed persons).[8] Moreover, with the introduction of Union citizenship, all Union nationals enjoy the freedom of movement but the non-economically active have a lesser bundle of rights than the economically active.[9] Such free movement is ensured by providing the right to healthcare when persons insured under a statutory public health scheme (who might have the right to benefits in kind or to reimbursement of healthcare costs) or persons covered by (centralised or decentralised) national health service move across borders and find themselves in various legal and social situations when the need for health care arises. They might be working in one Member State and living in or staying temporarily in another Member State for private or professional reasons. Moreover, cooperation among Member States' social security (including healthcare) systems is necessary in cases when healthcare cannot be provided in the home Member State and has to be provided (based on the prior approval/authorisation of the home Member State) in another Member State. Therefore, the objective of the Social Security Coordination Regulations is also to contribute towards improving the standard of living of mobile persons and conditions of their employment.[10]

Such cooperation has been in existence since the first Social Security Coordination Regulations were adopted in 1958. Those early regulations provided for the right to cross-

[7] Highest attainable standard of health is mentioned as a standard of the right to health e.g. in Article 12 International Covenant on Economic, Social and Cultural Rights and in Point 11 of Part I (initial and revised) European Social Charter.

[8] Article 48 TFEU. See also G. Strban, Social Law 4.0 and the Future of Social Security Coordination, in: U. Becker, O. Chesalina (eds) Social Law 4.0, New Approaches for Ensuring and Financing Social Security in the Digital Age, Studien aus dem Max-Planck-Institut für Sozialrecht und Sozialpolitik, Band 74, Nomos, 2021, p. 336.

[9] Non-withstanding the fact that non-economically active persons should have sufficient resources for themselves and their families so not to become an unreasonable burden of the host Member State and comprehensive sickness insurance in the host Member State according to the Citizens Directive 2004/38/EC on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States, OJ L 158, 30.4.2004.

[10] Recital 1 Regulation (EC) 883/2004.

border healthcare, although only in cases of urgent treatment[11] and when moving residence to another Member State.[12]

In addition to the cross-border healthcare rights set out in the Social Security Coordination Regulations, the CJEU has developed a parallel system of cross-border healthcare rights funded by state social security system, based directly on the Treaty provisions concerning free movement of goods and services. Free movement of services can be both active (i.e. free movement of service providers) and passive (i.e. free movement of service recipients).[13] The provisions on the free movement of services apply also to healthcare, i.e. medical services. In general, the CJEU has found that medical services are services within the meaning of Article 56 TFEU, since they are provided for remuneration, their organisation and delivery being irrelevant.[14] Consequently, the requirement of prior authorisation for cross-border healthcare presents an obstacle to such free movement and can be objectively justified exceptionally, only in certain cases.

This CJEU case law is now codified by the Cross-Border Healthcare Directive, which might bring us to a certain paradox of a regulation comparing to a directive. The latter has to be transposed into national law, whereas regulations apply directly. Hence, the reader of national social security law is more likely to be aware of a directive rule, than of the one of a regulation, since they have to be studied in addition to national law (and might sometimes use odd language, drawing also from other legal systems). This is evident also in cross-border healthcare. The rules of the Cross-Border Healthcare Directive had to be transposed into national law by 25 October 2013,[15] whereas the Social Security Coordination Regulations, in their current version, are directly applicable since the 1 May 2010. Yet, more discussions were raised when the Directive had to be transposed than when the new Regulations were negotiated and became applicable. The reason might also lie in the fact that the rules of the current Regulations were not modified much compared to its predecessors, i.e. Regulations (EEC) 1408/71 and 574/72, at least concerning the rules governing cross-border healthcare.

Unlike the objectives of the Social Security Coordination Regulations, the objective of the Cross-Border Healthcare Directive is not limited to facilitating access to safe and high-quality healthcare in another Member State and ensuring patient mobility in accordance with the case law of the CJEU, but also to promote cooperation on healthcare between Member States for the benefit of EU citizens, regarding prescriptions, rare diseases, eHealth, and health technology assessment.[16]

However, neither instrument aims at harmonising national healthcare systems. Member States retain their exclusive competence over the organisation and delivery of healthcare on their territory.

Although the Cross-Border Healthcare Directive attempts to clarify its relationship with the Social Security Coordination Regulations and applies without prejudice to them, the relationship between both instruments on EU cross-border healthcare law is not always completely straightforward. This might have an impact on matters such as the information

[11] Only when (temporarily) staying in another Member State (Ger. *bei einem vorübergehenden Aufenthalt im Hoheitsgebiet eines anderen Mitgliedstaats)* benefits in case of urgent medical treatment, including hospitalisation were provided (Ger. *Leistungen, wenn sein Zustand sofort ärztliche Betreuung einschließlich Krankenhauspflege erforderlich macht*).

[12] Article 19 Regulation (EEC) 3/1958 on social security rights of migrant workers, OJ 30, 16.12.1958.

[13] CJEU (joined) cases C-286/82 (and C-26/83) *Luisi and Carbone*, EU:C:1984:35. This case concerned the recipients of tourism and medical services outside their home Member States and the status of the monies used to provide for such services. There was no issue as to the reimbursement for the medical services provided. It can be assumed that they were provided privately. It was only some fourteen years later in the Kohll case (Case C-158/96 EU:C1998 :171) that it became clear that medical services provided in a Member State other than the competent Member State could be reimbursable by that State. Prior to the Kohll case it had been assumed by the Member States that health care services provided outside the competent Member State had been exhaustively regulated by the Social Security Coordination Regulations. This assumption proved to be false – to the consternation of many Member States.

[14] Cases C-158/96 *Kohll*, EU:C:1998:171 and C-120/95 Decker, EU:C:1998:167 and subsequent. Strban, 2013, p. 395.

[15] Article 21 Directive 2011/24/EU.

[16] Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, Brussels, 12.5.2022, COM(2022) 210 final.

sharing to and by healthcare providers, national contact points and most importantly, cross-border patients. In light of these considerations, the question analysed under subsequent chapters is how both legal pathways (one under the Social Security Coordination Regulations and the other under the Cross-Border Healthcare Directive) are aligned and what are the distinctions among them, especially for the cross-border moving patient.[17]

3.2. Legal bases of the EU instruments on cross-border healthcare

The distinctive objectives of the EU cross-border healthcare legal instruments, i.e. the Social Security Coordination Regulations and the Cross-Border Healthcare Directive, reflect the different legal bases of the two instruments.

The Social Security Regulation are based on Article 48 TFEU, situated in the chapter on freedom of movement of workers.[18] Article 48 stipulates that the European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure, adopt such measures in the field of social security as are necessary to provide freedom of movement for workers. To this end, they shall make arrangements to secure for employed and self-employed migrant workers and their dependants: aggregation of periods and export of benefits. Only the law governing the application of substantive social security law in cross-border situations is harmonised amongst the Member States. The substantive content of national social security system remains within the exclusive competence of the Member States.

The sensitivity of Member States with respect to their social security systems has been acknowledged as we see in the so-called 'alarm procedure' or 'emergency brake procedure' provided for by Article 48 TFEU. In case a Commission proposal could have an impact on important aspects of a Member State's social security system (including its scope, cost or financial structure) or would affect the financial balance of that system, that Member State may refer the matter to the European Council.

Other Treaty provisions may also be relevant to the field of social security, for example Article 21 (3) TFEU regarding non-discrimination and citizenship of the EU, which is a possible legal basis for social security and social protection measures. Article 79(2) (b) TFEU has been used as a legal basis to extend the Social Security Regulation to certain third country nationals.

In addition, for the economically non-active persons, another legal basis, i.e. Article 352 TFEU remains necessary, according to which unanimity is always required. Also, this is an expression of reluctance of the Member States to transfer the competence in the social security field (including healthcare) to the EU.

Article 48 TFEU applies to 'employed and self-employed migrant workers'. It seems that self-employed persons were added to the chapter of free movement of workers, just to provide a direct legal basis for coordination of their social security. Normally, other chapters, such as freedom of establishment and freedom of providing services would be applicable to them.

[17] Certain, limited coordination of cross-border healthcare may also be achieved by unilateral measures of each of the Member States, e.g. by reimbursing urgent healthcare costs, or by multilateral intragovernmental agreements. Legal instruments outside of EU law are not subject of the present report.

[18] Chapter 1 Workers, under Title IV Free movement of persons, services and capital TFEU.

For inclusion of some third-country nationals in the EU social security coordination mechanism another legal basis had to be used.[19] Some countries who have joined the EU in its first enlargement in 1973, i.e. the United Kingdom (which is no longer a member of the EU), Ireland and Denmark, have the right to opt out of this regime (or had to indicate explicitly that they want to be bound by the measure by opting in). For Regulation (EC) 859/2003 (extending the personal scope of Regulation 1408/71 to third-country nationals) Denmark opted out and Ireland and the UK opted in. The legal consequence was that Denmark was under no legal obligation to ensure equal treatment to third-country nationals in social security matters.

For the new Regulation (EU) 1231/2010, Denmark again opted out, while Ireland opted in. However, the situation has changed for the UK, since it opted out (and later left the EU entirely). The result is that in the UK, the former Regulation (EEC) 1408/71 (as extended by the Regulation (EC) 859/2003) remained applicable[20] (also, by the Withdrawal Agreement)[21] in the relations between the Member State (other than Denmark) and the UK.

In addition, based on the European Economic Area ('EEA') Agreement with the EEA EFTA States (Iceland, Norway and Liechtenstein)[22] and a special agreement with Switzerland[23] in June 2012 and in April 2012, respectively, Regulation (EC) No 883/2004 became applicable also for movements between these States and EU Member States.

Conversely, the Cross-Border Healthcare Directive is based on Articles 114 and 168 TFEU. According to the provision of Article 114, the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, may adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. It might be noticed that in ordinary legislative procedure not all Member States voted in favour of the Directive 2011/24/EU.[24]

As mentioned above, the Cross-Border Healthcare Directive had to be transposed in the Member States since 25 October 2013. It is also applicable in the EEA, the compliance date being 1 August 2015. However, it does not apply to Switzerland, and it no longer applies to the United Kingdom as of the beginning of 2021.[25]

Moreover, Article 15 of Directive 2011/24/EU has been deleted and replaced by Regulation (EU) 2021/2282 on health technology assessment and amending Directive 2011/24/EU.[26]

The Charter of Fundamental Rights and the general principles of non-discrimination and proportionality are equally a potential source of social security rights as has been demonstrated by the *A* and *WO* cases discussed below in Section 3.4.2.

---

19 *Camille Petit v Office national des pensions* (C-153/91) EU:C:1992:354.

20 By virtue of Regulation (EC) 859/2003 and Article 90(1)(a) of Regulation (EC) 883/2004.

21 Article 30 Withdrawal Agreement.

22 *Cf.* Article 29 Agreement on the European Economic Area, OJ L 1, 3.1.1994, and its Annex VI.

23 *Cf.* Article 8 Agreement between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons, OJ L 114 30.4.2002, and its Annex II.

24 Poland, Austria, Portugal and Romania voted against it and Slovakia abstained.

25 See glossary on cross-border healthcare in the Commission Staff Working Document Accompanying the document Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, COM(2022) 210 final, Brussels, 12.5.2022.

26 *Cf.* Article 35 Regulation (EU) 2021/2282, OJ L 458, 22.12.2021.

3.3. Scope

3.3.1. Personal scope

The Regulations

First, to come within the scope of the Regulations, persons must be in a situation that is not purely internal to one Member State.[27]

Second, there is a nationality condition. The Regulations cover EU citizens as well as the nationals of Norway, Liechtenstein, Iceland and Switzerland.[28] Stateless persons and refugees who reside in a Member State are also covered.[29] Moreover, Regulation 1231/2010 expands the application of the Regulations to other third country nationals who legally reside in a Member State other than Denmark.[30]

Third, to fall under the Regulations, people must be 'or have been subject to the legislation of one or more Member States'.[31] 'Legislation' is broadly defined as various types of regulation[32] relating to social security branches, including sickness. A person who is entitled to benefits or liable for contributions under the legislation of a Member State is subject to that legislation.[33] Insurance against one of the social security risks suffices.[34]

The Regulations also offer some protection to the family members and survivors of the above groups, irrespective of their nationality.[35]

They 'apply to the survivors of persons who have been subject to the legislation of one or more Member States, irrespective of the nationality of such persons, where their survivors are nationals of a Member State or stateless persons or refugees residing in one of the Member States.'[36]

Chapter 1 of Title III Regulation (EC) No 883/2004 – on sickness benefits, maternity and equivalent paternity benefits and long-term care benefits – essentially grants rights to 'insured persons', 'pensioners', and their 'family members'. These concepts merit further attention.

For the purpose of that chapter, 'insured person' is defined as 'any person satisfying the conditions required under the legislation of the Member State competent under Title II to have the right to benefits, taking into account the provisions of this Regulation'.[37]

---

[27] *Camille Petit v Office national des pensions* (C-153/91) EU:C:1992:354 .

[28] Article 2(1) Regulation No (EC) 883/2004; Decision No. 76/2011 of the EEA Joint Committee; Decision No. 1/2012 of the EU-Swiss Joint Committee.

[29] Article 2(1) Regulation No (EC) 883/2004.

[30] Article 1 and recital 19 Regulation No. 1231/2010.

[31] Article 2(1) Regulation (EC) No 883/2004.

[32] Article 1(l) Regulation (EC) No 883/2004.

[33] *Y v Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885 , para 39.

[34] E.g. *Bestuur der Bedrijfsvereniging voor de Metaalnijverheid v L. J. Mouthaan* (39/76) EU:C:1976:181 .

[35] See further *Bestuur van de Sociale Verzekeringsbank v J.M. Cabanis-Issarte* (C-308/93) EU:C:1996:169 , para 34.

[36] Article 2(2) Regulation (EC) No 883/2004.

[37] Article 1(c) Regulation (EC) No 883/2004. In *Y v Centraal Administratie Kantoor*, the CJEU held that three criteria must be satisfied for a person to be 'insured' (*Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885). First, the benefit in question must be a social security benefit covered by the Regulation (EC) No 883/2004. Second, the person must be subject to the legislation of a Member State (the competent State). Third, they should satisfy the eligibility conditions governing the benefit, taking into account the provisions of the Regulations. On right-to-reside conditions and comprehensive sickness insurance, see *A v Latvijas Republikas Veselības ministrija* (C-535/19) EU:C:2021:595.

Chapter 1 of Title III Regulation (EC) No 883/2004 consists of 3 sections. Section 1 is entitled 'Insured persons and members of their families, except pensioners and members of their families'; Section 2 is entitled 'Pensioners and members of their families'; Section 3 is entitled 'Common provisions'. In the *Y v Centraal Administratie* case referred to above, the Netherlands government attempted to argue that the categories of 'insured persons' and 'pensioners' were mutually exclusive so that the claimant, being the recipient of a pension, could not be considered as an insured person. The CJEU rejected that argument, in part based on the above-mentioned definition of 'insured person'. It ruled:

> 'The concept of 'insured person', within the meaning of Regulation No 883/2004, … includes, in a general and exhaustive manner, nationals of Member States, stateless persons and refugees residing in a Member State who are or who have been subject to the legislation of one or more Member States, as well as the members of their families and their survivors…, provided that they satisfy the conditions required under the legislation of the competent Member State to have the right to benefits'.[38]

The definition of 'family member' depends on the benefit in question. For benefits in kind covered by Chapter 1 of Title III (i.e. sickness benefits, maternity and equivalent paternity benefits and long-term care benefits), a family member is 'any person defined or recognised as a member of the family or designated as a member of the household by the legislation of the Member State in which he/she resides'.[39] For other benefits, a family member is 'any person defined or recognised as a member of the family or designated as a member of the household by the legislation under which benefits are provided'.[40] In all cases, the concept of 'family member' is governed by national legislation.[41] However, the requirement that family members reside in the same household as the insured person or pensioner is waived if they are mainly dependent on the insured person or if they are pensioners.[42]

In respect of the benefits with which this report is concerned, the legislation of the Member State of residence is decisive in determining who is or is not a family member. This means that the competent Member State might be liable for healthcare provided to persons whom it would not deem to be part of the insured person's family under its legislation.[43] While the Member State of residence retains the competence to define who is a family member, when exercising that competence, it must comply with the free movement rights of the Treaty.[44] Two cases are worth highlighting.

Caisse pour l'avenir des enfants concerned family allowances for the child of the spouse of a frontier worker active in Luxembourg. The claim was rejected on the ground that the child (i) did not live in Luxembourg and (ii) was not a family member of the frontier worker. Luxembourg's definition of family members (applicable because Luxembourg was the competent State, and the benefit was a family benefit) excluded the children of the spouse or registered partner. The CJEU reasoned that the benefit at stake was a social advantage within the meaning of Article 7(2) Regulation 492/2011. In a previous case, it had held that the children of the spouse or the registered partner of a frontier worker could rely on that provision to claim social advantages, if the worker provides for their maintenance.[45] In

[38] *Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885, para 52.

[39] Article 1(i)(1)(ii) Regulation (EC) No 883/2004.

[40] Article 1(i)(1)(i) Regulation (EC) No 883/2004.

[41] Note that the Regulation provides a residual definition of family members should national legislation fail to distinguish between family members and other persons (Article 1(i)(2) Regulation (EC) No 883/2004).

[42] Article 1(i)(3) Regulation (EC) No 883/2004.

[43] For discussion, see G. Strban, B. Spiegel and P. Schoukens, 'The application of the social security coordination rules on modern forms of family' (2020), MoveS Analytical Legal Report 2019, https://ec.europa.eu/social/BlobServlet?docId=22856&langId=en; G. Strban, 'Cross-border healthcare and social security rights' in F. Pennings and G. Vonk (eds), *Research Handbook on European Social Security Law* (Cheltenham: Elgar, forthcoming), section 3.1.

[44] *Caisse pour l'avenir des enfants v FV and GW* (C-802/18) EU:C:2020:269 , paras 68-69.

[45] *Noémie Depesme and Others v Ministre de l'Enseignement supérieur et de la recherche* (C-401/15 to C-403/15) EU:C:2016:955 .

Caisse pour l'avenir des enfants, the national legislation drew a distinction based on the place of residence of the child:

> 'all children residing in Luxembourg can claim the family allowance in question, which implies that any child forming part of the household of a worker residing in Luxembourg can claim the same allowance, including the children of that worker's spouse. By contrast, non-resident workers can claim that allowance solely for their own children, to the exclusion of a spouse's children with whom they have no child-parent relationship.'[46]

Such a residence condition was held to constitute indirect discrimination on the ground of nationality, which was not objectively justified. While Regulation (EC) No 883/2004 empowered Luxembourg to define the notion of 'family member', in so doing it had to comply with the objectives and principles set out in Article 45 TFEU and Article 7(2) Regulation 492/2011.[47]

A second case worth highlighting arose in a different context. In *Coman*, the CJEU held that for the purpose of residence rights under Directive 2004/38 and Article 21(1) TFEU, spouses include same-sex spouses who married in a Member State where such marriages were recognised.[48] While not directly applicable to the issue that occupies us now, it remains to be seen whether that case has implications for social security law.

The Member State of residence must comply, not only with the free movement rights of the Treaty, but also with the Charter of Fundamental Rights of the European Union. Particularly relevant are Article 7, which lays down the right to respect for private and family life; Article 21, which prohibits discrimination on the grounds of sexual orientation; and Article 24, which sets out the rights of children.[49] The extent to which those provisions open up entitlement to social security benefits for family members who are not recognised as such by the relevant Member State is yet to be tested before the CJEU.

The Directive

The Directive defines its personal scope by reference to the Regulations. Article 3(b) of the Directive defines 'insured person' as

> '(i) persons, including members of their families and their survivors, who are covered by Article 2 of Regulation (EC) No 883/2004 and who are insured persons within the meaning of Article 1(c) of that Regulation; and
>
> (ii) nationals of a third country who are covered by Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010, or who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits'.

In *Y v Centraal Administratie Kantoor*, the CJEU relied on Regulation (EC) No 883/2004 to determine the scope of the Directive. It held that for a person to be classified as an 'insured person' for the purposes of the Directive he or she had to fulfil all the conditions set out in Article 2 and Article 1 (c) of Regulation (EC) No 883/2004.

Unlike the Regulation, the Directive uses the concept of 'Member State of affiliation'. This could be read as setting a further requirement of affiliation. However, in *Y v Centraal Administratie Kantoor* the CJEU held that '[n]otwithstanding its wording, that concept does

---

[46] *Caisse pour l'avenir des enfants* (C-802/18) EU:C:2020:269, para 55.

[47] Provided the worker supported the child in question.

[48] *Relu Adrian Coman and Others v Inspectoratul General pentru Imigrări and Ministerul Afacerilor Interne* (C-673/16) EU:C:2018:385.

[49] See *V.M.A. v Stolichna obshtina, rayon „Pancharevo'* (C-490/20) EU:C:2021:1008.

not require, as the referring court has rightly noted, 'affiliation' to the compulsory sickness insurance scheme of a Member State.'[50]

3.3.2. Material scope

This section analyses the boundaries of the material scope of the Regulations and the Directive. To a large extent, they overlap. This raises the question as to how to deal with situations where both instruments do or could apply.

Healthcare

The Regulations cover sickness benefits, maternity and equivalent paternity benefits, and benefits in respect of accidents at work and occupational diseases.[51] These can be benefits in cash or in kind.

Sickness benefits in kind are 'intended to supply, make available, pay directly or reimburse the cost of medical care and products and services ancillary to that care.'[52] Sickness benefits may be preventive as well as curative.[53]

Just like sickness benefits, maternity and equivalent paternity benefits are coordinated under Chapter 1 of Regulation (EC) No 883/2004. They differ from family benefits as they cover the first months after birth.[54] More specifically, maternity benefits 'cover the period of physical incapacity of the worker owing to childbirth.'[55]

The Directive applies 'to the provision of healthcare to patients, regardless of how it is organised, delivered and financed.'[56] It defines healthcare as 'health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices'.[57] This broad definition covers the sickness and maternity benefits in kind mentioned in the Regulations. It also covers benefits in kind in respect of accidents at work and occupational diseases.[58]

Long-term care

The Regulations apply to long-term care benefits, even though they have so far not been included explicitly within the material scope of the Regulations. Those benefits, which cover the risk of dependency upon others for daily activities, share features with invalidity

[50] *Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885, para 57.

[51] Article 3(1) Regulation (EC) No 883/2004.

[52] Article 1(va)(i) Regulation (EC) No 883/2004, which also applies to maternity and equivalent paternity benefits. For benefits in respect of accidents at work and occupational diseases, see Article 1(va)(ii) Regulation (EC) No 883/2004. See further Administrative Commission for the Coordination of Social Security Systems, Decision No S5 of 2 October 2009 on interpretation of the concept of benefits in kind as defined in Article 1(va) of Regulation (EC) No 883/2004 in the event of sickness or maternity pursuant to Articles 17, 19, 20, 22, 24(1), 25, 26, 27(1, 3, 4 and 5), 28, 34 and 36(1 and 2) of Regulation (EC) No 883/2004 and on calculation of the amounts to be refunded under Articles 62, 63 and 64 of Regulation (EC) No 987/2009, OJ C 106, 24.4.2010, p. 54.

[53] *Helmut Heinze v Landesversicherungsanstalt Rheinprovinz* (14/72) EU:C:1972:98, para 6.

[54] Recital 19 in the preamble to Regulation (EC) No 883/2004.

[55] V. Paskalia, *Free Movement, Social Security and Gender in the EU* (Oxford: Hart Publishing, 2007), 239. Advocate General Jacobs stated that maternity benefit schemes 'presumably have as their object the welfare of the mother and the newly-born infant, and award benefit for a limited period of time to all those who satisfy the conditions laid down for the receipt of the benefit' (Opinion of A.G. Jacobs in *Commission v Luxembourg (childbirth and maternity allowances)* (C-111/91) EU:C:1993:92, para 31).

[56] Article 1(2) Directive 2011/24.

[57] Article 3(a) Directive 2011/24.

[58] Guidance note of the Commission services on the relationship between Regulations on the coordination of social security systems and Directive on the application of patients' rights in cross border healthcare, AC 246/12, 4.

pensions, old-age pensions,[59] family benefits and social assistance. Nevertheless, the CJEU categorises long-term care benefits as sickness benefits for the purpose of the Regulations meaning that they are coordinated as such.[60] The CJEU acknowledges that 'benefits relating to the risk of reliance on care are at most supplementary to the "classic" sickness benefits that fall within that provision *stricto sensu* ('sickness benefits *stricto sensu*') and are not necessarily an integral part of them.'[61] Long-term care benefits therefore constitute atypical sickness benefits, distinguished from sickness benefits *stricto sensu* by the fact that they are intended to be paid on a long-term basis.

The definition of long-term care benefits for the purpose of the Regulations is based on case-law:

> 'the notion of dependence refers, in essence, to a situation in which, as a result of his reduced autonomy, a person is reliant on the assistance of others in order to carry out the basic routines of everyday life […].
>
> It also follows from the case-law deriving from Case C-160/96 *Molenaar* [1998] ECR I-843 that, in the absence of provisions in Regulation No 1408/71 referring specifically to the risk of reliance on care, the Court has treated benefits relating to that risk as 'sickness benefits' within the meaning of that regulation'.[62]

In the *A* case, the CJEU seems to have taken a restrictive view of the concept of long-term care benefits by focussing on their medical dimension.[63] It emphasised that 'treating the risk of reliance on care in the same way as the risk of sickness assumes that the purpose of benefits designed to provide cover against the risk of reliance on care is to improve the state of health and the quality of life of persons reliant on care'.[64] As the personal assistance was not intended 'to improve the beneficiary's state of health associated with his disability' (though it was clearly intended to improve his quality of life), it was not a sickness benefit.[65]

In its proposal to revise the Regulations, the European Commission suggested to define long-term care benefits as:

> 'any benefit in kind, cash or a combination of both for persons who, over an extended period of time, on account of old-age, disability, illness or impairment, require considerable assistance from another person or persons to carry out essential daily activities, including to support their personal autonomy; this includes benefits granted to or for the person providing such assistance'.[66]

The Directive excludes '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'.[67] This

---

[59] As the CJEU recognised in *Joao Filipe da Silva Martins v Bank Betriebskrankenkasse - Pflegekasse* (C-388/09) EU:C:2011:439, para. 48.

[60] E.g. *Manfred Molenaar and Barbara Fath-Molenaar v Allgemeine Ortskrankenkasse Baden-Württemberg* (C-160/96) EU:C:1998:84 ; *Friedrich Jauch v Pensionsversicherungsanstalt der Arbeiter* (C-215/99) EU:C:2001:139; *Silvia Hosse v Land Salzburg* (C-286/03) EU:C:2006:125; *Commission v European Parliament and Council (SNCBs)* (C-299/05) EU:C:2007:608; *Petra von Chamier-Gliszczinski v Deutsche Angestellten-Krankenkasse* (C-208/07) EU:C:2009:455; *Commission v Germany (Länder benefits for the blind, the deaf and the disabled)* (C-206/10) EU:C:2011:283. This qualification holds even where the long-term care benefit does not have the essential object of supplementing sickness benefits (*Commission v Parliament and Council (SNCBs)* (C-299/05) EU:C:2007:608, para 70).

[61] *da Silva Martins* (C-388/09) EU:C:2011:439, para 47.

[62] *European Commission v Germany (long-term care benefits)* (C-562/10) EU:C:2012:442 , paras 44-45.

[63] *A* (C-679/16) EU:C:2018:601.

[64] *A* (C-679/16) EU:C:2018:601, para 43.

[65] *A* (C-679/16) EU:C:2018:601, para 46.

[66] Proposed Article 1(vb) (Commission, 'Proposal for a Regulation 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' COM(2016)815 final/2, Article 1(9)(d)). The Administrative Commission would draw up a list of long-term care benefits. See also General Secretariat of the Council, 'Proposal for a Regulation 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 – Analysis of the compromise text with a view to agreement' 15068/21 Add 1, Article 1(9)(d).

[67] Article 1(3)(a) Directive 2011/24. Recital 14 in the preamble to Directive 2011/24 adds: 'This Directive should not apply to services the primary purpose of which is to support people in need of assistance in carrying out routine, everyday tasks. More specifically, this

definition is similar, but not necessarily identical, to the definitions found in CJEU case-law on the Regulations and in the proposed amendments to the Regulations. The notion of long-term care for the purposes of the Directive is a Union concept. The CJEU has summarised its approach as follows:

> 'It follows from the requirements of the uniform application of EU law and of the principle of equal treatment that the terms of a provision of EU law which does not contain any express reference to the law of the Member States for the purpose of determining its meaning and scope must be given an autonomous and uniform interpretation throughout the European Union, which interpretation must take into account not only the wording of that provision but also its context and the objective pursued by the legislation in question'.[68]

It remains to be seen whether the wording, the context and objectives of the Directive are sufficiently similar to the wording, context and objectives of the Regulations for the definitions of long-term care benefits to be identical.

At any rate, it is worth bearing in mind that claimants might be able to claim long-term care benefits on the basis of the free movement rights of the TFEU, even if the CJEU's case law on planned healthcare based on Article 56 TFEU cannot as such be transposed to long-term care benefits.[69]

Non-contracted Healthcare Providers

A major difference between the Regulations and the Directive concerns non-contracted healthcare providers (i.e. private healthcare providers which are not part of the social security system).

The Regulations only create rights *vis-à-vis* public healthcare providers and those private healthcare providers that are part of the social security system.[70] **The Directive** covers healthcare, 'regardless of how it is organised, delivered and financed', provided by 'any natural or legal person or any other entity legally providing healthcare on the territory of a Member State'.[71] Accordingly, the Directive includes not only public healthcare providers and those private healthcare providers that are part of the state social security system, but also non-contracted healthcare providers. As a result, patients have the right to obtain reimbursement for treatments by non-contracted healthcare providers established in another Member State, even if they cannot obtain reimbursement for such treatments by non-contracted healthcare providers established in their Member State of affiliation.[72]

Unplanned healthcare

The Regulations cover both unplanned and planned healthcare but subjects them to different rules.[73]

Directive should not apply to those long-term care services deemed necessary in order to enable the person in need of care to live as full and self-determined a life as possible. Thus, this Directive should not apply, for example, to long-term care services provided by home care services, in assisted living facilities and in residential homes or housing ('nursing homes')."

[68] *AFMB e.a. Ltd v Raad van bestuur van de Sociale verzekeringsbank* (C-610/18) EU:C:2020:565; [2021] 1 C.M.L.R. 17, para 50.

[69] *von Chamier-Glisczinski* (C-208/07) EU:C:2009:455; *Commission v Germany (long-term care benefits)* (C-562/10) EU:C:2012:442; *A* (C-679/16) EU:C:2018:601.

[70] Article 1(l) and Article 3(1) Regulation (EC) No 883/2004; *WO v Vas Megyei Kormányhivatal* (C-777/18) EU:C:2020:745, paras 36-37.

[71] Article 1(2) and Article 3(g) Directive 2011/24.

[72] Article 1(4) Directive 2011/24.

[73] See sections 3.4.1 and 3.4.2 respectively.

Arguably **the Directive** was principally designed to regulate access to planned healthcare.[74] For instance, the (non-binding) preamble of the Directive says that it 'should apply to individual patients who *decide to seek* healthcare in a Member State other than the Member State of affiliation.'[75] Prior authorisation sits uneasily with unplanned healthcare: can a person be expected to request prior authorisation for healthcare necessitated by an injury (see below, under chapter 3.4.1)?[76]

Yet, there are good reasons to believe that the Directive also applies to unplanned healthcare. First, the patient is defined as 'any natural person who seeks to receive *or receives* healthcare in a Member State'.[77] A second reason is the breadth of the definition of healthcare for the purpose of the Directive, which mentions neither the intention of the patient nor the necessary nature of the healthcare. A third reason is that, before the adoption of the Directive, the CJEU held that unplanned healthcare falls under the freedom to receive services.[78] While not conclusive on its own *WO* could be read as a further pointer in that direction.[79]

The Commission's view is that the Directive applies to unplanned healthcare.[80] This view is shared by the Member States[81] and enjoys support in the literature.[82]

Medical assistance

The Regulations do not cover 'social and medical assistance'.[83] There is little case-law on the notion of medical assistance.[84] In general, the CJEU takes a broad interpretation of the notion of social security. In the same spirit, it has adopted a narrow definition of social assistance.[85] It may be assumed that a similar approach would also inform its definition of medical assistance should a case arise.[86] The *Heinze* case concerned a package intended to fight tuberculosis, consisting of medical treatment, aid to integration into working life, economic aid, and aid of a prophylactic nature. Under German law, that package was considered not to be part of social security, but rather part of a programme to fight the contagious disease by curing patients and protecting those around them from contagion. Although the possibility of the package being classified as medical assistance was mentioned in the proceedings, the CJEU qualified those benefits as sickness benefits. More recently, the CJEU held that 'a benefit falls within the concept of "social and medical assistance", which is excluded from the scope of Regulation No 883/2004 by virtue of

---

74 G. Strban (ed.), G. Berki, D. Carrascosa and F. Van Overmeiren, 'Access to healthcare in cross-border situations' (2016), FreSsco Analytical Report, https://ec.europa.eu/social/BlobServlet?docId=17130&langId=en 2016, 49.

75 Recital 11 Directive 2011/24, emphasis added; Strban (ed.), Berki, Carrascosa and Van Overmeiren, 'Access to healthcare in cross-border situations' (2016), 39.

76 See *WO v Vas Megyei Kormányhivatal* (C-777/18) EU:C:2020:745 . See further Strban (ed.), Berki, Carrascosa and Van Overmeiren, 'Access to healthcare in cross-border situations' (2016), FreSsco Analytical Report, 38; T. Sokol, L. Mintas Hodak and A. Abramovic, 'Patient Mobility Directive: One Step Forward or Two Steps Back for Cross-border Healthcare?' (2012) Croatian Yearbook of European Law and Policy 143, 153.

77 Article 3(h) Directive 2011/24, emphasis added.

78 *Commission v Spain (unscheduled care)* (C-211/08) EU:C:2010:340 .

79 *WO v Vas Megyei Kormányhivatal* (C-777/18) EU:C:2020:745 .

80 Guidance note of the Commission services on the relationship between Regulations on the coordination of social security systems and Directive on the application of patients' rights in cross border healthcare, AC 246/12, 4.

81 Strban (ed.), Berki, Carrascosa and Van Overmeiren, 'Access to healthcare in cross-border situations' (2016), FreSsco Analytical Report, 39.

82 E.g. Sokol, Mintas Hodak and Abramovic, 'Patient Mobility Directive' (2012) Croatian Yearbook of European Law and Policy 143, 153, 155, 160; Strban (ed.), Berki, Carrascosa and Van Overmeiren, 'Access to healthcare in cross-border situations' (2016), FreSsco Analytical Report, 37-39, 49; A. P. van der Mei, 'Cross-Border Access to Healthcare and Entitlement to Complementary '*Vanbraekel* Reimbursement': Annotation to Case C-211/08, Commission v Spain (unscheduled care)' (2011) 36 European Law Review 431, 438-439.

83 Article 3(5)(a) Regulation (EC) No 883/2004.

84 See further G. Strban, 'Cross-border healthcare and social security rights' in F. Pennings and G. Vonk (eds), Research Handbook on European Social Security Law (Cheltenham: Edward Elgar, forthcoming), section 3.2.

85 See e.g. *Rita Frilli v Belgium* (1/72) EU:C:1972:56 .

86 See observation of the European Commission in *Heinze* (14/72) EU:C:1972:98, at page 1109.

Article 3(5)(a) thereof, where its grant is dependent on an individual assessment of the personal needs of the applicant for that benefit'.[87]

The notion of 'medical assistance' seems irrelevant to **the Directive**, which does not mention it and defines 'healthcare' broadly.[88]

Public vaccination programmes against infectious diseases

The Directive does not cover '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.'[89] Covid-19 vaccination programmes are therefore clearly excluded from the scope of the Directive.

The Regulations make no mention of vaccination programmes. It has been argued that the Covid-19 vaccination programmes are not covered by the Regulations.[90] The following paragraphs will evaluate possible arguments supporting that conclusion and find them to be unpersuasive.

First, it could be argued that Covid-19 vaccination programmes are not sickness benefits. However, this would run counter the broad definition of sickness benefits in kind. The CJEU held that 'the concept of social security [is] to be regarded as including the aim of preventing the spread of disease, which cannot be regarded as a mere measure of social assistance.'[91] The *Heinze* judgment discussed above qualifies preventative measures aimed at fighting a contagious disease as sickness benefits. The fact that the Directive expressly excludes vaccination programmes further suggests that, if it was not for the exclusion, they would qualify as healthcare. From the start of the roll-out of the vaccines, it seems that they form part of the benefit basket. It may be assumed that the Covid-19 vaccination programmes are based on 'legislation' within the meaning of the Regulations.

Second, it could be argued that Covid-19 vaccination programmes constitute medical assistance, which is excluded from the scope of the Regulations.[92] While medical assistance is a nebulous concept, it is to be interpreted narrowly and its connection to the need makes it unlikely to cover vaccination programmes intended for the whole (adult) population, even if the entitlement is staggered on the basis of age and risk profile.

Third, it could be argued that Covid-19 vaccination programmes fall under Article 3(5)(b) Regulation (EC) No 883/2004, which provides that the Regulation does not apply to:

> 'benefits in relation to which a Member State assumes the liability for damages to persons and provides for compensation, such as those for victims of war and military action or their consequences; victims of crime, assassination or terrorist acts; victims of damage occasioned by agents of the Member State in the course of their duties; or victims who have suffered a disadvantage for political or religious reasons or for reasons of descent.'

[87] A v Latvijas Republikas Veselības ministrija (C-535/19) EU:C:2021:595, para 33.

[88] G. Strban, 'Cross-border healthcare and social security rights' in F. Pennings and G. Vonk (eds), *Research Handbook on European Social Security Law* (Cheltenham: Edward Elgar, forthcoming), section 3.2.

[89] Article 1(3)(c) Directive 2011/24; its Chapter IV does apply to such programmes.

[90] See G. Strban, 'Cross-border healthcare and social security rights' in F. Pennings and G. Vonk (eds), Research Handbook on European Social Security Law (Cheltenham: Elgar, forthcoming), section 3.3.

[91] *Heinze* (14/72) EU:C:1972:98, para 4.

[92] Article 3(5)(a) Regulation (EC) No 883/2004.

This too seems an uneasy fit, as vaccination programmes neither concern liability for damage nor provide for compensation.[93]

Fourth, could it be argued that Covid-19 vaccination programmes are not social security, for they are discretionary? It is settled case-law that for a benefit to be considered as social security it must be 'granted to the recipients, without any individual and discretionary assessment of personal needs, on the basis of a legally defined position'.[94] That is the case where 'the grant of a benefit is made with regard to objective criteria which if satisfied, give entitlement to the benefit without the competent authority being able to take other personal circumstances into consideration'.[95] While the timing and possibly number of vaccines depend on the risk profile, they are administered without individual and discretionary assessment of personal needs – or at least without more individual assessment than is normal for healthcare. Fifth, while Covid vaccination programmes were not necessarily restricted to 'insured persons', given that most vaccines were administered to insured persons, this should not be decisive for their qualification under the Regulations.

In conclusion, the reasons for excluding Covid-19 vaccination programmes from the Regulations are unpersuasive. As the relevant Commission service argues,[96] such programmes should be classified as sickness benefits in kind, subject to the Regulations. This does not preclude distinctions made on the basis of e.g. age or risk profile.

Organ transplants

The Directive does not cover 'allocation of and access to organs for the purpose of organ transplants'.[97] Provided they are part of the benefits basket, organ transplants are covered by **the Regulations**.[98]

3.4. Different types of healthcare abroad

The Social Security Regulation identify three distinct cross-border healthcare situations to which different sets of coordination rules apply, namely when the residence of the claimant is in a Member State other than the competent Member State (Articles 17 and 18 of Regulation 883/2004), when a person is receiving necessary healthcare during a temporary stay outside the competent Member State (Article 19 of Regulation 883/2004), and when a person travels for the purpose of receiving benefits in kind outside the Member State of residence (Article 20 of Regulation 883/2004). The Directive does not distinguish between these situations, it applies the same rules to all cross-border healthcare provision. However, the specific rules applied to the insured person residing in a Member State other than the competent Member State are set by the definition of the 'Member State of affiliation' and derogations in Article 7(2) of the Directive.

The distinction between planned and unplanned healthcare is relevant under the Social Security Coordination rules. Indeed, if an insured person travels to another Member State with the purpose of obtaining a medical treatment there, he/she must, according to Article 20 of Regulation 883/2004 read in conjunction with Article 26 of Regulation 987/2009, 'seek

[93] A different issue would be that of compensation for harm suffered as a result of compulsory vaccination.

[94] *Commission v Slovak Republic (Christmas bonus)* (C-361/13) EU:C:2015:601, para 47.

[95] *Commission v Slovak Republic (care allowance)* (C-433/13) EU:C:2015:602, para 73. See further paras 72-82 of that judgment and *A* (C-679/16) EU:C:2018:601, paras 32-40.

[96] Position expressed in the Administrative Commission.

[97] Article 1(3)(b) Directive 2011/24.

[98] See further Administrative Commission for the Coordination of Social Security Systems, Recommendation No S1 of 15 March 2012 concerning financial aspects of cross-border living organ donations, OJ C 240, 10.8.2012, p. 3.

authorisation from the competent institution'. Conversely, such distinction does not exist in the Directive that applies to all types of cross-border healthcare services.

In this regard, under the social security coordination rules, the decisive element is the intention of the person in the moment in which he/she decided to go in another Member State: a medical treatment is planned if the travel has been done in order to receive it.[99] Conversely, if the need for healthcare arises during a stay abroad that has been done for other purposes – such as tourism, education or a business trip – the situation falls in the 'unplanned' category, and it is regulated by Article 19 of Regulation 883/2004 and Article 25 of Regulation 987/2009.

3.4.1. Unplanned/necessary cross-border healthcare

According to Article 19 (1) of Regulation 883/2009, when an insured person needs medical care while staying temporarily outside of the competent Member State, he/she shall be treated in the same manner as the insured persons of the Member States of stay, whereas the costs are borne by the competent Member State. The notion of care necessary on medical grounds is broader than emergency care and includes those treatments that are necessary for the continuation of the stay abroad taking into account the nature of the benefits and the length of the stay.[100] In such situations, insured person can use their European Health Insurance Card (EHIC) as a proof of entitlement to access necessary care abroad.[101] Article 19 (2) provides specific rules for patients in need of continuous or recurrent treatment(s). In order to ensure that such treatment will be at their disposal once staying abroad, prior agreement shall be received from the healthcare provider.[102]

The application of the Directive to cross-border healthcare situations in which the need for medical intervention occurs unexpectedly raises some questions as the Directive was not initially designed to cover unplanned healthcare.[103]

Probably the most beneficial characteristic of the Directive's application to unplanned/urgent medical care is that – unlike the Social Security Regulation – the medical costs can be reimbursed even if the patients received the necessary treatment from a private/non-contracted health care provider whose costs would not be reimbursed under the provisions of the Social Security Regulation as such care falls outside the scope of the Social Security Regulation. Thus, in such cases, it appears that the Directive ensures a higher level of protection. In most other cases of unplanned healthcare, the Regulations seem to offer a more satisfactory solution for the patient.

Applying the same set of rules to both planned and unplanned healthcare provision can result in paradoxical situations. This is especially true when we apply the Directive's authorisation rules consistently in each situation regardless of whether or not the healthcare service required is unforeseen. Since the Directive permits Member States to provide for a system of prior authorisation for the reimbursement of certain costs of cross-border healthcare services furnished by a private health care provider, theoretically it would be possible for a Member State to refuse reimbursement of the costs of unplanned hospital treatment obtained without prior authorisation by a purely private provider. For instance, suppose an insured person suffers a ski accident during a skiing holiday abroad and the

[99] See G. Strban, G. Berki, D. Carrascosa, F. Van Overmeiren, Access to healthcare in cross-border situations. FreSsco Analytical Report 2016, European Commission (2017), 35. This issue is analysed also by the Court in Case C-777/18 WO, 39.

[100] AC decision S3 defines necessary care as benefits which become necessary on medical grounds with a view to preventing an insured person from being forced to return, before the end of the planned duration of stay, to the competent Member State to obtain the necessary treatment.

[101] See AC decisions S1 and S2 on the EHIC.

[102] The list of these treatments is incorporated in AC decision S3.

[103] The proposal for the Directive stated that it does not address the assumption of costs of healthcare which become necessary on medical grounds during a temporary stay of insured persons in another Member State. See also the section on unplanned healthcare in point 3.3.2 on material scope above.

emergency helicopter takes him or her to the nearest private clinic located in the ski resort. In this case, the application of the Regulations does not even come into play, since purely private providers operating outside the statutory healthcare system are excluded from their scope. Under the Directive's rules, the patient can request reimbursement of the medical costs based on the domestic tariffs in the Member State of affiliation. However, since the Directive allows to make the reimbursement of overnight hospital accommodation costs dependent on prior authorisation,[104] the competent Member State is free to refuse the reimbursement in the absence of such prior authorisation. Although there does not appear to be any evidence that any Member State would apply this reasoning, the reality of this problem is proven by the fact that this question was expressly addressed in the Administrative Commission (AC).[105] The AC was of the view that treatment by a private provider should be reimbursed if it becomes necessary during a temporary stay and there is no realistic possibility to obtain prior authorisation for the treatment. Undeniably, this interpretation is both rational and reflects reality. For example, in case of an accident requiring urgent or immediate treatment where a patient is admitted to a private facility (this being the most readily available facility in the circumstances) it is simply not practical to expect such a patient to request a prior authorisation under the Directive for the necessary treatment. This interpretation is not entirely in line with the current wording of the Directive which does not engage with the concept of medical necessity. Further, the view of the AC (or any of its working groups) is not binding on the Member States.[106] [107] It must be noted though, that recent case law of the CJEU[108] confirmed that urgency of a treatment must be considered by the competent institution when deciding about an application for reimbursement – both in the context of the Regulations and the Directive. However, this was concluded in case of planned treatments, thus it does not seem to entirely dissolve the paradox above. Nevertheless, some opinions suggest that this case law must be interpreted as confirming that prior authorisation under the Directive's regime cannot be required in case of unplanned healthcare. However, our standpoint is that there is a relevant difference between the distinction between planned and unplanned and the distinction between urgent and non-urgent care. The CJEU dealt with a case of planned care that turned urgent due to the health deterioration of the person concerned and pinpointed that in such a case reimbursement of costs cannot be denied even in the lack of prior authorisation. Whether the same is true for all unplanned healthcare situations – which does not necessarily need be urgent (e.g. during a longer stay abroad) – is uncertain.

Steering of the patients (namely directing them towards the treatment route that is more advantageous for the provider or the insurer) presents an issue particularly in cases of unplanned healthcare.[109] Patients – especially under the pressure of urgent need of healthcare – tend to accept (even appreciate) such advice – often without being aware of their potential disadvantageous consequences to them. The most effective way of combatting these practices is to empower patients by providing them with clear, easily accessible information on their cross-border healthcare rights[110] and to monitor the providers and insurers to check whether they meet their obligations under EU law.

[104] Cross-Border Healthcare Directive, Article 8 (2)(a)(i).

[105] Administrative Commission for the Coordination of Social Security Services, Minutes of the Working Party of the Administrative Commission on Patients' mobility, AC 332/11, 4 October 2011.

[106] Giuseppe Romano v Institut national d'assurance maladie-invalidité (98/80) EU:C:1981:104; [1983] 2 C.M.L.R. 698.

[107] Gabriella Berki, Free movement of patients in the EU – A patient's perspective, Intersentia, 2018, p. 89.

[108] Case C-777/18 WO.

[109] For instance, it has been reported that in some touristic areas, tourists are generally directed to healthcare facilities falling outside the scope of the Regulations.

[110] See Chapter 4 below.

3.4.2. Planned cross-border healthcare

Prior authorisation

The obligation to obtain an authorisation for the patient wishing to be treated abroad and thus having the relevant costs covered by the State where he/she is insured represents the operational answer to the need to find a balance between the individual right to health and the preservation of the accessibility, universality and quality of national healthcare systems. This need has found recognition in both the Regulations and the Directive, albeit in different terms.

Regarding the social security coordination rules, prior authorisation is a structural component of the legal regime, being framed as an obligation for the patient wishing to travel to another Member State with the purpose of receiving a treatment there. Regulation (EC) 883/2004 leaves considerable autonomy to the Member States when it comes to the granting of such authorisation. The only limits can be found in the second sentence of Article 20(2) Regulation (EC) No 883/2004 that provides that competent institutions are obliged to grant the authorisation when two cumulative conditions are satisfied. First, when the treatment in question is among the benefits provided for by the legislation in the Member State where the person concerned resides. Second, when the treatment cannot be provided 'within a time limit which is medically justifiable, taking into account his/her current state of health and the probable course of his/her illness'.

Conversely, Directive 2011/24/EU establishes that, as a rule, prior authorisation cannot be required as a pre-requisite for the reimbursement of the cost of cross-border health care. Member States have to ensure that the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation. National authorities can resort to the requirement of prior authorisation only by way of exception to such a rule and only when, as highlighted in Article 8(1) of the Directive, it is 'necessary and proportionate to the objective to be achieved, and [it does not] constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients'. The restrictive approach adopted by the legislator reflects the origins of the Directive, being the codification of the CJEU's case-law on the application of Treaty rules on free movement of services to cross-border healthcare. In this context, subjecting the assumption or reimbursement of costs incurred by the patient abroad to prior authorisation has been consistently considered as a restriction of the freedom to provide services, enshrined in Article 56 TFEU unless it can be objectively justified.[111]

The Directive identifies the categories of cases in which Member States can make the reimbursement of medical costs abroad subject to prior authorisation. First, this can occur in case of specific planning requirements associated with the health care to be provided. This will be the case where the treatment in question: i) involves overnight hospital accommodation of the patient for at least one night; ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment.[112] Second, the Directive allows Member States to impose a prior authorisation requirement when it involves treatments presenting a particular risk for the patient or the population and, third, when the healthcare provider 'on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care'.[113]

[111] See Judgment of 28 April 1998, *Kohll*, C-158/96, EU:C:1998:171, para. 35.

[112] Article 8(2), letter a), of Directive 2011/24/EU.

[113] Article 8(2), letter b) and c) of Directive 2011/24/EU.

Under the Directive, Member States can refuse the authorisation when: i) the patient will be exposed with reasonable certainty to a patient-safety risk; ii) the general public will be exposed with reasonable certainty to a substantial safety hazard; iii) this 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; iv) this healthcare can be provided on its territory within a time limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of the patient.[114]

Treatment without prior authorisation

With regard to both regimes, the CJEU has identified some situations where the patient is entitled to have the costs reimbursed even without a prior authorisation provided that all the other conditions for the reimbursement of health care costs incurred outside the competent state are met.

The first of these situations occurs when the person, wishing to be treated abroad, makes an application for authorisation that is rejected by the competent authorities, but it is then subsequently established that the latter decision was unjustified. As held in *Vanbraekel*, in such a case 'that person is entitled to be reimbursed directly by the competent institution by an amount equivalent to that which it would ordinarily have borne if authorisation had been properly granted in the first place'.[115]

The second situation – which may prove more problematic – arises when the person is prevented from applying for the authorisation or is not able to wait for the decision of the competent authority because of reasons relating to his or her state of health or to the need to receive urgent planned care.

This scenario has been first discussed in *Elchinov*, a case concerning a Bulgarian citizen suffering from a serious illness that had been treated in a German hospital before obtaining the authorisation he had applied for. The CJEU found that the national legislation, excluding in all cases payments for treatments obtained without authorisation, was contrary to social security coordination rules read in the light of Treaty provisions on free movement of services.[116]

This interpretation, based on an analysis of the joint recourse to the two set of rules governing the provision of health care abroad has been recently confirmed, and even extended, in *WO*.[117] The judgment concerned the case of a Hungarian national who had suffered a retinal detachment in 1987 and was diagnosed with glaucoma in 2015. Since the treatments provided by Hungarian medical establishment were not effective, he decided to contact a specialist in Germany. The examination by that specialist showed that the eye was at risk of being seriously impaired – to the extent of total loss of sight - unless treated immediately. WO was operated on immediately. The Hungarian authorities rejected the application of WO for reimbursement of the cost of this surgery, pointing to the fact that it was undertaken without the required prior authorisation. Unlike *Elchinov*, Mr WO had not even requested the authorisation, although 20 days passed between his first contact with the doctor in Germany and the surgery and there was nothing preventing him to submit the application. This notwithstanding, the CJEU held that the *Elchinov* doctrine was applicable here, since, had Mr WO applied for the authorisation, 'he could not have waited for the decision of the competent institution'.[118] On this basis, the CJEU concluded that Article 20 of Regulation (EC) No 883/2004, read in the light of Article 56 TFEU, is to be interpreted as

[114] Article 8(6), letters a), b), c) and d) of Directive 2011/24/EU.

[115] Judgement of 12 July 2001, *Vanbraekel et al.*, C-368/98, EU:C:2001:400, para. 34.

[116] Judgment of 5 October 2010, *Elchinov*, C-173/09, EU:C:2010:581, paras 45-47, 51 and 75.

[117] Judgment of 23 September 2020, *WO*, C-777/18, EU:C:2020:745.

[118] Para. 54.

granting to an insured person who has received a scheduled treatment in another Member State without having applied for authorisation the right to be reimbursed. More specifically, it held that the right to the reimbursement exists if 'between the date on which the appointment for the purposes of a medical examination and possible treatment in another Member State was made and the date on which that treatment was given to the insured person in that Member State, to which he or she had to travel, that person was, for reasons relating to his or her state of health or to the need to receive urgent treatment there, in a situation which prevented him or her from applying for such authorisation from the competent institution or was not able to wait for the decision of that institution on such application'.[119] The CJEU came to the same conclusion when analysing the issue under the rules on the free movement of services. Despite admitting that eye surgery either requires hospital care or major non-hospital care, it found that legislation excluding the reimbursement in a situation of emergency for lack of prior authorisation is a disproportionate restriction of the freedom to provide services, enshrined in Article 56 TFEU, and it violates Article 8(1) Directive 2011/24/EU.[120]

Access to equally effective and timely treatment

With regard to both legal regimes, a key aspect concerning the decision to grant or refuse the authorisation to go abroad for receiving a medical treatment is whether an equally effective treatment can be given,[121] to use the terminology found in both Article 20(2) of Regulation (EC) No 883/2004 and Article 8(6), letter d) of Directive 2011/24/EU, 'within a time limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each patient concerned'. The use of the same expression reveals the existence of a strong convergence between the two regimes on this point, even though, as this report will show, some divergences persist.

This process of convergence started in *Inizan*, a case concerning the compatibility with what is now Article 56 TFEU of a national provision making the assumption of the cost of planned hospital treatment. Here, the CJEU interpreted the requirement then contained in the second subparagraph of Article 22(2) of Regulation No 1408/71 in the same way as it interpreted the expression 'without undue delay' used in case-law on the free provision of services.[122] In *Watts*, Advocate General Geelhoed pointed out that it would 'not make sense to apply different criteria in the context of both provisions where the basic issue is the same, namely whether hospital treatment can be provided within an acceptable time.[123]

Over time, the CJEU has identified the elements that national authorities need to consider in assessing whether an equally effective treatment is available in due time in the Member State of affiliation. Relying on the case-law concerning the application of then Article 49 EC Treaty to the cross-border movement of patients,[124] in *Watts,* the CJEU held that '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'.[125] The formula has been consistently used in several other cases.

---

119 Para. 55.

120 Para. 85

121 The expression is used by the Court, see, for instance, Judgment of 12 July 2001, *Geraets-Smits and Peerbooms*, C-157/99, ECLI:EU:C:2001:404, paras. 103-104. See also F. Pennings, 'The Cross-Border Healthcare Directive: More Free Movement for Citizens and More Coherent EU Law?' (2011) European Journal of Social Security 424, 430.

122 Judgment of 23 October 2003, *Inizan*, C-56/01, EU:C:2003:578, para. 46.

123 Opinion of 15 December 2005, *Watts*, C-372/04, EU:C:2005:784, para. 101.

124 See Judgment of 12 July 2001, *Geraets-Smits and Peerbooms*, C-157/99, EU:C:2001:404, para. 104.

125 Judgment of 16 May 2006, C-372/04, *Watts*, EU:C:2006:325, para. 62.

In *Petru*,[126] the CJEU added an important piece to the mosaic, clarifying that the assessment also needs to consider the conditions of national healthcare providers. The judgment concerned the case of a Romanian citizen who travelled to Germany for a heart surgery, in the belief that the Romanian hospital establishment was inadequate in this regard. The Romanian authorities refused to issue the authorisation – and, thus, to reimburse the costs – pointing to the fact that the same treatment was available in Romania and that the systemic inadequacies complained of by the patient were irrelevant. The CJEU rejected the argument and held that Member States are obliged to grant the authorisation when their healthcare systems are unable to provide in a timely manner the treatment, due to a lack of medication and basic medical supplies and infrastructure. It is worth highlighting that the latter assessment needs to be carried out by considering all the medical establishments of the State and not just the one chosen by the patient.[127]

More recently the CJEU has been asked to clarify whether the assessment of the availability of an equally effective and timely treatment in the State of affiliation needs to be carried out in the light of non-medical considerations pertaining to the patient's personal circumstances. This question was raised in *A*,[128] a case concerning the father of a minor suffering from a congenital heart defect who, despite being affiliated to the Latvian healthcare system, wanted his son to be operated in Poland. In Latvia, this type of surgery was carried out using a blood transfusion, but the applicant, who was a Jehovah's Witness, refused to consent to it as blood transfusion was incompatible with his religious beliefs. He wished for his son to have surgery in Poland which could be performed without a blood transfusion. The Latvian authorities refused to grant the authorisation on the grounds that this operation was available in the State of affiliation and that the religious preferences of the person concerned were irrelevant. The CJEU dealt with the issue from the perspective of both the Regulations and the Directive but came to different conclusions in the light of the disparity between the reimbursement systems established by the two instruments.

The CJEU first found that the assessment whether to grant the authorisation under Article 20 of Regulation (EC) No 883/2004 consists exclusively in examining medical considerations and does not involve the consideration of the patient's personal choices. However, when assessing whether to grant the authorisation under Article 20 Regulation (EC) No 883/2004, the Member States must respect the Charter of Fundamental Rights. In the case at hand, the refusal constituted indirect discrimination on the grounds of religion, but the CJEU found that this difference was based on an objective and reasonable criterion. Allowing patients to choose the place where to receive a medical treatment based on their religious beliefs could give rise to additional costs and, thus, put in jeopardy the financial stability of the national healthcare system. According to Article 35 Regulation (EC) No 883/2004, the benefits in kind provided by the Member State of treatment must be refunded in full.[129] As pointed out by the CJEU, '[a]s a result, in a situation where benefits in kind provided in the Member State of stay give rise to higher costs than those relating to benefits which would have been provided in the insured person's Member State of residence, the obligation to refund in full may give rise to additional costs for the Member State of residence'.[130]

This reasoning is not applicable in the case of the Directive. Article 7 provides that the reimbursement is calculated based on the fees for healthcare in the Member State of affiliation without exceeding the actual costs of the treatment received. Therefore, in this case there is no risk of additional costs for the system and a Member State cannot claim that refusing the authorisation is a proportionate restriction to the freedom to provide

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

127 *Petru*, paras 33-36.

128 Judgment of 29 October 2020, *A*, C-243/19, EU:C:2020:872.

129 *A*, paras 34-56.

130 *A*, para. 49.

services.[131] Yet, the CJEU acknowledged that the restriction could be justified on other grounds namely to maintain treatment capacity or medical competence, leaving to the referring judge the task of assessing this issue with regard to the case at hand. If the national judge considers that the system of prior authorisation is necessary and proportionate, the competent authorities have to take into account only the patient's medical conditions to the exclusion of other factors. It is worth observing that, in reaching this conclusion, the CJEU pointed out that 'there is no reason which seriously justifies different interpretations depending on whether the context is Article 20(2) of Regulation (EC) No 883/2004 or Article 8(5) and (6)(d) of Directive 2011/24, since in both cases the question is whether the hospital treatment required by the patient's medical condition can be provided on the territory of his or her Member State of residence within an acceptable time which ensures its usefulness and efficacy'.[132] That being the case, where the Member State of affiliation refuses to grant prior authorisation on the grounds that the requirements laid down in Article 8(5) have not been met, it must respect Article 21(1) of the Charter and such a refusal does constitute indirect discrimination on the grounds of religion. However, whether the difference in treatment pursues the legitimate objective of maintaining treatment capacity or medical competence and its proportionality must be assessed by the referring court. In particular, that court must consider whether the taking into account of patients' religious beliefs when implementing Articles 8(5) and 6(d) of the Directive gives rise to a risk for the planning of hospital treatment in the Member State of affiliation.

3.4.3. Residence in another Member State

Typical cross-border healthcare scenarios revolve around two Member States: the competent Member State or Member State of affiliation, on the one hand, and, on the other, the Member State of treatment. However, one of the main ways in which a third Member State can be involved is when the person concerned resides outside the competent Member State. That is the case, for instance, for frontier workers: under Article 11(3)(a) of Regulation (EC) No 883/2004, they are subject to the legislation of the State where they work. Another example would be pensioners. While in principle they are subject to the legislation of their Member State of residence by virtue of Article 11(3)(e) of Regulation (EC) No 883/2004, that provision applies 'without prejudice to other provisions of this Regulation guaranteeing him/her benefits under the legislation of one or more other Member States.' Chapter 1 of Title III of Regulation (EC) No 883/2004 contains such provisions for pensioners. Moreover, Article 16(2) of Regulation (EC) No 883/2004 gives them an opt-out:

> 'A person who receives a pension or pensions under the legislation of one or more Member States and who resides in another Member State may at his/her request be exempted from application of the legislation of the latter State provided that he/she is not subject to that legislation on account of pursuing an activity as an employed or self-employed person.'

This section looks at the position of non-residents, i.e. persons who reside outside the competent Member State.[133] Unless stated otherwise, it is assumed that the competent Member State (under the Regulations) coincides with the Member State of affiliation (under the Directive). As we will see, they can diverge for non-residents.

Healthcare in Member State of residence

[131] *A*, paras 72-78.

[132] *A*, para. 82.

[133] As discussed in section 3.3.1, residence also impacts the definition of 'family member'.

The Regulations

Article 17 of Regulation (EC) No 883/2004 provides that insured persons (and their family members) who reside outside the competent Member State shall receive the benefits in kind provided by the institution of the State of residence, in accordance with its legislation, as if they were insured under that legislation. The benefits will be provided on behalf of the institution of the competent Member State.

There are separate rules for pensioners. Article 1(w) of Regulation (EC) No 883/2004 provides that 'pension' covers not only pensions but also lump-sum benefits which can be substituted for them and payments in the form of reimbursement of contributions and, subject to the provisions of Title III, revaluation increases or supplementary allowances'. The word 'pension' typically refers to old-age pensions, survivors' pensions, and invalidity pensions.[134] It is also used, on occasion, in relation to benefits in respect of accidents at work or occupational diseases.[135]

The rules for pensioners depend on whether they are economically active or not. Article 17 of Regulation (EC) No 883/2004 also applies to those pensioners and their family members 'who are entitled to benefits under the legislation of a Member State on the basis of an activity as an employed or self-employed person'.[136] Other pensioners and their family members can claim benefits in kind in their Member State of residence on the basis of Articles 23 to 26 of Regulation (EC) No 883/2004.

Article 23 of Regulation (EC) No 883/2004 reads:

> 'A person who receives a pension or pensions under the legislation of two or more Member States, of which one is the Member State of residence, and who is entitled to benefits in kind under the legislation of that Member State, shall, with the members of his/her family, receive such benefits in kind from and at the expense of the institution of the place of residence, as though he/she were a pensioner whose pension was payable solely under the legislation of that Member State.'

Due to its limited scope, that provision needs flanking by further provisions. Article 24 of Regulation (EC) No 883/2004 applies where a pensioner is not entitled to the benefits in kind of the Member State of residence. Such a pensioner

> 'shall nevertheless receive such benefits for himself/herself and the members of his/her family, in so far as he/she would be entitled thereto under the legislation of the Member State or of at least one of the Member States competent in respect of his/her pensions, if he/she resided in that Member State.'

The benefits in kind are then provided by the institution of the Member State of residence, as if the pensioner were entitled to its pension and to its benefits in kind. The difference with Article 23 of Regulation (EC) No 883/2004 concerns the financing of the benefits. Under Article 24 of Regulation (EC) No 883/2004, if the pensioner is entitled to benefits in kind under the legislation of one Member State only, that Member State shall bear their costs. If the pensioner is entitled to benefits in kind under the legislation of two or more Member States, the costs shall be borne by the Member State to whose legislation the pensioner was subject for the longest period of time.

---

[134] E.g., Article 11(2) Regulation (EC) No 883/2004, Article 28(2) Regulation (EC) No 883/2004, Chapters 4 and 5 Regulation (EC) No 883/2004.

[135] Article 11(2) Regulation (EC) No 883/2004.

[136] Article 31 Regulation (EC) No 883/2004.

By virtue of Article 25 of Regulation (EC) No 883/2004, this approach also applies to pensioners who do not receive a pension from their Member State of residence if (i) that Member State does not make entitlement to benefits in kind subject to periods of insurance or work and (ii) 'the pensioner and the members of his/her family would be entitled to such benefits if they resided in [the] Member State' bearing the costs of the benefits in kind.

Article 26 of Regulation (EC) No 883/2004 concerns family members who do not reside in the same Member State as the pensioner. Those family members are entitled to the benefits in kind of the Member State of residence in accordance with its legislation, provided the pensioner is entitled to benefits in kind under the legislation of a Member State. Those benefits are provided at the expense of the Member State responsible for bearing the costs of the pensioner's benefits in kind provided in their Member State of residence.

The Directive

The Directive does not cover healthcare provided in the Member State of residence.[137] Indeed, it defines the 'Member State of affiliation' as 'the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment *outside the Member State of residence*'.[138]

Healthcare in the competent Member State / Member State of affiliation

The Regulations

People residing outside the competent Member State might wish or need to access healthcare in the competent State rather than their State of residence. Article 18(1) of Regulation (EC) No 883/2004 provides that the insured person and their family members are entitled to the benefits in kind of the competent Member State while staying there. These benefits will be provided and funded by the competent Member State, in line with its legislation, as if the person concerned resided on its territory.

More restrictive rights apply to *some* family members of frontier workers and to some pensioners and their family members.

Frontier workers are a subcategory of non-residents. They are defined as 'any person pursuing an activity as an employed or self-employed person in a Member State and who resides in another Member State to which he/she returns as a rule daily or at least once a week'.[139] The family members of frontier workers are entitled to the benefits in kind of the competent Member State when staying there, unless that State is listed in Annex III.[140] If listed, the family members residing in the same State as the frontier worker are only 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.'[141]

The competent Member State can also restrict the entitlement to benefits in kind of pensioners and their family members residing in another Member State. Article 18(1) of Regulation (EC) No 883/2004 applies *mutatis mutandis* to

[137] Guidance note of the Commission services on the relationship between Regulations on the coordination of social security systems and Directive on the application of patients' rights in cross border healthcare, AC 246/12, 19.

[138] Article 3(c)(i) Directive 2011/24, emphasis added. See also Article 3(c)(ii) Directive 2011/24.

[139] Article 1(f) Regulation (EC) No 883/2004.

[140] Article 18(2) Regulation (EC) No 883/2004.

[141] Article 19(1) Regulation (EC) No 883/2004.

> 'a person receiving a pension or pensions under the legislation of one or more Member States and entitled to benefits in kind under the legislation of one of the Member States which provide his/her pension(s) or to the members of his/her family who are staying in a Member State other than the one in which they reside […] when they stay in the Member State in which is situated the competent institution responsible for the cost of the benefits in kind provided to the pensioner in his/her Member State of residence and the said Member State has opted for this and is listed in Annex IV.'[142]

That Annex is entitled 'More rights for pensioners returning to the competent Member State' and lists 15 Member States. The benefits in kind shall be provided at the expense of the Member State that would have been responsible if they had been provided to the pensioner in their Member State of residence.[143]

Where the competent Member State is not listed in Annex IV, pensioners and their family members are only entitled to necessary healthcare.[144]

There are special rules for retired frontier workers regarding the continuation of a treatment which began in the Member State of last (self-)employment.[145]

The Directive

In principle, the Directive does not cover healthcare sought in the Member State of affiliation, which usually coincides with the competent Member State under the Social Security Regulation. Indeed, it defines 'cross-border healthcare' as 'healthcare provided or prescribed in a Member State other than the Member State of affiliation'.[146] When does the Directive nonetheless apply to non-residents claiming healthcare in the competent Member State? The question might be relevant if the healthcare is provided by a non-contracted healthcare provider.

Healthcare sought in the competent Member State is cross-border healthcare where that State is not the Member State of affiliation. The Directive defines the Member State of affiliation as 'the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009'.[147] Often, the competent Member State under the Regulations is competent to grant prior authorisation and is therefore the Member State of affiliation under the Directive. That is, however, not always the case, as will be discussed in the next subsection. In particular, the competent Member State and the Member State of affiliation can differ for persons residing outside their competent Member State, as the Member State of residence may be competent to award prior authorisation under the Regulations. The difficulty with this reasoning is that such authorisation is not needed to obtain healthcare in the competent Member State.

The Directive expressly envisages two further situations. First, Article 7(2)(a) of the Directive says that a Member State shall provide healthcare at its own expense and 'in accordance with its legislation' to people staying on its territory, if (i) it is listed in Annex IV to Regulation

---

142 Article 27(1)-(2) Regulation (EC) No 883/2004.

143 Article 19(4) Regulation (EC) No 883/2004.

144 Article 27(1) Regulation (EC) No 883/2004.

145 Article 28 Regulation (EC) No 883/2004.

146 Article 3(e) Directive 2011/24.

147 Article 3(c)(i) Directive 2011/24, which applies to insured persons covered by Article 2 Regulation (EC) No 883/2004. For third-country nationals who are covered by Regulations 859/2003 or 1231/2010 and who satisfy the entitlement conditions of the Member State of affiliation, Article 3(c)(ii) Directive 2011/24 defines that Member State as 'the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010. If no Member State is competent according to those Regulations, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State'.

(EC) No 883/2004 and (ii) 'in compliance with that Regulation has recognised the rights to sickness benefits for pensioners and the members of their families, being resident in a different Member State'. Such healthcare shall be provided under the legislation of the Member State in question, as if the person resided there. Annex IV concerns non-resident pensioners staying in the competent Member State. It therefore seems that this provision, which expressly derogates from Article 7(1) of Directive 2011/24,[148] applies even to healthcare sought in the Member State of affiliation. Admittedly, it features in a chapter entitled 'Cross-Border Healthcare', but unlike Article 7(1) it mentions 'healthcare' rather than 'cross-border healthcare'.

A second derogation from Article 7(1) of Directive 2011/24 is found in Article 7(2)(b), which reads:

> 'if the healthcare provided in accordance with this Directive is not subject to prior authorisation, is not provided in accordance with Chapter 1 of Title III of the Regulation (EC) No 883/2004 and is provided in the territory of the Member State that according to that Regulation and Regulation (EC) No 987/2009 is, in the end, responsible for reimbursement of the costs, the costs shall be assumed by that Member State. That Member State may assume the costs of the healthcare in accordance with the terms, conditions, criteria for eligibility and regulatory and administrative formalities that it has established, provided that these are compatible with the TFEU.'

This provision also seems to apply even to healthcare provided in the Member State of affiliation.

Planned healthcare in a third Member State

What is the situation when a person obtains healthcare in a Member State other than the competent Member State and the Member State of residence? We will begin by considering planned healthcare.

The Regulations

Under the Regulations, the reimbursement of planned healthcare costs is conditional upon prior authorisation. This authorisation must be granted where two conditions are fulfilled: (i) the healthcare is part of the benefit basket of the Member State of residence and (ii) it cannot be provided 'within a time limit which is medically justifiable, taking into account his/her current state of health and the probable course of his/her illness.'[149]

The place of residence impacts the procedure for obtaining planned healthcare. A non-resident shall request prior authorisation from the institution of the Member State of residence.[150] Having forwarded the request to the competent Member State without delay, the institution of the Member State of residence assesses whether authorisation must be granted because the healthcare is part of its benefit basket and cannot be provided within a medically justifiable time limit on its territory.[151] It communicates its conclusion to the institution of the competent Member State, which may refuse prior authorisation only in two situations:

---

[148] Article 7(1) Directive 2011/24 reads: 'Without prejudice to Regulation (EC) No 883/2004 and subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if
the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.'

[149] Article 20(2) of Regulation (EC) No 883/2004.

[150] Article 26(2) Regulation (EC) No 987/2009.

[151] Article 26(2) Regulation (EC) No 987/2009; Article 20(2) Regulation (EC) No 883/2004.

- Where the same treatment can be provided on its territory 'within a time-limit which is medically justifiable, taking into account the current state of health and the probable course of illness of the person concerned'; or

- Where the institution of the Member State of residence concludes that the healthcare is not part of its benefit basket or can be provided on its territory within a medically justifiable time limit.

In certain situations, the competence to grant prior authorisation shifts to the institution of the Member State of residence. The Member State of residence becomes the Member State of affiliation for the purposes of the Directive.

First, under Article 26(3) of Regulation (EC) No 987/2009 the institution of the Member State of residence shall grant prior authorisation if the insured person is entitled to prior authorisation under Article 20(2) of Regulation (EC) No 883/2004 and 'is in need of urgent vitally necessary treatment'.[152] That institution immediately informs the institution of the competent State.

Second, Article 26(1) of Regulation (EC) No 987/2009 says that, for the purposes of that Article, 'the competent institution shall mean the institution which bears the cost of the scheduled treatment'. There are various ways in which this institution may differ from the institution of the competent Member State. For instance, in principle, economically inactive persons are subject to the legislation of their Member State of residence;[153] however, in the circumstances defined in Articles 24 and 25 Regulation (EC) No 883/2004 the costs of their healthcare is borne by another Member State.

Third, Article 26(1) of Regulation (EC) No 987/2009 makes an exception and designates the Member State of residence as competent to grant prior authorisation 'in the cases referred to in Article 20(4) and 27(5) of the basic Regulation, in which the benefits in kind provided in the Member State of residence are reimbursed on the basis of fixed amounts'.[154]

The Directive

The place of residence of the claimant is not only relevant in the context of the Regulations, but also in the case of the Directive. Article 3(c)(i) Directive 2011/24 defines the 'Member State of affiliation' as 'the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009'. Accordingly, when the Regulations vest the Member State of residence with that competence, then it becomes the Member State of affiliation.

The recent *Y v Centraal Administratie Kantoor* case illustrates the issues that can arise for non-residents seeking healthcare in a third Member State (i.e. a Member State other than the competent Member State and the Member State of residence) on the basis of the Directive.[155] The patient was a resident in Belgium receiving a Dutch old-age pension. Normally, economically inactive persons are subject to the legislation of their State of residence.[156] However, economically inactive pensioners who do not receive a pension from their Member State of residence can request to be exempt from the application of its legislation.[157] Accordingly, the competent Member State was the Netherlands rather than

[152] Article 26(3) Regulation (EC) No 987/2009.

[153] Article 11(3)(e) Regulation (EC) No 883/2004.

[154] Article 26(1) Regulation (EC) No 987/2009.

[155] *Y v Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885 .

[156] Article 11(3)(e) Regulation (EC) No 883/2004.

[157] Article 16(2) Regulation (EC) No 883/2004.

Belgium. Article 24 Regulation (EC) No 883/2004 meant that she was entitled to healthcare in Belgium at the expense of the Netherlands:

> 'A person who receives a pension or pensions under the legislation of one or more Member States and who is not entitled to benefits in kind under the legislation of the Member State of residence shall nevertheless receive such benefits for himself/herself and the members of his/her family, in so far as he/she would be entitled thereto under the legislation of the Member State or of at least one of the Member States competent in respect of his/her pensions, if he/she resided in that Member State'.

While Y paid a special contribution in the Netherlands, she was not covered by the Dutch compulsory healthcare insurance scheme nor was she required to contribute to that scheme. Y requested prior authorisation from the Dutch institution for healthcare in Germany, and then underwent further, non-authorised, healthcare there – both surgery and post-operative treatments. Y then sought reimbursement for these non-authorised treatments, to no avail. The referring court held that there was no right to reimbursement under the Regulations since the patient would not have been entitled to prior authorisation from the Dutch institution even had she requested it in time, as the Belgian institution had certified that the treatment could have been provided to Y within the same time frame as in Germany.

The national court asked whether the patient could claim reimbursement from the Dutch institution for post-operative care, which was not subject to prior authorisation, on the basis of the Directive. This in turn depended on whether the patient –a pensioner entitled to the benefits in kind in her Member State of residence at the expense of the Member State responsible for paying her pension, but to whose sickness insurance scheme she was not affiliated – fell within the personal scope of the Directive.

This case focused on two conditions governing the status of 'insured person' for the purposes of the Directive: was the claimant (i) subject to the legislation of a Member State and (ii) an 'insured person' for the purpose of the Regulations?

Y was subject to the legislation of a Member State, even though she had no compulsory sickness insurance in the Netherlands, as she received a Dutch old-age pension and was liable in principle to pay contributions but was exempt from doing so since she was not resident in the Netherlands.[158]

A trickier issue was whether a person in her situation would be an insured person for the purposes of the Regulations, defined as 'any person satisfying the conditions required under the legislation of the Member State competent under Title II to have the right to benefits, taking into account the provisions of this Regulation'.[159] This was dependent on the fulfilment of three cumulative criteria.

First, the benefits ought to be a social security benefit covered by Chapters 1 or 3 of Title III, which was not contested.[160]

Second, the Member State in question ought to be competent.[161] Y requested exemption from Belgian legislation under Article 16 Regulation (EC) No 883/2004. Under Article 24, she was entitled to benefits in kind at the expense of the Netherlands. The Netherlands was therefore the competent State under Title II of Regulation (EC) No 883/2004.

[158] *Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885, para 39 read with para 18

[159] Article 1(c) Regulation (EC) No 883/2004.

[160] *Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885, para 40.

[161] *Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885, paras 41-43.

The third and most problematic condition was that Y had to satisfy all eligibility requirements for those benefits under that legislation, taking into account the provisions of the Regulations.[162] The Netherlands argued that the claimant's lack of compulsory sickness insurance precluded her from being an insured person. The CJEU was of the view that this restrictive interpretation of 'insured person' overlooks the fact that Article 24(1) Regulation (EC) No 883/2004 entitled her to benefits in kind, and therefore contravened Article 1(c) Regulation (EC) No 883/2004. The entitlement conditions laid down in Dutch legislation essentially replicated the conditions of Article 24 Regulation (EC) No 883/2004, which were fulfilled in the case at hand.

The Netherlands further sought to draw a distinction between 'insured persons' and 'pensioners', such that the latter were by definition not 'insured persons'.[163] The CJEU rejected the idea that both categories would be mutually exclusive. It recalled that the concept of 'insured person' covers 'any person', without drawing such distinction. Mutual exclusivity would go against the modernising and simplifying goal of Regulation (EC) No 883/2004. That led the CJEU to define the concept of 'insured person' for the Regulations as including

> 'in a general and exhaustive manner, nationals of Member States, stateless persons and refugees residing in a Member State who are or who have been subject to the legislation of one or more Member States, as well as the members of their families and their survivors …, provided that they satisfy the conditions required under the legislation of the competent Member State to have the right to benefits'.[164]

The fact that separate sections of Title III, Chapter 1 of Regulation (EC) No 883/2004 are dedicated to 'insured persons' and 'pensioners' (and their family members) is merely meant to account for the specificities of the position of pensioners, without creating two mutually exclusive categories of persons. The section on pensioners is a *lex specialis* to the section on insured persons in general.

This discussion about the scope of the Regulations served one purpose only: to determine whether a person in the situation of the claimant was an 'insured person' for the purpose of the Directive, which refers to the concept of 'insured person' under the Regulations. The CJEU noted that the notion of 'Member State of affiliation', which is central to the Directive, does not, in fact, presuppose 'affiliation' to the compulsory sickness insurance scheme of a Member State.[165] As the claimant was an 'insured person' for the purpose of the Directive (subject to verification by the referring court) and the Netherlands had not subjected the healthcare in question to prior authorisation, she could not be deprived of reimbursement on the basis that she had not obtained prior authorisation. In conclusion, a pensioner entitled, under Article 24 Regulation (EC) No 883/2004, to the benefits in kind of their Member State of residence at the expense of the Member State paying their pension, is an insured person under the Directive even if not compulsorily insured against sickness in the latter State.

Unplanned healthcare in a third Member State

The Regulations

[162] *Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885, paras 44-48.
[163] *Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885, paras 49.
[164] *Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885, para 52.
[165] *Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885, para 57.

Under the Regulations, an insured person and their family members staying in a third 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.'[166] Those benefits are provided by the institution of the Member State of stay, in line with its legislation, as if the person was insured under that legislation. The costs are borne by the competent Member State. For some benefits listed by the Administrative Commission, prior agreement is however needed between the institution of the Member State of stay and the person concerned.[167]

The Directive

As regards the Directive, the 'Member State of affiliation' is defined as 'the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009'.[168] However, the Regulations do not allow prior authorisation requirements for unplanned healthcare. Presumably the Member State of affiliation would be the one that would have been competent to grant prior authorisation had it been requested for planned healthcare under the Regulation. As we have seen, that may be the competent Member State or the Member State of residence, depending on the situation.

3.5. Reimbursement of medical costs

Both, the Social Security Regulation and the Cross-Border Healthcare Directive enable economic access to cross-border healthcare by covering or reimbursing of healthcare costs, although to a distinctive amount. According to Social Security Regulation costs are covered at the amount of the public tariffs in the Member State of treatment and according to the Cross-Border Healthcare Directive up to the tariffs of the Member State of affiliation (not exceeding actual costs of healthcare).

Settlement of healthcare costs among public healthcare institutions under the **Social Security Regulation** occurs when a person is residing in another Member State. In such case, the competent Member State shall issue an S1 form, which is to be submitted to the competent institution in the Member State of residence. Such institution can then issue a national health insurance card (or another relevant national document). In this way, equal treatment with national patients is enabled. The only distinction is that costs of such healthcare are later reimbursed by the responsible social security institution from the competent Member State to the institution in the Member State of residence.[169]

Direct settlement among the institutions also applies when EHIC is used for necessary healthcare. However, in both cases, i.e. residing outside of the competent Member State or using EHIC, the patient might be required to pay directly to the healthcare provider. This will happen, when also national patients are required to pay for healthcare directly (usually at a primary healthcare level) and are entitled to full or partial reimbursement from the competent institution. Examples of such systems, operating on primary healthcare cost reimbursement mechanism,[170] could be the French, Belgian or Luxemburgish systems. In such a case, the

[166] Article 19(1) Regulation (EC) No 883/2004.

[167] Article 19(2) Regulation (EC) No 883/2004.

[168] Article 3(c)(i) Directive 2011/24.

[169] K-J Bieback, 'Artikel 17', in M Fuchs (Hrsg.), Europäisches Sozialrecht, Baden-Baden, Nomos 2018, p. 292.

[170] Conversely, secondary reimbursement of costs may exist in systems providing healthcare in natura (also so called third party payment system), but healthcare cannot be guaranteed in due time at providers included in the public healthcare system. Then, a patient may visit a private medical doctor nationally and claim reimbursement. A similar situation might occur with urgent healthcare, when every medical doctor (within or outside of a public healthcare system) is called upon to assist (and has a right

patient can seek reimbursement in the Member State of treatment or in the competent Member State upon return. For planned healthcare, Regulations require prior authorisation provided by the social security institution in the competent Member State.[171] The competent institution may decide to grant the prior authorisation or not. However, it must be granted when two conditions are fulfilled, i.e. if the treatment is among the benefits provided in the person's own public healthcare system and cannot be provided there within a time limit which is medically justifiable, taking into account his or her current state of health and the probable course of the illness.[172] In this case, the CJEU has interpreted both conditions. For instance, it decided that if a national institution does not finance a certain treatment, it does not automatically mean that healthcare is outside of the benefits provided in the competent Member State.[173] Concerning the second condition of timely access to healthcare, the CJEU for example evaluated the issue of national waiting lists. They have to be managed individually (medically assessed without legal restrictions)[174] and the reason why healthcare cannot be provided without undue delay does not seem to be a concern for the Court.[175]

Where both above mentioned conditions are fulfilled, but the cross-border treatment is urgent and the patient was prevented from applying for prior authorisation or was not able to wait for the decision, s/he is entitled to reimbursement of cross-border healthcare costs even without applying for such authorisation.[176] Additionally, if travel costs are covered by the national system, a patient is entitled to them also in cross-border situations.[177]

Under certain conditions, a system of prior authorisation for reimbursement of cross-border healthcare costs may be introduced also under the **Cross-Border Healthcare Directive**.

Under the Cross-Border Healthcare Directive, healthcare costs should be reimbursed up to the level of costs that would have been assumed by the Member state of affiliation, had this healthcare been provided on its territory. A more extensive coverage of medical costs, compared to the ones in the Member State of treatment could be required, *e.g.,* if the latter would have a larger co-payment regime than the Member State of affiliation.[178] Such reimbursement should, however, not exceed the actual costs of the healthcare received.[179] Hence, enrichment of a patient (or "making money")[180] with the so-called *Vanbraekel* supplement,[181] which had to be paid, even when the actual costs in the state of treatment

to be paid). G. Strban. Temelji obveznega zdravstvenega zavarovanja [Basic principles of mandatory health insurance], Cankarjeva založba, Ljubljana 2005, p. 39.

171 Article 20 Regulation (EC) 8783/2004 and Article 26 Regulation (EC) 987/2009. Also e.g. case C-145/03 - Keller, EU:C:2005:211.

172 On the procedure for issuing such authorization case C-56/01 - Inizan, EU:C:2003:578, case C - 372/04 - Watts, EU:C:2006:325.

173 In case C-173/09 - *Elchinov*, EU:C:2010:581, the Court argued that 'where the list of medical benefits reimbursed does not expressly and precisely specify the treatment method applied but defines types of treatment, on the one hand, that it is for the competent institution of the Member State of residence of the insured person to assess, applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and the available scientific data, whether that treatment method corresponds to benefits provided for by the legislation of that Member State. It also follows, on the other hand, that, if such is the case, an application for prior authorisation cannot be refused on the ground that such a treatment method is not available in the Member State of residence of the insured person, since such a ground, if it were accepted, would imply a restriction on the scope of the second subparagraph of Article 22(2) of Regulation No 1408/71.'

174 Case C - 372/04 - *Watts*, EU:C:2006:325.

175 Case C-268/13- *Petru*, EU:C:2014:2271.

176 Case C-777/18 - *Vas Megyei Kormányhivatal*, EU:C:2020:745.

177 Article 26(7) Regulation (EC) 987/2009, case C-466/04 - *Acereda Herrera*, EU:C:2006:405.

178 Explanation of reimbursement in case of comfort requests by the patient could be found in the Appendix to the Guidance note of the Commission, point II. 2.

179 Recital 32 and Article 7(4) Directive 2011/24/EU.

180 Hatzopoulos, V., Harvey, T., Coming into line: the EU's Court softens on cross-border health care, Health Policy Econ. Law, Volume 8, Issue 1, 2013, p. 1.

181 Case C-368/98 - *Vanbraekel*, EU:C:2001:400. Compare with Art. 26 (7) of Regulation (EC) 987/2009.

were lower than reimbursement tariffs in the state of affiliation, is avoided. This had already been indicated by the Court, before the Cross-Border Healthcare Directive was passed.[182]

Member state of affiliation is nevertheless free to reimburse higher actual costs of treatment and even related non-medical costs, like accommodation and travel costs, or extra costs of persons with disabilities. However, it is not obliged to do so under the Cross-border healthcare.[183] Member States may adopt provisions in accordance with the TFEU aimed at ensuring that patients enjoy the same rights when receiving cross-border healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the Member State of affiliation.[184] Hence, depending on the patient's entitlements domestically, transport costs may not be covered, or they may be covered only to the nearest medical doctor.

Moreover, a so-called gate-keeping function of the general practitioner can be preserved (in Member states where it is put in place) and so-called 'doctor hopping' or 'doctor shopping' prevented.[185] The Cross-Border Healthcare Directive enables the Member State of affiliation to impose the same conditions, criteria of eligibility, regulatory and administrative formalities on a cross-border patient as apply to healthcare provision on its territory. This includes assessment by the general practitioner with whom the patient is registered.[186] Hence, once a general practitioner refers a patient to a specialist treatment at a secondary level of healthcare, such healthcare can be received within a Member State of affiliation or in another Member State (with prior authorisation, if required and regulated).

Even if Member States might have used the same procedures for granting prior authorisation under both legal instruments, i.e. the Social Security Regulation and the Cross-Border Healthcare Directive, the distinction has been clearly outlined by the CJEU, referring also to the scope of social security coverage, i.e. level of covered costs of cross-border healthcare. Under the Social Security Regulation, cross-border healthcare is covered according to the prices in the Member State of treatment, equally as for patients insured under that legislation. Under the Cross-Border Healthcare Directive, level of reimbursement is limited to the prices in the Member State of affiliation (and not exceeding actual costs of treatment). Actually, direct (co-)payments might be covered under the Regulations[187] and under the Directive but shall never exceed actual healthcare costs.

The CJEU seems to be allowing a combination of both legal instruments when deciding on prior authorisation. Cross-border medical assessment of equal or equally effective healthcare may be performed (and reimbursed) according to the Cross-Border Healthcare Directive and subsequently used for the purposes of issuing prior authorisation under the Social Security Regulation. Setting an additional condition of medical assessment from national public health system (next to healthcare being among the benefits and not available in due time) is a condition beyond the requirements of the Social Security Regulation and disproportionately limits free movement of services under the TFEU.[188]

---

[182] Case C-173/09 – *Elchinov*, *Elchinov*, EU:C:2010:581, paragraph 81 as well as operative part of the judgment (maybe not so explicit in English, but very clear in German, French and Bulgarian, which was language of the case, *i.e.,* 'jedoch nur bis zur Höhe der tatsächlichen Kosten', 'dans la limite des frais réellement exposés', 'но в границите на действително направените разходи', respectively). See also Article 7(4) Directive 2011/24/EU.

[183] Also Recital 13 of the Cross-Border Healthcare Directive reiterates that only the costs of healthcare to which a person is entitled according to the legislation of the member state of affiliation should be reimbursed.

[184] Article 7(5) Directive 2011/24/EU.

[185] G. Strban. Temelji obveznega zdravstvenega zavarovanja [Basic principles of mandatory health insurance], Cankarjeva založba, Ljubljana 2005, p. 260.

[186] Article 7(7) Directive 2011/24/EU.

[187] Article 26(7) Regulation (EC) 987/2009 (reminiscence of decision in case C-368/98 - *Vanbraekel and Others*, EU:C:2001:400).

[188] Case C-538/19 - *Casa Naţională de Asigurări de Sănătate and Casa de Asigurări de Sănătate Constanţa*, EU:C:2021:809. G. Strban, 'Cross-border healthcare and social security rights' in F. Pennings and G. Vonk (eds), *Research Handbook on European Social Security Law* (Cheltenham: Elgar, forthcoming).

Under the Regulations, benefits in kind provided by the institution of one Member State on behalf of another are normally reimbursed in full, based on their actual amount.[189] However, reimbursement on the basis of actual expenditure is not appropriate for some Member States due to their legal or administrative structures.[190] Those States are Ireland, Spain, Cyprus, Portugal, Sweden and the United Kingdom.[191] Reimbursement to those Member States shall occur on the basis of fixed amounts rather than actual expenditure[192] in respect of benefits in kind provided to:

> '(a) family members who do not reside in the same Member State as the insured person, as provided for in Article 17 of the basic Regulation; and to (b) pensioners and members of their family, as provided for in Article 24(1) and Articles 25 and 26 of the basic Regulation'.[193]

[189] Article 35(1)-(2) Regulation (EC) No 883/2004; Article 62(1) Regulation (EC) No 987/2009.

[190] Article 35(2) Regulation (EC) No 883/2004.

[191] Annex 3 to Regulation (EC) No 987/2009.

[192] Article 35(2) Regulation (EC) No 883/2004.

[193] Article 63 Regulation (EC) No 987/2009. See also Article 64-65 Regulation (EC) No 987/2009.

4. Provision of clear information on cross-border healthcare

Essential to the effectiveness of cross-border healthcare rights is being aware/well informed about of these rights and the rules on how to invoke them in different situations. However, it has been repeatedly reported that the European patients do not feel well informed about their cross-border healthcare rights.[194] In 2021, 72% of the patients surveyed felt not well informed. Although there is a slight improvement compared to the result in 2014, when 78% felt this way, this is still roughly three quarters of the patients.

Clear and accessible information is crucial in relation to the interplay between the Directive and the Regulations. The Directive expressly puts the choice between the two legal routes into the hands of the patients. However, it provides that the Member State of affiliation shall ascertain whether the conditions for a prior authorisation laid down in the Social Security Regulation have been met. Where those conditions are met, the prior authorisation shall be granted pursuant to that Regulation *unless the patient requests otherwise*.[195] In this context, it is important to note that in many cases, the patients' choice will have financial consequences that could not be fully corrected by applying the more beneficial set of rules at the reimbursement stage.[196]

So, the question is how the European patients are expected to make an informed choice and opt for the best possible healthcare solution for themselves, if they are not (fully) aware of all the implications of their choice. Public and stakeholder consultations suggest that the complex legal relationship between the Directive and the Regulations is very difficult for citizens to understand and is equally problematic for health insurance institutions to communicate to patients.[197]

In this section, the focus is put on the information to the patients, and specifically on the co-existence and relationship between the Regulations and the Directive. It is examined how the information to patients is currently disseminated, what is required from the Member States in terms of information for patients and how the information provision could be further developed.

4.1. Information provision for patients on the Regulations and the Directive – state of play

Patients can obtain information on cross-border healthcare from several sources, such as national healthcare authorities,[198] healthcare providers, patient organisations, and EU institutions. With the intention of providing patients with accurate and transparent information on cross-border healthcare, the Cross-Border Healthcare Directive required that Member States designate national contact points (NCPs) which patients can directly turn to.[199]

[194] This was confirmed recently by the public consultation cited above and by the 2021 Eurobarometer survey. Standard Eurobarometer 95 Spring 2021 Europeans' opinions about the European Union's priorities, p. 134.

[195] Cross-Border Healthcare Directive, Article 8 (3).

[196] SWD(2022) 200 final, p. 47.

[197] SWD(2022) 200 final, p. 46.

[198] Authorities responsible for the national healthcare schemes.

[199] Cross-Border Healthcare Directive, Article 6. The list of NCPs is available on the European Commission's website.

In order to facilitate the dissemination of information, the European Commission has developed and published a toolbox on cross-border healthcare,[200] which is divided into two main parts, one for patients and one for NCPs. The part of the toolbox that concentrates on how NCPs can improve their communication with patients, providing them with clear and accessible information on all aspects of accessing medical treatment abroad, contains a set of guiding principles adopted in 2019. Among the principles on information provision to patients, it is emphasised that *NCPs inform patients on the existence of two parallel routes if appropriate. They make a clear distinction on the use of the Social Security Regulations versus Directive 2011/24/EU, and the respective consequences for patients*.[201] This was repeated in a more recently adopted set of specific principles on prior authorisation.[202]

Nevertheless, a fresh analysis of the NCPs' websites found that less than half of the NCPs provide information on the distinction between the Directive and the Regulations.[203] Complying with the principles and informing patients about these issues would increase patients' understanding of their rights when obtaining healthcare abroad.

4.2. Information obligations under the Directive and the Regulations

As described above, the Directive and the Regulations differ on a number of points, among others their aim, their legal base and scope. These differences stem from different concepts: whereas the Regulations have guaranteed free movement of workers by coordinating the social security schemes since the 1950s, the Directive grew out of the case law of the CJEU paving the path to a new cross-border healthcare route in the 1990s and looking at patients as the service recipients. This patient-centred, customer-friendly approach is mirrored in the Directive's information rules.

(1) When it comes to information provision, the Regulations' focus is on the information flows among the relevant institutions in the Member States and does not specifically provide for any information obligations in relation to cross-border healthcare rights towards the insured persons.

Nonetheless, in light of the principle of good administration, the Coordination Regulations provide some rules of relevance on the Member States' information duties. According to these rules, the institutions are required to respond to all queries within a reasonable period of time and to provide the persons concerned with any information required for exercising the rights conferred on them by the Regulations.[204] Additionally, Member States shall ensure that the necessary information is made available to the persons concerned in order to inform them of the changes introduced by the Regulations to enable them to assert their rights. They shall also provide for user-friendly services.[205]

Although the declaration of this *timely reply obligation* is very laudable, there are some vague points in its phrasing: both the timeframe and the content of the information provision raise doubts and the practical implications and criteria of user-friendly services remain unclear.

[200] Toolbox for Cross-Border Healthcare.

[201] Guiding Principles and Indicators for the practice of National Contact Points (NCPs) under the Cross-border Healthcare Directive 2011/24/EU, p. 13.

[202] Guiding principles for information provision on prior authorisation systems across Member States, p. 13.

[203] SWD(2022) 200 final, p. 20., p. 46.

[204] Regulation (EC) No 883/2004, Article 76 (4).

[205] Regulation (EC) No 987/2009, Article 3 (1).

First of all, what can be considered a reasonable period of time within which healthcare authorities are required to provide information? As an instrument of coordination, the Regulations do not intend to harmonise the processing times in the Member States, but in the absence of any provision of national law this gives rise to uncertainty for the patient who has no indication how long it may take to receive the required information. Also, the Regulation does not regulate what happens if the authority fails to respond within a reasonable time. This might be especially relevant for patients in urgent situations.

An additional question to which there is no reference in the Regulations, is in which language the requested information should be provided by the Member State. In this respect, one may presume that the national rules and policies on the language regime to be used in the Member State must be applied, and national authorities can be expected to communicate in the official language(s) of their Member State. However, when those languages are unfamiliar to the patient, this directly leads to a linguistic obstacle, which – for lack of a satisfying alternative solution so far[206] – potentially results in extra costs for the patient. Such a situation can easily occur if a foreign (incoming) patient tries to collect information about treatment options in a Member State other than the Member State of residence. Although the Regulation provides for an obligation of authorities, institutions and tribunals not to reject applications or other documents submitted to them on the grounds that they are written in an official language of another Member State, recognised as an official language of the Community institutions,[207] this does not mean that they have the duty to respond to those applications in the language in which they were formulated.

Another concern relates to the material scope of the provision. According to the Regulation, the national healthcare authorities are only obliged to inform the patients about matters related to the rights included in the Regulations. Strictly interpreted, in a cross-border healthcare situation, the Member States can fulfil this requirement without even mentioning the additional entitlements of patients based on article 56 TFEU or the Cross-Border Healthcare Directive.

To sum up, institutions are not required by the Regulations to take any initiatives of information dissemination on the complex nature of various patient routes on their own but are required to reply to the inquiries of patients and although the codification of information duties is a creditable improvement of the coordination mechanism, it suffers from several weaknesses.

(2) The Cross-Border Healthcare Directive clearly articulates the patients' need for information on cross-border healthcare.[208] It acknowledges that appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights in cross-border healthcare in practice.

In contrast to the rather generic provisions of the Regulations, the Cross-Border Healthcare Directive specifies the Member States' obligations and splits the responsibility of delivering reliable information to the patients between the Member State of treatment and the Member State of affiliation, as detailed in *Table 1* below. Primarily, the Member State of affiliation must provide information on the patients' rights and entitlements in that state in relation to receiving cross-border healthcare and the Member State of treatment must inform the patient about the standards and guidelines on healthcare quality and safety laid down in that state.

[206] G. Berki: Lightning or Lightning Bug: The Role of the Language Gap and the Access to Proper Information on Entitlements in Cross-border Patient Mobility. European Journal of Health Law 2017 Mar;24(1).

[207] Regulation (EC) No 883/2004, Article 76 (7).

[208] Recital 48 of the Preamble of the Cross-Border Healthcare Directive.

Table 1: The Member States' responsibilities in relation to information provision under the Cross-Border Healthcare Directive

Responsible Member State	The scope of the information provision	The content of the information provision
Member State of affiliation	patients' rights and entitlements in that Member State relating to receiving cross-border healthcare	*from the national contact point*:[209] information on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards (1) the terms and conditions for reimbursement of costs and (2) procedures (2a) for accessing and determining those entitlements and (2b) for appeal and redress[210]
Member State of treatment	standards and guidelines on quality and safety laid down by that MS	*from the national contact point*:[211] relevant information on the standards and guidelines, including (1) provisions on supervision and assessment of healthcare providers, (2) information on which healthcare providers are subject to these standards and guidelines and (3) information on the accessibility of hospitals for persons with disabilities
		from healthcare providers:[212] relevant information to help individual patients to make an informed choice, including (1) on treatment options, (2) on the availability, quality and safety of the healthcare they provide in that state, (3) on prices, as well as (4) on their authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability

Source: Summary based on the Cross-Border Healthcare Directive

It is to be noted that while the Member State of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on their rights and entitlements in that Member State relating to receiving cross-border healthcare, *a clear distinction shall be made between the rights which patients have by virtue of the Directive and rights arising from the Social Security Regulation.*[213] As it is the NCP's responsibility to communicate this to the patient, it is concerning that a high share of NCPs do not even mention this on their websites.

Compared to the rules of the Regulations, the rules of the Directive are more specific and detailed and guarantee access to a broader scale of information. Despite this, they do not offer a solution to the problem that if a patient wants to collect all relevant information concerning a certain treatment abroad, this involves at least three entities he/she needs to contact in (at least) two different Member States. So even if a patient possesses the necessary language skills to acquire the essential information, the multi-source investigation puts a considerable burden on him/her.

In the next section, the current sources of information are examined: (a) the national healthcare authorities, (b) the national contact points, and (c) the healthcare providers. We

[209] Cross-Border Healthcare Directive, Article 6 (4).
[210] Cross-Border Healthcare Directive, Article 5 (b).
[211] Cross-Border Healthcare Directive, Article 4 (2) (a).
[212] Cross-Border Healthcare Directive, Article 4 (2) (b).
[213] Cross-Border Healthcare Directive, Article 5 (b).

also explore whether these actors aware of their obligations concerning information provision and capable of fulfilling them.

4.3. Sources of information on cross-border healthcare

4.3.1. National healthcare authorities

National healthcare authorities – irrespective of how the healthcare system is organised in the Member State concerned – are the most traditional sources of information when it comes to healthcare rights, entitlements and conditions attached to them. They have the required knowledge both of the legislative background and of the daily practice. They are often even involved in the legislative procedures. Thus, they are very well positioned to offer expert advice to patients in cross-border healthcare situations. Despite this, these authorities (healthcare funds, health insurers) – besides taking into account the patients' interests – have financial concerns too: while the patient wants to benefit from the most favourable situation possible, the national healthcare authorities have to balance between the interest of the patient and of the national healthcare system itself.[214] In cases concerning cross-border healthcare in the CJEU, national governments have often raised the argument that patient mobility might endanger the financial sustainability of the national healthcare budget. Therefore, provided that they act in good faith, it can be presumed that national healthcare authorities will fully inform the patients about all possible options. However, at the same time, it must be borne in mind that they have a duty to safeguard the financial equilibrium of their healthcare systems and might therefore encourage patients to opt for the treatment which is more economical for the state. Beside potentially guiding patients down that path, it is a further issue that the personnel of these institutions are usually mostly familiar with the national system of the Member State within whose health care system they work and thus may not be familiar with the health care systems of other Member States, thus, they simply may not have the necessary knowledge or experience to advise patients on the best possible course of action for them.

At the same time, national authorities cooperate on the EU level[215] (e.g. within the framework of the Administrative Commission for the coordination of social security systems),[216] thus, they have the platforms, tools and legal mechanisms to handle cross-border cases and to provide all the relevant information and are also specifically trained for it.

4.3.2. National contact points

As mentioned above, the national contact points were introduced by the Cross-Border Healthcare Directive [217] as the bodies responsible for providing patients with information about cross-border healthcare. They present an added value of the Directive: they are to be a neutral source of reliable, transparent, and easily accessible[218] information on cross-border healthcare issues. Since they were created to carry out this specific task,[219] it is to be expected that the persons working at the NCPs can answer most of the patients' relevant questions related to cross-border treatments, and if they cannot, that they have the

[214] M. Frischhut, R. Levaggi, Patient mobility in the context of austerity and an enlarged EU: The European Court of Justice's ruling in the Petru Case. Health Policy, Volume 119, Issue 10.
215 Regulation (EC) No 987/2009, Article 76.
[216] Regulation (EC) No 987/2009, Article 71-72.
[217] Cross-Border Healthcare Directive, Recital 48-49 and Article 6.
[218] Cross-Border Healthcare Directive, Article 6 (5).
[219] Cross-Border Healthcare Directive, Article 6 (3)-(4).

competence to find the answer quickly through their professional network of NCPs in other Member States, healthcare providers, healthcare authorities and other organisations. Therefore, it is highly important that the NCPs work closely together both with the relevant European and national institutions as well as with each other. Ultimately, they must also provide information on the clear distinction and differences between the Directive and the Regulations. In order to fulfil this obligation, NCPs receive much support from the European Commission, for instance in the form of the above-mentioned Toolbox and training opportunities.

4.3.3. Healthcare providers

The position of the healthcare providers is probably the most delicate of the entire information provision process. Although patients might trust them the most and expect the information related to all aspects of healthcare primarily from them, they are often neither trained nor willing to function as a source of non-medical information: their focus is on the practical provision of the healthcare services, not on the technical and legal aspects attached to such services. Nevertheless, they have certain information obligations under the Directive and the Member States must ensure that they act accordingly. The Directive provides that healthcare providers must offer relevant information to help individual patients to make an informed choice, including on treatment options, on the availability, quality and safety of the healthcare they provide in that state, on prices, as well as on their authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability.[220]

In addition to these obligations imposed on the bodies laid down in the Social Security Regulation and the Cross-Border Healthcare Directive, the European Union itself takes serious efforts to spread proper information on patients' rights in cross-border healthcare in various ways.

4.4. Tools to improve informed decision-making

In the situations where both legal routes (the Social Security Regulation and the Directive) can be used, the patient might find him/herself in a complex decision-making process, for which the assessment of all relevant information is necessary. To facilitate them to make an informed choice, patients have already a number of tools at their disposal as described above, but further measures can be suggested.

(1) *Focus on the tools in existence*: there is already accurate, patient-friendly information available, e.g. Manual for Patients on cross-border healthcare.[221] Information material like the checklist, the FAQ and the decision tree make the complex topic of cross-border healthcare more visible and easier to understand. Yet, many patients do not seem to find their way to this information. It would be important to make this information easily accessible also for disabled patients[222] perhaps by the increased involvement of disability support groups. Further promotion of these tools seems to be necessary.

(2) *Continued development of NCPs*: NCPs are a unique source of information and must continue to play a leading role in cross-border healthcare. Thus, it is crucial that their personnel are continuously offered learning and training opportunities with regard to all

[220] Cross-Border Healthcare Directive, Article 4 (2) (b).

[221] See here.

[222] It was reported that patients with disabilities face difficulties finding information on their cross-border healthcare rights. SWD(2022) 200 final, p. 20.

aspects of healthcare management and administration both on national and EU level, such as legal, linguistic and communication trainings. The cooperation between NCPs is also vital, so joint events (trainings, workshops, conferences, meetings etc.) should be further supported in order to encourage the exchange of best practices and mutual learning. Moreover, NCPs should be more visible to patients,[223] and they should be more active in disseminating information to both the general public and specific patient groups (e.g. patients with rare diseases). While taking such proactive approach, they could carry out regional (e.g. in border regions) and national information campaigns and host awareness-raising events both online and in person.

(3) *Involvement of further players in information dissemination*: patient organisations should play a larger role in raising patients' awareness, since their basic role is to empower patients by providing support, information and education. Although initiatives can be seen in this direction, their full potential seems far from being deployed. Nevertheless, it is a welcome development that NCPs are also required to consult with them.[224]

(4) *Strengthening the weakest point*: as healthcare providers are very likely the main source of information for patients it is desirable to enable them to inform patients better – further training opportunities should be offered for the healthcare professionals and for other staff members of healthcare providers (especially administrative staff) to enable them to provide patients with the information necessary to enforce their EU law rights. At the same time, national healthcare authorities – in cooperation with the European Commission – should develop a monitoring system to ensure that all the obliged parties fulfil their obligations under EU law (including e.g. information obligations and acceptance of EHIC).

(5) *Talk to the people, so they listen*: As people get most of their information from social media these days, these platforms cannot be neglected. Legislators and policy makers should not underestimate the power of social media tools but use them wisely to get the information where they intend them to. Cross-border healthcare social media campaigns have been successful in the past, for instance the short, humorous videos on the EHIC. Influencer marketing could also be considered as a possible way to better inform patients. The potential of fashionable tools like podcasts could also be explored. When considering these options, a team of communication experts would be a great asset.

[223] Just over half of the public consultation respondents were aware that NCPs existed. SWD(2022) 200 final, p. 19.

[224] Cross-Border Healthcare Directive, Article 6 (1).

5. Access to cross-border telemedicine under the Regulations and the Directive

5.1. Introduction

There is no legally binding definition of telemedicine under EU law. Directive 2011/24/EU mentions it twice, but without defining it. One of the most-quoted definition is the one elaborated by the Commission in a Communication of 2008, according to which telemedicine consists of 'the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients'.[225]

Telemedicine covers a wide array of services, since the technological evolution has greatly increased the number of healthcare activities that can be performed remotely.[226] This is the case for:

- teleconsultation, which can replace the traditional in-person medical consultation by allowing the physician to perform examination remotely by using specific technological devices, such as a digital stethoscope;
- teleintervention, whereby the physician can perform a surgical operation without touching the body of the patient thanks to the use of robots or other machines;
- telemonitoring, which refers to the possibility of keeping under control different aspects of the patient's health situation either via automated electronic means or by web-based or phone-based data entry.

5.2. Scenarios for planned healthcare

The Covid-19 pandemic has increased the use of telemedicine, prompting renewed calls for the design of a stronger and clearer regulatory framework. Reimbursement of the costs related to the cross-border recourse to telemedicine is one of the aspects to be clarified.

It is generally accepted that telemedicine, when it has a cross-border character, falls within the scope of application of Cross-Border Healthcare Directive. It is often stated that Article 20 of Regulation (EC) No 883/2004 is not applicable to telemedicine services as it expressly requires the physical presence of the patient in the Member State of treatment, even though, as we will see, this assumption does not hold in all cases.

This report seeks to deepen and refine this analysis. To this end, it elaborates seven scenarios for planned healthcare. These scenarios are simplified in that no account is taken

[225] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society /COM/2008/0689 final/. A slightly different definition has been proposed by the Commission in the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space COM/2022/197 final. According to Article 2(2), letter l), 'telemedicine' means the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location'.

[226] See V.L. Raposo, 'Telemedicine: The Legal Framework (or the Lack of it) in Europe' [2016] 12 *GMS Health Technology Assessment*.

of family members or pensioners, and that it is assumed that the patient resides in the Member State of affiliation.

Scenario 1. Telemedicine provided by a healthcare provider based in the State of affiliation

Member State of affiliation	Member State of telemedicine provider
A	A

In the first scenario, the healthcare consists exclusively of telemedicine, which is provided by a healthcare provider based in the State of affiliation (see the *Table* above). The patient may feel no need to rely on EU law. Article 20 of Regulation (EC) No 883/2004 does not apply, as the patient is not 'travelling to another Member State'. The same goes for Directive 2011/24/EU, since this is not cross-border healthcare, defined as 'healthcare provided or prescribed in a Member State other than the Member State of affiliation'.[227]

The healthcare provider might face restrictions on practising telemedicine imposed by the Member State of establishment. For instance, some Member States reportedly reimburse telemedicine only where it is preceded by an in-person examination or exclude reimbursement for telemedicine altogether.[228] In some cases, the Member State of establishment's regulation of telemedicine could be challenged on the basis of EU law.[229]

Scenario 2. Telemedicine and in-person healthcare provided by a healthcare provider based in the State of affiliation

Member State of affiliation	Member State of physical treatment	Member State of telemedicine provider
A	A	A

In the second scenario, the patient receives not only telemedicine but also in-person healthcare in the State of affiliation (see the *Table* above). The outcome is similar to the previous scenario: neither the Directive nor the Regulations apply as the patient and the healthcare provider are in the same Member State and neither of them cross borders.

Scenario 3. Telemedicine provided by a healthcare provider based in a State other than the State of affiliation

Member State of affiliation	Member State of telemedicine provider
A	B

[227] Article 3(e) Directive 2001/24.

[228] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society, COM(2008)689 final, 8; R. Janeckaitė, 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU' (2020) Vilnius University Open Series 86, 91, 93.

[229] See Janeckaitė, 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU' (2020) Vilnius University Open Series 86, 91-92.

In the third scenario, the healthcare, consists exclusively of telemedicine which is provided by a healthcare provider based in Member State B to a patient in Member State A (see the *Table* above). For instance, psychological therapy could be provided through videoconferencing.

Article 20 of Regulation (EC) No 883/2004 does not apply, as the patient has not travelled to another Member State. Neither do the other provisions of Title III, Chapter 1 of Regulation (EC) No 883/2004.

The Directive deems healthcare provided through telemedicine to be provided in the Member State of establishment of the healthcare provider.[230] Member State B is therefore the Member State of treatment. As a result, this constitutes cross-border healthcare for the purpose of the Directive.[231]

Article 7(1) of Directive 2011/24 provides that 'the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is *among the benefits to which the insured person is entitled in the Member State of affiliation*.'[232]

If the healthcare is not among the benefits of the Member State of affiliation, regardless of whether it is provided in-person or through telemedicine, there is no right to reimbursement. Equally clear is the situation where the healthcare is among the benefits of the Member State of affiliation, even when provided through telemedicine. In that case, there is a right to reimbursement, subject to the normal conditions laid down in the Directive.

More complex is the situation where the healthcare is among the benefits of the Member State of affiliation if provided in-person, but not if provided through telemedicine. The Commission reports that 'some national legal systems require the physical presence of the patient and health professional at the same time and in the same place, for a medical act to be legally valid'.[233] Would a Member State be bound to reimburse telemedicine in cases where it covers the healthcare only if provided in-person? The Directive is not clear on this point.[234]

A requirement that healthcare is delivered in-person can be framed in two ways. First, it would be seen as part of the definition of 'the benefits to which the insured person is entitled in the Member State of affiliation' for the purpose of Article 7(1) of Directive 2011/24. The argument would then be that such telemedicine is not part of the benefit basket, not because of its substance, but because of its form of delivery (i.e. through telemedicine). This would be a narrow and formalistic interpretation of the benefit basket. It would give Member States wide discretion to rule out reimbursement for telemedicine, by simply stipulating that healthcare is covered only if provided in person.

Arguably a better way to view the requirement that healthcare is delivered in-person is as one of the 'conditions, criteria of eligibility and regulatory and administrative formalities' mentioned in Article 7(7) of Directive 2011/24. Healthcare that is covered only if provided in-person would be seen as part of the benefit basket even when delivered through telemedicine, as the substance of the healthcare rather than its form is decisive. The requirement to provide it in-person would be examined in the light of Article 7(7) of Directive 2011/24, which reads:

---

230 Article 3(d) Directive 2011/24.

231 Article 3(e) Directive 2011/24.

232 Emphasis added. See also recital 13 Directive 2011/24.

233 Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services, SWD(2012) 414 final, 5.

234 R. Janeckaitė, 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU' (2020) Vilnius University Open Series 86, 93.

> 'The Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, *including healthcare received through means of telemedicine*, the same *conditions, criteria of eligibility and regulatory and administrative formalities*, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, *if this is necessary* for determining the individual patient's entitlement to healthcare. However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an obstacle to the free movement of patients, services or goods, unless it is *objectively justified* by planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.'[235]

Article 7(7) of Directive 2011/24 offers some support for the proposition that Member States can require the *initial* assessment by a health professional to be in person where necessary to determine the individual patient's entitlement to healthcare.[236] However, it would not support a requirement that *all* healthcare is provided in person. Indeed, every such requirement would constitute an obstacle to the free movement of services and therefore need objective justification on the grounds mentioned in Article 7(7) of Directive 2011/24/EU. While some types of healthcare might pass that test, others would not. For instance, it would be difficult to justify that all daily alcohol abuse therapy sessions ought to be in person.

The above arguments support the conclusion that there is a right to reimbursement for at least some telemedicine where the healthcare would be among the benefits to which the insured person is entitled in the Member State of affiliation if it were provided in person rather than by telemedicine. This would be in line with the fact that the Directive explicitly covers telemedicine and seeks to further the free movement of services. Its recital 26 draws a parallel:

> 'The Court of Justice has held that the Treaty provisions on the freedom to provide services include the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member State in order to receive it there. The same should apply to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through eHealth services.'

Article 56 TFEU covers not only situations where patients physically move to another Member State to receive healthcare services, but also situations where only the healthcare service 'moves'.[237] There is a parallel with non-contracted providers: much like patients can seek healthcare provided by a non-contracted provider based in another Member State that would not be reimbursed if provided in the Member State of affiliation, they could seek healthcare by a telemedicine healthcare provider based in another Member State that would not be reimbursed if provided in the Member State of affiliation.

It remains to be seen which interpretation of the Directive is correct. If there is no right to reimbursement on the basis of the Directive in cases where only in-person treatments are

---

[235] Emphases added.

[236] Strictly speaking, this would fall under the next scenario, which combines physical treatment in the Member State of affiliation with telemedicine provided in (or from) another Member State.

[237] See Judgment of 10 May 1995, *Alpine Investments*, C-348/93, EU:C:1995:126, para. 22.

reimbursed in the Member State of affiliation, due to a narrow interpretation of the benefit basket, there may still be a right to reimbursement on the basis of Article 56 TFEU. The *Kohll* case-law lends itself to being transposed to such a scenario[238], and recital 26, quoted above, calls for such transposition. That said, this should be confirmed by the CJEU, which has at times resisted extending its *Kohll* ruling.[239]

Scenario 4. Telemedicine provided by a healthcare provider based in a State other than the State of affiliation and in-person healthcare in the State of affiliation

Member State of affiliation	Member State of physical treatment	Member State of telemedicine provider
A	A	B

In the fourth scenario, alongside telemedicine in Member State B, a patient receives in-person healthcare in Member State A (see the *Table* above).

Article 20 of Regulation (EC) 883/2004 does not apply, as the patient does not travel to another Member State.

Under the Directive, the telemedicine is considered to be provided in Member State B. In this case the three questions discussed above arise:

- Is telemedicine among the benefits to which the insured person is entitled in the Member State of affiliation in the light of Article 7(1) of Directive 2011/24?
- If there is a requirement of in-person provision, is it objectively justified under Article 7(7) of Directive 2011/24?
- If there is a requirement of in-person provision for the purposes of reimbursement of cross-border healthcare costs, does it comply with Article 56 TFEU?

A further complication under the Directive arises from the kind of telemedicine that could be provided. In the previous scenario, all healthcare was provided through telemedicine; by definition, then, the telemedicine was directly provided by the healthcare provider to the patient. In this scenario, there are three possibilities.[240] First, the telemedicine could be provided directly by the healthcare provider in Member State B to the patient in Member State A (professional-to-patient telemedicine). Second, the healthcare provider in Member State A could consult a healthcare provider in Member State B, who would not directly offer healthcare to the patient (professional-to-professional telemedicine). An example would be a general practitioner consulting a specialist to interpret an X-Ray (teleradiology). Third, the above two options could be combined where for instance the telemedicine consists of both a consultation directly to the patient and a consultation to the healthcare provider in Member State A (professional-to-patient and professional-to-professional telemedicine).

It is unclear what legal consequences the provision of telemedicine may have. The Directive seems designed to apply to professional-to-patient telemedicine.[241] Does it also apply to professional-to-professional telemedicine?[242] This might constitute 'healthcare', which the

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

[239] It should be noted that the CJEU has resisted extending the *Kohll* case-law to long-term care benefits (*European Commission v Federal Republic of Germany (long-term care benefits)* (C-562/10) EU:C:2012:442).

[240] Based on Janeckaitė, 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU' (2020) Vilnius University Open Series 86, 90, who also considers telemedicine services provided via collaborative economy platforms.

[241] Janeckaitė, 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU' (2020) Vilnius University Open Series 86, 93.

[242] Janeckaitė, 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU' (2020) Vilnius University Open Series 86, 93.

Directive defines as 'health services provided by health professionals to patients to assess, maintain or restore their state of health', without mentioning to whom healthcare is *directly* provided.[243] Similarly, the right to reimbursement covers 'the costs incurred by an insured person' without distinguishing between professional-to-patient and professional-to-professional telemedicine. However, is it truly irrelevant that professional-to-professional telemedicine operates one step removed from the patient, who might be issued a single bill covering the professional-to-professional advice necessary to his effective treatment and does the logic of the Directive not presuppose that there is only one Member State of treatment?[244]

This raises the further question as to whether treatments are to be considered separately or together. For instance, is a consultation in Member State A, with both a general practitioner attending in person and a specialist attending remotely from Member State B to be seen as *one* treatment? Such joint analysis would require both treatments to be located in one Member State. Neither Member State seems appropriate for the reasons set out below.

Locating both treatments in Member State B would be at odds with the definition of the 'Member State of treatment' as 'the Member State on whose territory healthcare is actually provided to the patient' (first sentence of Article 3(d) Directive 2011/24/EU), as the in-person treatment took place in Member State A. The result of such fiction would be that the Directive applies not only to the telemedicine but also to the in-person treatment in Member State A, which seems problematic as it is not cross-border healthcare (defined as 'healthcare provided or prescribed in a Member State other than the Member State of affiliation').[245] It could be argued that the in-person treatment is an accessory to the telemedicine. However, this argument becomes harder to maintain should the centre of gravity of the healthcare lie with the in-person treatment (e.g. scans, main specialists), with only very limited involvement from the healthcare provider based in Member State B. In any case, deeming in-person healthcare in Member State A to take place in Member State B might make it subject to prior authorisation, even though it could not be subjected to prior authorisation were it not combined with telemedicine.

Locating both treatments in Member State A would run counter to the second sentence of Article 3(d) Directive 2011/24, which reads: 'In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established'. It would mean that the Directive does not apply, as all healthcare is deemed to take place in the Member State of affiliation, even though the telemedicine is in fact cross-border healthcare.

Therefore, a joint analysis of treatments is problematic, both because it contravenes Article 3(d) Directive 2011/24 and because of its effects. The components of a dual consultation (or more broadly related treatments) ought to be considered separately. A separate analysis avoids having to either treat the in-person healthcare as cross-border healthcare or the telemedicine as purely internal healthcare. It also aligns with the separate analysis of related treatments for the purpose of deciding whether prior authorisation can be required.[246] Difficulties might however arise where both treatments are intertwined. Moreover, there are open questions regarding professional-to-professional telemedicine. Further research is needed on this issue.

[243] Article 3(a) Directive 2011/24.

[244] Janeckaitė, 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU' (2020) Vilnius University Open Series 86, 93.

[245] Article 3(e) Directive 2011/24.

[246] E.g. *WO v Vas Megyei Kormányhivatal* (C-777/18) EU:C:2020:745 , paras 79-80.

Scenario 5. Telemedicine and in-person healthcare provided by a healthcare provider based in a State other than the State of affiliation

Member State of affiliation	Member State of physical treatment	Member State of telemedicine provider
A	B	B

The fifth scenario, involves a patient obtaining in-person healthcare as well as telemedicine in a Member State other than the State of affiliation (see the *Table* above).

Article 20 of Regulation (EC) No 883/2004 is likely to apply to such cases, as the insured person travels to another Member State in order to receive healthcare.[247] If such a person has a prior authorisation for the treatment in question, they are entitled to 'the benefits in kind provided, on behalf of the competent institution, by the institution of the place of stay, in accordance with the provisions of the legislation it applies, as though [they] were insured under the said legislation.'[248] Some issues could arise, even assuming that both healthcare providers are public or contracted. The main question is whether the telemedicine is 'among the benefits provided for by the legislation in the Member State where the person concerned resides',[249] which we assume to be the Member State of affiliation. If the healthcare is not among those benefits, Member State A does not have to grant prior authorisation. Three possibilities arise:

- The healthcare is not among the benefits of the Member State of affiliation, whether provided in-person or through telemedicine: in this case, there is no right to authorisation.

- The healthcare is among the benefits of the Member State of affiliation, whether provided in-person or through telemedicine: in this case, there is a right to authorisation if the patient cannot be given such treatment within a time limit which is medically justifiable.

- The healthcare is among the benefits of the Member State of affiliation only if provided in-person, and not if provided through telemedicine: the solution to this case is unclear, but as said above,[250] excluding a treatment not because of its substance, but because of its form of delivery (i.e. through telemedicine) would be a narrow interpretation of the benefit basket.

The Directive does apply in this scenario, as both the in-person treatment and the telemedicine take place in a Member State other than the State of affiliation. The questions discussed in relation to the previous scenarios arise:

- Is telemedicine among the benefits to which the insured person is entitled in the Member State of affiliation in the light of Article 7(1) Directive 2011/24/EU?

- If there is a requirement of in-person provision, is it objectively justified under Article 7(7) Directive 2011/24/EU?

- If there is a requirement of in-person provision for the purposes of reimbursement of cross-border healthcare costs, does it comply with Article 56 TFEU?

---

[247] The issue of the joint or separate treatment of in-person healthcare and telemedicine will be discussed in scenario vii.

[248] Article 20(2) of Regulation (EC) No 883/2004.

[249] Article 20(2) Regulation (EC) No 883/2004.

[250] See para. 5.2(iii).

The issue of a joint or separate treatment of the in-person healthcare and the telemedicine has less practical relevance in this scenario, as both are (deemed to be) provided in the same Member State. They ought to be treated separately for the purpose of prior authorisation under the Directive.[251]

Scenario 6. In-person healthcare by a healthcare provider based in a State other than the State of affiliation and telemedicine in the State of affiliation

Member State of affiliation	Member State of physical treatment	Member State of telemedicine provider
A	B	A

In the sixth scenario, which is probably less common, the patient travels to Member State B to obtain healthcare, and at the same time obtains telemedicine from their Member State of affiliation (see the *Table* above).

Article 20 of Regulation (EC) 883/2004 is plainly applicable to the healthcare obtained in Member State B. It is less clear whether it also applies to the telemedicine from the healthcare provider based in Member State A. This raises the question of the severability of the healthcare, but this time in the context of the Regulations rather than the Directive: is the healthcare provided in Member State A and Member State B to be treated jointly or separately? Unlike the Directive, the Regulations lack a provision treating telemedicine as having taken place in one particular Member State.

The Directive applies to the in-person treatment. However, it does not apply to telemedicine, which is deemed to take place in the Member State of affiliation. It would only be different if the in-person healthcare and the telemedicine were considered jointly and deemed to be located in Member State B, which, as argued above, is problematic.

Scenario 7. Telemedicine and in-person healthcare by healthcare providers based in two different States others than the State of affiliation

Member State of affiliation	Member State of physical treatment	Member State of telemedicine provider
A	B	C

The final scenario involves not two but three Member States. A patient travels to Member State B and obtains telemedicine from a healthcare provider based in Member State C (see the *Table* above).

Article 20 Regulation (EC) 883/2004 applies to the in-person healthcare provided in Member State B. Whether it also covers the telemedicine, depends on whether the in-person healthcare and the telemedicine are treated separately or jointly. If treated separately, then telemedicine is not covered by Article 20 Regulation (EC) 883/2004, as the patient travels to Member State B but not to Member State C. If treated jointly and located in Member State B, then the telemedicine might fall under Article 20 Regulation (EC) 883/2004. The same

[251] E.g. *WO* (C-777/18) EU:C:2020:745, paras 79-80.

reasoning applies in a situation where telemedicine is not provided at the same time as the physical treatment, but at a later moment, as a follow-up care.

The Directive applies to the in-person treatment and to the telemedicine. As previously, the following questions arise:

- Is the telemedicine among the benefits to which the insured person is entitled in the Member State of affiliation in the light of Article 7(1) Directive 2011/24/EU?
- If there is a requirement of in-person provision, is it objectively justified under Article 7(7) Directive 2011/24/EU?
- If there is a requirement of in-person provision for the purposes of reimbursement of cross-border healthcare costs, does it comply with Article 56 TFEU?

The issue of severability also recurs. If both treatments are considered separately, as is advisable in this context, then the analysis is to be conducted separately for Member State B and Member State C. If on the other hand the treatments are to be considered jointly, then a difficult question of localisation arises: are they both deemed to take place either in Member State B or in Member State C? Such joint consideration inevitably is at odds with the definition of 'Member State of treatment' as 'the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established'.[252]

5.3. Some comments

While the Directive mentions telemedicine, its application to telemedicine is far from straightforward in all but the simplest of scenarios. A major open question relates to the situation where the Member State of affiliation would reimburse healthcare had it not been provided through telemedicine. Further sets of issues relate to professional-to-professional telemedicine and to the joint or separate analysis of related treatments.

It is often stated that the Regulations do not apply, if the patient does not travel to another Member State.[253] Whilst this may frequently be true, our analysis has shown that Article 20 of Regulation (EC) 883/2004 may apply to some scenarios involving telemedicine. While they were 'not enacted with telemedicine in mind',[254] the Regulations may be applicable, raising a number of intractable issues.

The applicability of Article 20 of Regulation (EC) 883/2004 only to situations where the insured person travels to another Member State for the purpose of receiving benefits in kind seems to be based on the assumption that this is the only way to seek healthcare. This assumption is belied by telemedicine: it is possible to seek healthcare abroad without travelling. The questions of whether reform is needed, and what shape it may take, go well beyond the remit of this report. Some authors could argue that there is 'no reason' for excluding telemedicine in cases where the patient does not travel,[255] but further research would be needed on this issue. At any rate, Member States could, on their own initiative,

[252] Article 3(d) Directive 2011/24.

[253] E.g. Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services, SWD(2012) 414 final, 17; C. Ionescu-Dima, 'Legal Challenges Regarding Telemedicine Services in the European Union' in C. George, D. Whitehouse and P. Duquenoy (eds), *eHealth: Legal, Ethical and Governance Challenges* (Heidelberg: Springer, 2013), 118.

[254] C. Ionescu-Dima, 'Legal Challenges Regarding Telemedicine Services in the EU' in George, Whitehouse and Duquenoy (eds), *eHealth: Legal, Ethical and Governance Challenges* (Heidelberg: Springer, 2013), 118.

[255] Janeckaitė, 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU' (2020) Vilnius University Open Series 86, 93.

decide to grant prior authorisation also for telemedicine, under the same conditions as they would for physical healthcare.

In broad terms, it should be noted that uncertainty regarding the application of the Directive and the Regulations to telemedicine is detrimental to patients. It also slows down the development of (cross-border) telemedicine. Finally, it hinders the uniform application of EU law. The Commission's review of the applicability of existing EU legislation to telemedicine services, scheduled for 2024, could be a suitable opportunity to further explore these questions.[256]

C. Ionescu-Dima, 'Legal Challenges Regarding Telemedicine Services in the EU' in George, Whitehouse and Duquenoy (eds), *eHealth: Legal, Ethical and Governance Challenges* (Heidelberg: Springer, 2013), 118.

6. Conclusions and recommendations

The Regulations and the Directive are the main pillars of the EU legal framework on cross-border healthcare. The two sets of acts pursue by and large the same general objective, but their specific objectives, their legal bases and their inner logic differ. The Regulations are social security coordination acts that have been adopted to foster the free movement of the economically active persons and, later, of EU citizens in general. Conversely, the Directive aims at facilitating the free movement of services in the healthcare sector and ensuring patient mobility.

According to the Directive, the two acts were supposed to create parallel regimes. In case they are both applicable, priority is given to the Regulations with the only exception being the patient's explicit request. However, the Report has shown that, in practice, their relationship is more complex.

As regards the personal scope of the Regulations and the Directive, recent case law has shed welcome light on the notion of 'insured person'. There remain questions as to the concept of 'family members'.

The material scope of the Regulations and the Directive overlap to a large extent but the outer edges of their material scope can be unclear. A first set of questions relates to long-term care benefits, which are covered only by the Regulations. Do the definitions of long-term care benefits in various CJEU cases align perfectly with one another, with the definition in pending reform proposals and with the definition provided by the Directive? What protection does the TFEU provide to persons seeking cross-border access to long-term care benefits? Second, while there are good reasons to believe that the Directive applies to unplanned healthcare, issues arise, especially where prior authorisation is required. Third, despite having been excluded from the Regulations since the 1950s,[257] medical assistance remains ill-defined. Finally, the Covid-19 pandemic lent urgency to the question of the place of public vaccination programmes in EU law. It was argued that, despite some Member States' arguments to the contrary, these are, in principle, subject to the Regulations.

The two sets of rules apply to several cross-border healthcare situations. The Regulations distinguish between the case in which the residence is in a Member State other than the competent Member State (Articles 17 and 18 Regulation No 883/2004), receiving necessary healthcare during a temporary stay outside the competent Member State (Article 19), and travelling with the purpose of receiving benefits in kind outside the Member State of residence (Article 20). Conversely, the Directive does not distinguish between these situations, as it applies the same rules to all cross-border healthcare provision.

The lack of distinction under the Directive's regime leads to a paradox if the rules on prior authorisation are applied consistently – also to healthcare the need for which occurred unexpectedly. In such situations, it is unrealistic to expect patients to request a prior authorisation, yet Member States are free to refuse the reimbursement of medical costs if they provide for a prior authorisation scheme under the Directive and the healthcare in question falls under its scope.

Influencing patient choice should be avoided through educating patients and monitoring providers and insurers' practices.

If an insured person travels to another Member State with the purpose of obtaining a medical treatment there, he/she must seek authorisation from the competent institution. In this context, prior authorisation is a structural component of the legal regime, being framed

[257] Article 2(3) Regulation 3/58.

as a duty for the patient wishing to travel to another Member State with the purpose of receiving a treatment there. Competent institutions are obliged to grant the authorisation when two cumulative conditions are met. First, the treatment in question must be among the benefits provided for by the legislation in the Member State where the person concerned resides. Second, the treatment cannot be provided 'within a time limit which is medically justifiable, taking into account his/her current state of health and the probable course of his/her illness'.[258] Conversely, the Directive establishes that, as a rule, prior authorisation cannot be required. Member States have to make sure that the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation. National authorities can resort to prior authorisation only when it is 'necessary and proportionate to the objective to be achieved, and [it does not] constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients.'[259]

With regard to both regimes, the CJEU has identified some situations where the patient is entitled to have the costs reimbursed even without a properly issued prior authorisation, provided that all the other conditions are met. More specifically, when applying the Regulations, Member States are required to reimburse the costs of planned healthcare received abroad without a prior authorisation or even without having applied for such an authorisation when the insured person was, for reasons relating to his or her state of health in need of urgent treatment, in circumstances that prevented him or her from applying, or he or she was not able to wait for the final decision of the competent institution.

Under both sets of rules, the most controversial aspects concerning the decision to grant or refuse the authorisation to go abroad for receiving a medical treatment is whether an equally effective treatment can be given, to use the terminology found in both sets of rules, 'within a time limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each patient concerned'.[260] The Report shows that the use of the same expression reveals the existence of a strong convergence between the two regimes on this point, even if certain divergences persist. Recent case-law has confirmed that, in deciding whether to grant a prior authorisation, competent authorities must only consider the patient's medical condition under both Article 20(2) of Regulation (EC) No 883/2004 and Article 8(5) of Directive 2011/24/EU. However, Member States must ensure that their prior authorisation systems fully comply with the Charter of Fundamental Rights. In the case of the Regulations, this obligation is offset by the need to preserve the financial stability of the national healthcare system. Conversely, with regard to authorisations granted under the Directive, Member States can derogate from it only if they demonstrate that respecting this obligation would put at risk the maintenance of treatment capacity and medical competence in the national healthcare system.

The position of non-residents breaks down into a multitude of complex scenarios. First, their access to healthcare in the State of residence is guaranteed under the Regulations, with specific rules for pensioners, but not covered by the Directive.

Second, non-residents can access healthcare in their competent State on the basis of the Regulations, with more restrictive rights for some family members of frontier workers and for some pensioners and their family members. The Directive does not cover healthcare provided in the Member State of affiliation. Still, the report identified cases in which it does apply to non-residents seeking healthcare in the competent Member State, e.g. where it is not the Member State of affiliation under the Directive.

Third, non-residents' access to healthcare in a Member State other than the competent State and the Member State of residence depends on whether it is planned. As regards planned healthcare under the Regulations, the conditions and procedures for obtaining

[258] Article 20(2) Regulation (EC) No 883/2004.
[259] Article 8(1) Directive 2011/24.
[260] Article 8(6)(d) Directive 2011/24; see also Article 20(2) Regulation (EC) No 883/2004.

authorisation are shaped by the place of residence. When the Regulations vest the competence to grant authorisations in the Member State of residence, it becomes the Member State of affiliation for the purpose of the Directive. Some of the complexities of such scenarios became apparent in the *Y v Centraal Administratie Kantoor* ruling.[261] Access to unplanned healthcare is more straightforward; the main issue concerns the identification of the Member State of affiliation.

The Directive treats patients as consumers and provides rules in order to empower them and enable them to make informed decisions on their cross-border treatments. It contains an extensive set of information obligations that must be met by both the Member State of affiliation and the Member State of treatment. Yet, EU citizens still do not feel well-informed about cross-border healthcare.

National authorities responsible for cross-border healthcare issues, national contact points, healthcare providers and patient organisations all play a distinctive role in information provision and patient education. It has been underlined in this Report that although several EU measures aim to provide patients with clear and coherent information, further initiatives seem to be necessary. It is recommended that greater use be made of the existing tools such as the cross-border healthcare manuals for patients, the continued exploitation of the full potential of the network of national contact points, helping both patient organisations and healthcare providers to fulfil their roles as essential information sources for patients and finally, giving wider publicity to these issues, including through social media platforms.

The regulation of cross-border telemedicine remains patchy, despite its surging practical importance due to technological innovation and the Covid-19 pandemic. Telemedicine lacks statutory definition at EU level. The application of the Regulations and the Directive to telemedicine ought to be clarified. By discerning various patterns of facts and law, this Report sought to reveal some of the interpretative and policy challenges to which telemedicine gives rise.

An important issue is the compatibility of national requirements that healthcare be provided in person rather than by telemedicine with Directive 2011/24. It was argued that such requirements are best framed, not as part of the definition of the benefit basket, but rather as the 'conditions, criteria of eligibility and regulatory and administrative formalities' mentioned in Article 7(7) of Directive 2011/24. The application of that provision remains uncertain.

The place of professional-to-professional telemedicine in EU law remains unclear. The Directive does not seem to be designed for such scenarios but might be applicable.

A recurring issue is whether connected treatments are to be considered separately or together under the Directive. While a joint analysis seems most problematic, a separate analysis might not be free from complications.

The common assumption that telemedicine falls outside the scope of Article 20 of Regulation (EC) No 883/2004 might prove to be false. The Regulations apply in full when a person travels to a Member State to obtain telemedicine there. Again, the issue as to whether telemedicine falls within the benefit basket arises, this time in the context of the Regulations.

A further unresolved point is the impact of the Treaty provisions on free movement of services on the access to telemedicine.

Telemedicine leaves many questions open. The Directive makes limited reference to telemedicine and there is no evidence that it was in the minds of the drafters of the

[261] *Y v Centraal Administratie Kantoor* (C-636/19) EU:C:2021:885.

Regulations. Further research should shed light on the domestic administrative and judicial application of the regulatory framework to telemedicine. In the meantime, we can only note that the uncertainty that surrounds cross-border telemedicine is detrimental to patients as well as the development of such healthcare.

GETTING IN TOUCH WITH THE EU

In person

All over the European Union there are hundreds of Europe Direct information centres. You can find the address of the centre nearest you at: https://europa.eu/european-union/contact_en

On the phone or by email

Europe Direct is a service that answers your questions about the European Union. You can contact this service:

- by freephone: 00 800 6 7 8 9 10 11 (certain operators may charge for these calls),
- at the following standard number: +32 22999696 or
- by email via: https://europa.eu/european-union/contact_en

FINDING INFORMATION ABOUT THE EU

Online

Information about the European Union in all the official languages of the EU is available on the Europa website at: https://europa.eu/european-union/index_en

EU publications

You can download or order free and priced EU publications at: https://op.europa.eu/en/publications. Multiple copies of free publications may be obtained by contacting Europe Direct or your local information centre (see https://europa.eu/european-union/contact_en).

EU law and related documents

For access to legal information from the EU, including all EU law since 1952 in all the official language versions, go to EUR-Lex at: http://eur-lex.europa.eu

Open data from the EU

The EU Open Data Portal (http://data.europa.eu/euodp/en) provides access to datasets from the EU. Data can be downloaded and reused for free, for both commercial and non-commercial purposes.

Publications Office
of the European Union